UNIVERSITY OF COPENHAGEN
FACULTY OF SCIENCE

PhD Thesis

Wieke Huizing Edinger

EU Food Health Law

Regulating the grey area between risk and safety

Supervisors: Helle Tegner Anker and Bernd van der Meulen

Submitted: 10/07/2016

Institute:	Department of Food and Resource Economics
Name of department:	Department of Science
Author:	Wieke Huizing Edinger
Title / Subtitle:	EU food health law: Regulating the grey area between risk and safety
Subject:	The role of EU food law for consumer protection from the potential negative health effects foods that do not fall within the scope of “risk” in Regulation 178/2002/EC, but which may be harmful to health due to, e.g., their nutritional composition
Supervisors:	Helle Tegner Anker, University of Copenhagen Bernd van der Meulen, Wageningen University
Submitted:	10 July 2016

This thesis has been submitted to the PhD School of the Faculty of Science, University of Copenhagen

Content

Abbreviations

ADI	Average Daily Intake
AVMS	Audio Visual Media Services
CAC	Codex Alimentarius Commission
CJEU	Court of Justice of the European Union
DGA	Daily Guideline Amount
EFSA	European Food Safety Authority
EC	European Communities
ECJ	European Court of Justice
ECR	Electronic Court Record
EEC	European Economic Communities
EU	European Union
FIR	Food Information Regulation
GFL	General Food Law Regulation
HFSS	High in Fat, Salt and/or Sugar
IOTF	International Obesity Task Force
NCD	Non-communicable diseases
OJ	Official Journal of the European Union
SCF	Scientific Committee on Food
SPS	Sanitary and Phytosanitary
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
TVWF	Television Without Frontiers
UCP	Unfair Commercial Practices
WHO	World Health Organisation
WTO	World Trade Organisation

Abstract

This thesis shows that the distinction between food safety and non-safety issues in Regulation (EC) No 178/2002, the General Food Law (GFL), results in a grey area of regulation. This grey area comprises foods that do not pose a food safety risk in a legal sense, but that could pose a threat to human health because of other factors, such as their nutritional composition. The growing prevalence of obesity and non-communicable diseases are examples of contemporary health challenges that are difficult to fit into the rather narrow concept of food safety risks in the GFL.

The conclusion is that EU food law does not address the grey area directly. Whereas the responsibility for the prevention or mitigation of food safety risks rests, in principle, with food operators, the main responsibility for the avoidance of non-safety health threats is placed with consumers, who are expected to make informed and rational dietary choices on the basis of the food information provided on food labels or generally available in society.

In recent years, the EU legislative has shown increased commitment to further empower consumers in pace with the advancement of modern manufacturing and advertising techniques. This development, however, does not indicate a departure from the average consumer as a protective benchmark in EU food information legislation. On the contrary, the reinforcement of food information legislation as the main tool for consumer protection from non-safety health risks from food reaffirms the assumption that consumers are capable of protecting their own health and well-being, provided they have access to a minimum amount of food information.

The EU Treaty does not provide an explicit legal basis for establishing food health legislation, but there appears to be ample room for the adoption of harmonising measures that could facilitate a better consumer protection from non-safety health risks at the EU level. The EU legislature should use this legislative competence to fill in the regulatory grey area. Two possible ways forward to better integrate food health into the EU food law framework are the broadening of the scope of risk in the GFL and the further adjustment of food information legislation to ensure proper consumer understanding of non-safety health risks from food.

Summary

This thesis contributes to the articulation and qualification of the grey area in EU food law that marks the regulatory gap between food safety risks and non-safety health threats. The growing prevalence of obesity and non-communicable diseases are examples of contemporary public health challenges that are difficult to fit into the rather narrow concept of food safety in Regulation EC No 178/2002, the General Food Law Regulation (GFL).

This thesis examines where the EU legislature has drawn the line between risk and safety, and evaluates the consequences in terms of consumer health protection from foods that do not pose a food safety risk in a legal sense, but that could compromise human health for other reasons, e.g., their nutritional composition. To this effect, this thesis presents an analysis of the scope and protective purpose of both EU food safety and EU food information legislation, which is based on the doctrinal interpretation of relevant legal provisions, as well as the examination of policy documents, relevant case law from the CJEU and literature. The results have been laid down in five scientific papers, three of which were previously published in scientific journals and one in conference proceedings. The fifth is in the process of being submitted for publication in a relevant scientific journal.

The analysis demonstrates that grey area results from the legislative choices that are at the basis of the GFL. Firstly, the definition of "risk" in the GFL is rather narrow due to its legal interlinkage with chemical, biological and physical hazards, only. Other threats to human health, such as those related to the nutritional composition of food, are methodically disregarded. By consequence, food safety risk assessment in the EU is essentially confined to classic food toxicology, while other research areas such as epidemiology and behavioural sciences are not systematically taken into account. The result is a regulatory gap with respect to how food composition and consumer behaviour are related and how they may affect human health.

Secondly, despite the regulatory gap, the responsibility for the health consequences of food choices is placed with the consumer, who is expected to be relatively knowledgeable and to exhibit rational, appropriate consumptive behaviour in view of the food information provided on the label or generally available.

From a risk management perspective, it may appear both reasonable and efficient to hold consumers responsible for the health consequences of consumptive behaviour that disregards the information

provided on food labels or otherwise. In regard of foods that fall within the regulatory grey area, however, such division of responsibilities can lead to compromising situations for consumers.

In accordance with the average consumer benchmark developed by the CJEU, the legal requirements to consumer information are based on a rather low denominator for protection. To protect themselves, consumers are expected to be able to decipher often quite technical data on the nature and composition of foodstuffs and to predict the shorter and longer-term effects on their health and well-being of their overall dietary and lifestyle-related choices.

The main conclusion of the thesis is that the current legislative framework of EU food law does not provide adequate consumer protection from grey area foods because of:

(a) A narrow scope of risk in the GFL, which confines food safety risk assessment to biological, chemical and physical hazards, only, systematically excluding the findings from other scientific disciplines, such as behavioural science and epidemiology;
(b) The influence of the behavioural factor of risk, as a result of which the potential negative health consequences from consumptive patters that are not deemed "normal" remain for the responsibility of the consumer.

The question arises whether the EU legislature could step in and regulate these grey area foods. Although the TFEU does not provide for a specific legal basis to adopt food health law and explicitly prohibits the harmonisation of public health legislation, this thesis shows that there is room for the adoption of harmonising measures to facilitate the protection of consumer health at the EU level.

In recent times, the EU legislator has adopted several rather restrictive measures in an area where consumer safety is not directly at stake. Not only have the rules on mandatory labelling been supplemented with nutrition information, but additional rules have been introduced in regard of voluntary food information that could impede the intelligibility of the mandatory particulars. In general, the consumer image that emerges from these legislative adjustments is that of a person who may well be oriented towards a nutritionally well-balanced diet, but who does not necessarily possess the relevant knowledge to make discriminating choices in this respect.

Whereas these developments illustrate an increased commitment from the EU legislator to empower consumers in pace with the advancement of modern manufacturing and advertising techniques, they do not indicate a departure from the average consumer benchmark for protection in food information legislation. On the contrary, the reinforcement of food information legislation as the main tool for

consumer protection from non-safety health risks from food reaffirms the basic assumption that consumers are capable of protecting their health and well-being, provided they have access to a minimum amount of information.

Arguably, to make appropriate food choices is difficult for well-informed consumers and even more so for persons who are more susceptible to marketing messages. Consumers are subjected to advanced marketing techniques and their choices are not always driven by rationality. A much-debated question in this context is what role the EU should play in relation to children, particularly in the field of food advertising to this age group.

From a traditional, risk-based perspective, the legitimacy of adopting restricting legislation depends on scientific proof of a risk to human health. However, whereas there is no doubt that food advertising indeed affects children, a causal relationship between advertising and health-related issues such as childhood obesity has not been – and probably cannot be – established.

A rights-based approach, on the contrary, derives from children's inherent age-related vulnerability their entitlement to special protection. The application of such rights-based focus in EU food law would allow for the rejection of the applicability to minors of the concept of informed choice and the consequent renunciation of food advertising to children as inherently misleading, ambiguous and confusing to them. Following this line of reasoning, the marketing of foods targeting or particularly suited to appeal to children would be prohibited in the sense of Article 7 of Regulation EU 1169/2011 on food information to consumers (FIR).

There is a need to fill in the regulatory gap between risk and safety through the development of EU food health law. Food health considerations should be integrated in EU food law by incorporating in the current legal set-up the risks to human health from the consumption of foods that fall outside the scope of food safety risk assessment, but which can nevertheless pose a threat to consumers' health and well-being.

There are two possible ways forward to better integrate food health into EU food law. Firstly, the scope of food safety risk analysis could be broadened by allowing the findings of other scientific disciplines to play a role in risk assessment. The result would be a more comprehensive appreciation of the potential health consequences of food consumption and a reduction of the information gap concerning how food composition, eating behaviour and health are interconnected.

A second option would be to accept that consumers do not have a common appreciation of what is "normal" consumptive behaviour and that food information legislation should facilitate a better understanding. A proper response would require a general revision of food information legislation to include particular consideration to more vulnerable consumers and, quite possibly, the finalisation of nutrition profiles to be able to distinguish between lower and higher quality food products.

The development of a legal infrastructure at EU level to deal with the health damage caused by the consumption of unhealthy foods and unbalanced diets is urgent in the face of the obesity epidemic that has Europe in its grip. This thesis demonstrates this urgency and contributes to finding solutions.

Resumé

Denne afhandling analyserer den gråzone i EU fødevarelovgivningen, der markerer det reguleringsmæssige tomrum mellem den retlige definition af en fødevaresikkerhedsrisiko og ikke-sikkerhedsmæssige sundhedstrusler. Den tiltagende udbredelse af fedme og ikke-smitsomme sygdomme i EU er eksempler på nutidige folkesundhedsmæssige udfordringer, der er svære at passe ind i det snævre fødevaresikkerhedsbegreb i Europa-Parlamentets of Rådets forordning EF Nr. 178/2002 af 28. januar 2002 om generelle principper og krav i fødevarelovgivningen, om oprettelse af Den Europæiske Fødevaresikkerhedsautoritet og om procedurer vedrørende fødevaresikkerhed (fødevareforordningen).

Afhandlingen undersøger, hvordan EU-lovgiveren har draget skillelinjen mellem risiko og sikkerhed, og studerer konsekvenserne for niveauet af forbrugerbeskyttelse mod sundhedstrusler fra fødevarer, der ikke udgør en sikkerhedsrisiko i retlig forstand, men som kan skade menneskers sundhed af andre årsager, herunder deres ernæringsmæssige sammensætning.

Afhandlingen omfatter en analyse af henholdsvis EU fødevaresikkerhedslovgivning og EU lovgivning om fødevareinformation til forbrugere med hovedvægten på lovgivningens rækkevidde i forhold til ikke-sikkerhedsmæssige sundhedstrusler. Analysen er baseret på fortolkning af de relevante lovbestemmelser, samt undersøgelse af lovforberedende dokumenter, relevant retspraksis fra EU-Domstolen og litteratur. Analysen er udmøntet i fem videnskabelige artikler, hvoraf de tre tidligere er blevet offentliggjort i videnskabelige tidsskrifter og en fjerde i en konference-publikation. Den femte artikel forventes indleveret til et relevant videnskabeligt tidsskrift.

Afhandlingens hovedkonklusionen er, at gråzonen er knyttet til to afgørende lovgivningsmæssige valg i fødevareforordningen.

For det første er definitionen af risikobegrebet i fødevareforordningen temmelig snæver på grund af den retlige sammenkædning med farer af kemisk, biologisk og fysisk karakter. Andre former for trusler mod menneskers sundhed, såsom dem, der vedrører den ernæringsmæssige sammensætning af fødevarer, er ekskluderet fra risikobegrebet. Konsekvensen heraf er, at den fødevaresikkerhedsmæssige risikovurdering hovedsageligt begrænses til klassisk toksikologi, mens der ikke systematisk tages hensyn til andre forskningsområder som epidemiologi og adfærdsrelateret

ekspertise. Dette resulterer i manglende viden med hensyn til, hvordan fødevarers sammensætning og forbrugeradfærd hænger sammen, og hvordan de kan påvirke menneskers sundhed.

For det andet anbringes det fulde ansvar for konsekvenserne af kostrelaterede valg hos forbrugeren. Dette må ses i modsætning til, at fødevareforordningen for så vidt angår sikkerhedsmæssige risici (jf. den snævre definition ovenfor) placerer ansvaret på fødevarevirksomheden. Forbrugeren forventes således at være relativt vidende og rationel, samt at udvise passende adfærd på baggrund af oplysningerne på en fødevares etiket eller de generelt tilgængelige oplysninger i samfundet.

Fra et risikostyringssynspunkt kan det virke både rimeligt og effektivt at påføre forbrugeren ansvaret for de sundhedsmæssige konsekvenser af adfærd og valg, der afviger fra fødevareinformation på etiketter eller anden tilgængelig information. Men med hensyn til de fødevarer, der falder i den såkaldte gråzone, kan en sådan ansvarsfordeling gøre det vanskeligt for forbrugerne at foretage de rette sundhedsmæssige valg.

I henhold til det af EU-Domstolen udviklede forbrugerbegreb er kravene til fødevareinformation til forbrugere baseret på en relativt lav fællesnævner for forbrugerbeskyttelse. For at beskytte sig selv mod potentiel fare må forbrugerne være i stand til at tyde ofte ganske tekniske data om karakteren og sammensætningen af levnedsmidler. Dernæst forventes forbrugerne at kunne forudsige konsekvenserne af deres samlede kost- og livsstilsrelaterede valg både på kortere og længere sigt.

Konklusionen er at den nuværende lovgivningsmæssige ramme i EU's fødevarelovgivning ikke giver tilstrækkelig beskyttelse til forbrugerne mod "gråzonefødevarer" på grund af:

(a) Et snævert risikobegreb i fødevareforordningen, der indskrænker den fødevaresikkerhedsmæssige risikovurdering til farer af biologisk, kemisk og fysisk karakter og som systematisk ser bort fra andre forskningsdiscipliner, såsom adfærdsrelateret viden og epidemiologi;
(b) Anvendelse af en adfærdsrelateret risikofaktor, som bevirker, at ansvaret for de potentielle negative sundhedsmæssige konsekvenser fra forbrugeradfærd og valg, som ikke vurderes at falde ind under "normalt" forbrug, forbliver hos forbrugeren.

Spørgsmålet er, om EU kunne træde til og regulere sådanne gråzonefødevarer. Selvom TEUF ikke fastsætter en specifik hjemmel til at vedtage fødevaresundhedslovgivning og udtrykkeligt forbyder harmonisering af medlemsstaternes lovgivning der vedrører offentlig sundhed, viser denne

afhandling, at der i EU er mulighed for at vedtage harmoniseringsforanstaltninger for at lette beskyttelsen af forbrugernes sundhed.

I den seneste tid har EU vedtaget flere restriktioner på et område, hvor forbrugernes sikkerhed ikke direkte er på spil. Reglerne om obligatorisk mærkning af fødevarer er blevet suppleret med næringsdeklarationen, og der er indført ny regulering af frivillig fødevareinformation, der kan vildlede forbrugeren med hensyn til de obligatoriske oplysninger. Det forbrugerbillede, der fremgår af disse lovgivningsmæssige justeringer, er af en forbruger, der sandsynligvis er interesseret i en ernæringsmæssigt velafbalanceret kost, men som ikke nødvendigvis har den relevante viden til at foretage velovervejede valg i dette henseende.

Udviklingen illustrerer et øget engagement fra EU-lovgiveren til at styrke forbrugernes position i takt med moderniseringen af produktionsmetoder og reklameteknikker. Den indikerer ikke en ændring i fortolkningen af forbrugerbegrebet i EU's fødevarelovgivning. Tværtimod bekræfter indsatsen for en forbedret forbrugeroplysning EU-lovgiverens grundlæggende antagelse, at forbrugere er i stand til at beskytte deres egen sundhed og trivsel så længe de har adgang til forbrugeroplysninger.

Det kan imidlertid være meget vanskeligt for forbrugeren at foretage passende valg af fødevarer. Forbrugerne udsættes for avancerede marketingteknikker og deres valg er ikke alene drevet af rationelle overvejelser. Et meget omdiskuteret spørgsmål i denne sammenhæng er, hvilken rolle EU skal spille i forhold til børn, især med hensyn til fødevarereklamer rettet mod denne aldersgruppe.

Betragtet fra en traditionel, risikobaseret synsvinkel, er legitimiteten af begrænsende lovgivning afhængig af, at der anføres videnskabeligt bevis for en reel risiko for menneskers sundhed. Men hvor der er ingen tvivl om, at reklamer for fødevarer har en påvirkning af børn er der ikke klarlagt – og kan der nok heller ikke klarlægges – en årsagssammenhæng mellem sådanne reklamer og sundhedsrelaterede problemer som fedme.

En rettighedsbaseret tilgang, derimod, knytter en ret til særlig beskyttelse til børnenes aldersrelaterede sårbarhed. Anvendelsen af en sådan rettighedsbaseret tilgang i EU's fødevarelovgivning giver mulighed for at afvise anvendelse af princippet om det informerede valg i forhold til mindreårige. Med en sådan tilgang kan fødevarerelaterede reklamer rettet mod eller særligt egnet til at appellere til børn blive betragtet som vildledende, således at de anses for at være forbudt i henhold til artikel 7 i Europa-Parlamentets og Rådets forordning (EU) Nr. 1169/2011 af 25. oktober 2011 om fødevareinformation til forbrugere (FIR).

Samlet set kan der argumenteres for, at der er behov for at udfylde hullerne i fødevarelovgivningen gennem udvikling af fødevaresundhedslovgivning i EU. Det kan f.eks. ske ved at udvide den nuværende retlige definition af fødevarerisikoen til at dække over ikke-sikkerhedsmæssige sundhedstrusler.

Der er to mulige veje frem til en bedre integration af fødevaresundhed i EU's fødevarelovgivning. For det første kunne rækkevidden af risikoanalysen udvides ved at lade resultaterne af andre videnskabelige discipliner spille en eksplicit rolle i den fødevaresikkerhedsmæssige risikovurdering. Resultatet ville være en mere omfattende evaluering af de mulige sundhedsmæssige konsekvenser af fødevareforbrug. Dette vil medføre øget viden om, hvordan fødevarers sammensætning, spiseadfærd og sundhed hænger sammen.

En anden mulighed ville være at acceptere, at forbrugerne ikke har en fælles forståelse af, hvad der er normal spiseadfærd, og at EU-lovgivningen således bør fremme en bedre forståelse. Et ordentligt svar kræver en generel revidering af lovgivningen om fødevareinformation med henblik på at sikre behørigt hensyn til mere sårbare forbrugere. Dernæst kan den omfattes den endelige vedtagelse af ernæringsprofiler for at kunne skelne mellem fødevarer af ringere eller bedre kvalitet.

I lyset af fedmeepidemien, der har Europa i sit greb, haster det med udviklingen af den lovgivningsmæssige infrastruktur, der vil muliggøre en EU-indsats mod sundhedsmæssige problemer forårsaget af indtagelse af usunde fødevarer og ubalanceret kost. Denne afhandling viser, at lovgivningsmæssige tiltag er mulige og bidrager med løsningsmodeller.

1 General introduction

1.1 Introduction

What is food safety? Can food that qualifies as safe still pose a threat of some kind to human health? If yes, does EU food law have role to play in eliminating or reducing such non-safety health risks? These are questions that concern the purpose and scope of food safety legislation in the EU, which are the focus of this thesis.

The analysis will concentrate on the General Food Law Regulation (GFL), which is the main instrument of EU food law.[1] It lays down the general principles and requirements for both EU and Member State food legislation.

Article 5 GFL establishes the general objectives of EU food law. Article 5(1) GFL prescribes that "[f]ood law shall pursue (…) a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade". At the same time, Article 5(2) GFL requires that "[f]ood law shall aim to achieve the free movement" of food and feed in the EU. Accordingly, EU food law is the result of the weighing and balancing of, on the one hand, the protection of consumers' health and other interests in relation to food and, on the other, the effective functioning of the internal market.[2] This endeavour has led to the acceptance of two fundamental principles of EU food law: the principle of food safety, set out in Article 14 GFL, and the principle of informed choice, laid down in Article 8 GFL.[3]

The principle of food safety is at the basis of strict safety rules that ban from the EU market all foods that are deemed to pose a risk to human health because they contain dangerous microorganisms or

[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, pp. 1-24.
[2] See also Article 1 of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[3] These principles originate in 1985, when the Commission produced its Communication to the Council and to the European Parliament on the Completion of the internal market for foodstuffs: Community legislation on foodstuffs, (COM(85), 603 final). In its Communication, the Commission set out the framework for consumer protection in EU food law based on, e.g., the basic assumption that if consumers are offered adequate food information, "it is not necessary to define these elements in law unless they are required for the protection of public health" (p. 8). See further Caoimhín MacMaoláin (2007). *EU food law: protecting consumers and health in a common market* (Oxford: Hart Publishing), at p. 72.

are contaminated with harmful substances – foods that are *unsafe*.[4] This system effectively establishes a consumer right to food safety and provides consumers with a claim against the responsible food operator if food does not live up to the safety requirements.[5]

The principle of informed choice guides EU food information legislation, which is defined in the Food Information Regulation (FIR) as the set of EU provisions governing food information "made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication".[6]

This way, EU food law creates the basis for a distinction between food safety and non-safety issues. Whereas safety issues are defined in terms of risk and met with stringent regulation, non-safety issues are dealt with primarily by providing food information to consumers, maintaining the principle of free choice and emphasising individual consumer responsibility. This system has its limitations, because food safety alone does not ensure a good consumer health.[7] Food can also affect human health and well-being for reasons that fall outside the scope of food safety. The growing prevalence of obesity and non-communicable diseases (NCDs) like diabetes and cardiovascular conditions is one example of a modern, food-related health challenge that seems difficult to fit into the rather narrow concept of food safety in the GFL.[8]

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[4] Article 14(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

[5] Article 19 of Regulation (EC) No 178/2002 (GFL, *supra* note 1) places on food operators the responsibility to withdraw foods that do not comply with food safety requirements from the market or to recall them from consumers. Pursuant to Article 21 of Regulation (EC) No 178/2002 (GFL, *supra* note 1), food operators that do not comply with these obligations are liable to consumers for any damages in accordance with the provisions of Council Directive 85/374/EEC on the approximation of the laws, regulation and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 07.08.1985, pp. 29-33.

[6] Article 2(2)(a) and (b) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ L 304, 22.11.2011, pp. 18-63.

[7] Articles 3(9) and (14) of Regulation (EC) No 178/2002 (GFL, *supra* note 1) link "risk" to "biological, chemical or physical" hazards, only.

[8] On its website, the WHO describes non-communicable diseases as "a group of conditions that includes cardiovascular diseases, cancer, mental health problems, diabetes mellitus, chronic respiratory disease and musculoskeletal conditions (...), which are largely preventable and which are linked by common risk factors, underlying determinants and opportunities for intervention" (http://www.euro.who.int/en/what-we-do/health-topics/noncommunicable-diseases/what-are-noncommunicable-diseases).

The question that is the focus of this thesis is to what extent EU food law addresses non-safety health threats by offering consumer protection from foods that are safe according to legal definition, but that can compromise human health for reasons that fall outside the scope of risk in the GFL, such as their nutritional composition.

The central question that this thesis aims to answer is, therefore:

> **To what extent does EU food law offer consumer protection from foods that are not deemed unsafe in a legal sense, but that may compromise human health due to other factors, e.g., their nutritional composition?**

The objectives of the thesis and main research questions will be further addressed in Section 1.3.

1.2 Background

1.2.1 The system of the GFL

The 2002 GFL harmonised the laws of the Member States in matters concerning food safety. The regulation is based on Articles 37, 95, 133 and 152(4)(b) of the EC Treaty, provisions that have since been converted to the Treaty on the Functioning of the European Union (TFEU). They are currently laid down in Article 43 TFEU on the common agricultural policy, Article 114 TFEU on the internal market, Article 207 TFEU on the common commercial policy and Article 168(4)(b) TFEU on veterinary and phytosanitary measures aimed to protect human health.[9] Together, these provisions provide the legal foundation for a well-functioning trade in safe food products in the EU.

The choice of a regulation as the preferred legal instrument underlines the Commission's intention at the time to develop an overarching set of definitions, principles and measures regulating the entire food supply chain. This way the Commission aimed not only to harmonise diverging national requirements but indeed to provide the basic framework for future EU food law.[10]

[9] Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007, OJ C 306, 17.12.2007, pp. 1-133.
[10] Commission proposal of 8 November 2000 for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law establishing the European Food Safety Authority, and laying down procedures in matters of food, COM(2000) final, at p. 5.

The GFL is a product of its time. It was adopted in the aftermath of a series of food safety incidents in late 1990s, which explains its strong focus on reinstating consumer confidence in the safety of the EU food supply.[11] To achieve this aim, the GFL established the principle of risk analysis and laid down the structures and mechanisms for the scientific substantiation of any decision related to food safety, including the creation of the European Food Safety Authority as an independent scientific risk assessor at the EU level.[12] Because of the separation between risk assessment and risk management chosen in EU food law, EFSA has not been given responsibility for deciding on the appropriate protective level in society, or for choosing the measures to ensure that level.[13]

Article 14(1) GFL constitutes the embodiment of the principle of food safety. It provides that "[f]ood shall not be placed on the market if it is unsafe". Article 14(2) GFL further specifies when food is deemed unsafe. This is so, firstly, if the food in question is considered to be injurious to health in regard to its "probable immediate and/or short and/or long-term effects", as well as its "probable cumulative toxic effects" on human health.[14] Secondly, foods will be deemed unsafe if they are considered unfit "for human consumption according to their intended use, for reasons of contamination or decay."[15]

The dividing line between safe and unsafe food is determined, essentially, by *risk*. Article 6(1) GFL states: "In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure."

Pursuant to the principle of risk analysis, "the three interconnected components of risk analysis [defined in the GFL] – risk assessment, risk management, and risk communication – provide a systematic methodology for the determination of effective, proportionate and targeted measures or

[11] *Ibid*.
[12] Article 6 of Regulation (EC) No 178/2002 (GFL, *supra* note 1), see also recital 34 of the Preamble.
[13] See in this sense Anna Szajkowska (2012). *Regulating food law* (Wageningen: Wageningen Academic Publishers), at p. 54.
[14] Article 14(2)(a) and (4)(a) and (b) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[15] Article 14(2)(b) and (5) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

other" protective actions that reduce, eliminate or avoid risks to human health.[16] Hence, in matters that concern human health and life, in principle, risk analysis is mandatory.[17]

Inversely, food law relating to consumer information or the prevention of misleading practices does not need such scientific foundation.[18] These issues are governed by the principle of informed choice laid down in Article 8(1) GFL, which provides: "Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume." This principle is at the basis of EU food information legislation. Accordingly, Article 3(1) FIR provides that "[t]he provision of food information to consumers shall pursue a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical considerations."[19]

1.2.2 EU policy in the area of diet, lifestyle and nutrition: A short overview

The GFL's strong focus on food safety reflects that, at the time of its adoption, nutrition and diet were not really issues of concern at the EU policy level. First from the mid-eighties, people became gradually aware of a correlation between diet and lifestyle on the one hand, and health and well-being on the other. This led to a number of sectoral initiatives in the area of public health, an important example of which is Europe against cancer, the first major public health prevention programme in Europe.[20] The programme focused on lifestyle as a health determinant and proposed action in relation to tobacco and alcohol consumption, as well as dietary habits.

In 1990, the Council adopted its Directive on nutrition labelling, which explicitly acknowledged the existence of a relation between diet and health, as well as between nutrition labelling and consumer

[16] Recital 17 of the Preamble to Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[17] Interestingly, in the Commission's original proposal, Article 6 was titled "protection of health". This was later amended to "risk analysis". See: Commission proposal for a GFL, *supra* note 10, at p. 38.
[18] Commission proposal for a GFL, *supra* note 10, at p. 9
[19] Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[20] Resolution of the Council and the Representatives of the Governments of the Member States, meeting within the Council, of 7 July 1986, on a programme of action of the European Communities against cancer, OJ C 184, 23.07.1986, pp. 19-20.

choice.[21] Around the same time, the Council adopted a resolution on an action programme on nutrition and health, which placed nutrition on the political agenda.[22]

On several occasions in the following years, the Council urged the Commission to develop targeted initiatives.[23] As a result, in 2003, the Commission established the Network on Nutrition and Physical Activity,[24] followed, in 2005, by the creation of the European Platform for Action on Diet, Physical Activity and Health.[25] Moreover, in 2007, the Commission adopted a White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues, which set forth the first overall EU nutrition policy and aimed at "reducing ill health due to poor nutrition, overweight and obesity".[26]

The Strategy's starting point was the conviction that consumers are ultimately responsible for their own lifestyle and that of their children. At the same time, however, it recognised that people's behaviour is influenced by their environment. For this reason, the Strategy focused its food-related actions on the provision of consumer information and on the availability of healthy alternatives, thus enabling consumers to make conscious and deliberate food choices at all times. The Strategy considered reformulation of manufactured foods as a policy option. To date, product reformulation initiatives remain largely voluntary.[27]

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[21] Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling of foodstuffs, OJ L 276, 06.10.1990, pp. 40-44.

[22] Resolution of the Council and of the Representatives of the Governments of the Member States, meeting within the Council, of 3 December 1990, concerning an action programme on nutrition and health, OJ C 329, 31.12.1990, pp. 1-3.

[23] This happened in 1992 by Conclusions of the Council and the Ministers for Health of the Member States, meeting within the Council, of 15 May 1992, on nutrition and health, OJ C 148, 12.6.1992, p. 2, in 2000 by Council Resolution of 14 December 2000 on health and nutrition, OJ C 20, 23.1.2001, p. 1, in 2002 by Council Conclusions of 2 December 2002 on obesity, OJ C 011, 17.01.2003, p. 3, in 2003 by Council Conclusions of 2 December 2003 on healthy lifestyles: education, information and communication, OJ C 022 , 27.01.2004, pp.1-2 and in 2005 by Council Conclusion on obesity, nutrition and physical activity, OJ C 213, 8.7.2014, pp. 1-6.

[24] The Network functions as an advisory platform to the European Commission and consists of national experts.

[25] The EU platform for action on diet, physical activity and health "is a forum for European-level organisations, ranging from the food industry to consumer protection NGOs, willing to commit to tackling current trends in diet and physical activity." The aim of the platform is "to provide an example of coordinated action" by different stakeholders "to encourage national, regional or local initiatives across Europe." See the Platform's website at http://ec.europa.eu/health/nutrition_physical_activity/platform/ (accessed 2 May 2016).

[26] White Paper of 30 May 2007 on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues, COM(2007) 279 final, at p. 2.

[27] To stimulate such voluntary measures, on 13 October 2011, the Commission put forward a draft Commission Regulation amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims, Doc. SANCO/11552/2011. The draft regulation contained a proposal to bring reformulated foodstuffs under the scope of the Regulation 2006/1924 on nutrition and health claims made on food. It was proposed that reformulated foods that provide a reduction in content of at least 15 % for energy, fat, saturated fat, salt/sodium should be allowed to bear the claim "now

The Strategy proposed a self-regulatory partnership approach. Its main implementation tools were the 2005 EU Platform and the High Level Group on Nutrition and Physical Activity, set up in December 2007.[28] Based on the White Paper, action has been undertaken at the EU level, e.g., to improve the provision of food information to consumers[29] and restrict food marketing to minors.[30]

On 29 April 2013, the Public Health Evaluation and Impact Assessment Consortium (PHEIAC) published its Report on the Evaluation of the implementation of the Strategy for Europe on Nutrition, Overweight and Obesity related health issues.[31] The report concluded that although most of the action taken at the EU and at the national levels had been of a relatively soft nature, the implementation of the Strategy had been "reasonably effective". At the same time, it articulated that evidence shows "that more intrusive measures, in particular stricter regulation and/or fiscal measures, would be more effective to combat overweight and obesity".[32]

The most recent EU policy instrument in the area of nutrition is the EU Action Plan on Childhood Obesity 2014-2020, which aims to "contribute to halting the rise in overweight and obesity in children and young people by 2020".[33] The Action Plan seeks to achieve this goal through a comprehensive, multi-sectoral approach addressing the varied behavioural risk factors associated with overweight and obesity. It identifies three main types of stakeholder that are to play a role: the EU Member States, the European Commission and international organisations such as the WHO and civil society. Key

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contains X % less [energy, fat, saturated fat, sodium/salt]" or any claim likely to have the same meaning for the consumer. However, the European Parliament voted against this proposal by resolution of 2 February 2012, P7_TA(2012)0022.

[28] White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues, *supra* note 26, at p. 4.

[29] Through the adoption of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.

[30] Through the adoption of Directive 2007/65/EC of the European Parliament and of the Council of 11 December 2007 amending Council Directive 89/552/EEC on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities, OJ L 332, 18.12.2007, pp. 27-45 (Audio Visual Media Services Directive). The Directive was subsequently codified in Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (codified version), OJ L 95, 15.4.2010, pp. 1-24.

[31] Public Health Evaluation and Impact Assessment Consortium (PHEIAC) (2013)**.** Final Report of 29 April 2013 on the Evaluation of the Implementation of the Strategy for Europe on Nutrition, Overweight and Obesity related health issues, http://ec.europa.eu/health/nutrition_physical_activity/docs/pheiac_nutrition_strategy_evaluation_en.pdf (accessed 24 August 2015).

[32] *Ibid*, at p. 8.

[33] EU Action Plan on Childhood Obesity 2014-2020 of 24 February 2014 [updated 12 March and 28 July 2014], http://ec.europa.eu/health/nutrition_physical_activity/docs/childhoodobesity_actionplan_2014_2020_en.pdf (accessed on 30 October 2015), at p. 8.

areas for action identified in the Action Plan are a healthy eating environment, the restriction of marketing and advertising to children, the provision of information and encouragement of physical activity. None of the action areas identifies the adoption of legislation as the way forward.[34]

1.2.3 Risk analysis in the GFL

The GFL defines "risk analysis" as "a process consisting of three interconnected components: risk assessment, risk management and risk communication".[35] This definition is in line with the Codex Alimentarius definition.[36]

Crucial for determining whether a food poses a risk that should be subject to management measures is "risk assessment". The GFL defines risk assessment as "a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation".[37] Distinct from risk assessment, risk management is defined as "the process (…) of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options".[38] Risk communication comprises then "the interactive exchange of information and opinions throughout the risk analysis process" between all the stakeholders involved.[39]

It follows from the definitions in the GFL that risk in a legal sense is a rather technical notion with a scope that is far narrower than what appears to be implied in the colloquial term. Article 3(9) GFL defines "risk" as "a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard". A "hazard", in turn, is defined as "a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect".[40] Accordingly, food safety risk analysis is confined to the scientific evaluation of the potential adverse health effects from only biological, chemical or physical hazards in foods. This means that any

[34] For an overview of the developed of nutrition and health policies in the EU, see Martin Holle (2014). Nutrition policy in the European Union. In: Bernd M.J. van der Meulen (ed.) *EU Food Law Handbook* (Wageningen: Wageningen Academic Publishers), at p. 485-522.
[35] Article 3(10) GFL of Regulation (EC) No 178/2002(GFL), *supra* note 1.
[36] Codex Alimentarius Commission (2015). *Procedural Manual* (24th edition, Rome: FAO/WHO).
[37] Article 3(11) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[38] Article 3(12) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[39] Article 3(13) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[40] Article 3(14) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

potentially negative effect on human health that cannot fit into this rather limited scope of risk will not be regarded as a food safety issue. By consequence, it will be viewed as a matter of consumer choice that, if necessary, is addressed by means of the provision of consumer information. This way, the principle of informed choice functions as a kind of safety net for non-safety issues, resulting in its rather broad application.

Despite the limitation of risk assessment to a narrow concept of risk and hazard, Article 6(3) GFL opens up for "other factors legitimate to the matter under consideration" to be taken into account for the purpose of risk management, "including societal, economic, traditional, ethical and environmental factors and the feasibility of controls".[41] This means that the risk manager is free to base the choice between available risk management options on considerations that are distinct from the risk assessment. There may even be a certain margin of discretion to choose measures that deviate from the results of risk assessment, i.e. from EFSA's scientific opinion. However, in light of the primacy in the GFL of science as a basis for food safety, the outcome of scientific risk assessment is of overriding importance, and the risk manager will be under the obligation to duly justify the reasons for setting aside scientific evidence.[42]

Finally, the GFL introduces a uniform basis for the application of the precautionary principle in the EU, which may be helpful when uncertainty exists as to whether a food poses a health risks.[43] In accordance with this principle, decision makers or risk managers may adopt measures when there is reasonable ground for concern that an unacceptable level of risk to health exists, while the available supporting information and data are not sufficiently complete to enable a comprehensive risk assessment. Such measures have to be non-discriminatory, proportional and should be provisional until comprehensive information can be gathered and analysed.[44] Moreover, the application of the precautionary principle is restricted to risks as defined by natural science during risk assessment, which limits its scope to food safety in the above narrow sense.[45]

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[41] Recital 19 of the Preamble to Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[42] See in this sense Szajkowska (2012). *Regulating food law*, *supra* note 13, at p. 54.
[43] Recital 20 of the Preamble to Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[44] Article 7 of Regulation (EC) No 178/2002 (GFL), *supra* note 1. See further the Communication from the Commission of 2 February 2000 on the precautionary principle, COM(2000) 1 final, at p. 18.
[45] According to Szajkowska, the precautionary "principle provides a *mechanism* within the risk analysis methodology enabling decision makers to take a measure where the relevant scientific evidence is insufficient, whereas scientific risk

To distinguish risk in a legal sense from the broader, more common concept, this thesis will apply the term "risk" in a narrow sense, as defined in the GFL. Any referral to a wider scope of peril will be clearly marked by the use of specific or alternative terminology, such as "health threat", "threats to human health", "lifestyle risk", "behavioural risk", etc.

1.2.4 Safe versus unsafe food: the emergence of a grey area of regulation

The split legal framework between food safety and non-safety issues, which is at the core of EU food law, gives rise to the existence of a grey area of regulation.[46] This grey area emerges from the gap between "white" (food free from threats to human health) and "black" (legally unsafe food) and represents the band in which health threats may occur that food safety regulation does not address.[47]

According to Bernd van der Meulen, the "double negation 'unsafe ... not'" in Article 14(1) GFL confirms that at the time of the adoption of the GFL, the EU legislature was well aware of its creation of this "continuum between safe and unsafe".[48] Van der Meulen finds support for his interpretation in Recital 26 to the Preamble of the GFL, which refers to the existence of diverging national criteria for establishing when a food is safe. Interestingly, Recital 27 of the Preamble to the GFL seems to indicate that the GFL was intended precisely to abolish these differences by offering an EU-wide definition of food safety. It does not. Instead, it offers criteria for establishing when food is *un*safe, which is not necessarily the same. Quite on the contrary, the negative definition laid down in Article 14(1) GFL appears to be more lenient than the positive definition originally included in the Commission proposal for a GFL, which stated: "Only food that is safe under normal and reasonably foreseeable conditions of use shall be placed on the market."[49] This formulation placed the burden of proof for the safety of food under "normal and foreseeable conditions of use" on the food operator.

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assessment and other legitimate factors determine the *content* of the measure." See Szajkowska (2012). *Regulating food law*, *supra* note 13, at p. 92.

[46] See, however, Bernd van der Meulen (2012). The Core of Food Law: A Critical Reflection on the Single Most Important Provision in All of EU Food Law. 7(3) *European Food and Feed Law Review*, pp. 117-125, at p. 117, according to whom Article 14 GFL is the core of EU food law. This seems to imply that for this author non-safety issues come at a second place.

[47] *Ibid*, p. 118.

[48] *Ibid*.

[49] Article 12(1) of the Commission proposal for a GFL, *supra* note 10, at p. 40. See further: Van der Meulen (2012). The Core of Food Law: A Critical Reflection on the Single Most Important Provision in All of EU Food Law, *supra* note 46, p. 118.

However, the grey area between risk and safety is not caused by the discrepancy between a negative and a positive wording alone. It follows from a combination of factors, addressed in this thesis, which together result in a narrow scope of risk and safety in the GFL.

From the perspective of contemporary EU food law, foods that fall within the grey area do not pose a food safety risk in that they do not carry biological, chemical or physical hazards. If they did, they would be "black", i.e., unsafe. From a broader, consumer-oriented point of view, however, it is not certain that the (normal or reasonably foreseeable) consumption of these foods will be free from any negative effects on people's functioning and well-being in the shorter and longer run. Such negative effect could result, for instance, from the regular consumption of food products that contain high amounts of sugar, salt or fat, or other less-beneficial substances. These potentially negative characteristics place these foods in the grey area of regulation between risk and safety.

1.2.5 Healthy versus unhealthy foods

Grey area foods are inevitably linked to rather fierce debate on healthy versus unhealthy foodstuffs.

Advocates for the introduction of some sort of classification that distinguishes less healthy food products from the healthier kind have argued that a clearer definition of the nutritional quality of food – both in absolute terms for the individual product and in relation to consumers' overall consumption patterns – would help consumers to make healthy dietary choices.[50] Opponents have argued that there "is no such thing as bad food, only bad diets".[51]

Illustrative in this respect is the 2013 Academy of Nutrition and Dietetics' position on a total diet approach to healthy eating.[52] The Academy stated that "labeling specific foods in an overly simplistic manner as 'good foods' and 'bad foods' is not only inconsistent with the total diet approach, but it

[50] Tim Lobstein and Sue Davies (2008). Defining and labelling 'healthy' and 'unhealthy' food. 12(3) *Public Health Nutrition*, pp. 331–340, at p. 331.
[51] See in this respect Elaine Watson (2013). Is the "there is no such thing as bad foods, only bad diets" argument helpful? Food Navigator USA, available online at: http://www.foodnavigator-usa.com/R-D/Is-the-there-is-no-such-thing-as-bad-foods-only-bad-diets-argument-helpful (last accessed 30 October 2015).
[52] Jeanne H. Freeland-Graves and Susan Nitzke for the Academy of Nutrition and Dietetics (2013). Position of the academy of nutrition and dietetics: total diet approach to healthy eating. 113(2) *Journal of the Academy of Nutrition and Dietetics*, pp. 307-317.

can cause many people to abandon efforts to make dietary improvements."[53] Therefore, it further held that "in contrast to the total diet approach, classification of specific foods as good or bad is overly simplistic and can foster unhealthy eating behaviors".[54]

Arguably, it is impossible to categorise foods into two single categories: good or bad. If anything, foods can be classified along a spectrum ranging from unhealthy to healthy, from products containing no nutrients at all and that, from a nutrition point of view, are best avoided (such as soft drinks) to products that are high in nutrients and should make out the larger part of any diet (such as many vegetables). Inevitably, however, most foods would end up somewhere in between because they possess a combination of positive and negative features.

Despite these obvious challenges in classifying foods as more or less healthy, continuous attempts are made to inform consumers about the nutrients in individual foods.[55] One of the more notorious endeavours in this regard resulted from Article 4(1) of Regulation (EC) 1924/2006, the Claims Regulation,[56] which obliged the European Commission to establish, by 19 January 2009, specific nutrient profiles that food or certain groups of foods must respect to be allowed to bear nutrition and health claims.

To provide the Commission with the necessary scientific basis for setting such nutrient profiles, the European Food Safety Authority (EFSA) produced, in 2008, a scientific opinion on the matter.[57] The outcome of this exercise was the recommendation for the adoption of nutrient profiles for food in general with exemptions from the general profile for a limited number of food groups that have

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[53] *Ibid*, at p. 307 (abstract). The Position further states that the Academy's "Total Diet" recommendations are consistent with the approach of the 2010 Dietary Guidelines for Americans (DGA), which define "total diet" as the combination of foods and beverages that provide energy and nutrients and constitute an individual's complete dietary intake, on average, over time.

[54] Freeland-Graves and Nitzke for the Academy of Nutrition and Dietetics (2013). Position of the academy of nutrition and dietetics: total diet approach to healthy eating, *supra* note 52, at p. 307 (abstract).

[55] See for examples of such attempts Lobstein and Davies. Defining and labelling 'healthy' and 'unhealthy' food, *supra* note 50, at p. 331.

[56] Regulation (EC) No 1924/2006 of the Parliament and of the Council of 20 December 2006 on nutrition and health claims made on food, OJ L 404, 30.12.2006, pp. 9-25 (Claims Regulation).

[57] European Food Safety Authority, Panel on Dietetic Products, Nutrition and Allergies (2008). Scientific Opinion on the setting of nutrient profiles for foods bearing nutrition and health claims pursuant to Article 4 of the Regulation (EC) No 1924/2006. 644 *The EFSA Journal*, pp. 1-44, http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/nda_op_ej644_nutrient%20profiles_en%2C3.pdf (accessed 10 May 2016).

important dietary roles but which would be at risk of having a negative profile (such as cheese). At the same time, however, the panel outlined the "inherent difficulty in seeking to apply to individual food products nutrient intake recommendations that are established for the overall diet".[58]

EFSA's report has not been able to settle the controversy. To date, the European Commission has not issued a proposal for setting the nutrient profiling model required by the Claims Regulation,[59] which is now way past its due date.

1.2.6 Choice, lifestyle and consumer behaviour in the GFL

Section 1.2.3 argued that, from the perspective of EU food law, risk has a rather narrow scope, so narrow, in fact, that lifestyle-related or behavioural hazards are generally disregarded for the purpose of food safety risk assessment. This is quite remarkable considering that the WHO reports that on an annual basis, lifestyle-related afflictions cause more than a quarter of the deaths among European citizens, so that "lifestyle" in fact poses one of the major public health challenges in the EU.[60]

Because of their exclusion from the scope of risk and food safety, lifestyle-related health issues are essentially regarded as a matter of individual consumer choice. Illustrative for the Commission's approach in this respect is the statement in its proposal for a GFL that:

> Consumers have the right to choose the types and amounts of foods they eat, and otherwise have the freedom to choose their diet. Where information is provided either on a label or otherwise, or information is generally available, and yet the consumer ignores this information in his choice of diet, or for example, consumes food at abnormal

[58] *Ibid*, at p. 4.
[59] Regulation (EC) No 1924/2006, *supra* note 56.
[60] According to the WHO, in the WHO European Region, 16 per cent of all deaths among adults over age 30 are caused by tobacco (www.euro.who.int/en/what-we-do/health-topics/disease-prevention/tobacco/news/news/2012/04/deaths-from-tobacco-in-europe), 6.5 per cent of deaths are related to alcohol consumption (www.euro.who.int/__data/assets/pdf_file/0006/184155/The-European-Health-Report-2012,-1.-Where-we-are.pdf) and 10-13 per cent of deaths are related to obesity (www.euro.who.int/en/what-we-do/health-topics/noncommunicable-diseases/obesity/facts-and-figures). See further Stephen D. Sugarman (2014). Using outcome regulation to contend with lifestyle risks in Europe: tobacco, unhealthy diets, and alcohol. In: Alberto Alemanno and Amandine Garde (eds). *Regulating Lifestyle Risks in Europe: Tobacco, Alcohol and Unhealthy Diets* (Cambridge: Cambridge University Press), pp. 332-354.

> levels which may ultimately lead to detrimental health effects, this Regulation does not consider these foods to be unsafe where other requirements of food law are met.[61]

EU food law thus addresses choice and behaviour by making a distinction between normal versus abnormal consumption patterns. Pursuant to Article 14(3)(a) and (b)GFL, (a) the normal conditions of use of a food, as well as (b) food information provided to consumers are factors that need to be taken into account when determining the safety of food. Consequently, whereas harm to human health from what is regarded as normal consumptive behaviour would generally raise alarm concerning the safety of the food in question, any deviation from the norm remains for the individual responsibility of the consumer.

Interestingly, EU food law does not contain indications of what is considered "normal" consumptive behaviour, nor does it prescribe that consumers be explicitly informed about normal versus abnormal consumptive levels. Instead, food labels include basic information particulars such as an ingredients list,[62] a nutrition declaration,[63] and details informing consumers on the safe use of the product.[64] Therefore, the correct interpretation and application of food information from a health perspective presupposes that consumers possess and apply a basic level of general knowledge of what is healthy and what is not.

Arguably, it can be difficult for the majority of consumers to transform the often rather technical information on food labels into useful messages about appropriate dietary habits and a healthy lifestyle. As convincingly argued by Garde and others, food consumption involves a multitude of considerations, of which long-term health is just one aspect.[65] Therefore, consumptive decisions will not always turn out as rational and well balanced as one may wish.[66]

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[61] Commission proposal for a GFL, *supra* note 10, at p. 11.
[62] Article 9(1)(b) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[63] Article 9(1)(l) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[64] Article 4(1)(b) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[65] Garde (2010). *EU law and obesity prevention* (The Netherlands: Kluwer Law International), at p. 14.
[66] See further on the subject of consumer choice Geraint Howells (2005). The potential and limits of consumer empowerment by information. 32(3) *Journal of Law and Society*, pp. 349-370; Jacob Jacoby (2000). Is it Rational to Assume Consumer Rationality? 6(1) *Roger Williams University Law Review*, pp. 81-161; Christine Jolls, Cass R. Sunstein and Richard Thaler (1998). A behavioral approach to law and economics. 50(5) *Stanford Law Review*, pp. 1471-1550, at p. 1476; Richard Thaler (1980). Toward a positive theory of consumer choice. 1(1) *Journal of Economic Behaviour and Organisation*, pp. 39-60.

The legal distinction within EU food law between safety and non-safety issues, as well as the corresponding split between food safety and food information legislation are of direct relevance to consumers. Within the context of EU food law, consumers' legal position and protective rights depend on which of their interests are at stake: their health and safety or their other interests, such as their economic interests and well-being.

For the purpose of foods safety legislation, consumers are regarded as essentially helpless in the face of health risks that fall within the scope of Article 14 GFL and that can be identified through scientific risk assessment. If no such risks are at hand, however, consumers are generally expected to be capable and in charge of their own food choices provided that they have access to a minimum number of information particulars about food products.[67]

The guiding norm behind the rather split personality of the EU consumer is the freedom to choose. Although not explicitly recognised as a consumer right within the EU context, the freedom to choose pertains to the core of the internal market.[68] Within the context of EU food law, consumers' freedom to choose what they eat is limited only if food poses a risk to human health. As long as food is safe, freedom rules out protection, no matter how difficult it may be to make appropriate, balanced choices and how multifaceted their potential effect on consumers' health.

1.2.7 What is food health law?

For many years, scholars and civil society organisations alike have called for the adoption of legislation to protect consumers from lifestyle-related afflictions, and much has been written on the potential role for the European Union in fighting such non-safety health scourges and promoting healthier lifestyles.[69] Garde has analysed in detail the legal possibilities and restraints to obesity

[67] Pursuant to Article 8 of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

[68] See Norbert Reich (1998). Some reflections on rethinking community consumer law. In: Ziegel, J.S. (ed.). *New developments in international commercial and consumer law: Proceedings of the 8th Biennial Conference of the International Academy of Commercial and Consumer Law* (Oxford: Hart Publishing), at p. 443.

[69] Tim Lang and Geof Rayner (2005). Obesity: a growing issue for European policy? 15(4) *Journal of European Social Policy*, pp. 301-327; Francesco Branca, Haik Nikogosian and Tim Lobstein (eds) (2007). *The Challenge of Obesity in the WHO European Region and the Strategies for Response* (Copenhagen: WHO Regional Office for Europe); Amandine Garde (2008). Food advertising and obesity prevention: what role for the European Union? 31(1) *Journal of Consumer Policy*, pp. 25-44; Garde (2010). *EU law and obesity prevention*, *supra* note 65; Rob Moodie, David Stuckler, Carlos Monteiro et al. (2013). Profits and pandemics: prevention of harmful effects of tobacco, alcohol, and ultra-processed food and drink industries. 381 (9867) *Lancet*, pp. 670-679. Some of the more recent contributions have been provided by Alberto Alemanno and Amandine Garde (eds) (2014). *Regulating Lifestyle Risks in Europe: Tobacco, Alcohol and*

prevention, arguing for strong EU intervention through regulation rather than self-regulation.[70] Alemanno and others have focused on the risk-side of the equation and addressed the challenges inherent to regulating choice-based risks from, e.g., alcohol, unhealthy diets and tobacco use.[71] Several authors have explored alternatives to stringent regulation, such as *nudge*.[72] In the area of tobacco, legislation is now in place.[73] Within the food arena the EU appears reluctant to intervene, favouring consumer information and self-regulation by industry over restrictive legislation.[74]

This thesis bears the title "EU food health law: regulating the grey area between risk and safety". The term EU food health law is chosen in an attempt to build a bridge between the areas of law that regulate food safety and food information, respectively. By linking food to health within a broader context than food safety in a narrow sense, the thesis addresses the grey area of regulation between risk and safety, which encompasses health threats that relate, e.g., to human behaviour and lifestyle. Other authors have referred to the regulation of these consumptive risks as opposed to safety risks as, e.g., "public health law", "nutrition regulation" and lifestyle regulation.[75] These methodologies have

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Unhealthy Diets (Cambridge: Cambridge University Press), *supra* note 60; Tania Voon, Andrew Mitchell and Jonathan Liberman (eds) (2014). *Regulating Tobacco, Alcohol and Unhealthy Foods: The Legal Issues* (Oxford: Routledge).

[70] Garde (2010). *EU law and obesity prevention, supra* note 65; Alemanno and Garde (2014). *Regulating Lifestyle Risks in Europe: Tobacco, Alcohol and Unhealhty Diets, supra* note 60.

[71] Alemanno and Garde (2014). *Regulating Lifestyle Risks in Europe: Tobacco, Alcohol and Unhealthy Diets, supra* note 60; Alemanno and Garde (2014). The Prevention of Non-Communicable Diseases in the European Union. In: Voon, Mitchell and Liberman (eds). *Regulating Tobacco, Alcohol and Unhealthy Foods: The Legal Issues, supra* note 69.

[72] The term "nudge" was originally defined by Richard Thaler and Cass Sunstein as "any aspect of the choice architecture that alters people's behavior in a predictable way without forbidding any options or significantly changing their economic incentives" in Richard Thaler and Cass Sunstein (2008). *Nudge: Improving decisions about health, wealth, and happiness* (New Haven, CT: Yale University Press), at p. 6. See further, e.g., Alberto Alemanno and Alessandro Spina (2013). Nudging Legally. On the Checks and Balances of Behavioural Regulation. 12(2) *International Journal of Constitutional Law*, pp. 429-456; Alberto Alemanno and Anne-Lise Sibony (2015). *Nudge and the Law. A European Perspective* (Oxford: Hart Publishing).

[73] Tobacco products are regulated in, e.g., Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ L 127, 29.04.2014, pp. 1-38.

[74] See for an overview of the potential barriers to the use of the law in the battle against obesity Jo Jewell J, Corinna Hawkes, Kate Allen (2013). *Law and obesity prevention: addressing some key questions for the public health community.* World Cancer Research Fund International Working Paper, http://www.wcrf.org/sites/default/files/WCRF-International-Law-and-Obesity-Prevention.pdf (accessed 27 October 2015).

[75] Michelle Mello, David Studdert and Troyen Brennan define a "public health law approach" in Michelle Mello, David Studdert and Troyen Brennan (2006). Obesity: The new frontier of public health law. 354(24) *The New England Journal of New Medicine*, pp. 2601-2610, at p. 2601. Alemanno and Garde focus on "regulating lifestyle risks" in, e.g., Alemanno and Garde (2014). *Regulating Lifestyle Risks in Europe: Tobacco, Alcohol and Unhealthy Diets, supra* note 60. Paula Fitzgerald Bone and Karen Russo France speak of "nutrition regulation" in Paula Fitzgerald Bone and Karen Russo France (*2003*). International Harmonization of Food and Nutrition Regulation: The Good and the Bad. 22(1) *Journal of Public Policy & Marketing*, pp. 102-110.

in common that they are based on the conviction that governments can and must use their power to regulate human consumptive behaviour to create conditions that allow people to lead healthier lives, either by providing consumer information or by adopting measures that are more restrictive.[76] They share the basic assumption promoted in modern behavioural law and economics that human behaviour is characterised by bounded rationality. Because humans do not always respond to the law in a rational way, the law must anticipate and accommodate a certain level of irrational behaviour to be effective.[77]

1.3 Objective and methodology

This thesis studies the legal distinction between food safety and non-safety in search of gaps, overlaps or frays. Its main objective is to examine to what extent EU food law comprises food health law, i.e., whether it offers consumer protection from foods that are not deemed unsafe in a legal sense, but which may pose a threat to human health as a result of, e.g., their nutritional composition. The central question of the thesis can thus be formulated as follows:

To what extent does EU food law offer consumer protection from foods that are not deemed unsafe in a legal sense, but that may compromise human health due to other factors, e.g., their nutritional composition?

The thesis contains five substantive chapters, as well as an introduction and a conclusion. Each of the substantive chapters addresses a different aspect of the thesis' main objective, corresponding with the research questions, identified below.

1. **To what extent does EU food law address consumer protection from non-safety health risks? (Chapter 2)**

   What is the purpose of EU food law? What is the scope of risk and safety in the GFL? Are there any food-related health threats that fall outside the scope of safety in the GFL? To what extent does EU food law address health threats from food that fall outside the scope of risk

[76] See further on this subject Mello, Studdert and Brennan (2006). Obesity: The new frontier of public health law, *supra* note 75. See also Simon Planzer and Alberto Alemanno (2010). Lifestyle Risks: Conceptualizing an Emerging Category of Research. 2(4) *European Journal of Risk Regulation*, pp. 335-337.
[77] See on this subject Jolls, Sunstein and Thaler (1998). A behavioral approach to law and economics. 50(5) *Stanford Law Review*, *supra* note 66.

and food safety in the GFL? Are consumers adequately protected from such non-safety health risks related to food?

2. **To what extent is the EU legislature competent to regulate non-safety health risks from food? (Chapter 3)**

   Could the EU legislature regulate the healthiness of food? What EU Treaty provisions are relevant for regulating consumer health protection from the potential negative effects from food? What are the limits to EU powers in the area of food health?

3. **What is the impact of the informed-choice paradigm on consumer health protection from grey area foods? (Chapter 4)**

   How does EU food law deal with the seeming conflict between the freedom of choice and a high level of consumer (health) protection? Is it possible to protect consumers adequately while, at the same time, guaranteeing them a genuine freedom of choice of what they eat, and *vice versa*? In case of conflict, which interest should prevail: freedom or protection? What is the position of weaker, credulous and gullible consumers: those who appear to have difficulties to manage their freedom and make appropriate food choices?

4. **Has EU food information legislation become more protective of consumers in recent times? (Chapter 5)**

   Can the entry into force of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods (the Claims Regulation)[78] and recent implementing measures be viewed as a sign that the legislature has adopted a more protective attitude towards consumers in an area where consumer safety is not directly at stake? Is the legislature moving away from "informed choice" as a guiding principle for consumer protection in EU food information legislation? Can EU food information legislation be characterised as paternalistic?

5. **To what extent does the EU legislature address protection of the most vulnerable consumers: children? (Chapter 6)**

[78] Regulation (EC) No 1924/2006, *supra* note 56.

> Could a ban on food advertising to minors be established within the EU legal order? To what extent does the EU Treaty provide for an EU competence to protect minors from the commercial promotion of food? Does the EU Treaty allow for the adoption of a rights-based approach to consumer protection?

The thesis will present an analysis of EU regulation of *food health* as opposed to *food safety* with a view to determining if EU food law lives up to its main purpose of ensuring a high level of protection of human life and health. Moreover, the thesis will assess the ways in which EU consumers are protected from health issues that fall outside the scope of risk and safety in the GFL, for example by means of food information.

The thesis is construed as a study of European food law predominantly based on the traditional methods for interpretation of the law, policy documents, case law and doctrine. The focus will be on the GFL (Regulation 178/2002) and the FIR (Regulation 1169/2011), including the preparatory works to these legal instruments. Several other pieces of legislation will be taken into consideration, as well, including the Claims Regulation,[79] the Labelling Directive,[80] the Audio Visual Media Services Directive[81] and the Unfair Commercial Practices Directive.[82] Moreover, the analysis will contain a comprehensive analysis of relevant case law from the CJEU, particularly concerning the development of the average consumer benchmark in misleading advertising.

The main subject – EU food law – will be placed within the broader context of EU law, with a particular focus on the Treaty provisions on EU competence within the area of public health and consumer protection.[83] Other legal disciplines will also be taken into account, such as EU consumer law, public health law and, to a lesser extent, trade law.

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[79] *Ibid*.
[80] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, OJ L 109, 6.5.2000, p. 29-42 (Labelling Directive).
[81] Directive 2007/65/EC, *supra* note 30.
[82] Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market, OJ L 149, 11.6.2005, p. 22-39 (Unfair Commercial Practices Directive).
[83] Arts 168 and 169 TFEU.

Finally, in light of the importance of scientific risk assessment for questions concerning the safety of foodstuffs, this thesis will take into consideration the relevant scientific terminology and procedures and describe the outcome and relevance of the scientific risk assessment of aspartame. Other scientific disciplines will be discussed, as well, including behavioural science, risk-benefit analysis and epidemiology.

Although EU food law is influenced heavily by international developments and agreements, in particular within the context of the World Trade Organisation (WTO), this study focuses on EU food law as laid down in the GFL, the FIR and other, more specific provisions relevant for food production and distribution.[84]

1.4 Set-up of the thesis

The research questions formulated in the previous section will be addressed in separate chapters that are all but one based on articles that were previously published or that are currently under review for future publication. Chapter 6 was not previously published.

Chapter 2 uncovers the breadth and scope of the grey area between safe and unsafe food. For this purpose it is analysed how, at the EU level, risk perception leads to conclusions about the safety of foods by looking into the two main instruments for consumer health protection within the ambit of food law: risk-based safety legislation, and the prohibition against the placing on the market of unsafe foods.[85] These instruments are closely related in that the decision whether or not a food is eligible for placing on the EU market depends to a large extent on the outcome of risk assessment.[86] It will be argued that the grey area in food safety legislation results from the interpretation and application of these instruments as prescribed in Articles 6 and 14 GFL.[87]

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[84] See for a comparison between EU and WTO food law, e.g. Alberto Alemanno (2007). *Trade in Food. Regulatory and Judicial Approaches in the EC and the WTO* (London: Cameron May).
[85] Arts 6(1) and 14(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[86] Alemanno (2007). *Trade in Food. Regulatory and Judicial Approaches in the EC and the WTO*, *supra* note 84, at p. 89. See further on the role of risk assessment in the process of risk analysis, e.g., Giandomenico Majone (2010). Foundations of risk regulation: Science, decision-making, policy learning and institutional reform. 1(5) *European Journal of Risk Regulation* (2010), pp. 5-19; Bernd van der Meulen and Menno van der Velde (2008). *European Food Law Handbook* (Wageningen: Wageningen Academic Publishers), at pp. 267-273; Szajkowska (2012). *Regulating Food Law*, *supra* note 13, at pp. 52-56*;* Ellen Vos (2000). EU food safety regulation in the aftermath of the BSE crisis. 23(3) *Journal of Consumer Policy*, pp. 227-255, at p. 229; Charles E. Yoe (2012). *Principles of risk analysis: decision making under uncertainty* (Boca Raton: Taylor & Francis Group LLC), at pp. 4.
[87] Regulation (EC) No 178/2002 (GFL), *supra* note 1.

On the basis of the example of aspartame, the thesis will discuss the implications of the existence of a grey area. It is demonstrated that risk analysis is driven by a relatively narrow concept of risk. In addition it is shown that the outcome of this process has been made dependent on consumer behaviour in view of what is generally perceived as normal versus risky behaviour in an average consumer.[88,89] By making this behavioural factor of risk one of the determinants for deciding whether or not a food is *safe*, the legislature relies on non-scientific factors as a basis for food safety.[90] This results in an information gap with respect to how food composition, eating behaviour and health are interconnected. Within the current legislative framework, the consumer must assume responsibility for the consequences of this information gap.

Chapter 3 analyses the extent to which the Treaty on the Functioning of the European Union (TFEU) offers a basis for EU consumer protection from the consumption of grey area foods. The Treaty contains several provisions that establish EU competence and which are of relevance to consumer (health) protection in relation to food, the most important being Article 168 in Title XIV on public health and Article 169 TFEU in Title XV on consumer protection, as well as Article 114 TFEU on the approximation of laws of the Member States.

Although 168(5) TFEU expressly prohibits the adoption of harmonising measures in public health matters, it is concluded that the EU can base its legislative competence in food health matters on Article 114 TFEU, possibly in conjunction with Article 169(2) TFEU.

From Chapter 4 onward, focus shifts from risk regulation to the position of the consumer in EU food law and the seeming conflict between consumers' right to choose what they eat and their need for

[88] The Court of Justice of the European Union has consistently "held that the 'reference consumer' is an average consumer who is reasonably well informed and reasonably observant and circumspect". See Case C-358/01, *Commission vs. Spain* [2003] I-13145, at para. 53. See also Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide) [1998] ECR-I-4657, at para. 31. The average consumer benchmark has been codified in several pieces of EU food legislation, e.g., Regulation (EU) No 1169/2011 (the FIR, *supra* note 6), and Regulation (EC) No 1924/2006 (Claims Regulation, *supra* note 56).

[89] See for a further discussion of the average consumer benchmark, e.g., Stephen Weatherill (2007). Who is the average consumer? In: Stephen Weatherill and Ulf Bernitz (eds). *The regulation of unfair commercial practices under EC directive 2005/29: New rules and new technique* (Oxford: Hart Publishing) and for an overview of Case Law from the CJEU see Hannes Unberath and Angus Johnston (2007). The double-headed approach of the ECJ concerning consumer protection. 44(5) *Common Market Law Review*, pp. 1237-1284. For a critical note on the average consumer benchmark, see Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 156.

[90] In accordance with Article 14(3) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

protection from harm. The question arises whether it is indeed possible to protect consumers adequately, while at the same time guaranteeing a genuinely free consumptive choice. This question is particularly relevant in relation to weaker consumer groups, who may encounter difficulties in managing their freedom and making the right choices.

In Chapter 4 the thesis demonstrates how the CJEU, seeking to strike a balance between freedom and protection, developed a protective standard based on an objectified image of the consumer and his needs: the average consumer.[91] Usually, the impetus for protection is the will to balance an unequal relationship in favour of the weaker party. Therefore, one would expect the benchmark food consumer to be relatively weak and unable to protect his or her interests. However, this is not necessarily the image that prevails throughout all of EU food law. Whereas, for the purpose of food safety, the consumer is indeed regarded as essentially helpless in relation to health risks that fall within the scope of Article 14 GFL, when faced with the more diffuse risks that characterise grey area foods, consumers are essentially expected to be capable of making rational and sounds food decisions – as long as they are provided with minimum information particulars.

Recent developments within EU food law have been said to indicate that the EU legislature has taken on a more protective or even paternalistic attitude towards the food consumer and his choice of diet. In chapter 5 it will be argued that, although the most recent legislative measures quite openly establish a link between informed choice and the rather abstract societal norm of what is good for the consumer, this does not justify the conclusion that food information legislation has become overly meddlesome in relation to EU consumers and their choice of food. Rather, a gradual maturing of the EU legislature's perception of its task appears to have taken place, which has resulted in an expansion from mere informed in the direction of educated choice as the underlying objective of the provision of food information to consumers.

Chapter 6 looks into the protection of a group of characteristically vulnerable consumers, children, with a particular focus on the marketing of unhealthy foodstuffs to this age group. It poses the question how a ban on food advertising to children could be established within the EU legal order, and thus

[91] See, e.g., Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide) and C-358/01, *Commission vs. Spain*, *supra* note 88.

elaborates on the work of Amandine Garde, who has extensively studied EU policy in regard to obesity, including advertising to children.[92]

The analysis comprises the balancing of the risk-based approach traditionally favoured at the EU level against a rights-based approach, which derives from children's intrinsic vulnerability their right to be protected from commercial exploitation. It is argued that a rights-based perspective paves the way for regarding food advertising practises targeting children as inherently misleading in the sense of Article 7 of the FIR.[93]

Chapter 7 provides an overall conclusion and recommendations for future research.

[92] Garde (2010). *EU law and obesity prevention*, *supra* note 65, at pp. 76-87.
[93] Regulation (EC) No 1169/2011 (FIR), *supra* note 6.

2 Food safety and the behavioural factor of risk[94]

Abstract

This chapter aims to demonstrate that the current application of the concepts of risk and (un)safety in the GFL[95] results in a grey area within EU food safety regulation. By means of the food safety risk assessment of aspartame it is illustrated that grey area foods, although not unsafe according to legal definition, could compromise human health because of other factors, e.g., their nutritional composition. It will be argued that the grey area emerges from a narrow focus of food safety risk assessment within the ambit of the GFL, which disregards certain types of hazards and causes an information gap with respect to how food consumption, eating behaviour and health are interconnected. At the same time, the scope of foods safety in the GFL is restricted to what is considered normal use of food in light of the information provided on food labels or generally available in society. By choosing this approach, the legislature has set rather high standards for what may be expected of the average consumer in terms of the understanding and avoidance of behavioural risks. As a result, the consumer bears the responsibility for the consequences of the information gap.

2.1 Introduction

When is food safe to eat and when is it not?

The majority of consumers are likely to answer this question by pointing out that safe food should not harm their health – in any way. Within the context of EU food law, however, it is not always that easy or straightforward to distinguish between safe and unsafe food.

The GFL, which provides a general framework for EU food law, does not clarify when food is safe. Instead, it prohibits the placing on the market of foods that are "unsafe",[96] thus focusing on ruling out unsafety rather than establishing *safety*.[97] The implications of such negative definition of food safety in the EU will be discussed in this chapter.

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[94] An earlier version of this chapter was published as Wieke Huizing Edinger (2014). Food Safety and the Behavioural Factor of Risk. 5(4) *European Journal of Risk Regulation* (2014), pp. 491-504.
[95] Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[96] Art. 14(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[97] See further Van der Meulen (2012). The Core of Food Law: A Critical Reflection on the Single Most Important Provision in All of EU Food Law, *supra* note 46, at p. 118.

The concept of unsafety within the ambit of the GFL is a legal construct, made operational by means of food safety risk analysis.[98] Food safety risk analysis, in turn, comprises a systematic way of gathering and evaluating information relevant for decision-making purposes when dealing with an identified hazard.[99] It will be argued, below, that the GFL applies a rather narrow concept of "risk" due to a limited focus on chemical, biological and physical hazards.[100]

These legislative choices, which are at the very core of the GFL, result in the emergence of a grey area between what is commonly accepted as safe and what is legally regarded as unsafe.[101] This grey area represents a continuum between harmless and harmful foods that fall outside the scope of risk and safety – or rather *un*safety – in the GFL.

Within the contours of the grey area, food that appears essentially harmless to human health can under certain conditions be deemed unsafe because it does not meet the quality criteria set out in EU food law.[102] Putrid food, for example, is deemed unsafe because it is considered "unfit for human consumption" – no matter whether it is injurious to health or not.[103] At the same time, foods that pass as safe according to legal definition may possess characteristics that can have a negative impact on human health. For example, foods containing so-called trans fatty acids have been associated with an

[98] Art. 3(10) of Regulation (EC) No 178/2002 (GFL), *supra* note 1. The main risk-related terms in the GFL are based on those provided by the Codex Alimentarius Commission (CAC) in its Procedural Manual, *supra* note 36. The CAC, in turn, was influenced by the terminology in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS-Agreement). See further on this subject Yoe (2012). *Principles of risk analysis: decision making under uncertainty*, *supra* note 86. See further on risk analysis in general Christopher Hood, Henry Rothstein and Robert Baldwin (2001). *The government of risk: Understanding risk regulation regimes* (Oxford: Oxford University Press) and specifically on food safety risk analysis, e.g., Alemanno (2007). *Trade in Food*, *supra* note 84, at pp. 78-103; Majone (2010). Foundations of risk regulation: Science, decision-making, policy learning and institutional reform, *supra* note 86, pp. 5-19; Szajkowska (2012). *Regulating food law*, *supra* note 13, at pp. 52-56; Vos (2000). EU food safety regulation in the aftermath of the BSE crisis, *supra* note 86.

[99] "Hazard" is defined in Art. 3(14) GFL as "a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect" (Regulation (EC) No 178/2002 (GFL), *supra* note 1). See further: Yoe (2012). *Principles of risk analysis: decision making under uncertainty*, *supra* note 86, at p. 4.

[100] A definition of "risk" can be found in Art. 3(9) in conjunction with Art. 3(14) of Regulation (EC) No 178/2002 (GFL), *supra* note 1. The risk concept in the GFL has been analysed in, e.g.: Alemanno (2007). *Trade in Food*, *supra* note 84, at pp. 81-83. See for a more technical angle M.J. Tijhuis, N. de Jong, M.V. Pohjola et al. (2012). State of the art in risk-benefit analysis: Food and nutrition. 50(1) *Food and Chemical Toxicology*, pp. 5-25, at p. 6. For a more theoretical perspective see Karsten Klint Jensen and Peter Sandøe (2002). Food safety and ethics: the interplay between science and values. 15(3) *Journal of Agricultural and Environmental Ethics*, pp. 245-253, at p. 245.

[101] Van der Meulen (2012). The Core of Food Law: A Critical Reflection on the Single Most Important Provision in All of EU Food Law, *supra* note 46, at p. 118.

[102] Art. 14(2)(b) GFL of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

[103] Art. 14(2)(b) and (5) GFL. See further the Commission proposal for a GFL, *supra* note 10, at p. 11.

increased risk of coronary heart disease.[104] Although EFSA, in its 2010 opinion, acknowledged the risk, it was not in favour of setting limits for intake because it did not want to compromise "adequacy of intake of essential nutrients".[105] Despite recognition of the potentially harmful effects of trans fats, so far, the EU has not taken legal measures to restrict their consumption.[106]

Another – arguably more controversial – example of foods that can have detrimental health effects are foods that are high in sugar, particularly sugar-sweetened beverages. Regular consumption is believed to be a significant factor contributing to health issues such as obesity, non-communicable diseases and dental problems.[107] According to the EU Commission's proposal for the GFL, however, such foods are not considered unsafe if they otherwise live up to the requirements of food law and "information is provided either on a label or otherwise, or information is generally available, and yet the consumer ignores this information in his choice of diet".[108]

Hence, although overconsumption of grey area foods such as sugary beverages may result in negative health effects, such effects are generally regarded as avoidable by ensuring that "consumers are appropriately informed as regards the food they consume".[109] This gives rise to the question whether

[104] See, e.g., Shyam M. Teegala, Walter C. Willett and Dariush Mozaffarian (2009). Consumption and health effects of trans fatty acids: a review. 92(5) *Journal of the Associations of Official Analytical Chemists International*, pp. 1250-1257.
[105] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) (2010). Scientific Opinion on Dietary Reference Values for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, *trans* fatty acids, and cholesterol, 8(3):1461 EFSA Journal, www.efsa.europa.eu/en/efsajournal/doc/1461.pdf (accessed on 9 May 2016), at p. 54.
[106] In view of Art. 30(7) of Regulation (EU) No 1169/2011 (FIR, *supra* note 6) it is currently being discussed whether the EU should adopt labelling requirements with respect to trans fats.
[107] A recent paper in *Nature*, one of the world's most prestigious scientific journals, points to a correlation between artificial sweeteners and glucose intolerance. See Jotham Suez, Tal Korem, David Zeevi et al. (2014). Artificial sweeteners induce glucose intolerance by altering the gut microbiota. 514 (7521) *Nature*, pp. 181-186. See further on this subject Vasanti Malik, Matthias Schulze and Frank Hu (2006). Intake of sugar-sweetened beverages and weight gain: a systematic review. 84 (2) *American Journal of Clinical Nutrition*, pp. 274-288. See also the note by the World Health Organisation on the launch, on 5 March 2014, of a public consultation concerning a revised sugars guideline. The WHO proposes a further reduction of the intake of sugars from 10% to 5% of total energy intake per day because of "increasing concern that consumption of free sugars, particularly in sugar-sweetened beverages, may result in both reduced intake of foods containing more nutritionally adequate calories and an increase in total caloric intake, leading to an unhealthy diet, weight gain and increased risk of noncommunicable diseases (NCDs)". Information on the public consultation is available on www.who.int/mediacentre/news/notes/2014/consultation-sugar-guideline/en/ (accessed on 7 May 2014).
[108] Commission proposal for a GFL, *supra* note 10, at p. 11.
[109] Recital 3 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.

food information sufficiently prepares consumers to avoid consumptive behaviour detrimental to their health.[110]

This chapter examines the breadth and scope of the grey area between safe and unsafe food. In addition, it explores the consequences in terms of consumer health protection of EU legislation allowing the marketing of food that is neither entirely risk-free, nor legally unsafe.

This chapter commences with an analysis of how, at EU level, perceived risks lead to conclusions about the safety of foods. For this purpose, Section 2.2 examines the two main instruments for consumer health protection within the ambit of food law: risk-based safety legislation, and the prohibition against the placing on the market of unsafe foods.[111] These instruments are closely related; the decision whether or not a food qualifies for placing on the market depends largely on the outcome of the risk assessment.[112] It will be argued that the grey area in food safety legislation results from the application of these instruments as prescribed in Articles 6 and 14 GFL, respectively.

In Section 2.3, using aspartame as an example, the implications of the existence of a grey area will be discussed. Not only is risk analysis driven by a relatively narrow concept of risk, but the outcome of the process has been made dependent on consumer behaviour in view of what is generally perceived as normal versus risky behaviour[113] in an average consumer.[114] By making this behavioural

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[110] Much has been written on consumers' ability and willingness to maximize their health and well-being and on how to respond to behavioural aspects from a policy perspective. See, for example, Alemanno and Spina (2013). Nudging Legally. On the Checks and Balances of Behavioural Regulation, *supra* note 72; Howells (2005). The potential and limits of consumer empowerment by information; Jacoby (2000). Is it Rational to Assume Consumer Rationality?, *supra* note 66; Jolls, Sunstein and Thaler (1998). A behavioral approach to law and economics, *supra* note 66; Thaler (1980). Toward a positive theory of consumer choice, *supra* note 66.

[111] Arts 6(1) and 14(1) GFL (Regulation (EC) No 178/2002 (GFL), *supra* note 1).

[112] Alemanno (2007). *Trade in Food*, *supra* note 84, at p. 89. See further on the importance of risk assessment for the outcome of risk analysis, e.g., Szajkowska (2012), *Regulating food law*, *supra* note 13, at pp. 52-56*;* Vos (2000). EU food safety regulation in the aftermath of the BSE crisis, *supra* note 86; Yoe (2012). *Principles of risk analysis: decision making under uncertainty*, *supra* note 86.

[113] Pursuant to Art. 14(3) of Regulation (EC) No 178/2002 (GFL), *supra* note 1, "[i]n determining whether any food is unsafe, regard shall be had: (a) to the normal conditions of use of the food by the consumer (…), and (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer (…)". See also Commission proposal for a GFL, *supra* note 10, at p. 11.

[114] When answering the question what may be expected of consumers, the Court of Justice of the European Union consistently refers to the benchmark consumer "reasonably well-informed and reasonably observant and circumspect". See in this sense Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide), *supra* note 88, at para. 31. See also Case C-358/01, *Commission vs. Spain*, *supra* note 88, at para. 53. See for a further discussion of the average consumer benchmarkStephen Weatherill

factor one of the determinants in the process of deciding whether a food is *safe*, the legislature sets aside a reliance on science as a basis for food safety.[115] This results in an information gap with respect to how food consumption, eating behaviour and health are interconnected, for which the consumer is forced to assume responsibility.

Section 2.4 offers a conclusion on the consequences of the system underlying EU food safety legislation, and its effect on the level of protection afforded to consumers regarding their health and other interests.

2.2 The legal framework

2.2.1 Objectives and instruments of EU food law

EU food law aims to protect human life and health and other consumer interests and to achieve the free movement of food and feed that is in agreement with the general principles and requirements of food law.[116] In other words, EU food law is directed at establishing a high level of protection of the consumer's life, health and other interests, and at making the free movement of foodstuffs within the EU dependent on compliance with the legal requirements protecting these consumer interests.[117]

Within the ambit of the GFL, the effort to balance the potentially conflicting interests of free trade and consumer protection[118] has resulted in the adoption of two general principles of EU food law, i.e., the principle of food safety[119] and the principle of informed choice.[120,121] The principle of informed choice can be seen as a context-specific application of the consumer's right to information

(2007). Who is the average consumer?, *supra* note 89 and Unberath and Johnston (2007). The double-headed approach of the ECJ concerning consumer protection, *supra* note 89.

[115] See further on the integration of behavioural or lifestyle-related factors in risk analysis, e.g., Planzer and Alemanno (2010). Lifestyle Risks: Conceptualizing an Emerging Category of Research, *supra* note 76; Thaler and Sunstein (2009). *Nudge: Improving decisions about health, wealth, and happiness*, *supra* note 72.

[116] Art. 5(1) and (2) of Regulation (EC) No 178/2002 (GFL), *supra* note 1).

[117] Bernd van der Meulen (2010). The function of food law. On objectives of food law, legitimate factors and interests taken into account. 5(2) *European Food and Feed Law Review*, pp. 83-90, at p. 85.

[118] See in this respect, e.g., Stefania Negri (2009). Food safety and global health: an international law perspective. 3(1) *Global Health Governance*, pp. 1-26, at p. 7.

[119] Set out in Art. 14 of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

[120] Set out in Art. 8(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

[121] Since the adoption of Council Resolution of 14 April 1975 on a preliminary programme of the European Economic Community for a consumer protection and information policy, OJ C 092, 25.04.1975, p. 1, the provision of information to consumers has been a fundamental principle of the EU. See further on the role of informed choice, e.g., Hans-W. Micklitz, Norbert Reich and Peter Rott (2009). *Understanding EU consumer law* (2nd ed., Antwerp: Intersentia), and Stephen Weatherill (2013). *EU consumer law and policy* (2nd ed., Cheltenham: Edward Elgar Publishing Limited).

that is guaranteed in the Treaty.[122,123] These principles reflect the idea that the healthy functioning of the internal market depends on two preconditions, i.e., consumer safety and consumer confidence,[124] so that the internal market concept simultaneously presupposes that consumers are at liberty to choose and feel safe and confident about the quality of the products for sale in the shops.[125]

Although food safety is one of the main objectives of EU food law, the GFL does not contain a legal definition of the concept.[126] From the outset, it appears to have a positive, inclusive connotation in that safety is directly linked to the achievement of, e.g., "a high level of protection of human life and health".[127] Following this line of argumentation, food safety legislation would aim at the optimisation of food production and distribution from a human health point of view, with health including food safety and (nutritional) quality.[128]

In contrast to this seemingly ambitious objective of food safety legislation, food *information* legislation[129] does not aim to steer, let alone optimise, food and food production.[130] Instead, it embraces the fundamental principle of consumer autonomy[131] and is based on the idea that adequate labelling offers a less intrusive and more flexible alternative to detailed legislation on the nature and

[122] The consumer right to information is expressly recognised in Art. 169(1) TFEU.
[123] See further on the informed consumer concept, e.g., Norbert Reich, Christopher Goddard and Ksenija Vasiljeva (2005). *Understanding EU Law* (2nd ed., Antwerp: Intersentia), at pp. 297-298, and Stephen Weatherill (1994). The role of the informed consumer in EC law and policy. 2 *Consumer Law Journal*, pp. 49-62.
[124] Recitals 1, 9 and 23 of the Preamble to Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[125] Thomas Wilhelmsson (2004). The abuse of the 'confident consumer' as a justification for EC consumer law. 27(3) *Journal of Consumer Policy*, pp. 317–337, at p. 320. See for an overview of the developments in EU consumer law and policy: Jules Stuyck (2000). European consumer law after the Treaty of Amsterdam: Consumer policy in or beyond the internal market. 37(2) *Common Market Law Review*, pp. 367-400; Micklitz, Reich and Rott (2009). *Understanding EU consumer law*, *supra* note 121; Weatherill (2013). *EU consumer law and policy*, *supra* note 121.
[126] Van der Meulen and Van der Velde (2008). *European Food Law Handbook*, *supra* note 86, at p. 261.
[127] Art. 1(1) and 5(1) GFL (Regulation (EC) No 178/2002 (GFL), *supra* note 1).
[128] MacMaoláin (2007) argues that nutritional value should be included in the factors that are taken into account in determining what qualifies as safe or high quality food, in *EU food law: protecting consumers and health in a common market*, *supra* note 3, at p. 224.
[129] The main food information rules are set out in Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[130] See for a commentary on the Regulation (EU) No 1169/2011 Olaf Sosnitza (2011). Challenges of the Food Information Regulation: Revision and Simplification of Food Labelling Legislation? 6(1) *European Food and Feed Law Review*, pp. 16-26. See further on EU food information legislation, e.g, Ilona Cheyne (2012). Consumer Labelling in EU and WTO law. In: Sanford Gaines, Brigitte Egelund Olsen and Karsten Engsig Sørensen (eds.). *Trade in the EU and the WTO, A Legal Comparison* (Cambridge: Cambridge University Press), pp. 309-332.
[131] Tatiana Klompenhouwer and Henk van den Belt (2003). Regulating functional foods in the European Union: Informed choice versus consumer protection? 16(6) *Journal of Agricultural and Environmental Ethics*, pp. 545-556, at p. 546.

composition of foodstuffs.[132] The main objective of food information is to enable consumers to make informed choices without being misled.[133] For this purpose, food information legislation limits producers' freedom of commercial expression[134] by prescribing the mandatory provision of certain information particulars, while prohibiting other types of information.[135]

For the purpose of ensuring a high level of food safety in the EU, the EU legislature has introduced two main instruments in Articles 6 and 14 GFL. Article 14 GFL establishes general "food safety requirements" and is directed at food producers, who are responsible for compliance.[136] The provision bans from the market food that is unsafe and lays down criteria for determining when food is unsafe.[137]

The second instrument of EU food safety legislation is laid down in Article 6(1) GFL and prescribes that "food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure". Food law is defined as "the laws, regulations and administrative provisions governing food in general, and food safety in particular" at the national and EU level.[138] Hence, the obligation covers all formal food legislation and day-to-day decisions concerning food.[139]

Article 6 GFL implies that for food laws that offer protection of consumer interests other than safety, no risk analysis is required. Food legislation that prescribes consumer information or targets misleading practices, for example, is, as a matter of principle, excluded from this obligation.[140]

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[132] After the acceptance of the principle of mutual recognition in the Court's seminal judgement in Case 120/78, *Rewe-Zentrale AG v Bundesmonopolverwaltung für Brantwein* (Cassis de Dijon) [1979] ECR 649) the Commission left the idea of adopting detailed "recipe laws" in favour of a well-developed and clear system of labelling, presentation and advertising of foodstuffs. See in this sense European Commission (1985). Communication from the Commission to the Council and to the European Parliament. Completion of the internal market for foodstuffs: Community legislation on foodstuffs, *supra* note 3, at p. 8.

[133] Art. 3(1) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6. See also the Regulation's Preamble, recital 4.

[134] Art. 11(1) of the Charter of Fundamental Rights of the European Union. The Charter was first published in the Official Journal of the European Communities, OJ C 364, 18.12.2000, pp. 1-22 and became legally binding when the Treaty of Lisbon entered into force on 1 December 2009, as the Treaty confers on the Charter the same legal value as the Treaties.

[135] See further on the principles underlying the presentation of food products Van der Meulen and Van der Velde (2008). *European Food Law Handbook*, *supra* note 86, at pp. 371-372

[136] Art. 17(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

[137] Art. 14(1) and (2) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

[138] Art. 3(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

[139] For an interpretation of the scope of Art. 6 of Regulation (EC) No 178/2002 (GFL) see Van der Meulen and Van der Velde. *European Food Law Handbook*, *supra* note 86, at p. 269. See further, Alemanno (2007). *Trade in Food*, *supra* note 84, at pp. 78-81; Ellen Vos and Michelle Everson (2009). *Uncertain risks regulated*, (Oxon: Routledge-Cavendish), at pp. 96-97.

[140] Commission proposal for a GFL, *supra* note 10, at p. 9.

Apparently, the EU legislature perceives a clear distinction between *risk* regulation and *information* regulation, which is directed at effectuating the consumers' right to information and protecting their economic interests rather than eliminating risk.[141] The result is a dichotomy between risk-based safety legislation and consumer information legislation, which is merely policy-driven. Where food poses a potential safety issue – a risk – the decision whether or not to adopt protective measures must be based on risk analysis. In the absence of any particular safety issue, it is left to consumers to select their diet freely, and legislation is limited to ensuring that this freedom remains relatively unimpaired.

The question arises where and on the basis of what criteria the EU legislature has drawn the line between food safety issues that must be subject to risk analysis and met with stringent regulation, and consumer information issues, where this is not deemed appropriate. The answer to this question is decisive for the scope of food safety and indicative for the existence of a grey area of regulation in EU food law. In search of the answer, the following section will look deeper into the process of risk analysis at the EU level.

2.2.2 Food safety risk analysis

Food safety risk analysis is defined in the GFL as "a process consisting of three interconnected components: risk assessment, risk management and risk communication".[142,143] Risk assessment is a scientific process, undertaken by an independent risk assessor[144] – generally EFSA[145] – and is aimed at risk characterisation.[146] Risk management is the political process of weighing policy alternatives in light of the outcome of the risk assessment.[147]

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[141] This does not imply that consumer information can never be used to regulate risks. An example of the use of consumer information as a risk management tool is the provision of information on the appropriate handling of food, such as raw chicken, as required by Article 9(1)(j) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[142] Art. 3(10) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[143] See further on the phases of risk analysis, e.g., Alemanno (2007). *Trade in Food*, *supra* note 84, at p. 78-100; Van der Meulen and Van der Velde (2008). *European Food Law Handbook*, *supra* note 86, at pp. 267-292; Szajkowska (2012). *Regulating food law*, *supra* note 13, at pp. 52-56; Vos (2000). EU food safety regulation in the aftermath of the BSE crisis, *supra* note 86, at p. 229; Yoe (2012). *Principles of risk analysis: decision making under uncertainty*, *supra* note 86, at p. 4. See further on risk analysis from an international perspective: FAO and WHO (2006). *Food safety risk analysis: A guide for national food safety authorities*, 87 FAO Food and Nutrition Paper, www.who.int/foodsafety/publications/micro/riskanalysis06.pdf?ua=1 (accessed 13 October 2014).
[144] Art. 6(2) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[145] Arts 22 and 23 of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[146] Art. 3(11) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[147] Art. 3(12) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

The components of risk analysis are distinct in that EU food law is based on the fundamental separation of risk assessment from risk management.[148,149] At the same time, they are interconnected in a regulatory process that demands full and interactive exchange of information – risk communication.[150]

With respect to the second component, risk management, Alemanno makes a further distinction between two stages. During what is referred to here as the risk evaluation stage, the risk manager determines, on the basis of the outcome of the risk assessment, what would be the acceptable level of risk and the appropriate level of protection in society. Hereafter, in the policy stage, the risk manager decides on a specific measure to achieve that protective level.[151]

In deciding on the appropriate response to a food safety risk, the risk manager is not bound by the outcome of risk assessment. Article 6(3) GFL stipulates that besides the results of risk assessment (with particular account to the scientific opinions from EFSA), other legitimate factors[152] and the precautionary principle may also play a role.[153] Whereas the precautionary principle may be invoked only to justify the adoption of provisional measures in case of scientific uncertainty about the seriousness of an identified risk,[154] other legitimate factors may be called upon to justify risk

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[148] Commission White Paper of 12 January 2000 on Food Safety, COM(1999) 719 final, at p. 13.

[149] See on the question whether risk assessment and risk management can indeed be viewed as separate processes, e.g., Sheila Jasanoff (1993). Relating risk assessment and risk management. Complete separation of the two processes is a misconception. 19(1) *EPA Journal*, pp. 35-37; Majone (2010). Foundations of risk regulation: Science, decision-making, policy learning and institutional reform, *supra* note 86, at p. 18; Erik Millstone (2009). Science, risk and governance: Radical rhetorics and the realities of reform in food safety governance. 38(4) *Research Policy*, pp. 624-636, at p. 626.

[150] Art. 3(13) of Regulation (EC) No 178/2002 (GFL), *supra* note 1. See also the Commission proposal for a GFL, *supra* note 10, at p. 9.

[151] Alemanno (2007). *Trade in Food*, *supra* note 84, at p. 86.

[152] See on the role of "other legitimate factors" in EU food law Alemanno (2007). *Trade in Food*, *supra* note 84, at pp. 395-396; Alberto Alemanno (2011). Risk vs Hazard and the Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt. 2(2) *European Journal of Risk Regulation*, pp. 169-171, at p. 171; Szajkowska (2012). *Regulating food law*, *supra* note 13, at pp. 125-130. See for a US perspective on the role of "other legitimate factors" in EU and US legislation: Marsha A. Echols (1998). Food safety regulation in the European Union and the United States: different cultures, different laws. 4 *Colombia Journal of European Law*, pp. 525-543.

[153] See further on the role of the precautionary principle in EU food safety law Alemanno (2007). *Trade in Food*, *supra* note 84, at pp. 407-412; Van der Meulen and Van der Velde (2008). *European Food Law Handbook*, *supra* note 86, at pp. 269-272; Szajkowska (2012). *Regulating Food Law*, *supra* note 13, at pp. 69-71 and 85-105. See for an overview of the origin and functioning of the precautionary principle: Helle Tegner Anker and Margaret Rosso Grossman (2009). Authorization of Genetically Modified Organisms: Precaution in US and EC Law. 4(1) *European Food and Feed Law Review*, pp. 3-22.

[154] Art. 7(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1, lays down the conditions for the application of the precautionary principle.

management decisions that are not (fully) in line with the outcome of scientific risk assessment.[155] Relevant considerations could be of societal, economic, traditional, ethical or environmental nature.[156]

The aforementioned evaluation stage of risk management may prove to be particularly critical for the outcome of risk management, and, consequently, for the scope of food safety. It is here that the decision is made "how safe is safe" – or rather: how unsafe is unsafe.[157] Although other legitimate factors may play a role, the primacy of science in the GFL means that the outcome of scientific risk assessment is of overriding importance for the risk management decision.[158]

Contrary to the actual process of risk assessment, which is generally depicted as evidence-based and value-free, the preliminary decision whether or not to initiate this process is, by its very nature, rather subjective.[159] Article 6(1) GFL does not provide a clear answer to the question when risk analysis is necessary and when "this is not appropriate to the circumstances or to the nature of the measure". In most situations the initiative is taken by decision-makers who look for a scientific foundation for a policy initiative concerning a perceived hazard.[160] In doing so, they make value judgements and normative choices with respect to the putative hazard to be assessed.[161] It is from these value-judgements and normative choices that the grey area appears.

In Section 3.2 the stratum of the grey area will be further explored by analysing the interpretation and application of the concept of risk in EU food law. Before that, a second aspect of the grey area will

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[155] Szajkowska (2012). *Regulating food law*, *supra* note 13, at pp. 125-130.
[156] Recital 19 of the Preamble to Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[157] Alemanno (2007). *Trade in Food*, *supra* note 84 at p. 88.
[158] *Ibid*. See further: Szajkowska (2012). *Regulating food law*, *supra* note 13, at p. 91.
[159] Alemanno (2007). *Trade in Food*, *supra* note 84, at p. 88. However, numerous scholars have contested that risk assessment can ever be value-free, e.g., Alemanno (2011). Risk vs Hazard and the Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt, *supra* note 152; Sheila Jasanoff (1987). Contested boundaries in policy-relevant science. 17(2) *Social Studies of Science*, pp.195-230; Jensen and Sandøe. Food safety and Ethics, *supra* note 100, at p. 247; Millstone (2009). Science, risk and governance: Radical rhetorics and the realities of reform in food safety governance, *supra* note 149, at p. 626.
[160] However, pursuant to Art. 29(1)(b) of Regulation (EC) No 178/2002 (GFL), *supra* note 1, EFSA may also issue scientific opinions on its own initiative.
[161] Jensen and Sandøe (2002). Food Safety and Ethics, *supra* note 100, at p. 247. See further Jasanoff (1987). Contested boundaries in policy-relevant science, *supra* note 159; Millstone (2009). Science, risk and governance: Radical rhetorics and the realities of reform in food safety governance, *supra* note 149, at p. 626.

be examined by looking into the second instrument of consumer health protection in the GFL: the prohibition against the placing on the market of unsafe food.

2.2.3 The prohibition against unsafe foods

Article 14 GFL, described by Van der Meulen as "the single most important provision in all of EU food law",[162] introduces a negative concept of safety that departs from the positive definition adopted by the Codex Alimentarius Commission,[163] as well as from the Commission's original proposal.[164] The negative formulation of Article 14(1) GFL does not in itself imply a limitation of the seemingly wide scope of safety that can be inferred from the regulation's objectives. It merely indicates that the legislature at the time sought to reduce the burden of proof on food producers to demonstrating that their products are not unsafe rather than safe.[165]

Although the practical implications of the adoption of a negative instead of a positive concept of food safety appear to be limited,[166] it has symbolic significance in that signals priority of legal certainty for food producers over consumer protection. A positive concept, in line with the definition of Codex Alimentarius, would have better reflected the objectives laid down in the GFL, as well as the precautionary approach that characterises EU food law, in general.[167]

Article 14(7) and (9) GFL add to the negative definition of food safety a presumption of safety of compliant foods. Thus, food is deemed safe insofar as it complies with applicable EU or Member

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[162] Van der Meulen (2012). The Core of Food Law: A Critical Reflection on the Single Most Important Provision in All of EU Food Law, *supra* note 46, at p. 117.
[163] The definition adopted by the Codex Alimentarius Commission is set out, e.g., in the Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969), http://www.codexalimentarius.org/standards/list-of- http://www.fao.org/docrep/005/y1579e/y1579e02.htm (accessed 10 May 2016).
[164] Commission proposal for a GFL, *supra* note 10. The Commission's amended proposal for a GFL of 7 August 2001, COM(2001) 475 final, does not give a reason for this shift. It is not based on an amendment from the European Parliament. See also Van der Meulen (2012). The Core of Food Law: A Critical Reflection on the Single Most Important Provision in All of EU Food Law, *supra* note 46, at p. 118.
[165] Van der Meulen (2012). The Core of Food Law: A Critical Reflection on the Single Most Important Provision in All of EU Food Law, *supra* note 46, at p. 118.
[166] Because, in practical terms, to proof that food is *safe*, it would be necessary to demonstrate that it is *not unsafe*. To fulfil this requirement, such system would have to be based on food safety criteria similar to those currently laid down in Article 14 of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[167] Van der Meulen (2012). The Core of Food Law: A Critical Reflection on the Single Most Important Provision in All of EU Food Law, *supra* note 46, at p. 119.

State laws. Because food is comprehensively regulated in the EU,[168] food producers may, in principle, expect their food products to be safe if they are produced, transported and distributed in conformity with the applicable legal requirements.[169]

Article 14(2) GFL defines the determinants of unsafety. It provides that food is deemed unsafe if it is considered to be "(a) injurious to health" or "(b) unfit for human consumption". From the outset, the legislature appears to have opted for a rather broad interpretation of unsafety, according to which, in principle, any potentially harmful effect on human health – albeit acute, short-term, long-term or accumulated – renders the food in question unsafe.[170] Article 14(5) GFL further broadens the reach of the provision by adding to the list foodstuffs that must be considered unfit because something is wrong with them, even if they do not pose a threat to human health. This way, the legislature has built a certain level of precaution into the rules, recognising that it "may be almost impossible to prove injury or probable injury to health with such food".[171]

Nevertheless, the scope of unsafety is by no means unlimited. Article 14(3) GFL provides that "[i]n determining whether any food is unsafe, regard shall be had: (a) to the normal conditions of use of the food by the consumer (…), and (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer (…)." Arguably, almost any food can become harmful if stored or prepared incorrectly. Therefore, as highlighted in the Commission's proposal for a GFL, "it is important to consider the likely and reasonably foreseeable use of the food and the processing or subsequent handling to which it is to be subject".[172]

Here, the grey area comes into view. Although food consumption that disregards "the normal conditions of use of the food" can be harmful to health, this risk does not necessarily render the food in question unsafe in a legal sense. For the purpose of Article 14 GFL, the legislature has thus drawn

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[168] Food law comprises, apart from the GFL, a multitude of EU and national instruments regulating aspects of food and food production and distribution. See for an overview of subjects also Tamara K. Hervey and Jean V. McHale (2004). *Health law and the European Union* (Cambridge: Cambridge University Press), at p. 348; MacMaoláin (2007). *EU food law: protecting consumers and health in a common market*, *supra* note 3; Van der Meulen and Van der Velde (2008). *European Food Law Handbook*, *supra* note 86; Raymond O'Rourke (2005). *European Food Law*, 3rd edition (Thomson, Sweet & Maxwell).

[169] See on the presumption of safety and its limits: Van der Meulen (2012). The Core of Food Law: A Critical Reflection on the Single Most Important Provision in All of EU Food Law, *supra* note 46, at pp. 122-124.

[170] Art. 14(4) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

[171] Commission proposal for a GFL, *supra* note 10, at p. 11.

[172] *Ibid*.

the line between safety and unsafety – between no risk and an unacceptable level of risk – at the point of normality, i.e., "normal use".[173] In other words, the consequences of the incorrect handling of food and of unusual patterns of consumption are placed outside the scope of (un)safety, the determining factor being to what extent the consumer exhibits normal behaviour in relation to the food.

By adding this behavioural factor of risk to the food safety requirements in Article 14 GFL, the EU legislature has created the duty for consumers to align their consumptive behaviour with available food information, while limiting the responsibility of food producers for the possible negative consequences of 'abnormal' consumptive patterns.

2.2.4 The contours of the grey area

The previous section discussed how EU food legislation aims to protect consumers' health by banning from the market food that is deemed unsafe because it poses an unacceptable health risk. This system calls into existence a grey area of foods that cannot be said to be entirely free from potential negative effects on human health, but these effects either

a) Fall outside the scope of risk in the GFL, and/or
b) Are avoidable by "normal" consumptive behaviour.

Based on an analysis of the scope of risk and normality within the context of the GFL and illustrated by means of the example of aspartame, Section 2.3 will discuss the causes and implications of the existence of a grey area.

2.3 Exploring the causes and implications of the grey area

2.3.1 Example: the case of aspartame

The previous section demonstrated that where EU food legislation aims to make a clear distinction between foods are safe and those that are unsafe, some foods fall somewhere between the two. They are grey area foods that fall in a grey area of regulation. In the following sections, it will be argued that aspartame is one such food.

[173] See in this sense Van der Meulen (2012). The Core of Food Law: A Critical Reflection on the Single Most Important Provision in All of EU Food Law, *supra* note 46, at p. 120.

Aspartame is chosen as an example because of its ubiquity in light or diet food products, popular with the weight-conscious public.[174,175] It will be discussed that there is scientific evidence that suggests that aspartame may not live up to its healthy image, but this evidence was not taken into consideration for the purpose of the food safety risk assessment of aspartame.

2.3.1.1 Potential health effects of aspartame

Aspartame is one of several artificial sweeteners that are used to replace sugar in many low calorie beverages and food products on the EU and the global market.

Following safety evaluations by the Scientific Committee for Food (SCF) in 1984[176] and 1988,[177] aspartame was authorised as an additive in the EU in 1994. In subsequent years, it was re-assessed six times and found not unsafe.[178] In its latest re-assessment report of 10 December 2013, EFSA concluded once more "that there were no safety concerns at the current ADI of 40 mg/kg bw/day".[179]

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[174] According to Carolyn de la Peña, the weight-conscious public often considers foods containing artificial sweeteners to be healthy foods. See Carolyn de la Peña (2010). Artificial sweetener as a historical window to culturally situated health. 1190 *Annals of the New York Academy of Science*, pp. 159-165. See also Dirk J.G. Bakker (1999). Consumer Behaviour and Attitudes toward Low-Calorie Products in Europe. 85 *World Review of Nutrition and Dietics*, pp. 146-158; Kirtida R. Tandel (2011). Sugar substitutes: Health controversy over perceived benefits. 2(4) *Journal of Pharmacology & Pharmacotherapeutics*, pp. 236-243, at p. 237.

[175] A Eurobarometer survey on food risk issues undertaken in 2005 showed that of the people that had changed their consumptive habits within the last twelve months before the survey, 34% had done so to lose weight. Of the respondents, 39% had opted to reduce sugar-intake, while 38% ate fewer calories. See European Commission (2006). 246/Wave 64.3 Special Eurobarometer, Health and Food, http://ec.europa.eu/health/ph_publications/eb_food_en.pdf (accessed on 22 May 2014), at pp. 36.

[176] Scientific Committee for Food (1985). Sweeteners – Opinion expressed on 14 September 1984. Reports of the Scientific Committee for Food (Sixteenth Series). EUR 10210 EN, Commission of the European Communities, Luxembourg.

[177] Scientific Committee for Food (1987). Sweeteners – Opinion expressed on 11 December 1987. Reports of the Scientific Committee for Food, (Twenty-first Series). EUR 11617 EN, Commission of the European Communities, Luxembourg.

[178] Scientific Committee for Food (1997). Minutes of the 107th Meeting of the Scientific Committee for Food held on 12-13 June 1997 in Brussels, available at: http://europa.eu.int/comm/food/fs/sc/oldcomm7/out13_en.html (last accessed on 19 May 2014); Scientific Committee on Food (2992). Opinion of 4 December 2002 holding an Update on the Safety of Aspartame, SCF/ADD/EDUL/222/ Final, http://ec.europa.eu/food/fs/sc/scf/out155_en.pdf (accessed on 21 October 2014); EFSA Panel of Food additives, flavourings, processing aids and materials in contact with food (AFC) (2006). Opinion of 3 May 2006 related to a new long-term carcinogenicity study on aspartame, 356 EFSA Journal, pp. 1-44; EFSA Panel on Food Additives and Nutrient Sources added to Food (2009). Updated opinion of 19 March 2009 on a request from the European Commission related to the 2nd carcinogenicity study on aspartame, taking into consideration study data submitted by the Ramazzini Foundation in February 2009, 1015 EFSA Journal, pp. 1-18; EFSA ANS Panel (2011). Statement of 8 February 2011 on two recent scientific articles on the safety of artificial sweeteners, 9(2):1996 EFSA Journal; EFSA ANS Panel (2013). Scientific Opinion of 10 December 2013, on the re-evaluation of aspartame (E 951) as a food additive, 11(12):3496 EFSA Journal (2013), at p. 263.

[179] EFSA (2013). Scientific Opinion on the re-evaluation of aspartame, *supra* note 178, at p. 152.

At the same time, scientific research of the acclaimed health benefits of artificial sweeteners appears rather inconclusive. Several studies have suggested that artificial sweeteners do not at all help to lose or maintain weight.[180] Some authors even found a positive correlation between artificial sweetener use and weight gain and type 2-diabetes,[181] while others found no correlation at all.[182] In light of the scientific uncertainty concerning the benefits of sweeteners such as aspartame, in 2011, EFSA advised against the acceptance of health claims that relate their use to the maintenance or achievement of a normal body weight. On the basis of the data presented, EFSA concluded "that a cause and effect relationship has not been established between the consumption of foods and beverages in which sugars have been replaced by intense sweeteners and contribution to the maintenance or achievement of a normal body weight."[183]

In accordance with Article 8(1) in conjunction with the Annex of the Claims Regulation, however, food producers that replace the sugar content in their products with artificial sweeteners may claim that their products are, e.g., "low in sugars" or "sugar-free", depending on the amount of sugar remaining in the product.[184] Because the consumers in the EU generally perceive sugary foods to be unhealthy,[185] claims referring to a food product's low sugar content may further enhance the positive

[180] See, e.g., Christopher Gardner, Judith Wylie-Rosette, Samuel S. Giddings et al. (2012). Nutritive sweeteners: current use and health perspectives: a scientific statement from the American Heart Association and the American Diabetes Association. 35(8) *Diabetes Care*, pp. 1798-1808.
[181] See, e.g., Sharon P. Fowler, Ken Williams, Roy G. Resendez et al. (2008). Fueling the obesity epidemic? Artificially sweetened beverage use and long-term weight gain. 16(8) *Obesity*, pp. 1894-1900; Qing Yang (2010). Gain weight by 'going diet?' Artificial sweeteners and the neurobiology of sugar cravings: Neuroscience 2010. 83(2) *Yale Journal of Biology and Medicine*, pp. 101-108, at p. 104.
[182] V. van Wymelbeke, M.E. Béridot-Thérond, V. de la Guéronnière et al. (2004). Influence of repeated consumption of beverages containing sucrose or intense sweeteners on food intake. 58 *European Journal for Clinical Nutrition*, pp. 425-34. See also Tandel (2011). Sugar substitutes: Health controversy over perceived benefits, *supra* note 174. Tandel suggests that well-designed large-scale studies in the general population are necessary to settle the controversy.
[183] EFSA Panel on Food Additives and Nutrient Sources added to Food (2011). Scientific Opinion on the substantiation of health claims related to intense sweeteners and contribution to the maintenance or achievement of a normal body weight (ID 1136, 1444, 4299), reduction of post-prandial glycaemic responses (ID 4298), maintenance of normal blood glucose concentrations (ID 1221, 4298), and maintenance of tooth mineralisation by decreasing tooth demineralisation (ID 1134, 1167, 1283) pursuant to Art. 13(1) of Regulation (EC) No 1924/2006. 9(6):2229 EFSA Journal, pp. 1-26, at p. 11.
[184] Regulation (EC) No 1924/2006, *supra* note 56.
[185] The Eurobarometer survey on health and food from 2005 showed that 28% of the European consumers consider that "healthy eating" means avoiding too much sugary food, European Commission, Special Eurobarometer, Health and Food, *supra* note 175.

image that consumers have of light foods in which sugar is replaced by a sweetener, such as aspartame.[186]

2.3.1.2 The food safety risk assessment of aspartame

In its 2013 safety evaluation of aspartame, EFSA based its conclusions on an assessment of chronic toxicity, as well as reproductive and developmental toxicity, as critical endpoints in the animal database.[187] In addition, EFSA evaluated epidemiological data on the relationship between aspartame consumption and certain physiological reactions in humans. With respect to the potentially negative effect of aspartame on appetite, hunger and food intake, EFSA stated:

> The Panel is aware that a number of studies have focused on the effects of aspartame on appetite, hunger and food intake. The Panel considered that these studies of the effect of aspartame (or other low calorie sweeteners) on eating behaviour were not relevant for the assessment of the safety of aspartame and that risk benefit assessment of aspartame are outwith the term of reference and the remit of the Panel.[188]

EFSA applied a stringent interpretation of its mandate to assess the safety of aspartame. As a result, the validity of available scientific evidence that questions the benefits of aspartame – evidence that may prove that the product is in fact not only ineffective, but indeed counterproductive in terms of perceived consumer benefit – remains untested for the purposes of food safety risk assessment.

2.3.2 The scope of risk in the GFL

The example of aspartame illustrates that some foods that are deemed safe in a legal sense can have negative effects on health that are not accounted for by food safety risk assessment. In the case of aspartame, critical scientific evidence on the relationship between consumption and altered consumptive behaviour was excluded from the food safety risk assessment.

Risk in relation to food safety is defined in Article 3(9) GFL as "a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard". "Hazard", in turn, is

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[186] See in this respect Bakker (1999). Consumer Behaviour and Attitudes toward Low-Calorie Products in Europe, *supra* note 174; De la Peña (2010). Artificial sweetener as a historical window to culturally situated health, *supra* note 174; Tandel (2011). Sugar substitutes: Health controversy over perceived benefits, *supra* note 174.
[187] EFSA (2013). Scientific Opinion on the re-evaluation of aspartame, *supra* note 179, at p. 151.
[188] *Ibid*, at p. 100.

described as "a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect".[189] Within the context of EU food law, a food safety risk can, in other words, be understood as the likelihood that a biological, chemical or physical agent present in a food causes an unacceptable effect on human health.[190]

Clearly, biological, chemical and physical hazards are not the only threats to human health from food consumption. Human health may also be jeopardised by hazards that fall outside this classic division, such as those of a nutritional nature. The proven relation between fast food consumption and the prevalence of obesity and non-communicable diseases (e.g., cancer, type-2 diabetes) shows that foods that are high in sugar, fat or sodium, for example, possess the intrinsic potential to cause harm to human health.[191] This potential becomes a significant risk if there is dietary over-exposure to these foods. In fact, health damage due to this type of nutrition-related hazard is believed to be many times greater than health issues attributable to biological, chemical and physical hazards.[192] Nutrition-related hazards, however, fall outside the definition of risk in the GFL.[193,194]

It is rather interesting that the legislature would opt to limit the scope of risk and, in doing so, *a priori* reject the applicability of risk analysis in a broader scientific context. As a result, risk assessment has developed as a scientific discipline mainly concerning classic food toxicology, which essentially

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[189] Article 3(14) of Regulation (EC) No 178/2002 (GFL), *supra* note 1. The GFL definitions of "risk" and "hazard" are based on the Codex Alimentarius definition of 2003, see: Codex Alimentarius Commission, Procedural Manual, *supra* note 36.

[190] Besides the technical definition in the GFL, there is no commonly accepted definition of 'food safety risk', or even 'risk'. Many authors have attempted to provide a definition, e.g., Alemanno (2007). *Trade in Food*, *supra* note 84, at p. 81; Ulrich Beck (1992). *Risk Society: toward a New Modernity* (London, Sage), at p. 21; Sheila Jasanoff (1993). Bridging the two cultures of risk analysis. 13(2) *Risk Analysis* (1993), pp. 123-129, at p. 124; Ortwin Renn (1998). The role of risk perception for risk management. 59(1) *Reliability Engineering and System Safety*, pp. 49-62, at p. 51.

[191] WHO (2011). *Global status report on noncommunicable diseases 2010*, www.who.int/nmh/publications/ncd_report2010/en/ (accessed on 26 May 2014), at p. vi.

[192] According to Tijhuis, De Jong, Pohjola et al. "the health loss due to unhealthy food and nutrition is many times greater than that attributable to unsafe food" in Tijhuis, De Jong, Pohjola et al. (2012). State of the art in risk-benefit analysis: Food and nutrition, *supra* note 100, at p. 6.

[193] Van der Meulen and Van der Velde (2008). *European Food Law Handbook*, *supra* note 86, at p. 269; Szajkowska (2012). *Regulating food law*, *supra* note 13, at p. 100.

[194] In 2003, the Codex Alimentarius Commission added to its Procedural Manual guidelines and working documents developed or in use by EFSA. EFSA Technical Report (2009) 294, 1-13, Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses. These principles are meant to be applied broader than in the context of the aforementioned committee, alone, which results in the assessment of risks to human health from inadequate and/or excessive intake of nutrients and related substances becoming an integral part of a broader food safety risk analysis (see: Procedural Manual, *supra* note 36, at p. 120). This is, however, not reflected in the GFL.

determines a maximum safe dose for human intake of hazardous agents or substances. Traditionally, other areas of research, such as epidemiology, play only a minor role in risk assessment.[195] In light of the seemingly ambitious objectives that appear to be at the core of the GFL, a broader, more inclusive notion of risk would have been appropriate.

Several scholars have proposed solutions that could result in a more integrated approach to risk. Jasanoff advocates a qualitative approach focusing on the ethical, legal, political and cultural aspects of research, illuminating the "blind spots" of traditional risk assessment.[196] Millstone supports the co-evolutionary model for risk analysis, which regards scientific and non-scientific considerations as interdependent and integrates socio-economic and political considerations in the framing assumptions for risk assessment.[197] Alemanno argues in favour of enhanced transparency and preservation of the "two souls of EU risk regulation", i.e. evidence-based regulation versus a more flexible, precautionary-oriented approach of risk.[198] Van Asselt and Renn propose a paradigm shift towards holistic "risk governance".[199] What these submissions have in common is that they are founded on the fundamental acknowledgement that risk assessment is not and cannot be a truly objective scientific process.[200] For that reason it is necessary to determine where "scientific evidence stops and where other concerns kick in".[201]

Admittedly, a narrow definition of risk does not single-handedly result in the limited scope of food safety within the current legal framework. As discussed in Section 2.2, risk management is not bound by the outcome of risk assessment, but acknowledges the relevance of other legitimate factors. This safety net allows more non-traditional, less scientifically defined potential hazards to be taken into consideration at the risk management level – at least in theory.

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[195] Tijhuis, De Jong, Pohjola et al. (2012). State of the art in risk-benefit analysis: Food and nutrition, *supra* note 100, at p. 7.
[196] Jasanoff (2013). Bridging the two cultures of risk analysis, *supra* note 190, at pp. 123 and 130.
[197] Millstone (2009). Science, risk and governance: Radical rhetorics and the realities of reform in food safety governance, *supra* note 149, at p. 627.
[198] Alemanno (2011). Risk vs Hazard and the Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt, *supra* note 152, at p. 171.
[199] Marjolein B.A. van Asselt and Ortwin Renn (2011). Risk Governance. 14(4) *Journal of Risk Research*, pp. 431-449, at p. 442.
[200] Jasanoff (2013). Bridging the two cultures of risk analysis, *supra* note 190, at p. 123.
[201] Alemanno (2011). Risk vs Hazard and the Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt, *supra* note 152, at p. 171.

In practice, however, the likelihood that a food would be declared unsafe on the basis of other legitimate factors appears negligible. The EU legislature has set aside the outcome of risk assessment only in situations where there was at least some level of scientific uncertainty, in which situation other relevant factors can play a precautionary role.[202]

Another influential factor in this respect is the behavioural factor of risk, as a result of which negative health effects that are deemed to result from abnormal consumptive patterns are excluded from the scope of unsafety. This factor will be further discussed in the following section.

2.3.3 The impact of the behavioural factor of risk

Section 2.3 indicated that Article 14(3) GFL excludes from the scope of unsafety, health risks that can be avoided as long as consumers follow the "normal conditions of use of the food" and "the information provided to the consumer". This provision can be seen as the application of the average consumer benchmark for the purpose of food safety, because consumers are expected to eliminate certain risks based on their compliance with product information provided on food labels or generally available.

Food information requirements with respect to safe and hygienic food use and preparation, handling, storage and recommended shelf life result from such considerations of avoidable risk.[203] The presence, for example, of a certain level of potentially harmful bacteria can be acceptable in raw foods that are supposed to be cooked, whereas the same level of bacteria is unacceptable in food that are generally eaten raw. Because the normal way of consuming poultry is cooked, poultry can be placed on the market containing the level of bacteria that would be reduced to acceptable once the meat is

[202] See for example "the BPA case study" in Alemanno (2011). Risk vs Hazard and the Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt, *supra* note 152, at p. 172 and the "EU ban on the use of growth promoting hormones" in Szajkowska (2012). *Regulating food law*, *supra* note 13, at p. 128. According to Anker and Grossman "the explicit reliance - and perhaps over-reliance - on the precautionary principle in the EC could be seen as a surrogate for policy decisions that consider broader consumer concerns about GMOs". See Anker and Grossman (2009). Authorization of Genetically Modified Organisms, *supra* note 153, pp. 3-22, at p. 21-22. See for the role of the WTO SPS-Agreement in this respect, e.g., James Flett (2010). If In Doubt, Leave It Out? EU Precaution in WTO Regulatory Space. 1(1) *European Journal of Risk Regulation*, pp. 20-31.

[203] See, e.g., Art. 4(b) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6, concerning the mandatory labelling of foods with information on, e.g., potentially harmful compositional attributes, as well as durability, storage and use of food.

cooked.[204] In situations like these, food safety risks are managed by means of providing consumer information on how to handle the food.

Interestingly, in its proposal for a GFL, the Commission stretched its interpretation of what may be expected of the average consumer even further, where it stated

> Where information is provided either on a label or otherwise, or information is generally available, and yet the consumer ignores this information in his choice of diet, or for example, consumes food at abnormal levels which may ultimately lead to detrimental health effects, this Regulation does not consider these foods to be unsafe where other requirements of food law are met.[205]

From a risk management point of view, it may appear reasonable to hold consumers responsible for the health consequences of consumptive behaviour that disregards consumer information. Risks do not need to be eliminated if they are manageable by other means, such as through the provision of adequate consumer information. However, it can be questioned to what extent the average consumer is capable of translating the often abstract and technical consumer information on food labels, into actual behaviour.[206,207]

The situation becomes even more complex if the concept of normal use is linked to information that is generally available in society. Here, consumers are not only expected to evaluate and manage the potential health risks of their consumptive behaviour by reading and complying with information available on food labels, but also to take into account a certain level of general knowledge about food consumption and its potential consequences on human health.

The example of aspartame illustrates the complexity of the reality that consumers deal with every day. Because of its classification as safe, aspartame is widely used as a replacement for sugar in foods

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[204] Commission proposal for a GFL, *supra* note 10, at p. 11.
[205] *Ibid*.
[206] See for a study on how nutrition labelling affects consumer choice George Baltas (2001). The Effects of Nutrition Information on Consumer Choice. March/April *Journal of Advertising Research*, at pp. 57-63.
[207] See on the subject of consumer understanding of food information, e.g., Howells. The Potential and Limits of Consumer Empowerment by Information, *supra* note 66, pp. 349-370; Garde (2010). *EU law and obesity prevention*, *supra* note 65, at pp. 12-14 and 155-157 and Thaler (1980). Toward a positive theory of consumer choice, *supra* note 66, pp. 39-60.

that are marketed as "low in sugars" or "sugar-free".[208] These claims may give consumers the impression that the foods in question are a healthy alternative to their sugary equivalent, or appropriate as a diet option.

As discussed in Section 2.3.1, scientific evidence indicates that artificial sweeteners may bear directly on the prevalence of obesity and NCDs,[209] suggesting that foods, in which sugar is replaced by artificial sweeteners, may in fact be unfit as a diet option. This evidence was however excluded from the food safety risk assessment of aspartame.

Nevertheless, consumers are expected to be able to distil relevant information from what is generally available, to evaluate it and to adapt their dietary habits accordingly. But how are consumers supposed to do so when – as in the case of aspartame – even scientists disagree on what constitutes a health risk?

In light of the principles of risk analysis that are at the basis of the GFL, ideally, a sound judgment about what is safe behaviour in relation to food should be based on the scientific assessment of the intrinsic hazards involved in its consumption, as well as of the level of exposure at which the risk materialises. Yet, by limiting the scope of risk to hazards of a chemical, biological and physical nature, the legislature has excluded the systematic scientific evaluation of, e.g., behavioural risks.

As discussed in Section 2.2.1 above, food information legislation cannot fully compensate for this deficit, because, in light of the Commission's interpretation in its proposal for the GFL, food information legislation is *a priori* excluded from the requirement of risk analysis.[210]

2.4 Conclusion

This chapter demonstrated how EU food safety regulation creates a grey area of foods that can be harmful to health without rendering them unsafe in a legal sense.

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[208] Annex to Regulation (EC) No 1924/2006, *supra* note 56.
[209] Fowler, Williams, Resendez et al. (2008). Fueling the obesity epidemic? Artificially sweetened beverage use and long-term weight gain, *supra* note 181. See further Tandel (2011). Sugar substitutes: Health controversy over perceived benefits, *supra* note 174, and Yang (2010). Gain weight by 'going diet?' Artificial sweeteners and the neurobiology of sugar cravings: Neuroscience 2010, *supra* note 181.
[210] Commission proposal of a GFL, *supra* note 10, at p. 11.

Section 2.2 described the general framework of food safety legislation in the EU. It was argued that although the GFL does not provide a definition of food safety, the link made in Article 5 GFL with the general objective of "a high level of protection of human life and health" in the EU, gives the concept a positive, inclusive connotation.

Despite this seemingly ambitious objective of EU food law, the GFL food safety regime applies a rather narrow concept of risk. This system creates a grey area of foods that cannot be said to be entirely free from potentially negative health effects, but these effects fall outside the scope of risk in the GFL and they are not subject to scientific risk assessment.

Based on the food safety risk assessment of aspartame, Section 2.3 illustrated the consequences of this legal system. When assessing the safety of aspartame, EFSA applied the rather narrow definition of risk prescribed in the GFL, resulting in the exclusion from the product's safety assessment of potentially highly relevant scientific evidence concerning the potential behavioural impact of aspartame.

Section 2.3.2 looked further into the definition of risk in the GFL as a function of a biological, chemical or physical hazard, which excludes other threats to human health, such as those related to the nutritional composition of food. Within this legal framework, food safety risk assessment is essentially confined to classic food toxicology. Other research areas, such as epidemiology and behavioural sciences, are not systematically taken into account. This system causes an information gap with respect to how, e.g., food consumption, eating behaviour and health are interconnected.

Section 2.3.3 argued that, although the risk management decision whether or not a food qualifies for placing on the EU market largely depends on the outcome of scientific risk assessment, the legislature has added to the equation an element that is not science-based. By instituting a relationship between food safety and consumer behaviour in light of the normal conditions of use and food information available to consumers, the legislature has introduced a subjective element in the distinction between safe and unsafe food. This *behavioural factor of risk* results in rather high standards as to what is expected of the average consumer.

The case of aspartame showed that this can lead to rather compromising situations for consumers. Consumers are expected to limit their consumption of aspartame to "normal" levels on the basis of food information that is, at best, inconclusive and, more likely, contradictory as to the health effects of aspartame consumption.

It is doubtful whether consumers are capable of interpreting and applying the sometimes rather technical information on food labels in a correct way. Moreover, in light of the information gap that results from a narrow concept of risk in the GFL, to translate common knowledge on food health into appropriate dietary choices is clearly even more difficult for consumers.

To ensure a high level of protection of human health and consumers' interests in relation to food in the EU, the information gap resulting from the narrow application of risk should be reduced by allowing for a more integrated approach to food safety. A broader definition of a hazard would permit the findings of research disciplines other than classic food toxicology to be taken into account for the purpose of food safety risk assessment, resulting in an overall better understanding of risk. Also for the purpose of risk management greater consideration of other legitimate factors, including aspects of consumer behaviour, would help to add the necessary flexibility to be able to react to new developments. This way, food safety risk analysis could deepen our understanding of the effects of food consumption on human health, as well as what can be deemed normal – or rather, appropriate – consumer behaviour in this respect.

By, thus, addressing explicitly the more complex risks involved in food consumption, the grey area between harmless and harmful may be reduced in favour of a notion of food safety that approaches the positive concept implied in Article 5 GFL.

3 EU competence to regulate the healthiness of food[211]

Abstract

The EU has developed a detailed and stringent set of food safety rules aimed at limiting or containing the risk that people experience negative health effects from the consumption of food. The legislature has focused on food safety in a relatively narrow sense, which does not include the potential threats to human health from foods with, e.g., negative nutritional features. EU food safety legislation seems rather successful in preventing food-borne illnesses. The public's concerns, however, have shifted towards the growing prevalence of lifestyle-related illnesses. There is convincing scientific evidence showing a correlation between obesity and non-communicable diseases and the consumption of unhealthy food. EU initiatives to tackle the root causes of these public health challenges focus on guiding consumer choice rather than regulating the composition and nutritional value of foods. The question arises whether the EU would at all be competent to step in and regulate the healthiness of food. This chapter analyses the extent to which the EU Treaties offer an appropriate legal basis.

3.1 Introduction

The protection of the EU citizens is a cornerstone of the EU legal system. The EU is involved in promoting the "interests of consumers" and ensuring "a high level of consumer protection", including the protection of consumers' "health, safety and economic interests" and the promotion of "their right to information, education and to organise themselves in order to safeguard their interests".[212] Moreover, the EU is obliged to ensure a "high level of human health protection in the definition and implementation of all Union policies and activities".[213] Consequently, also within the area of EU food law, consumer (health) protection is a leading concept. In fact, one of the main purposes of EU food law is to pursue "a high level of protection of human life and health and the protection of consumers' interests".[214]

[211] An earlier version of this chapter was published as Wieke Willemijn Huizing Edinger (2014). Food Health Law: A Legal Perspective on EU competence to Regulate the 'Healthiness' of Food. 9(1) *European Food and Feed Law Review*, pp. 11-19.
[212] Article 169(1) TFEU.
[213] Article 168(1) TFEU.
[214] Article 5(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

This chapter examines the scope of the EU's task of safeguarding consumers' health and enquires whether the EU's obligations and competences reach further than keeping consumers safe from food-borne illness. Must and can the EU institutions play a role in ensuring that the food we consume keeps us fit and in good physical shape? This chapter also studies whether EU food law is successful in achieving its objectives in this respect.

Peoples' health can be jeopardised by foods that contain dangerous microorganisms or that are contaminated with harmful substances. For that reason, with the adoption of the GFL, the EU legislature has implemented a detailed and stringent set of rules, aiming at minimising food safety risks. However, food safety in a narrow sense, understood as the absence or minimisation of chemical, biological and physical hazards,[215] does not in itself ensure consumer health. There are other food-related issues that can pose serious health threats. The growing prevalence of obesity and non-communicable diseases[216] (NCDs) like diabetes and cardiovascular conditions is an important example of a modern, food-related health challenge that is difficult to fit within a narrow concept of food safety. According to the World Health Organisation (WHO), NCDs are the leading cause of premature death globally, killing more people each year than all other causes combined.[217]

The WHO points at an unhealthy diet as one of the main risk factors for the development of NCDs.[218] It is commonly accepted that the increase of unhealthy consumption patterns is directly related to the growing availability of low-priced processed foods and ready-to-consume meals that contain high levels of fats, salt and sugar but are low in micro-nutrients (HFSS foods). Boldly put, if cheap junk food were less available, people would suffer less from NCDs.[219] Against this background it appears legitimate to ask if the EU could intervene and put an end to junk food.

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[215] Articles 3(9) and (14) of Regulation (EC) No 178/2002 (GFL), *supra* note 1, link "risk" to "biological, chemical or physical" hazards only.

[216] On its website, the WHO describes non-communicable diseases as "a group of conditions that includes cardiovascular diseases, cancer, mental health problems, diabetes mellitus, chronic respiratory disease and musculoskeletal conditions (...), which are largely preventable and which are linked by common risk factors, underlying determinants and opportunities for intervention", see (http://www.euro.who.int/en/what-we-do/health-topics/noncommunicable-diseases/what-are-noncommunicable-diseases).

[217] WHO (2011). *Global status report on noncommunicable diseases 2010*, www.who.int/nmh/publications/ncd_report2010/en/ (accessed on 26 May 2014), at p. vi.

[218] *Ibid*.

[219] This is a simplified assumption because obesity and non-communicable diseases result from a combination of factors, of which overconsumption is just one. There are, however, clear indications of a correlation between overweight and fast-food consumption. A study by the University of Minnesota following the eating habits of more than 3,000 American

This chapter seeks to map the extent to which the EU is empowered to protect consumers from the potential harmful health effects from the (over)consumption of foods that have negative nutritional features, i.e. HFSS foods. The underlying query is whether the current legal framework aimed at consumer health protection addresses nutrition-related health challenges in an appropriate way.

3.2 EU competence in the area of food health

The TFEU does not provide a specific legal basis to adopt legislation addressing the healthiness and nutritional quality of food, i.e. food health law. It does, however, contain a number of provisions that appear relevant in this context.

Apart from the provisions providing a more general competence in the area of agriculture[220] and the internal market,[221] the Treaty contains two substantive provisions that may be relevant for the protection of the European citizen from the potential harmful effect of food consumption on human health and well-being. They are Article 168 in Title XIV on public health, which, together with Articles 43 and 114 TFEU, has provided the legal basis for the adoption of the GFL, and Article 169 TFEU in Title XV on consumer protection.

In accordance with Articles 4(1) and 6(a) TFEU, Article 168 TFEU provides the EU with a supportive competence. Accordingly, the EU's legislature powers in the area of the protection and improvement of human health are limited to supplementing Member State policy. In regard to consumer protection, Article 4(2)(f) TFEU assigns the EU a shared competence.

Article 43 TFEU establishes the legal basis for the adoption of measures aiming to create the common organisation of agricultural markets and the adoption of the measures necessary for the achievement of the objectives of the Common Agricultural Policy (CAP), e.g., the increase of productivity, the stabilisation of markets, ensuring reasonable prices.[222]

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adults between 18 and 30 years of age over a period of 15 years showed that the people who frequested fast-food restaurants more than twice a week weighed an average 4.5 kg more than those who went infrequently. The study also showed twice the increase in insulin resistance among the members of the fast-food loving group, making them more susceptible to developing type-2 diabetes (Mark Pereira, Alex Kartashov, Cara Ebbeling et al. (2005). Fast-food habits, weight gain, and insulin resistance (the CARDIA study): 15-year prospective analysis. 365(9453) *The lancet*, pp. 36-42.

[220] Article 43 TFEU.

[221] Article 114 TFEU.

[222] Article 39 TFEU.

Article 114 TFEU offers a more general basis for the adoption of harmonising measures that envisage the establishment and the functioning of the internal market.[223] It has for example been applied as the legal foundation for measures governing the marketing of processed foodstuffs that do not fall within the ambit of agriculture.

The following sections will address the question whether any of these provisions provide the EU with the competence to regulate food health.

3.2.1 Public Health

Article 168(1) TFEU prescribes that "[a] high level of human health protection shall be ensured in the definition and implementation of all EU policies and activities."

Although this "mainstreaming provision"[224] establishes a broad obligation for the EU legislature always to consider the health aspects of any of its legislative initiatives, it does not create an independent EU competence to regulate matters of public health – let alone food health. On the contrary, the second section of Article 168(1) TFEU clarifies that the provision operates under the subsidiarity principle for health as laid down in Article 6(a) TFEU, so that EU action in the field of public health is principally limited to complement Member States' initiatives.

Also Article 168(5) TFEU points in the direction of a limited scope of EU competence in the area of public health where it establishes that the EU may not harmonise the laws and regulations of the Member States. The attributed power to adopt measures designed to protect and improve human health is limited to incentive measures.

Article 168(4) TFEU, however, contains three exceptions to the limitation of EU competence to supportive measures that all relate to so-called common safety concerns. Potentially relevant in this context is Article 168(4)(b) TFEU, which creates a shared competence to adopt "measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health". This provision, among others, is the basis of the GFL.[225]

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[223] As envisaged in Articles 26-27 TFEU.
[224] Tamara K. Hervey and Jean V McHale (2015). *European Union Health Law: Themes and Implications* (Cambridge: Cambridge University Press, at p. 62.
[225] The GFL was based on Articles 37, 95, 133 and 152(4)(b) of the EC Treaty, which are now transposed in Articles 43, 114, 153 and 168(4)(b) TFEU.

The Treaty does not specify the types of measures understood to pertain to the "veterinary and phytosanitary field" and, simultaneously, to pursue "the protection of public health". This makes the provision's exact scope vague and in need of interpretation and clarification.

An indication of what was intended to be included in the provision's range can be obtained by drawing a parallel with Annex A to the WTO's SPS-agreement, to which the EU is a party.[226] Article 1 of Annex A includes as sanitary or phytosanitary measures those applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Whereas Article 1(a) and (b) relate to measures that are either veterinary or phytosanitary in nature, item (b) concerns measures that are purely sanitary (and, as far as feed is concerned, veterinary) that are not mentioned in Article 168(4) TFEU. Article 1(d) relates to the limitation of damages from the entry, establishment or spread of pests and is not relevant in the context of this thesis.

If Article 168(4)(b) TFEU must be interpreted in accordance with the SPS-Agreement, its scope is confined to the measures included in Article 1(c) of Annex A to the SPS-Agreement. This would rule out the provision's applicability as a legal basis for the adoption of measures that envisage the

[226] WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), which entered into force with the establishment of the World Trade Organization on 1 January 1995, https://www.wto.org/english/docs_e/legal_e/15-sps.pdf (accessed 11 May 2016).

protection of consumers from food-related health risks linked to, e.g., the composition and nutritional value of food.[227]

However, the SPS-Agreement does not control the interpretation of EU competence according to the Treaty.[228] Because the protection of human life and health from the negative effects resulting from, e.g., the composition and nutritional characteristics of food has not been explicitly excluded it is, therefore, relevant to pose the question whether the Treaty intended to limit the scope of Article 168(4)(b) TFEU to this extent.

Before the adoption of the Treaty of Maastricht,[229] the EU had no explicit competence in the field of health. The legal basis used for the legislation adopted in the area was the more general objective in Article 2 EEC of "the raising of the standard of living and quality of life".[230] Similarly, before the inclusion in the Treaty of Amsterdam of Article 152(4)(b) EC (now Article 168(4)(b)), Article 37 EC (now Article 43 TFEU) was applied as a principal legal basis for legislative proposals in agriculture-related matters relating to the protection of human health or the quality of foodstuffs.[231]

Article 37 EC (now Article 43 TFEU) empowered the Council to adopt the measures necessary to pursue the objectives of the Common Agricultural Policy. The CJEU has given this provision a broad interpretation, allowing the legislature a great deal of liberty in choosing the means of achieving the aims, while accepting the simultaneous pursuit of other objectives and permitting the adoption of both measures to harmonise national provisions and measures that go beyond the harmonisation of national

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[227] See also: Garde. *EU law and obesity prevention*, *supra* note 65, at p. 65.

[228] The SPS Agreement "regulates the use of measures necessary to protect human, animal or plant life or health so that they do not arbitrarily or unjustifiably discriminate between World Trade Organisation (WTO) members. If international standards exist, they are required to be used as a basis for Union measures. However, the parties to the SPS Agreement have the right to set their own relevant standards, provided that such standards are based on scientific evidence." See in this sense Preamble 12 to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (Animal Health Law), OJ L 84, 31.3.2016, pp. 1-208.

[229] Treaty on European Union, signed at Maastricht on 7 February 1992, OJ C 191, 29.07.1992, pp. 1-67.

[230] Treaty establishing the European Economic Community (EEC Treaty or Treaty of Rome), OJ 25.3.1957, not published. See further Tamara K. Hervey and Jean V. McHale (2004). *Health law and the European Union* (Cambridge: Cambridge University Press), at p. 73.

[231] For example, Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market, OJ L 224, 18.8.1990, pp. 29-41, which enacted the worldwide ban on sales of British beef in 1996, was based on Article 43 of the Treaty.

provisions.[232] Article 43 TFEU thus has, for a long time, provided the main legal basis for the adoption of harmonising measures to protect the health of plants, animals and humans and is still often so applied, sometimes in combination with Article 168(4)(b) TFEU in food safety related matters.[233]

Article 168(4)(b) TFEU was included in the Treaty with the adoption of the Treaty of Amsterdam as Article 152(4)(b) EC,[234] apparently as a response to the BSE-crisis in the end of the Nineties.[235] In the aftermath of the BSE crisis, the Temporary Committee of Inquiry into BSE advised a modification of the Treaty. The Committee was of the opinion that the agricultural provision in the Treaty did "not provide a suitable framework for dealing with animal health or food quality matters", and recommended that, until the amendment of the Treaty, "Article 100a on the internal market be used as the legal basis for its proposals in all agriculture-related matters which affect or could affect the protection of health or the quality of foodstuffs." Article 37 EC (now Article 43 TFEU) was to "be used only for matters relating to the administration and day-to-day management of the agricultural markets."[236]

Thus, an explicit legal basis for the adoption of health protection measures in the veterinary and phytosanitary field was established. Hervey and McHale subscribe to the assertion of Van der Mei and Waddington[237] that the insertion of Article 152(4)(b) in the EC Treaty was not meant to extend EU competence, but merely to bring explicit attention to an already existing EU competence, which until then had been regarded as implied in Article 37 EC.[238] A similar view is reflected in the opinion of Advocate General Tizzano of 7 April 2005 with respect to joined cases C-453/03, C-11/04, C-12/04 and C-194/04, in which he states that "[p]rior to the Treaty of Amsterdam, measures relating to the Common Agricultural Policy which also pursued the objective of protecting public health had

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[232] E.g., Case 68/86, *United Kingdom v. Council* (Hormones) [1988] ECR 855, at paras 10-16.
[233] Alison McDonnell, Paul J.G. Kapteyn, Kamiel Mortelmans et al. (2008). *The law of the European Union and the European Communities: with reference to changes to be made by the Lisbon Treaty*. (4th ed., The Netherlands: Kluwer Law International), at p. 381.
[234] Treaty of Amsterdam amending the Treaty on European Union, the Treaty establishing the European Communities and certain related acts, signed in Amsterdam on 2 October 1997, OJ C 340, 10.11.1997, pp. 1-85.
[235] Anne Pieter van der Mei and Lisa Waddington (1998). Public health and the Treaty of Amsterdam. 5(2) *European Journal of Health Law*, pp. 129-154, at p. 137.
[236] Report of 7 February 1997 of the Temporary Committee of Inquiry into BSE on alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and national courts, Part A. II. Recommendations for the future, A4-0020/97, at p. 43.
[237] Van der Mei and Waddington. Public health and the Treaty of Amsterdam, *supra* note 235, at p. 129–154.
[238] *Ibid*, at p. 137. See also Hervey and McHale. *Health law and the European Union*, *supra* note 230, at p. 16.

to be adopted, in accordance with the consultation procedure, on the basis of Article 37 EC. Since the Treaty of Amsterdam entered into force, some of those measures may be based on Article 152 EC."[239] In his view, the adoption of Article 152(4)(b) EC was intended to bring procedural rather than substantive changes to EU competence.

If, indeed, the adoption of Article 152(4)(b) EC was not meant to extend the exercise of powers by the EU, it certainly was not intended to *limit* it either. Therefore, if Article 37 EC created a "Community competence in all agriculture-related matters which affect or could affect the protection of health or the quality of foodstuffs", certainly Article 168(4)(b) TFEU would not have recalled this competence.[240] In line with this reasoning it could be argued that the protection of consumers from nutritional health risks is an implied EU competence.[241]

Nevertheless, even if Article 168(4)(b) TFEU must be given a more limited interpretation, the prohibition from harmonisation in public health matters contained in Article 168(5) TFEU is not absolute. Therefore, Article 168(5) TFEU does not stand in the way of recourse to Article 114 TFEU for the adoption of harmonising measures in the public health sphere. The relation between Articles 114 and 168(5) TFEU will be further discussed, below.

3.2.2 Consumer Protection

Article 169(1) TFEU establishes that "[i]n order to promote the interests of consumers and to ensure a high level of consumer protection, the EU shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their rights to information, education and to organise themselves in order to safeguard their interests." In accordance with Article 169(2) TFEU the EU contribution can take the form of "(a) measures adopted pursuant to Article 114 in the context of the completion of the internal market" or "(b) measures which support, supplement and monitor the policy pursued by the Member States."[242] Apart from pursuing an active consumer policy, the EU

[239] Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04, *Nederlandse Vereniging Diervoederindustrie (Nevedi) v Productschap Diervoeder*, [2005] ECR I-10423, Opinion of AG Tizzano, at paras 4 and 5.
[240] See further on this issue MacMaoláin (2007). *EU food law: protecting consumers and health in a common market*, *supra* note 3, at p. 223 and Garde. *EU law and obesity prevention*, *supra* note 65, at pp. 23, 65.
[241] See in this sense Hervey and McHale. *Health law and the European Union*, *supra* note 230, at p. 70.
[242] Article 169(2) (a) and (b) TFEU.

is also obliged to consider "consumer protection requirements (…) in defining and implementing other EU policies and activities."[243]

Like public health, consumer protection first became an independent EU policy area when the 1992 Maastricht Treaty was adopted.[244] The growing interest in the position of the consumer was the natural consequence of the creation of the single market, which offered greater variety of choice but also brought new and increased risks to consumers.

Maastricht introduced a specific legal basis for consumer protection in Article 129a EC.[245] Prior to the enactment of this provision, measures offering consumer protection had been based on the flexibility clause in Article 235 EEC (now Article 352 TFEU).[246] After the adoption of the Single European Act in 1987,[247] these measures were primarily founded on Article 100a EEC (now Article 114 TFEU), which prescribed that harmonising measures aiming at the establishment of the internal market must take a base in, *inter alia*, a high level of consumer protection. For example, the 1990 Council Directive on nutrition labelling was based on Article 100a EEC.[248]

The Treaty of Amsterdam strengthened the consumer protection provision by expressly recognising information, education and association as subjective consumer rights. Health, safety and economic interests of consumers continued to have the status of interests and objectives of consumer policy, without being acknowledged as rights under Article 153(1) EC.[249] The Treaty amendment did make it clear that it was an EU responsibility to *ensure* a high level of protection rather than to merely *contribute* to the achievement thereof. Finally, Article 153(2) EC was added to the provision,

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[243] Article 12 TFEU (former Article 153(2) EC).
[244] In Article 3(s) EC, later renamed 3(t) EC, now repealed. The substance of Article 3 EC is now spread over Articles 7 TFEU and 13(1) and 21(3)(b) TEU.
[245] Article 129 EC was subsequently renumbered Article 153 EC with the adoption of the Treaty of Amsterdam and is now numbered Article 169 TFEU.
[246] See for an overview of the use of Article 235 EEC as a legal basis Rachel Frid (1995). *The relation between the EC and international organisations: Legal theory and practice* (The Hague: Kluwer Law International), at pp. 83-92.
[247] Single European Act, signed at Luxembourg on 17 February 1986 and at The Hague on 28 February 1986, OJ L 169, 29.06.1987, pp. 1-29.
[248] Council Directive 90/496/EEC, *supra* note 21.
[249] Stuyck (2000). European consumer law after the Treaty of Amsterdam: Consumer Policy in or beyond the internal market, *supra* note 125, at pp. 383-385.

prescribing that "consumer protection shall be ensured in the definition and implementation of all EU policies and activities."[250]

EU competence in the area of consumer protection is more encompassing than in the field of public health. Whereas public health is, in principle, a supportive competence, consumer protection is partly shared,[251] partly supportive.[252]

The TFEU provides contradicting indications regarding the scope of the EU competence to adopt harmonising measures that aim to protect consumer's health, safety and other interests. At a first glance, Articles 169(2) and 114 TFEU appear to establish a rather broad EU competence, limited only by the requirement that harmonisation must serve the internal market. However, Article 168(5) TFEU prohibits harmonisation in public health related matters, which indicates that consumer *health* matters are excluded from the scope of Article 114 TFEU. Then again, this interpretation contradicts the explicit reference to consumer's health in Articles 169(1) and 114(3) TFEU.

Here, the functional provision of Article 114 TFEU may prove decisive. In its seminal judgement in Tobacco Advertising I, the CJEU made it clear that the prohibition of harmonisation of public health measures in Article 168(5) TFEU (at that time Article 129(4) EC) does not stand in the way of the adoption of harmonising measures with an impact on public health based on other Treaty provisions as long as there was no circumvention of "the express exclusion of harmonisation laid down in Article 129(4) of the Treaty."[253]

Weatherill argues that Articles 168 and 169 TFEU and Article 114 TFEU do not interfere with or subordinate each other, so that there would not be a circumvention of Article 168(5) TFEU as long as the criteria of Article 114 TFEU are satisfied. Similarly, despite the restriction in Article 168(4) TFEU of EU competence to minimum-harmonisation, full harmonisation of national measures aiming

[250] Article 153(2) EC was later amended into article 12 TFEU, as part of the general list of considerations that must be taken into account when developing EU policy.
[251] In accordance with Articles 2(2) and 4(2)(f) TFEU.
[252] In accordance with Articles 2(5) and 6 TFEU.
[253] Case C-376/98**,** *Germany v. Parliament and Council* [2000] ECR I-8419, at paras 77-79.

to protect consumers' health and safety remains possible "in so far as divergences between national laws obstruct the functioning of the internal market."[254]

Notwithstanding its seemingly broad scope, the practical significance of Article 169 TFEU for EU food law has, to date, been limited. However, the adoption of the 2011 Food Information Regulation may indicate a change.[255] Although this regulation only refers to Article 114 TFEU as a legal basis, in its first recital it contains a direct reference to Article 169 TFEU, underlining the Regulation's main purpose of ensuring a high level of consumer protection, including consumer health.

3.2.3 The internal market

The previous section noted that Articles 168(4) and 169(2)(a) TFEU both establish an EU competence to adopt harmonising measures in the field of consumer (health) protection. It was argued in Section 3.2.1 that, for the purpose of Article 168(4) TFEU, the objective of safety is prioritised over the internal market. In Section 3.2.2 it was demonstrated that harmonisation within the framework of Article 169(2)(a) is principally restricted within the limits of Article 114 TFEU.

The core question arises if Article 114 TFEU provides a proper legal basis to regulate food health.

There are several arguments that point in the direction of an affirmative answer. An earlier version of Article 114 TFEU provided the legal basis for the few remaining European "recipe laws", e.g., the Chocolate Directive that regulates the composition, manufacturing specifications, packaging and labelling of cocoa and chocolate products to ensure their free movement within the EU.[256] If the EU can set standards for chocolate, certainly it could regulate junk food, as well.

The Chocolate Directive is however not representative for how the EU regulates food. On the contrary, after the adoption of "the principle of mutual recognition"[257] after the judgement of the CJE in the seminal *Cassis de Dijon* case,[258] the EU set aside the idea that developing European standards

[254] Stephen Weatherill (2011). The Limits of Legislative Harmonization Ten Years after Tobacco Advertising: How the Court's Case Law has become a 'Drafting Guide'. 12(3) *German Law Journal*, pp. 827-864, at p. 834.
[255] Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[256] Directive 2000/36/EC of the European Parliament and of the Council of 23 June 2000 relating to cocoa and chocolate products intended for human consumption, OJ L 197, 3.8.2000, pp. 19–25.
[257] European Commission (1985). Communication from the Commission to the Council and to the European Parliament. Completion of the internal market for foodstuffs: Community legislation on foodstuffs, *supra* note 3, at pp. 1, 7 and 13.
[258] Case 120/78, *Rewe-Zentrale AG v Bundesmonopolverwaltung für Brantwein* (Cassis de Dijon), *supra* note 132.

for all food products was vital to realise the Common Market and focused instead on reconciling "the free movement imperative with national regulatory diversities."[259] Only a few examples of food standards remain in force.

The question arises whether this means that Article 114 TFEU can no longer be applied as a legal basis for the adoption of food health law.

In light of the Court's case law, Article 114 TFEU can be used as a legal basis for the adoption of harmonising measures aimed at preventing "future obstacles to trade resulting from the heterogeneous development of national laws" only if the emergence of such obstacles is *likely* and the measure in question is designed to prevent them.[260] If these conditions are fulfilled, "the Community legislator cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made."[261] In fact, as was noted above, Article 114(3) TFEU explicitly prescribes that harmonising measures that aim at the establishment or the functioning of the internal market must "take as a base a high level of protection" of health, safety and (other) consumer interests.

In other words, Article 114 TFEU authorises the EU to adopt harmonising legislation, even if the measures at hand aim to protect public health. However, the EU can only regulate where and to the extent that Member States have created or are about to create obstacles to trade as a result of differences in national levels of protection. As for food health, it is not difficult to imagine the distortion of the internal market that would result from the adoption of diverging national provisions.[262] A potential distortion is, however, not sufficient to legitimise the adoption of

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[259] Alemanno (2007). *Trade in Food*, *supra* note 84, at p. 42.
[260] Case C-350/92 *Spain v Council* [1995] ECR I-1985, at para. 35. See further Case C-376/98 *Germany* v *Parliament and Council* (Tobacco Advertising I) [2000] ECR I-8419, at para. 86; Case C-377/98 *Netherlands v Parliament and Council* [2001] ECR I-7079, at para. 15; Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, at para. 61; Case C-210/03, *Swedish Match* [2004] ECR I-11893, at para. 30; Case C-380/03 *Germany v Parliament and Council* (Tobacco Advertising II) [2006] ECR I-11573, at para. 38.
[261] Case C-376/98 *Germany* v *Parliament and Council* (Tobacco Advertising I), *supra* note 260, at para. 88; Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco*, *supra* note 260, at para. 62; Case C-210/03, *Swedish Match*, *supra* note 260, at para. 3.
[262] Chapter 6 of this thesis, for example, discusses fundamentally different approaches among Member States to the protection of children from food advertisements.

harmonising legislation. The Treaty provides other mechanisms that aim to prevent the creation of national obstacles to trade, i.e., Articles 34-36 TFEU (ex-Articles 28-30 EC).

Consistent case law of the CJEU from the beginning of the seventies has resulted in a broad interpretation of Article 34 TFEU, which prohibits "[q]uantitative restrictions on imports and all measures having equivalent effect (…) between Member States."[263] Garde has argued that "[t]here is no doubt that national rules regulating food composition, food packaging and portion sizes all constitute measures having an equivalent effect to quantitative restrictions and that they fall, as such, within the scope of Article 34 TFEU."[264] Therefore, these national measures – and likely all national measures that aim to ensure food health – may, in principle, fall within the scope of this prohibition.

There are exceptions to the prohibition. Article 36 TFEU lists the possible justifications for national measures that hinder international trade, including the protection of health and life of humans. Moreover, Member States can justify non-discriminatory national measures that serve an objective of public interest, such as public health and consumer protection. To be accepted, such measures must be proportionate in light of the objective pursued.[265]

As illustrated by Garde[266] and MacMaoláin,[267] the CJEU has been hesitant to accept the proportionality of national rules that aim at setting nutritional standards for food products or otherwise regulating the contents of food, arguing that lesser nutritional characteristics do not pose a real threat to human health. Illustrative in this respect is the Court's judgement in Commission vs. France, where it reasoned that

> a Member State may not invoke public health grounds in order to prohibit the importation of a product by arguing that its nutritional value is lower or its fat content higher than another product already available on the market in question. It is plain that the choice of foodstuffs available to

[263] Case 8/74 *Procureur du Roi v. Benoît and Gustave Dassonville* (Dassonville) [1974] ECR 837 and Case 120/78, *Rewe-Zentrale AG v Bundesmonopolverwaltung für Brantwein* (Cassis de Dijon), *supra* note 132.
[264] Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 253.
[265] Case 120/78, *Rewe-Zentrale AG v Bundesmonopolverwaltung für Brantwein* (Cassis de Dijon), *supra* note 132, at para. 13.
[266] Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 254-255.
[267] MacMaoláin (2007). *EU food law: protecting consumers and health in a common market*, *supra* note 3, at pp. 49, 239.

consumers in the Community is such that the mere fact that an imported product has a lower nutritional value does not pose a real threat to human health.[268]

In this and similar cases, the Court points in the direction of labelling requirements that would enable the consumer to make informed choices as the appropriate protective measure.

Garde has found indications in the case law from the CJEU that the Court "may be willing to move away from its restrictive approach to the nutrition arguments".[269] This could mean that, in the near future, Member State measures aimed at regulating food health may qualify to stand the proportionality test, but the Court has not yet taken this final step.

From the observation that the CJEU has refused to accept food health-related trade obstacles as proportionate, one could conclude that, similarly, harmonisation on the basis of Article 114 TFEU would be precluded. Because Article 114 TFEU limits EU competence to the harmonisation of Member State measures that have a direct effect on the functioning of the internal market or that are likely to establish trade obstacles, surely it would outlaw harmonising initiatives in areas where, *a priori*, national measures are regarded as prohibited trade barriers in the sense of Article 34 TFEU.

The Court's attitude towards positive harmonisation in the area of consumer protection, however, differs substantially from its view on negative harmonisation, which is driven by the principle of mutual recognition.[270] While the Court has more or less systematically disqualified Member States' legislative interventions aimed at protecting consumers' health and other interests as disproportionate, it has been more favourable towards EU action in this area. In this respect the CJEU consistently holds that "the Community legislator must be allowed a broad discretion in areas which involve political, economic and social choices on its part, and in which it is called on to undertake complex assessments."[271] Because the Court has found such discretion to be appropriate where the regulation of tobacco advertising is concerned,[272] there is reason to believe that it will also endorse recourse to

[268] Case C-216/84, *Commission v. France* [1988] ECR 793, at para. 15.
[269] Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 257.
[270] See for an elaborate overview of the case law of the CJEU Unberath and Johnston (2007). The double-headed approach of the ECJ concerning consumer protection, *supra* note 89.
[271] Case C-344/04, *International Air Transport Association v Department of Transport* [2006] ECR I-403, at para 80.
[272] Case C-376/98 *Germany* v *Parliament and Council* (Tobacco Advertising I), *supra* note 260; Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco*, *supra* note 260.

Article 114 TFEU as a legal basis for the adoption of harmonising measures in the area of food health. So far, however, this remains to be tested.

3.3 Conclusion

This chapter explored the extent of EU competence to address consumer protection from the potential harmful health effects from the (over)consumption of foods that have negative nutritional features.

The EU Treaty prescribes that public health and consumer protection must systematically be taken into account when defining and implementing all other EU policies and activities.[273]

However, Article 168(5) TFEU prohibits, in principle, the adoption of harmonising measures in the field of public health. An exception is established in Article 168(4) TFEU, which allows for harmonisation to meet a number of "common safety concerns", of which, food safety is of relevance in the context of this chapter.

From its formulation, it may seem that Article 168(4)(b) TFEU would limit EU competence to regulating food safety in a rather narrow sense. However, the EU can base its legislative competence in food health matters on Article 114 TFEU, possibly in conjunction with Article 169 TFEU. Article 169(1) TFEU expressly states that "[i]n order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers." For this purpose, the EU shall adopt, e.g., "measures adopted pursuant to Article 114 in the context of the completion of the internal market."[274]

In light of the case law of the CJEU, the prohibition in Article 168(5) TFEU of the adoption of harmonising measures in public health issues does not stand in the way of the elimination of barriers to trade on the basis of Article 114 TFEU. The adoption of such harmonising measures is thus, in principle, restricted by the limits set by article 114 TFEU only. Accordingly, the harmonisation must serve to undo a genuine distorting effect on the internal market of differences between Member State laws.

[273] Articles 12 and 168(1) TFEU.
[274] Article 169(2)(a) TFEU.

In line with the case law from the CJEU, the EU legislator "must be allowed a broad discretion in areas which involve political, economic and social choices on its part, and in which it is called on to undertake complex assessments."[275] Accordingly, the legality of such measures can be challenged only if the measure in question is clearly disproportionate in relation to the objectives that it wishes to pursue. How the CJEU will deal with the proportionality test in relation to measures regulating food health is a question that remains unanswered.

While the issue may be complex, it follows from this analysis that the TFEU provides the EU legislature the competence it needs to be able to regulate food health law.

[275] Case C-344/04, *International Air Transport Association v Department of Transport*, *supra* note 271, at para 80.

4 The gullible consumer in EU food law[276]

Abstract

This chapter provides a legal characterisation of the EU food consumer. It demonstrates how the legislative choices at the core of EU food legislation result in an image of a consumer who is essentially helpless in the face of health risks that fall within the scope of Article 14 GFL and that can be identified by means of scientific risk analysis. Confronted with other than these well-defined food safety risks, however, consumers are expected to be fundamentally capable and in charge, provided that they are granted access to a minimum amount of information about food products. The guiding principle behind this split consumer personality is the freedom to choose. It is argued that in matters that fall outside the scope of risk in the GFL, consumers' freedom overrules their need for protection, no matter how difficult the choice and multifaceted its impact.

4.1 Introduction

EU consumers are free to choose how they live their lives and what they eat. This right of consumer autonomy follows from the right to market access that is at the heart of the EU.[277] Although the free movement of goods essentially addresses producers and distributors of goods, the effective functioning of the internal market is largely dependent on the active engagement of consumers in cross-border trade.[278] Therefore, the internal market simultaneously presupposes that consumers have access and are at liberty to choose between the products that are placed on the market.

EU law prescribes that "[i]n order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests."[279] From a legal point of view, the principle of free choice appears

[276] An earlier version of this chapter was previously published as a conference paper as W.W. Huizing Edinger (2013). The gullible consumer in EU food law. In Helene Röcklinsberg and Per Sandin (eds). *The Ethics of Consumption. The Citizen, the Market and the Law*, Proceedings of EurSafe 2013 (Wageningen: Wageningen Academic Publishers), pp. 135-141.
[277] Micklitz, Reich and Rott (2009). *Understanding EU consumer law*, *supra* note 121, at p. 48.
[278] *Ibid*, at p. 9.
[279] Article 169(1) TFEU.

difficult to reconcile with this call for consumer protection, because freedom presupposes absence of intervention, whereas protection necessitates regulation, resulting in limits to freedom.

This chapter looks into how this seeming conflict between freedom and protection is dealt with at the EU level, with a particular focus on the consumption of food. Is it possible to protect consumers adequately while at the same time guaranteeing them a genuine freedom of choice of what they eat? In case of conflict, which interest should prevail: freedom or protection? What is the position of credulous and gullible consumers who appear to have difficulties to manage their freedom adequately and to make appropriate choices?

The CJEU, seeking to strike a fair balance between the various interests at stake, has developed a protective standard based on an objectified image of EU consumers and their needs. Usually, the impetus for legal protection is the will to balance an unequal relationship in favour of the weaker party. Therefore, one would expect the objectified food consumer to be relatively weak and unable to protect his or her own interests, but this is not necessarily the consumer image that prevails throughout EU food law.

4.2 The EU consumer, consumer protection and consumer rights

The terms *consumer*, *consumption* and *consume* are readily associated with food. Somehow, one is more likely to imagine someone consuming an apple than a contract. Nevertheless, in a legal sense, the overall consumer concept comprises both of these activities – and many more.

Arguably, the everyday consumer concept is very broad: we all seem the fall within its scope one way or another. This may explain why EU law does not contain a single legal definition of the EU consumer. The EU Treaties do not provide such definition and, although Article 169 TFEU holds a reference to consumers' basics rights and interests, it does not specify by whom and under what conditions these can be enjoyed. Thus, the consumer notion remains implied in the Treaty and must be further delimited by exploring its historical and practical application.

The consumer movement emerged as a response to the growing complexity of the market. At the same time, however, consumer protection policy developed as a corollary of the internal market before it was accepted as an independent task for the EU. The result, as identified by Unberath and

Johnston, is a "double-headed approach" to consumer protection within the EU.[280] Where national rules aimed at protecting consumer interests compete directly with the free market interests protected by the Treaties, a liberal, market-oriented approach was adopted from early on. This negative harmonisation, harmonisation through the suppression of national rules that violate the Treaties, favours deregulation and adheres to a relatively low denominator for protection of consumers' rights and interests.[281]

For the purpose of positive harmonisation, harmonisation through the adoption of positive EU legislation, Unberath and Johnston have identified a protective standard that results in a rather consumer-friendly, trade-restricting interpretation of the rules in question.[282] The result is an intriguing blend of consumerism where the EU legislature has adopted harmonising legislation, and tradeism where this is not the case.

Considering the above schism, it is not surprising that the consumer concept remains vague and consumer rights have not been made very explicit in the EU Treaties. In fact, only few of these rights, i.e. the rights to information, education and association, have actually been formalised.[283]

The question arises to what level of protection the EU food consumer is entitled on the basis of the above Treaty provisions. To answer this question, this chapter will examine how the consumer concept has developed within positive EU food law.

4.3 The EU food consumer and his protectable interests

With the adoption of the GFL,[284] the consumer explicitly and irrevocably entered EU food legislation. Article 3(18) GFL defines the "final consumer" as "the ultimate consumer of a foodstuff, who will not use the food as part of any food business operation or activity." Accordingly, food consumers are the end-users of the food, those who actually *eat* it, alone or shared with others in a private atmosphere.

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[280] Unberath and Johnston (2007). The double-headed approach of the ECJ concerning consumer protection, *supra* note 89, at p. 1244.
[281] *Ibid*.
[282] *Ibid*, at p. 1238.
[283] Apart from Article 169 TFEU, Article 38 of the Charter of Fundamental Rights of the European Union refers to consumers. The latter provision, however, does not grant directly applicable rights to consumers. *Supra* note 134.
[284] Regulation (EC) No 178/2002 (GFL), *supra* note 1.

The Preamble to GFL acknowledges the importance of consumer protection by identifying two preconditions for the well-functioning of the internal market, i.e., consumer safety and consumer confidence.[285] These basic concerns reflect the general principles of EU food law laid down in the GFL, i.e., the principle of food safety and the principle of informed choice.[286] Despite the fact that choice and safety are not formalised consumer rights in the EU Treaties, both have gained unambiguous status as guiding values within the area of EU food law.

On the basis of the principle of food safety, the EU legislator has developed a dense net of strict safety rules that aim to protect the health and safety of consumers and that place the full responsibility for safe food production and marketing on food operators.[287] This system confirms the acceptance of a horizontal consumer right to food safety in the sense that consumers may expect the food they eat not to harm their health, so that they have a claim on the food operator if they do suffer harm from food.

The principle of informed choice, which can be seen as a context-specific application of the consumer right to information, is embedded in mandatory rules that complement the general rules concerning unfair commercial practices with specific requirements for the provision of food information to consumers. The main provisions can be found in the FIR.[288]

Pursuant to Article 3(1) FIR, food information legislation aims to provide "a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical considerations." In accordance with Article 8 FIR, the provision of appropriate food information is a responsibility of food operators.

The consumer right to information is thus converted into a subjective entitlement to be offered insight in an objectified series of mandatory particulars about any food product and to be protected from being misled.[289] The result is, effectively, the acceptance of a consumer right to *informed choice*, its protective element contained in the objectified consumer need for data to be able to fully understand

[285] Recitals 1 and 9 of the Preamble to Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[286] The principle of food safety is laid down in Articles 14 and the principle of informed choice in Article 8 of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[287] Arts 5(1) and 17 of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[288] Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[289] See in this sense Article 8 of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

their choice and its consequences.

EU food law thus comprises two designated areas of consumer protection legislation that differ considerably in character. The legislature's approach to food safety has resulted in a protective system that aims to limit exposure to chemical, biological or physical hazards from food.[290] Apparently, the EU legislature has concluded that consumers, in general, are unable to protect themselves from such health threats, resulting in solid harmonisation based on a relatively high level of protection. Only incidentally we see that the responsibility for dealing with food safety risks is placed with the consumer. For instance, salmonella-infected raw poultry meat may be placed on the market provided that adequate instructions for use are placed on the product's packaging, even though inadequate compliance may induce health risks.[291]

Where mandatory information requirements are favoured over stringent food safety rules, the conclusion seems justified that the EU legislature has deemed it disproportionate to impose additional requirements on the food producer and concluded, instead, that consumers are able to protect themselves, provided that they are offered objectively necessary information particulars.

As a result, the objectified EU food consumer is perceived in a different way in matters relating to the safety of food than in non-safety issues. In areas with well-identified health and safety challenges, consumers are perceived as rather weak and vulnerable, and in need of protection. Where health threats fall outside the scope of safety, however, consumers are in principle expected to take care of themselves by making subjective choices that will maximise their personal benefit.

This division of responsibilities between food operators and consumers is relatively unproblematic as long as a health threat falls within the seemingly narrow concept of risk in the GFL.[292] In reality, however, it is not always easy to predict the longer and short-term effects of a food on health and well-being, especially if the manifestation of these effects depends on the overall pattern of consumption and lifestyle of the person consuming it.

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[290] See on this issue, Chapter 2.
[291] Article 9(1)(g) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[292] As defined in Arts 3(9) and 14 of Regulation (EC) No 178/2002 (GFL), *supra* note 1. See further Chapter 2.2 on the scope of risk in the GFL.

In case of scientific uncertainty, the precautionary principle contained in Article 7 GFL may come into play. In accordance with this principle, provisional risk management decisions may be taken if "the possibility of harmful effects on health is identified but scientific uncertainty persists" concerning the reality and seriousness of that risk.[293] However, the application of the precautionary principle is restricted to risks as defined by natural science, which, from the outset, appears to limit its scope to food safety in the above narrow sense.[294] Despite the existence of uncertainties concerning the health effects of a food in light of the overall diet, the final responsibility for the consumptive decision in such cases remains with the consumer.

4.4 The food consumer according to the CJEU

The split personality of the food consumer can be seen as the result of the case law from the CJEU in the field of negative harmonisation, which generally seems to favour trade over other legitimate interests.

It is consistent case law from the CJEU that national measures that have the potential to hinder trade within the internal market can be permitted only to the extent that they are "necessary on grounds of public interest listed in Article 36 [of the EEC Treaty, now Article 36 TFEU], such as the effective protection of human health, or in order to satisfy mandatory requirements relating *inter alia* to consumer protection."[295] This applies for all national rules that lay down requirements "such as those relating to designation, form, size, weight, composition, presentation, labelling, packaging", even if those rules apply to national and imported products alike.[296] Furthermore, in line with the proportionality principle, Member States "may not invoke those grounds of public interest or mandatory requirements in order to justify a measure restricting imports unless the same objective cannot be achieved by any other measure which restricts the free movement of goods less."[297]

[293] Article 7(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[294] Pursuant to Article 7(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1, the precautionary principle can only be invoked in situations where a potential risk has been identified and an assessment of that risk has taken place.
[295] Case 216/84, *Commission v. France*, *supra* note 268, para. 7.
[296] Joined Cases C-267/91 and C-268/91 *Keck and Mithouard* [1993] ECR I-6097, para. 15. See also Case C-470/93 *Verein gegen Unwesen in Handel und Gewerbe Köln eV v. Mars GmbH* (Mars) [1995] ECR1-1923, para. 12.
[297] Case 216/84, *Commission v. France*, *supra* note 268, para. 7.

Where the protection of health and life of humans is concerned, the Court has consistently held that "in so far as there are uncertainties at the present state of scientific research it is for the Member States, in absence of harmonisation, to decide what degree of protection they intend to assure, having regards however to the requirements of the free movement of goods within the Community".[298]

In regard to health protection, the Court has further delimited the application of the proportionality principle underlying Article 36 TFEU to the existence of a "real threat to human health."[299] Accordingly, "[a] decision to prohibit marketing, which indeed constitutes the most restrictive obstacle to trade in products lawfully manufactured and marketed in other Member States, can only be adopted if the real risk alleged for public health appears sufficiently established on the basis of the latest scientific data available at the date of the adoption of such decision."[300]

The application of the proportionality principle has interesting implications for the part of food law that is concerned with food quality and nutritional value. Keeping in mind that it is very difficult for a Member State to prove that a food is unsafe pursuant to the requirements of positive EU food law, it may be clear that it is practically impossible to intervene in the circulation of foodstuffs that are safe in a strictly legal sense, but that are qualitatively or nutritionally inferior to other, comparable products. In light of the stringent application of the precautionary principle to scientific criteria, it cannot be of help in this respect.

The rationale of this system appears to be that consumers are best served with genuine choice and competition, even if the increase in choice is at least partly created by allowing products of lesser quality or with inferior nutritional characteristics to enter the market. Here, mandatory labelling requirements are viewed as the protective measure that is least restrictive on the free movement within the EU.[301] Although this standpoint is understandable from a commercial point of view, it may prove to be particularly problematic where gullible consumers are concerned, i.e., those people that find themselves in a disadvantageous position because of their age, social or economic status or for other reasons.

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[298] Case 120/78, *Rewe-Zentrale AG v Bundesmonopolverwaltung für Brantwein* (Cassis de Dijon), *supra* note 132, para. 41.
[299] Case 216/84, *Commission v. France*, *supra* note 268, para. 15.
[300] Case C-192/01 *Commission v Denmark* [2003] ECR.1-9693, para. 48.
[301] Case 216/84, *Commission v. France*, *supra* note 268, paras 12 and 15.

It may be clear that the protective effect of food information depends heavily on how the consumer understands and processes the information provided. For example, if a food label contains instructions for use, it is essential that the consumer understands this information to be imperative – and responds by complying to avoid health risks.[302]

The situation gets more complicated when food information does not concern immediate health threats, but (nutritional) characteristics that may induce negative health consequences depending on the consumptive pattern adopted by the consumer in question. This type of information presupposes that the consumer is capable not only of deciphering often quite technical messages, but also of acting rationally on the information contained therein. In other words, consumers are expected to fully comprehend the effects of food on their health and well-being in the shorter and longer run and to adapt their overall diet and lifestyle. It may be clear that this is a mouthful for any consumer and particularly so for the more gullible kind.

The EU legislature, confronted with the question of what information is required to enable consumers to protect themselves adequately, adopted the objectified consumer image developed by the EU, which "takes as a benchmark the average consumer, who is reasonably well-informed and reasonably observant and circumspect," thus embracing quite an optimistic standard of consumers' general insight and cognitive skills.[303]

When provided with product information, the average consumer is expected to be "reasonably circumspect"[304] and "capable of taking in, with some attention, the information appearing on products which he is invited to buy", as opposed to the "[t]he casual consumer [who] does not pay enough attention to the fine print on a product but is more likely to be influenced by the colour of the pack, by the designs on the pack or by slogans (…)"[305] Moreover, it is expected that "consumers whose purchasing decisions depend on the composition of the products in question will first read the list of ingredients," and, consequently, to understand and act rationally upon the information particulars

[302] See for example the requirement in Article 9(1)(g) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[303] See Recital 16 of the Preamble of Regulation (EC) 1924/2006 (Claims Regulation), *supra* note 56. Recital 41 to the Preamble of Regulation (EU) No 1169/2011 (FIR), *supra* note 6, also refers to the average consumer as a benchmark.
[304] Case C-470/93 *Verein gegen Unwesen in Handel und Gewerbe Köln eV v. Mars GmbH* (Mars), *supra* note 296, para. 24.
[305] Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide), *supra* note 88, Opinion of A-G Mischo, para. 97-98.

provided to them.[306] Finally, consumers are deemed capable of distinguishing between mandatory particulars and commercial information, which they are expected to take with a grain of salt.[307]

The adoption of harmonised rules for food safety and food information legislation has not changed the Court's practise with respect to consumer (health) protection. In fact, the adoption of these rules positively harmonises the Court's negative interpretation of consumer's rights and interests.

As a consequence, the lower protective standard reflected in consumer information legislation becomes decisive also in questions where consumer health may indeed be at stake, e.g., food quality and nutritional composition. Because the consumption of a food with inferior (nutritional) characteristics does not pose a real, immediate threat to human health, the potential negative effects on human health resulting from their consumption are viewed as a consumer information issue rather than a food safety issue. Accordingly, consumers are expected to protect themselves from the materialisation of these negative effects by rationally applying their right to free choice.

4.5 Conclusion

EU consumer protection is not only "double-headed" in the sense that the protection of the consumer in the field of negative harmonisation is based on a lower common denominator than in the field of positive harmonisation. In regard to positive EU food law, the consumer also appears to have a split personality, because their overall characterisation depends on which of their interests are at stake and how these interests are categorised.

This split consumer personality results from the seemingly sharp distinction between food safety-related issues and food information matters. The consumer is viewed as essentially helpless in relation to health risks that fall within the scope of food safety risks in the GFL and that can be identified through scientific risk assessment. Where potential health risks are more vague and unpredictable – for instance under influence of other than purely scientific considerations, such as economic and behavioural reflections – consumers are regarded as fundamentally capable and in charge, provided that they have access to a minimum number of information particulars to guide their choice.

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[306] Case C-51/94 *Commission v Germany* [1995] ECR I- 3617, para. 34.
[307] Accordingly, "[r]easonably circumspect consumers may be deemed to know that there is not necessarily a link between the size of publicity markings relating to an increase in a product's quantity and the size of that increase", see Case C-470/93 *Verein gegen Unwesen in Handel und Gewerbe Köln eV v. Mars GmbH* (Mars), *supra* note 296, para. 24.

The guiding principle behind this split is the freedom to choose which, although not explicitly recognised as a consumer right within the EU context, continues to be one of the core values of the internal market. In practice, consumers' freedom to choose what they eat is limited only in relation to food safety issues. If food is safe, freedom rules out protection, no matter how difficult it may be for consumers to make appropriate, balanced choices and how multifaceted the potential effect on their health and well-being.

5 Promoting educated consumer choices. Has EU food information legislation finally matured?[308]

Abstract

Contemporary EU food information legislation combines and balances the two main consumer interests, i.e., the consumer right to information and the freedom of choice, into one single protective standard: informed choice. Although the recent legislative measures quite openly establish a link between informed choice and the rather abstract societal norm of what is good for the consumer, this does not justify the conclusion that food information legislation has become overly meddlesome in relation to EU consumers and their choice of food. Rather, there has been a gradual maturing of the EU legislature's perception of its task from the mere provision of basic details to ensuring educated consumer choices. This development is a logical and necessary consequence of the growing complexity of food choices.

5.1 Introduction

Recent developments within EU food law have been said to indicate that the EU legislature has taken on a more protective attitude towards the food consumer and his choice of diet. Since the entry into force of the – heavily debated – Regulation (EC) No 1924/2006 on nutrition and health claims made on food (Claims Regulation)[309] and recent implementing measures, nutrition and health claims have been prohibited unless expressly authorised and included in a list of permitted claims. The legislature has thus adopted restrictive measures in an area where consumer safety is not directly at stake – a policy which before was reserved for apparent health risks.

In the view of Werner Schroeder and Andreas Müller, the shift from the abuse principle to the interdiction principle results in "paternalistic legislation".[310] Similarly, Tatiana Klompenhouwer and Henk van den Belt have suggested that the 2006 Claims Regulation focuses on steering consumers

[308] An earlier version of this chapter was published as Wieke Huizing Edinger (2016). Promoting educated consumer choices: has EU food information legislation finally matured? 39(1) *Journal of Consumer Policy*, pp. 9-22.
[309] Regulation (EC) No 1924/2006 (Claims Regulation), *supra* note 56.
[310] Werner Schroeder and Andreas Müller (2011). The mechanisms of EU food law after the entry into force of the Lisbon Treaty. 35 *Ernährung/Nutrition*, pp. 122-129, at p. 124.

toward the healthier choice of food rather than (just) facilitating informed choice. In their opinion, "informed choice is quietly and subtly being subordinated to public health objectives."[311]

Also the 2011 FIR has been said to reveal a change of attitude towards the food consumer in comparison to earlier labelling laws.[312] According to Andreas Meisterernst, the adoption of the FIR indicates a departure from the average consumer benchmark developed by the CJEU.[313] To support his argument Meisterernst points at the requirement in Article 7(2) FIR that food information must be "easy to understand" and "clear" which, in his view, favours a notion of a consumer who is less empowered.[314]

This chapter aims to establish whether the EU legislature has really assumed a more active role towards EU consumers and their choice of food, indeed one that can be characterised as overly interventionist or paternalistic.[315] Is it true that the legislature has set aside the notion of the well-informed, reasonable and circumspect consumer and started to meddle directly with what people eat? Has the freedom to choose given way to some form of dietary nudge? These questions concern the protective purpose and scope of EU labelling legislation in force, which are the focus of this chapter.

It is a general principle of contemporary EU food law that it must "provide a basis for consumers to make informed choices in relation to the foods they consume."[316] To understand the purpose of EU labelling legislation it is therefore necessary to analyse what, legally, constitutes an informed choice. What information particulars must be provided to the consumer for food choices to qualify as well-informed, and who is responsible for doing so? In that respect, do the latest legislative developments indicate a change of approach?

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[311] Klompenhouwer and Van den Belt (2003). Regulating functional foods in the European Union: Informed choice versus consumer protection?, *supra* note 131, at p. 554.
[312] Regulation (EU) No 1169/2011 (FIR) amends and gathers in one horizontal instrument the EU labeling requirements in, e.g., Regulations (EC) No 1924/2006, Council Directive 90/496/EEC and Directive 2000/13/EC, see note 6.
[313] See, e.g., Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide), *supra* note 88, para. 37.
[314] Andreas Meisterernst (2013). A new benchmark for misleading advertising. 8(3) *European Food and Feed Law Review*, pp. 91-96, at p. 96.
[315] See on the concept of paternalism: Gerald Dworkin (1972). Paternalism. 56(1) *The Monist*, pp. 64-84; John Kleinig (1983). *Paternalism (*Totowa, N.J.: Rouman & Allanheld); Anthony I. Ogus (2005). Regulatory paternalism: When is it justified? In: Hopt, K.J. et al. (eds). *Corporate governance in context: Corporations, states, and markets in Europe, Japan, and the US* (Oxford: Oxford University Press).
[316] Article 8(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

Consumers are all different and so are their individual circumstances and preferences. For that reason, it is practically impossible to standardise consumers' need for food information. Nevertheless, to establish uniform criteria for the labelling, presentation and advertising of all foodstuffs to facilitate informed consumer choices is precisely what EU food information legislation intends to do. Therefore, inevitably, it adheres to the image of an objectified European consumer, whose characteristics influence the scope of EU labelling legislation.

It will be demonstrated in this chapter that although the recent legislative developments signpost a growing awareness of the need to provide special protection to certain groups of particularly vulnerable consumers, they do not indicate an overall paradigm shift. Instead, it is argued, the current legislative trends reflect a gradual maturing of the EU legislature's perception of its task from the mere provision of food information to ensuring educated consumer choices. This development is a logical and necessary consequence of the growing complexity of food choices.

The chapter commences with an introduction of the system and main principles relevant for food information legislation and continues with an analysis of its evolution over time against the background of the case law of the CJEU, as well as policy development in the field of consumer protection legislation, including aspects of nutrition and health. It ends with a conclusion on whether the latest legislative initiatives mark a shift of approach towards EU consumers and their choice of diet.

5.2 The system and main principles of EU food information legislation

5.2.1 EU food consumers and their legitimate interests

EU food law serves, first and foremost, to protect consumers. In accordance with Article 5(1) GFL, EU food law must 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". At the same time, Article 5(2) GFL provides that EU "[f]ood law shall aim to achieve the free movement (…) of food and feed" in the EU. Thus, EU food law is the result of the balancing of the protection of consumers' health and other interests in relation to food and the effective functioning of the internal market.[317] This exercise has resulted in the acceptance of two fundamental principles

[317] Article 1 of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

of EU food law: the principle of food safety in Article 14 GFL, and the principle of informed choice in Article 8 GFL.[318]

Based on the principle of food safety, a dense net of strict safety rules has been developed that ban from the EU market all foods that are deemed to pose a risk to human health because they contain dangerous microorganisms or are contaminated with harmful substances – foods that are unsafe.[319] This system effectively establishes a consumer right to food safety and provides consumers with a claim against food operator who are negligent in this respect.[320]

The principle of informed choice is at the basis of EU food information legislation, which is defined in the FIR as the set of EU provisions governing food information made available to consumers by means of labels, "other accompanying material or any other means including modern technology tools or verbal communication".[321] Accordingly, not only food labelling in a narrow sense, but all business-to-consumer communication about food products, including the presentation and advertising of such products, fall within the scope of EU food information legislation.

Article 3(1) FIR provides that food information "shall pursue a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, societal and ethical considerations."[322] It implements Article 8 GFL, which confirms the status of informed choice as a guiding principle of EU food information legislation.[323]

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[318] In its Communication Completion of the internal market for foodstuffs: Community legislation on foodstuffs, the Commission laid down the framework for consumer protection in EU food law based on the basic assumption that if consumers are offered adequate food information, it would not be necessary to define these elements in law, unless necessary for the protection of their health. See European Commission (1985). Communication from the Commission to the Council and to the European Parliament. Completion of the internal market for foodstuffs: Community legislation on foodstuffs, *supra* note 3. See further MacMaoláin (2007), *EU food law: protecting consumers and health in a common market*, *supra* note 3, at p. 72.

[319] Article 14(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.

[320] Article 19 of Regulation (EC) No 178/2002 (GFL, *supra* note 1) places on food operators the responsibility to withdraw foods that do not comply with food safety requirements from the market or to recall them from consumers. Pursuant to Article 21 of Regulation (EC) No 178/2002 (GFL), food operators that do not comply with these obligations are liable to consumers for any damages in accordance with the provisions of Council Directive 85/374/EEC on the approximation of the laws, regulation and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 07.08.1985, pp. 29-33.

[321] Article 2(2)(a) and (b) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.

[322] Article 3(1) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.

[323] Article 8(1) GFL states

To ensure informed consumer choices, Article 7, which is the central provision of the FIR, establishes that food information shall not mislead consumers as to the nature, characteristics and effects of food.[324] Article 7(2) further provides that "[f]ood information shall be accurate, clear and easy to understand for the consumer."

For this purpose, the FIR lays down two types of provisions, i.e. mandatory labelling requirements[325] and rules regulating the provision of voluntary food information to consumers.[326] The mandatory requirements prescribe in detail the contents and lay-out of food labels that inform consumers about the identity, composition and properties of food, as well as the safe use thereof.[327] The rules on voluntary food information restrict the provision by food operators of additional information particulars to prevent promotional statements from negatively affecting the consumer's understanding of the mandatory particulars.[328]

The FIR combines and balances two main consumer interests, i.e. a consumer right to information and free choice, into one single protective standard: informed choice.

Consumer choice can be regarded as the counterpart of the fundamental freedom of "active market participants" (producers, traders, importers, etc.) to engage in cross border transactions, a right that is at the very core of the EU internal market.[329] Consumer protection through, e.g., the provision of information extends this right to "passive market participants" – consumers – by ensuring that they have confidence in the viability of the market.[330] In this light, the free movement of goods and informed consumer choice are interdependent in that the internal market's success in terms of increased welfare for EU citizens rests on consumers' actual engagement in cross-border shopping.[331]

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[324] Article 7(1)(a)-(d) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6, specify in detail under what conditions food information is deemed misleading.
[325] Articles 4 and 9-35 of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[326] Articles 36 and 37 FIR (Regulation (EU) No 1169/2011 (FIR), *supra* note 6).
[327] Article 4(1) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[328] Recital 47 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[329] Reich (1998). Some reflections on rethinking community consumer law, *supra* note 68, at p. 443.
[330] Micklitz, Reich and Rott (2009). *Understanding EU consumer law*, *supra* note 121, at. pp. 6-28.
[331] Wilhelmsson (2004). The abuse of the 'confident consumer' as a justification for EC consumer law, *supra* note 125, at p. 320.

Although EU Law does not expressly establish a consumer right to information, Article 169(1) TFEU acknowledges its existence. It has been disputed whether this right can be interpreted to include a duty for businesses actively to furnish the consumer with certain information particulars. Stefan Leible does not think so, pointing out that the provision contains a general and abstract policy norm, addressed to the EU legislature.[332] According to Reich, however, an indirect right for consumers to receive food information can be distilled from the case law of the CJEU concerning justifiable restrictions to trade under the *Cassis de Dijon* doctrine, discussed below.

The question arises what level of food information is deemed necessary to protect consumers adequately, while at the same time ensuring that their autonomy remains relatively unimpaired. In other words: where did the legislature draw the line between the information part of the equation and the choice part of the equation, when prescribing informed choice?

It will be demonstrated, below, how the concept of informed choice emerged against the background of the case law of the CJEU in the field of negative harmonisation.[333] As a result, the legislature abandoned the idea of regulating food through the adoption of so-called recipe laws in favour of a "well-developed and clear system of labelling".[334] At the same time, the notion was influenced by the advancement of the EU's policy in the area of consumer protection.

First, however, a short overview of contemporary food information legislation will be presented.

5.2.2 Short overview of EU food information legislation in force

The FIR establishes the general framework for the provision of food information to consumers, comprising food labelling in a narrow sense, as well as any form of food advertising.

[332] Stefan Leible (2010). Consumer information beyond food law. 5(6) *European Food and Feed Law Review*, pp. 316-324, at p. 218.
[333] See for an extensive overview of the case law of the CJEU concerning the free movement of goods Unberath and Johnston (2007). The double-headed approach of the ECJ concerning consumer protection, *supra* note 88.
[334] See MacMaoláin (2007). *EU food law: protecting consumers and health in a common market*, *supra* note 3, at p. 72. See further European Commission (1985). Communication from the Commission to the Council and to the European Parliament. Completion of the internal market for foodstuffs: Community legislation on foodstuffs, *supra* note 3, at p. 9.

In the field of mandatory labelling, the FIR combines and consolidates Directives 2000/13/EC,[335] 90/496/EEC,[336] as well as a number of other horizontal acts regulating the obligatory indication of information particulars on foodstuffs.[337]

As for the provision of voluntary food information to consumers, the FIR complements the general rules concerning unfair business-to-consumer practices laid down in Directive 2005/29/EC,[338] the Unfair Commercial Practices Directive, with specific rules concerning the provision of food information to consumers and prohibiting the use of information that would mislead the purchaser or attribute medicinal properties to food. These general provisions are, in turn, complemented with specific provisions regulating the use of nutrition and health claims in the Claims Regulation.[339]

In addition to these horizontal measures, a number of vertical instruments regulate the labelling of certain specific groups of foodstuffs, such as Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.[340]

5.3 The development of the concept of informed choice

Viewed from the perspective of protective purpose, the development of EU food information legislation from the first attempts to harmonise Member States' food labelling laws to the adoption of the FIR, can be roughly divided into three stages, i.e., the approximation stage, the acceptance of the information paradigm and the nutrition stage.

5.3.1 Approximation of national laws

Food labelling was among the priority areas of the 1975 preliminary programme for a consumer protection and information policy,[341] which was directed at improving the quality of life of European

[335] Directive 2000/13/EC (Labelling Directive), *supra* note 80.
[336] Council Directive 90/496/EEC, *supra* note 21.
[337] See in this regard Recital 12 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[338] Directive 2005/29/EC, *supra* note 82.
[339] Regulation (EC) No 1924/2006 (Claims Regulation), *supra* note 56.
[340] Regulation (EC) 1830/2003/EC of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, OJ L 268, 18.10.2003, pp.24-28.
[341] Annex to Council Resolution of 14 April 1975 on a preliminary programme of the European Economic Community for a consumer protection and information policy, OJ C 092, 25.04.1975, pp. 1-16.

consumers through the protection of their basic rights.[342] Similarly, the first labelling directive, Council Directive 79/112/EEC,[343] stated in its Preamble that "the prime consideration for any rules on the labelling of foodstuffs should be the need to inform and protect the consumer".[344]

Based on the fundamental recognition that consumers require at least a minimum amount of information to avoid being misled about the nature and characteristics of foodstuffs, the Directive prescribed that mandatory information particulars needed to be included in the labelling of all food products.[345] With regard to voluntarily added information, the Directive established a general prohibition against food labelling and advertising that could mislead the consumer or attribute medicinal characteristics to the food in question.[346] The Directive thus placed on food professionals both the positive obligation actively to provide consumers with specific data that would enable them to distinguish between foods on the basis of their essential characteristics, and the negative obligation to refrain from creating a false or misleading image of their products by means of additional wording or imagery, or in food advertising.

Directive 79/112/EEC, thus, entailed full harmonisation of food labelling laws by prescribing a series of basic information particulars that were mandatory for all foodstuffs, so that their absence would result in a marketing prohibition.[347] Simultaneously, the Directive expressly acknowledged that it was incomplete, and that the adoption of additional requirements would be necessary to duly inform the consumer.[348]

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[342] Misleading advertising was another priority. In 1979, the Commission produced a first proposal for a directive (OJ C 194, 1.9.1979, p. 3), which resulted in the final adoption, in 1984 of Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising, OJ L 250, 8.2.1979, pp. 17-20. This Directive is at the basis of the current legal framework concerning unfair commercial practices, to which the FIR is a *Lex specialis*.

[343] Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation of foodstuffs for sale to the ultimate consumer, OJ L 33, 08.02.79, pp.1-14.

[344] Recital 6 of the Preamble to Council Directive 79/112/EEC.

[345] See in this sense Recitals 6 and 7 of the Preamble to Council Directive 79/112/EEC. See further on this topic: J. Claude Cheftel (2005). Food and nutrition labelling in the European Union. 93(3) *Food Chemistry*, pp. 531-550, at p. 531.

[346] Arts 2 and 3 of Council Directive 79/112/EEC.

[347] Arts 3(1) and 15(1) of Council Directive 79/112/EEC.

[348] Recital 8 of the Preamble to Council Directive 79/112/EEC.

5.3.2 The acceptance of the information paradigm

In the meantime, with its 1979 seminal decision in *Cassis de Dijon*, the CJEU had created a broad basis for informed consumer choice by acknowledging the fundamental equivalence of the laws of the Member States. This decision paved the way for the acceptance of the principle of mutual recognition as the basis for the free movement of goods and services, making full harmonisation of Member States' national legislation unnecessary.[349]

The Court applied a broad interpretation of potential justifications for obstacles to the free movement of goods by adding to the list contained in Article 36 of the EEC Treaty (now Article 36 TFEU) the so-called "mandatory requirements", including "the protection of public health, the fairness of commercial transactions and the defence of the consumer."[350] At the same time, it closed the door to protective measures that were more restrictive than food labelling in situations where consumer health was not at stake.[351] The Court dismissed such interventions as disproportionate by pointing out that they did not serve "a purpose which is in the general interest"[352] and stated that "it is a simple matter to ensure that suitable information is conveyed to the purchaser (…) on the packaging of products."[353]

This outspoken preference for food information over more stringent protective measures appears to be founded on a strong conviction that consumers will, through their demands, determine appropriate quality standards on the market.[354] Hence, if choice is the end, consumer information is the means to achieve such end.

In the aftermath of the CJEU's decision in *Cassis de Dijon*, the Commission adopted a "new approach" to harmonisation in the area of foodstuffs, aimed at defining a framework for food legislation containing only provisions justified as "necessary to satisfy essential requirements in the

[349] Case 120/78, *Rewe-Zentrale AG v Bundesmonopolverwaltung für Brantwein* (Cassis de Dijon), *supra* note 132. See further European Commission (1985). Communication from the Commission to the Council and to the European Parliament. Completion of the internal market for foodstuffs: Community legislation on foodstuffs, *supra* note 3.
[350] *Ibid*, para. 8.
[351] *Ibid*, para. 14.
[352] *Ibid*.
[353] *Ibid*, para. 13.
[354] See in this sense Case 120/78, *Rewe-Zentrale AG v Bundesmonopolverwaltung für Brantwein* (Cassis de Dijon), Opinion of A-G Capotorti, *supra* note 132, p. 673.

general interest."[355] With respect to the protection of consumer interests other than health, this approach resulted in a shift of focus from the enactment of recipe laws to developing Directive 79/112/EEC into a full-fledged system for the labelling, presentation and advertising of foodstuffs.

Although, according to the Commission, the Directive already went a long way in protecting consumers from misleading practices, further-going harmonisation and the adoption of supplementing measures were required, in particular in areas where vertical quality requirements for specific foods were absent.[356] Accordingly, in the years that followed, several amendments to Council Directive 79/112/EEC were adopted, adding new mandatory labelling requirements and revising others. The amended rules were finally consolidated in Directive 2000/13/EC, which aimed to provide for "detailed labelling, in particular giving the exact nature and characteristics of the product which enables the consumer to make his choice in full knowledge of the facts."[357] Once more, the Directive simultaneously recognized its own limitations by stating that it lacked "inclusion in the compulsory indications of all the indications which must be added to the list applying in principle to the whole range of foodstuffs."[358]

Besides improving EU labelling legislation, the Commission proposed the introduction of a harmonised scheme for the voluntary provision of nutrition information "to allow the average consumer to judge the nutritional quality of a food since products with apparently similar lists of ingredients can have very different nutritional properties."[359] This recommendation led to the adoption of the 1990 Directive on nutrition labelling of foodstuffs[360] that laid down rules concerning the provision of nutrition information on foods, and prohibited all other forms of nutrition labelling.[361]

These developments indicate a growing awareness on the part of the legislature that efficient consumer choice implies more than the simple comparison of foods on the basis of their list of ingredients, and that consumers require additional information enabling them to consider the

[355] European Commission (1985). Communication from the Commission to the Council and to the European Parliament. Completion of the internal market for foodstuffs: Community legislation on foodstuffs, *supra* note 3, at p. 5.
[356] *Ibid*, at p. 9.
[357] Recital 8 of the Preamble to Directive 2000/13/EC (Labelling Directive), *supra* note 80.
[358] Recital 10 of the Preamble to Directive 2000/13/EC (Labelling Directive), *supra* note 80.
[359] European Commission (1985). Communication from the Commission to the Council and to the European Parliament. Completion of the internal market for foodstuffs: Community legislation on foodstuffs, *supra* note 3, at p. 10.
[360] Council Directive 90/496/EEC, *supra* note 21.
[361] Arts 2 and 11(1) of Council Directive 90/496.

qualitative characteristics of the products in question. At the same time, it was acknowledged that consumers, in light of the basic level of dietary education of the general public, needed to be further empowered to be able to correctly understand and apply such information.[362]

5.3.3 Nutrition phase

While *Cassis de Dijon* provided the basis for the future framework of EU food law, including mandatory food labelling, a common view on voluntary food information to consumers was only beginning to develop. The increased focus on diet and nutrition from the beginning of the 1990s accelerated this development.

Within a decade, Council focus evolved from a pledge to "find more effective ways of providing all Community citizens with the vital knowledge and education (…) to make the necessary choices for ensuring appropriate nutrition in keeping with individual needs"[363] into a direct call on the Commission to "develop the use of nutritional labelling, by adapting it to the needs of consumers, and of other means of providing nutritional information."[364] The Council stated: "despite the progress which has been made in the field of nutritional information and labelling there is still not a sufficient guarantee of reliable, consistent and accessible information on the nutritional characteristics of foodstuffs and on the nutritional quality of diets."[365] The Council legitimised its call for action by pointing at "nutrition as one of the key determinants of human health"[366] which, in turn, is "an essential part of the quality of life."[367] The improvement of the quality of life was mentioned in Article 2 of the Maastricht Treaty among the main objectives of the European Community.[368]

[362] Recitals 4 and 9 of the Preamble to Council Directive No 90/496.
[363] Resolution of the Council and of the Representatives of the Governments of the Member States, meeting within the Council, of 3 December 1990, concerning an action programme on nutrition and health, *supra* note 22, Recital 7.
[364] Council Resolution of 14 December 2000, *supra* note 23, Recital 18. See further on this topic: Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 27.
[365] Council Resolution of 14 December 2000, *supra* note 23, Recital 10.
[366] Ibid, Recital 3.
[367] Ibid, Recital 1.
[368] The objectives of the European Union are now described in Article 2 TEU and no longer contain a reference to the "quality of life".

The increased attention to the role of diet and nutrition as factors in the development of non-communicable diseases led to two major Commission initiatives in the field of food labelling.[369]

In July 2003, the Commission proposed a Regulation on nutrition and health claims made on foods (Claims Regulation), complementing the general nutrition labelling provisions contained in Council Directive 90/496/EEC.[370] The Claims Regulation was finally adopted on 20 December 2006, after more than three years of intense debate. Although expressly intended to assist consumers in choosing a healthy diet,[371] the Claims Regulation turned out to be another element in the prevention of misleading advertising rather than a tool for informing and educating consumers.[372]

The Claims Regulation complements the general prohibition against misleading advertising with specific rules concerning the use of food claims.[373] The main reason for the adoption of a *lex specialis* concerning misleading claims appears to be their "positive image,"[374] that makes them particularly attractive as a marketing tool in relation to the consumer who is "trying to make a healthy choice in the context of a balanced diet."[375]

The legislature acknowledged both the potential and the danger of claims in guiding consumer choice. Whereas truthful claims can be a powerful means of enabling consumers to make healthy food choices in the context of a balanced diet, untruthful claims may have the exact opposite effect and encourage consumers to make choices that would run counter to scientific advice.[376] Therefore, the legislature opted for the introduction of a system of pre-market approval of claims based on, inter alia, the scientific substantiation of the claim by the food business operator.[377]

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[369] In its White Paper on A Strategy for Europe on Nutrition, Overweight and Obesity related health issues the Commission reiterated the importance of nutritional labelling and regulation of the use of nutrition and health claims to better inform consumers, *supra* note 26.
[370] Regulation (EC) No 1924/2006 (Claims Regulation), *supra* note 56.
[371] Recitals 1 and 29 to the Preamble of Regulation 1924/2006 (Claims Regulation), *supra* note 56.
[372] See further on this subject Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 143.
[373] Recital 3 of the Preamble to Regulation 1924/2006 (Claims Regulation), *supra* note 56.
[374] Recital 19 of the Preamble to Regulation 1924/2006 (Claims Regulation), *supra* note 56.
[375] Recital 11 of the Preamble to Regulation 1924/2006 (Claims Regulation), *supra* note 56.
[376] Recital 10 of the Preamble to Regulation 1924/2006 (Claims Regulation), *supra* note 56.
[377] Article 6 of the Regulation 1924/2006 (Claims Regulation), *supra* note 56.

Hereafter, it took the Commission until 2008 to propose a revision of the rules on nutrition labelling as a part of a more comprehensive review of the general rules for labelling of foodstuffs.[378] The Commission proposed that nutrition labelling be integrated in the horizontal mandatory labelling rules because "nutrition labelling is an established way for providing information to consumers to support health conscious food choices. There is wide agreement that the effectiveness of nutrition labelling can be strengthened as a means to support consumers' ability to choose a balanced diet."[379] The result of this effort to synergise consumer information and education with respect to food was the final adoption, in 2011, of the FIR.[380]

The FIR repealed Directive 2000/13[381] and later amendments in favour of streamlined and modernised rules "taking into account new developments in the field of food information."[382] Unlike its predecessors and distinct from other areas of consumer protection legislation, the FIR was given the form of a regulation rather than a directive, entailing a framework law which is directly applicable in all EU Member States.[383]

With respect to mandatory labelling, Article 4(1)(c) FIR expressly acknowledges that the provision of nutrition information to consumers is a prerequisite for informed consumer choice. For that reason, the FIR introduces mandatory nutrition labelling of, e.g., saturated fat, sugars and salt to "assist nutrition actions as part of public health policies."[384] Thus, the regulation absorbs and further develops Directive 90/496 on nutrition labelling by prescribing scientific advice and mandatory labelling of "the most important nutrients bearing a relationship to the risk of development of obesity and noncommunicable diseases".[385]

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[378] Proposal of 30 January 2008 for a Regulation of the European Parliament and of the Council on the provision of food information to consumers, COM(2008) 40 final.
[379] *Ibid*, at p. 2
[380] Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[381] In accordance with Article 53(1) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6, Directive 2000/13/EC (Labelling Directive, *supra* note 80) was repealed as from 13 December 2014.
[382] See in this sense Recital 9 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[383] Article 38(1) of Regulation (EU) No 1169/2011 (FIR) establishes that "as regards the matters specifically harmonised by this Regulation, Member States may not adopt nor maintain national measures unless authorized by Union law."
[384] Recitals 34 and 36 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[385] Proposal for the FIR, *supra* note 378, at p. 8.

With regard to voluntary food information, Articles 36 and 37 FIR introduce a general framework for the provision of voluntary food information to consumers. Article 36(1) FIR provides that the voluntary addition of information concerning mandatory particulars must live up to the same requirements as mandatory labelling. For example, if food operators choose to include voluntary elements in the nutrition declaration, this information must live up to the requirements set for mandatory particulars.

Besides the requirement that food information shall not be misleading,[386] the FIR prescribes in Article 36(2)(b) that voluntary food information shall not be "ambiguous or confusing for the consumer" and that "it shall, where appropriate, be based on the relevant scientific data."[387]

The addition of these requirements concerning voluntary food information appears to be a directly inspired by Article 3 (a)-(c) and (e) of the Claims Regulation, which specifies that claims may not "be false, ambiguous or misleading", "give rise to doubt about the safety and/or nutritional adequacy of other foods", "encourage or condone excess consumption" or "refer to changes in bodily functions which could give rise to or exploit fear in the consumer". In addition, Article 5(2) of the Claims Regulation provides that claims may only be used "if the average consumer can be expected to understand the beneficial effects" expressed therein, whereas Article 6 of the Claims Regulation requires a scientific substantiation of nutrition and health claims.

Thus, in recent years, food labelling has evolved from offering basic information on the main ingredients and characteristics of foods to also including extensive data on their nutritional composition. In addition, rules have been adopted that further restrict the use of voluntary information, such as claims, to the detriment of the mandatory particulars.

5.4 The average consumer and the nutrition information yardstick

The information paradigm at the basis of EU labelling legislation is founded on the conviction that consumers cannot effectively use their freedom to choose unless they are furnished with at least a minimum number of details about the products. In this light, mandatory labelling, empowering

[386] Article 36(2)(a) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[387] Article 7(2)(b) and (c) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.

consumers to discriminate between foods on the basis of their basic characteristics, is regarded as a prerequisite to informed choice.

However, the provision of information does not only serve the consumer, it also creates a consumer responsibility. Once furnished with the essential mandatory particulars consumers are not only expected to make well-informed choices, but also to avoid being misled. For this purpose, they are deemed capable of evaluating the validity of promotional statements and imagery by reading the label of the food in question.[388] Accordingly, the rules on misleading food information adhere to the image of a consumer who is "reasonably well-informed and reasonably observant and circumspect" – the average consumer benchmark developed by the CJEU.[389]

In the previous section it was demonstrated that, whereas the rules on mandatory labelling were originally directed at furnishing consumers with basic details on the nature and quantity of ingredients, in recent years the emphasis has shifted to including qualitative elements, such as the main nutrients and energy value. At the same time, additional rules have been introduced regulating the provision of voluntary food information that could divert consumers from the facts and encourage them to make unhealthy food choices.[390]

The consumer image that emerges from this recent information overhaul is that of a person who may very well be oriented towards a nutritionally balanced diet, but who does not necessarily possess the relevant knowledge to make discriminating choices in this respect.[391] For that reason, the FIR prescribes that mandatory nutrition information should be "simple and easily understood" by the "average consumer."[392]

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[388] Moritz Hagenmeyer (2012). *Food information regulation: Commentary on regulation (EU) No. 1169/2011 on the provision of food information to consumers* (Berlin: Lexxion Verlagsgesellschaft), at p. 79.
[389] See, e.g., Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide), *supra* note 88, para. 37. Recital 16 of the Preamble to Regulation 1924/2006 (the Claims Regulation, *supra* note 56) refers explicitly to the applicability of this benchmark, as does Recital 18 of the Preamble to Directive 2005/29/EC (*supra* note 82), which, in view of Recital 5 of the Preamble to the FIR (Regulation (EU) No 1169/2011, *supra* note 6), contains the general framework in regard to misleading information.
[390] In addition, the legislature sees room for further improvement of consumers' understanding of food information through education and information campaigns. See Recital 10 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[391] Recital 10 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[392] Recital 41 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.

Accordingly, for the purpose of mandatory labelling, the FIR adheres to a notional member of the "general public," who has an "interest in the relationship between diet and health and in the choice of an appropriate diet to suit individual needs," but who, at the same time, lacks "knowledge of the basic principles of nutrition."[393] This yardstick for protection appears derived from Directive 90/496/EEC, which equally aimed to protect the "average consumer" who was characterised as having a "low level of knowledge on the subject of nutrition."[394]

The legislator believes that voluntary food information can negatively affect the clarity of mandatory labelling.[395] In this regard, consumers are considered to be particularly vulnerable in the face of promotional statements related to diet and health.[396] Hence, the Claims Regulation characterises consumers as persons who will often have an unjustifiably positive impression of foods bearing nutrition and health claims, making them highly susceptible to being misled to making unhealthy food choices.[397] Therefore, the Claims Regulation prescribes that claims must be truthful, clear and reliable, and accompanied by nutrition labelling.

Meisterernst has argued that the legislature, by establishing further requirements to voluntarily provided food information, has abandoned the notion of the empowered consumer (Meisterernst 2013, p. 96). He refers in this respect to Article 7(2) FIR, according to which voluntarily provided food information must be "easy to understand" and "clear." According to Meisterernst, this terminology indicates that the protective benchmark in misleading advertising is now the casual, inattentive consumer, who does not properly read food labels, but is guided by first impressions.

The legislature's referral to a consumer who, from the outset, is rather ill-informed and vulnerable as regards the relation between nutrition and health, however, by no means implies that the average consumer benchmark has been generally set aside. On the contrary, the Preamble to the FIR explicitly states that nutrition information should be "simple and easily understood" in order "[t]o appeal to the average consumer and to serve the informative purpose for which it is introduced."[398] With regard to

[393] Recital 10 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[394] Recital 9 of the Preamble to Council Directive 90/496/EEC, *supra* note 21.
[395] Recital 47 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[396] Recital 10 of the Preamble to Regulation 1924/2006 (Claims Regulation), *supra* note 56.
[397] *Ibid.*
[398] Recital 41 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.

misleading advertising, Directive 2005/29/EC on unfair commercial practices[399] and the Claims Regulation, unambiguously refer to the "average consumer."[400]

Moritz Hagenmeyer promotes a viewpoint that differs from Meisterernst's.[401] According to Hagenmeyer, "unintelligible indications regularly entail the risk of deception," so that Article 7(2) FIR would be no more than a specification of the circumstances in which food information must be deemed misleading in the sense of Article 7(1) FIR. Likewise, Hagenmeyer argues that Article 36(2)(b) FIR, which prohibits the voluntary provision of food information which is "ambiguous or confusing to the consumer" is no more than a specification of the circumstances in which food information must be deemed misleading in the sense of Article 36(2)(a) seen in conjunction with Article 7(1) FIR.

Hagenmeyer's submission is supported by the recent judgement of the CJEU in Case C-453/13, which concerned, *inter alia*, the labelling of mechanically separated meat. In its judgement, the Court pointed out that Directive 2000/13 required labelling in clear terms by removing "any ambiguity" as to the exact nature and characteristics of the product "which enables the consumer to make his choice in full knowledge of the facts."[402] Apparently, the Court perceived ambiguous food information as misleading already under Article 2(1)(a)(i) of Directive 2000/13. Therefore, Article 36(2)(b) FIR cannot be more than a clarification of what is seen as misleading under Article 36(2)(a) in conjunction with Article 7(1) FIR, just as Article 7(2) is a specification of the circumstances under which food information in general is deemed misleading.

The benchmark for protection in misleading advertising therefore continues to be the average consumer, who, once furnished with sufficient and accurate mandatory food information is deemed "reasonably well-informed and reasonably observant and circumspect".[403] The FIR and the Claims Regulation do not alter this test, but merely specify in more detail than before the circumstances in

[399] Directive 2005/29/EC, *supra* note 82.
[400] Recital 18 of the Preamble to Directive 2005/29/EC, the Unfair Commercial Practices Directive, *supra* note 82, and Recital 16 of the Preamble to Regulation 1924/2006 (Claims Regulation), *supra* note 56.
[401] See in this respect Hagenmeyer (2012). *Food information regulation: Commentary on regulation, supra* note 388.
[402] Case C-453/13 *Newby Foods v Food Standards Agency*, para. 65, not yet published.
[403] Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide), *supra* note 88, para. 31.

which voluntarily provided food information, by masking the true characteristics of a food, is thought to distort the average consumer's informed choice.

5.5 Conclusion

The principle of informed choice, which is at the basis of EU food information legislation,[404] essentially establishes a consumer right to be furnished with enough accurate information to be able to distinguish between food products on the basis of their basic characteristics.[405]

Whereas this paradigm presupposes that consumers in general possess the will, as well as the necessary intellectual skills to understand and apply food labelling, it simultaneously acknowledges that without governmental interference ensuring them at least a minimum number of details about the products, consumers cannot effectively use their freedom to choose.[406]

Once furnished with appropriate information on, e.g., the identity, composition and properties of food, consumers are expected in principle to make rational decisions as regards the foods they consume, as well as to separate food facts from promotional fiction. To prevent consumers from being misled, the EU rules on mandatory food labelling have been complemented with a general prohibition against the provision of food information that may distort consumer choice in an unjustified way.[407]

This chapter demonstrated that the criterion for information particulars that must be included in mandatory labelling has developed from requiring ever more detailed information on the nature and characteristics of foodstuffs to including information that is regarded to be of significant value to the majority of consumers or of generally accepted benefit.[408] Accordingly, the quantity of information deemed necessary to sufficiently empower consumers to make efficient food choices has dramatically

[404] Article 4 of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[405] *Ibid.*
[406] Different: Unberath and Johnston (2007). The double-headed approach of the ECJ concerning consumer protection, *supra* note 89, p. 1250.
[407] Article 7 of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[408] According to Article 4(2) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6, the need for mandatory food information shall be based on the "widespread need on the part of the majority of consumers for certain information to which they attach significant value or of any generally accepted benefits to the consumer."

increased. This is particularly clear with regard to nutrition, where labelling has transitioned from a voluntary framework to becoming mandatory on all foods.[409]

At the same time, the EU legislature has become more active in regulating the voluntary provision of food information to consumers. With the adoption of Council Directive 90/496/EEC on nutrition labelling and the 2006 Claims Regulation, the EU legislature has progressively restricted the use of nutrition and health claims on food labels and in food advertising. Thereafter, with the adoption of the 2011 FIR, the legislature took the first steps in drawing up the contours of a general framework for the provision of voluntary food information to consumers.

The rationale behind these legislative initiatives is a growing concern that the provision of voluntary food information may undermine the clarity of – or even outright mask – essential information communicated by means of mandatory particulars on food labels.[410] Nutrition and health claims, for example, are viewed to possess powerful marketing potential, whereas consumers are generally unable to appraise their truthfulness, even when they are given the overall nutritional characteristics of the food in question. For that reason, foods bearing claims are regarded as having the intrinsic potential to mislead consumers into believing that, from a health point of view, they are favoured over foods that do not bear claims. This may encourage consumers to make choices that they would not have made if no claim had been affixed to the food.

Although recent legislative measures quite openly establish a link between informed choice and the rather abstract societal norm of what is good for the consumer, this does not justify the conclusion that food information legislation has become overly intrusive or even paternalistic. Rather, it seems to be the logical and necessary consequence of the increased complexity of food choices as a result of modern manufacturing methods and food advertising strategies. In such environment, consumers need more information to be sufficiently empowered to consider all aspects of food consumption that are relevant to their choice, and they need to be instructed to understand the provided data adequately.

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[409] The effectiveness of nutrition labelling has, however, been questioned. Recent studies have shown that while consumers generally express that they like and use nutrition labelling to choose more healthful options, they appear to pay limited attention to such labels in real life. See for an overview: Stefan Storcksdieck genannt Bonsmann, and Josephine Wills (2012). Nutrition labeling to prevent obesity: Reviewing the evidence from Europe. 1(3) *Current Obesity Reports*, pp. 134–140.

[410] Proposal for the FIR, *supra* note 378, para. 40.

Contemporary food information legislation does not limit consumers' autonomy or nudge them in the direction of the objectively rights choices, which could result in paternalistic legislation. Quite the contrary, by empowering consumers with information, EU food information legislation not only aims to ensure the provision to consumers of objective factual food information, but also to counterbalance commercial communications that may divert consumers from the facts by randomly enhancing certain aspects of a food. This way, EU food information legislation seeks to enable consumers to make free and genuinely informed choices – educated choices.

6 Banning Food Marketing and Advertising to Children. Reflections on a Future Role for the Food Information Regulation[411]

Abstract

In recent years, the potential negative impact on children of food marketing and advertising has been the subject of intense debate. From a traditional, risk-oriented point of view, a ban against certain marketing and advertising techniques can only be justified if a causal relationship can be established with a potentially serious negative effect on health. Because this is very difficult, the focus in this chapter is on the feasibility of a rights-based approach, which derives from children's inherent age-related vulnerability their right to special protection. On the basis of a study of the EU legislative framework and relevant rulings from CJEU, this chapter demonstrates how a ban on marketing practices targeting children could be established within the EU legal order by excluding children from the informed choice-paradigm that underlies the FIR. This approach paves the way for dismissing food advertising practises directed at children on the ground that they are as intrinsically misleading.

6.1 Introduction

In January 2005 the EU Commissioner for Health and Consumer Affairs at the time, Markos Kyprianou, expressed in a Financial Times interview that the food industry would be given a year to stop advertising junk food to children and improve product labelling – or face legislation.[412]

More than a decade has passed and multiple initiatives have been taken to combat obesity and stimulate healthy eating among children. Leading food industry members have pledged to voluntarily restrict food advertising to children in the European Union.[413] The 2007 Audio Visual Media Services (AVMS) Directive obliges both the European Commission and the Member States to encourage media service providers to develop codes of conduct regarding commercial communications of, particularly, foods high in fat, salt and/or sugars (HFSS foods) that accompany or are included in

[411] When this thesis was submitted, the text of the current chapter was in the process of being submitted for publication in a relevant scientific journal.

[412] The article in question is accessible through registration at the Financial Time's internet page: http://news.ft.com/cms/s/3bed32fa-6a87-11d9-858c-00000e2511c8.html (last accessed 8 August 2015).

[413] This EU Pledge was launched as a commitment to the European Union Platform for Action on Diet, Physical Activity and Health in 2007. Information on the Pledge is available at: www.eu-pledge.eu (accessed 6 August 2015).

children's programmes.[414] Furthermore, legislation has been adopted regulating food information to consumers,[415] including nutrition and health claims made on foods.[416] On a Member State level, statutory measures vary from a strict ban on all TV-advertising to children in Sweden to less restrictive measures in other Member States, whereas in about half of the EU Member States self-regulatory food advertising codes have been developed.[417]

Despite the apparent broad consensus on the need to limit children's exposure to commercial messages concerning foods, advertising to minors continues.[418] The 2011 report of the International Association for the Study of Obesity (IASO) showed that advertising to children had not significantly fallen in the EU, whereas in some Member States it had in fact increased.[419] The more recent evaluation of the implementation of the Strategy for Europe on Nutrition, Overweight and Obesity related health issues resolved that the self-regulatory regimes adopted within the framework of the AVMS Directive have not had a noteworthy impact on actual advertising practices.[420]

What is even more striking is that none of the initiatives taken at the EU or at the national level address the packaging or in-store and point-of-sale marketing of foods, whereas the promotion of foods by means of, e.g., familiar media characters shown on or in connection with foods have been

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[414] Adopted as Article 3(e)(2) of Directive 2007/65/EC (AVMS), *supra* note 30. The AVMS was subsequently codified as Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (codified version), OJ L 95, 15.4.2010, pp. 1-24.
[415] In Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[416] Regulation 1924/2006 (Claims Regulation), *supra* note 56.
[417] PHEIAC Report on the Evaluation of the Implementation of the Strategy for Europe on Nutrition, Overweight and Obesity related health issues, *supra* note 31, at p. 86.
[418] Both the WHO and the UN have urged for action in this area. It is a key policy action in the WHO Global Action Plan 2013–2020 for the Prevention and Control of Noncommunicable Diseases (NCDs), which was endorsed by the World Health Assembly in May 2013, that governments play a leading role in reducing children's overall exposure to food marketing. As a follow-up of the Political Declaration of 19 September 2011 of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, the UN General Assembly, in its resolution No. 68/300 of 10 July 2014 on the outcome of the high-level meeting of the General Assembly on the comprehensive review and assessment of the progress achieved in the prevention and control of non-communicable diseases, subscribed to the implementation of the WHO Action Plan, as well as to the 2011 WHO set of recommendations on the marketing of foods and non-alcoholic beverages to children, endorsed by the Sixty-third World Health Assembly in 2010.
[419] Tim Lobstein, Triin Parn and Ange Aikenhead (2011). A junk-free childhood: Responsible standards for marketing foods and beverages to children. Briefing paper from the StanMark Project of the International Association for the Study of Obesity, http://www.worldobesity.org/site_media/uploads/IASO_food_marketing_report_30_June_2011.pdf (accessed 24 August 2015).
[420] PHEIAC Report on the Evaluation of the Implementation of the Strategy for Europe on Nutrition, Overweight and Obesity related health issues, *supra* note 31, at pp. 90-91.

mentioned to be among the most powerful advertising techniques targeted children.[421] For this very reason, the pressure group Foodwatch and the Dutch consumer organisation Consumentenbond have criticized the recent adaption of the Dutch Advertising Code as not going nearly far enough.[422]

This chapter serves to analyse whether the EU could resort to more stringent legislative action to duly protect the most vulnerable consumers: children. It is based on a legal analysis of the EU legislative framework and relevant rulings from CJEU. It elaborates on the work of Amandine Garde, who has extensively studied EU competence to tackle obesity in a broad sense, including the advertising of foods to children.[423]

Garde has discussed the merits and shortcomings of EU legislation in force in protecting minors from the potential negative health effects of the marketing and advertising of foods high in fat, salt or sugar, HFSS foods.[424] This chapter takes the next step by examining how and to what extent an actual advertising ban could be incorporated in the existing EU legal framework, with a particular focus on food packaging and labelling as important marketing tools. It will be argued that the 2011 Food Information Regulation (FIR) and, more specifically, the rules concerning misleading food information, provide a suitable point of departure for implementing a ban on food advertising to children.

The analysis will start with a brief description of some of the more common marketing techniques used in relation to children, followed by an analysis of the EU legal framework in force.

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[421] Jennifer A. Kotler, Jennifer M. Schiffman and Katherine G. Hanson (2012). The influence of media characters on children's food choices. 17(8) *Journal of Health Communication: International Perspectives*, pp. 886-898; Vivica I. Kraak and Mary Story (2014). Influence of food companies' brand mascots and entertainment companies' cartoon media characters on children's diet and health: a systematic review and research needs, 16(2) *Obesity Review*, pp. 107-126; Aron M. Levin and Irwin P. Levin (2010). Packaging of healthy and unhealthy food products for children and parents: the relative influence of licensed characters and brand names. 9(5) *Journal of Consumer Behaviour*, pp. 393-402.

[422] Foodwatch. *Nieuwe reclamecode lost probleem kindermarketing niet op*, http://www.foodwatch.org/nl/onze-campagnes/onderwerpen/kindermarketing/actuele-nieuwsberichten/nieuwe-reclamecode-lost-probleem-kindermarketing-niet-op/ (accessed 21 August 2015). See also Consumentenbond. *Nieuwe reclamecode is zoethoudertje*, http://www.consumentenbond.nl/actueel/nieuws/2014/nieuwe-reclamecode-voedingsmiddelen-is-zoethoudertje/ (accessed 21 August 2015).

[423] Garde (2010). *EU law and obesity prevention*, *supra* note 65, pp. 76-87.

[424] *Ibid.* See also Amandine Garde and Marine Friant-Perrot (2014). The regulation of marketing practices for tobacco, alcoholic beverages and foods high in fat, sugar and salt – a highly fragmented landscape. In: Alberto Alemanno and Amandine Garde (eds). *Regulating Lifestyle Risks*. *The EU, alcohol, tobacco and unhealthy diets* (Cambridge: Cambridge University Press), at pp. 69-93. Finally, see Amandine Garde (2011). Advertising Regulation and the Protection of Children-Consumers in the European Union: In the Best Interests of… Commercial Operators? 19 *International Journal of Children's Rights*, pp. 149–171.

After that, the legitimacy of more stringent EU action in this area will be discussed. The Treaty provisions relevant for the protection of minors from the commercial promotion of food will be examined and the proportionality of a marketing ban will be considered.

The analysis will continue to discuss how a ban on food advertising to children could be established within the EU legal order, balancing the risk-based approach traditionally favoured at the EU level against a rights-based approach that derives from children's intrinsic vulnerability their right to be protected from commercial exploitation. It will be argued that a rights-based perspective could be used to exclude children from the informed choice-paradigm that underlies the FIR. This approach paves the way for regarding food advertising practises targeting children as inherently misleading.

6.2 The state of play in the EU

6.2.1 How is food marketed to children?

Children are subject to food marketing in many ways. A first example of a promotional technique that is readily used to draw the attention of children is the depiction on the packaging and in promotional ads and materials of familiar characters, like celebrities or licensed characters.[425] These can be figures created for entertainment purposes and subsequently used in advertising, or trade mascots specifically created for branding and advertising purposes. Multiple studies conclude that the use of familiar media characters has a significant effect on children's perception and choice of food and brand.[426]

Another means to promote food products to children is the use of direct messages like health and nutrition claims on foods, or more hidden cues associated with health, strength, fun, being 'cool' or

[425] Matthew Lapierre, Sarah Vaala, Deborah Linebarger (2011). Influence of licensed spokescharacters and health cues on children's ratings of cereal taste. 165(3) *Archives of Pediatrics & Adolescent Medicine*, pp. 229-234; Richard Mizerski (1995). The relationship between cartoon trade character recognition and attitude toward product category in young children. 59(4) *Journal of Marketing*, pp. 58-70; Christina Roberto, Jenny Baik, Jennifer Harris et al. (2010). Influence of licensed characters on children's taste and snack preferences. 126(1) *Journal for Pediatrics*, pp. 88-93; Judith Garretson and Ronald Niedrich (2004) Spokes-characters creating character trust and positive brand attitudes. 33(2) *Journal for Advertising*, pp. 25-36.

[426] Kotler, Schiffman and Hanson (2012). The influence of media characters on children's food choices, *supra* note 421; Kraak and Story (2014). Influence of food companies' brand mascots and entertainment companies' cartoon media characters on children's diet and health, *supra* note 421; Levin and Levin (2010). Packaging of healthy and unhealthy food products for children and parents, *supra* note 421.

well-being.[427] Examples are the depiction of happy, energetic persons or familiar figures having fun, the use of colours associated with health (e.g., green) or pictures of fresh fruit on the packaging of food products or in advertisements.

A third marketing strategy applied to children is the offering of free toys, gifts, discounts or competitions with the sale of the food.[428]

Overall, research shows that only a small percentage of food advertisements address children directly. Rather, children are targeted through indirect, symbolic messages that depict children or personalities that children associate with as happy, active and playful while enjoying the advertised foods. These convey the message that happiness and well-being can be achieved by consuming the advertised food.[429]

To cover all of these techniques, a ban on the marketing and advertising to children of foodstuffs should not only address direct advertising, but also messages that target children in a more diffuse, indirect way.[430] Moreover, to be effective and to cover both direct and indirect marketing messages, a ban on food advertising should be broad and cover not only HFSS foods but any type of commercial food advertising to children.

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[427] Jessica Castonguay, Christopher McKinley, Dale Kunkel (2013). Health-related messages in food advertisements targeting children", 113(5) Health Education, pp.420-432; Carol Noble, Michael Corney, Anita Eves, Michael Kipps, Margaret Lumbers (2000). Food choice and school meals: primary schoolchildren's perceptions of the healthiness of foods and the nutritional implications of food choices. 19(4) *International Journal of Hospital Management*, pp. 413-432; Leslie Mikkelson, Caitlin Merlo, Virginia Lee V, Carol Chao (2007). *Where's the fruit? Fruit content of the most highly-advertised children's food and beverages*. Study prepared by Prevention Institute at the Oakland Center of Community well-being, http://www.preventioninstitute.org/component/jlibrary/article/id-56/127.html (accessed 24 August 2015).

[428] Gill Cowburn and Anna Boxer (2010). Magazines for children and young people and the links to Internet food marketing: a review of the extent and type of food advertising. 10(10) *Public Health Nutrition*, pp. 1024–1031; Michael McGinnis, Jennifer A. Gootman, Viveca I. Kraak (2006). *Food marketing to children and youth: threat or opportunity?* (Washington DC: National Academies Press).

[429] Lana Hebden, Lesley King and Bridget Kelly (2011). Art of persuasion: An analysis of techniques used to market foods to children. 47(11) *Journal of Paediatrics and Child Health*, pp. 776-782.

[430] *Ibid.*

6.2.2 The EU legal framework in force

The main pieces of legislation that regulate aspects of food marketing and advertising to children are the Unfair Commercial Practices Directive (UCP)[431], the AVMS Directive,[432] the Claims Regulation[433] and the Food Information Regulation (FIR).[434] In regard to the UCP and AVMS Directives, Garde has concluded that they "have missed, so far, the opportunity to adequately tackle an important aspect of childhood obesity" in that they focus on the contents of individual advertisements rather than the repetitive effect of advertising.[435] With respect to the Claims Regulation and the predecessor of the FIR, the Labelling Directive,[436] Garde has argued that they maintain the principle of free informed choice so that "[t]he extent to which vulnerable consumers including children can derive tangible health benefits on the basis of such legislation is unclear."[437]

On the basis of a series of indicators, this section will outline the merits and shortcomings of the legal framework in force in protecting children from the potential negative effects of food advertising. These indicators are (i) the measure's scope (what advertising practises does it cover; is it specifically related to foods or to all goods?), (ii) its aim (what is the protective purpose of the measure at hand?) and (iii) whether or not the measure recognises children's inherent vulnerability.

6.2.2.1 The AVMS Directive

The AVMS Directive aims to regulate the cross-border transmission of audio-visual media services by media service providers and is, therefore, only relevant in relation to marketing and advertising through audio-visual media such as television broadcastings and on-demand television, i.e., television advertising, sponsorship, teleshopping and product placement.[438] Other media and other types of commercial messages fall outside the Directive's scope.

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[431] Directive 2005/29/EC, *supra* note 82.

[432] Directive 2007/65/EC, subsequently codified in Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (codified version), OJ L 95, 15.4.2010, pp. 1-24, *supra* note 30.

[433] Regulation 1924/2006 (Claims Regulation), *supra* note 56.

[434] Regulation (EU) No 1169/2011 (FIR), *supra* note 6.

[435] Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 228.

[436] Directive 2000/13 of the European Parliament of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, OJ L 109, 6.5.2000, p. 29.

[437] Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 228.

[438] Article 1(1) of Directive 2010/13/EU (AVMS), *supra* note 30.

The AVMS Directive contains two provisions that are relevant for commercial messages directed at children, i.e. Article 9(1)(g) and 9(2), the latter of which directly addresses food advertising to this age group and explicitly recognises that children belong to a group of consumers who are particularly vulnerable and require special protection.

Article 9(1)(g) AVMS provides that

> Audiovisual commercial communications shall not cause physical or moral detriment to minors. Therefore they shall not directly exhort minors to buy or hire a product or service by exploiting their inexperience or credulity, directly encourage them to persuade their parents or others to purchase the goods or services being advertised, exploit the special trust minors place in parents, teachers or other persons, or unreasonably show minors in dangerous situations.[439]

In addition, Article 9(2) AVMS prescribes:

> Member States and the Commission shall encourage media service providers to develop codes of conduct regarding inappropriate audiovisual commercial communications, accompanying or included in children's programmes, of foods and beverages containing nutrients and substances with a nutritional or physiological effect, in particular those such as fat, trans-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended.[440]

As Garde has pointed out, these provisions show several weaknesses. In the first place, although Article 9(1)(g) AVMS sets out a rather encompassing restriction of commercial messages that could physically or morally harm minors, it is subsequently narrowed down to messages that directly exhort or encourage minors to purchase the advertised products or to persuade others to buy them for them. Messages that more subtly lure minors into buying a product by means of imagery and similar indirect messages appear, therefore, to be excluded from the provision's scope.[441]

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[439] Article 9(1) of Directive 2010/13/EU (AVMS), *supra* note 30.
[440] *Ibid*.
[441] See further on Article 16 of Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by Law, Regulation or Administrative Action in Member States concerning the pursuit of television broadcasting activities, OJ L 298, 17.10.1989, pp. 23-30, as later revised by Directive 97/36/EC of the European Parliament and of the Council of 30 June 1997 amending Council Directive 89/552/EEC on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities, OJ

Article 9(2) AVMS limits the obligation placed on the Member States and the Commission to *encouraging* the development of codes of conduct. In addition, the provision only targets *inappropriate* food marketing and advertising to children, without clarifying what foods must be taken into consideration and what commercial behaviour is deemed (in)appropriate in this respect. Finally, the AVMS does not provide a definition of children, nor does it specify what is meant by "accompanying or included in children's programmes".[442] All in all, the provision leaves quite a large margin of discretion, which is reflected in the differences between the codes that have been developed to date.[443]

6.2.2.2 UCP Directive[444]

The UCP Directive is a measure of full harmonisation aiming to protect consumers from unfair commercial practices harming their economic interests.[445] The Directive does not expressly pursue to protect consumers' health and safety.[446]

Article 5 UCP prohibits all unfair business-to-consumer commercial practices. Commercial practices are considered unfair if they meet two complementary criteria. In the first place, the practice must be contrary to the requirements of "professional diligence", which, in accordance with Article 2(g) UCP, means "the standard of special skill and care which a trader may reasonably be expected to exercise towards consumers, commensurate with honest market practice and/or the general principle of good faith in the trader's field of activity".

Secondly, to be deemed unfair, the commercial practice in question must materially distort – or be likely to materially distort – the economic behaviour of the average consumer with regard to the product. Thus, it must "appreciably impair the consumers' ability to make an informed decision, thereby causing the consumer to take a transactional decision that he would not have taken

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L 202, 30.7.1997, pp. 60-70 *(* (Television Without Frontiers Directive, TVWF), which preceded Article 9(1)(g). See Garde (2010). *EU Law and Obesity Prevention*, *supra* note 65, at p. 188.

[442] Article 9(2) of Directive 2010/13/EU (AVMS), *supra* note 30.

[443] Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 194.

[444] Directive 2005/29/EC (Unfair Commercial Practices Directive, UCP), *supra* note 82.

[445] Article 1 of Directive 2005/29/EC (Unfair Commercial Practices Directive, UCP), *supra* note 82.

[446] Garde has stated that the UCP excludes from its scope health and safety concerns. It does not explicitly do so. Rather, it states in Article 3(3) that it is "without prejudice to to Community or national rules relating to the health and safety aspects of products", thus declaring the prevalence of such more specific EU and national rules. See Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 224.

otherwise".[447] Misleading and aggressive commercial practices are considered to be particularly unfair.[448]

The extent to which commercial messages directed at children would be regarded unfair under the UCP depends, therefore, on whether such messages are both unethical and influential. In this respect, it is important to notice that children are not necessarily considered to be average consumers in the context of the UCP. Pursuant to Article 5(3) UCP, "commercial practices which are likely to materially distort the economic behaviour only of a clearly identifiable group of consumers who are particularly vulnerable to the practice or the underlying product because of their mental or physical infirmity, age or credulity in a way which the trader could reasonably be expected to foresee, shall be assessed from the perspective of the average member of that group". Accordingly, the UCP explicitly recognises children's particular vulnerability as consumers.[449] At the same time, however, the provision makes it clear that also vulnerable consumers are expected to be able to identify exaggerated statements or statements that are not meant to be taken literally.

Illustrative in this respect are Article 5(5) and Section 28 in Annex I UCP, which establish that any inclusion in an advertisement of a direct exhortation to children to buy advertised products or persuade their parents or other adults to buy advertised products for them, is considered to be inherently aggressive and, therefore, unfair in all circumstances. So far, the question what must be understood to be a "direct exhortation" has not been answered by the CJEU. However, a 2013 decision from the Supreme Court of Austria points in the direction of a rather narrow interpretation. In relation to a campaign promoting the sale of a sticker album and collectible stickers, the Austrian Supreme Court judged that advertisements directed at children as such do not establish unfair commercial practices and that a direct exhortation was only apparent in respect to the album ("go get the album"), but not the stickers ("collect the stickers").[450]

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[447] Article 2(e) of Directive 2005/29/EC (Unfair Commercial Practices Directive, UCP), *supra* note 82.
[448] Article 5(4) of Directive 2005/29/EC (Unfair Commercial Practices Directive, UCP), *supra* note 82.
[449] See in this sense Garde (2011). Advertising regulation and the protection of children-consumers in the European Union: In the best interest of…Commercial Operators?, *supra* note 424, at p. 153.
[450] Judgement No. 4Ob244/12d of the Supreme Court in Vienna of 19 March 2013. A summary of the case is available at https://webgate.ec.europa.eu/ucp/public/index.cfm?event=public.cases.showCase&caseID=565&articleID (accessed 30 July 2015).

Despite the above limitations, from the outset, the UCP appears to support the interpretation that the marketing and advertising of goods to children is inherently unfair because their age-related vulnerability vis-à-vis commercial communications inevitably exposes their economic behaviour to material distortion. For this reason, marketing to children is contrary to the requirements of professional diligence and, consequently, unfair.

However, in regard to foodstuffs, the Food Information Regulation is considered a *lex specialis* which prevails over the UCP. Therefore, the FIR governs whether the food advertising to children would indeed be considered unfair.[451]

6.2.2.3 The Claims Regulation[452]

The Claims Regulation harmonises the law of the Member States concerning nutrition and health claims to ensure the effective functioning of the internal market while providing a high level of consumer protection. The regulation's scope is limited to nutrition and health claims made on food labels or in the presentation or advertising of foods.[453]

Claims, pursuant to Article 2(2)(1) of the Claims Regulation, include "any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics".

Article 5(1)(a) of the Claims Regulation provides that claims on foods are permitted only if they are made in relation to a nutrient or other substance with a "beneficial nutritional or physiological effect, as established by generally accepted scientific evidence". Accordingly, commercial communications that do not claim a nutritional or health-related effect do not fall within the scope of the Regulation.

In light of the rather stringent pre-approval scheme that applies to food claims, advertisements for unhealthy foods directed to children will often refrain from expressly claiming a beneficial nutritional or physiological effect. Rather, they will make use of imagery to convey indirect messages relating

[451] Joint Cases C-421/00, 426/00 and 16/01 *Sterbenz and Haug* [2003] ECR I-1065, at para 25. See further on the relation between the UCP and the FIR Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 227.
[452] Regulation (EC) No 1924/2006 (Claims Regulation), *supra* note 56.
[453] Article 1(2) of Regulation (EC) No 1924/2006 (Claims Regulation), *supra* note 56.

to a state of mind, a feeling, a societal norm. It is doubtful whether such implied associations of a food product with, e.g., physical activity, energy and happiness would constitute claims in the meaning of the Claims Regulation.

It must be noted that, although the Claims Regulation takes as a benchmark the average consumer,[454] in regard to particularly vulnerable groups of consumers, such as children, it subscribes to an assessment of the impact of the claim from the perspective of the average member of that group.[455] Accordingly, it cannot be ruled out that certain types of indirect messages targeting children may, indeed, be deemed to contain claims, which are subject to pre-approval by the European Commission.

6.2.2.4 The Food Information Regulation[456]

Article 3(1) FIR prescribes that "the provision of food information shall pursue a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical considerations." The regulation implements the principle of informed choice, which is at the core of EU food legislation.[457] On the basis of the principle of informed choice food consumers are expected to be able to make rational decisions about the foods they consume and to distinguish between food facts and promotional fiction, provided they are furnished with adequate information on, e.g., the identity, composition and properties of the food.

To ensure informed consumer choices, Article 7(1) FIR provides that food information shall not be misleading to consumers as to the nature, characteristics and effects of food. It contains a non-exhaustive list of information particulars that are deemed misleading.[458] In addition, Article 7(2) specifies that "[f]ood information shall be accurate, clear and easy to understand for the consumer."

Article 7 covers both mandatory and voluntary food information, including the advertising and presentation of foods.[459] In regard to voluntary food information, Article 36(2)(b) and (c) FIR adds

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[454] See, e.g., Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide), *supra* note 88, para. 37.
[455] Recital 16 of the Preamble to Regulation 1924/2006 (Claims Regulation), *supra* note 56.
[456] Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[457] Article 8(1) of Regulation (EC) No 178/2002 (GFL), *supra* note 1.
[458] Article 7(1)(a)-(d) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6, specifies into detail (but not exhaustively) under what conditions food information is deemed misleading.
[459] Article 7(4) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.

that "it shall not be ambiguous or confusing for the consumer" and that "it shall, where appropriate, be based on relevant scientific data." This requirement is particularly relevant for food advertising.[460]

Interestingly and contrarily to the AVMS Directive, the UCP and the Claims Regulation, references to children-consumers are virtually absent in the FIR. The FIR consistently refers to (final) consumers, without differentiating between the average and informed adult consumer and other, inherently more vulnerable groups.[461]

While the protective benchmark in the FIR is derived from the presumption of informed choice, the rules on misleading food information refer to the image of a consumer who is "reasonably well-informed and reasonably observant and circumspect" – the average consumer benchmark developed by the CJEU.[462] In cases where an advertisement is addressed to a particular group of consumers, however, the Court has held that it was for the national court to ascertain in the circumstances of the particular case whether the advertisement in question could be misleading.[463]

6.2.3 Schematic comparison and conclusions in regard to the current legal framework

The above analysis of the merits and shortcomings of the current EU legal framework in relation to the protection of children from food advertising can be schematically summarised as follows:

[460] See in this sense Hagenmeyer (2012). *Food information regulation: Commentary on regulation (EU) No 1169/2011 on the provision of food information to consumers*, *supra* note 388, at p. 349.
[461] The FIR refers to "consumers" (in, e.g., Article 1), the "final consumer" (in, e.g., Article 3(1)) and the "average consumer" (in, e.g., Article 35(1)(d) and Recital 41 and 43 of the Preamble).
[462] See, e.g., Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide), *supra* note 88, para. 37. Recital 18 of the Preamble to Directive 2005/29/EC (Unfair Commercial Practices Directive , *supra* note 82) concerning unfair business-to-consumer commercial practices refers explicitly to the applicability of this benchmark. In view of Recital 5 of the Preamble to the FIR, Directive 2005/29/EC contains the general framework concerning misleading information. See further on the informed consumer benchmark: Unberath and Johnston (2007). The double-headed approach of the ECJ concerning consumer protection, *supra* note 88.
[463] Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide), *supra* note 88, para. 34.

	Scope					Objective		Specific for children
	Covers labelling & presen-tation	Covers adver-tising	Covers mislead-ing practices	Covers aggres-sive practices	Specific for food	Aims to protect health and safety	Aims to protects economic interests	Recognises the inherent vulnerability of children
AVMS	-	+	-	+	+	+	+	+
UCP	+	+	+	+	-	-	+	+
Claims	+	+	+	-	+	+	-	+
FIR	+	+	+	-	+	+	+	-

Whereas the scope of the AVMS is rather limited and does not cover all forms of food marketing to children, the UCP is essentially focused on the protection of consumers' economic interests only. Although, the Claims Regulation, in principle, applies to all means of food marketing to children, it covers only nutrition and health claims made on foods.

In relation to food information, the FIR prevails over the UCP. The FIR is encompassing both in scope and purpose and it covers both food advertising and food labelling, while it awards equal importance to the protection of consumers' health and of their other interests. From the outset, therefore, it seems to be the appropriate piece of EU legislation to address food advertising to children. However, since the FIR does not explicitly acknowledge children-consumers as particularly vulnerable, the question remains unanswered whether this consumer groups can derive an entitlement to special protection from the regulation's provisions.[464]

6.3 Can the EU ban food advertising to children?

When Kyprianou openly threatened to adopt legal measures restricting food advertising to minors, he must have had his doubts as to what extent the EU is actually competent to do so. Only a few years before, in its ruling in *Tobacco Advertising I*, the CJEU had severely reprimanded the EU legislature for crossing the boundaries of EU competence in regulating advertising.[465] At the time, several

[464] Garde (2010). *EU law and obesity prevention*, *supra* note 65, at pp. 227-228.
[465] Case C-376/98 *Germany* v *Parliament and Council* (Tobacco Advertising I), *supra* note 260.

lawsuits brought before the Court to clarify the issue, remained undecided.[466] The question arises, therefore, whether the EU Treaty allows the adoption of such measures.

6.3.1 EU competence to restrict food advertising to children[467]

Two specific Treaty provisions are of potential relevance for the protection of minors from the commercial promotion of foods: Articles 168 and 169 of the Treaty on the Functioning of the European Union (TFEU). In addition, Article 114 TFEU regulating the EU's more general competence in the area of the internal market may come into play.

Article 168 TFEU establishes EU competence in the area of public health. The second section of Article 168(1) TFEU applies the subsidiarity principle laid down in Article 6(a) TFEU, so that EU action in this field must, in principle, remain restricted to complementing Member States' initiatives.[468] Only in a limited number of areas does the EU have a shared competence. The most relevant example in this context is the competence to adopt measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health, i.e. food safety legislation.[469]

In accordance with Article 168(5) TFEU, the EU may adopt incentive measures designed to protect and improve human health and, in particular, to combat major cross-border health scourges, an example of which could be obesity. However, the provision explicitly excludes any harmonisation of the laws and regulations of the Member States designed to protect and improve human health.

Whereas EU competence in the field of public health is predominantly supportive, in the area of consumer protection, it is partly supportive, partly shared.[470] According to Article 169(1) TFEU, "the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their rights to information, education and to organise themselves in order to safeguard their interests". In light of Article 169(2) TFEU, this contribution exists in either harmonising

[466] Important in this respect are Joined Cases C-154 and 155/04 *Alliance for Natural Health*, [2005] ECR I-6451 and Case C-380/03 *Germany v Parliament and Council* (Tobacco Advertising II), *supra* note *260*.
[467] See Chapter 3 for a more in-depth analysis of EU competence to regulate consumer protection from the negative effects of the consumption of HFSS foods.
[468] *Ibid*, at p. 13. See further Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 60.
[469] Article 168(4)(b) TFEU.
[470] Articles 2(5) and 6 TFEU 2(2) and 4(2)(f) TFEU, respectively.

measures adopted pursuant to Article 114 TFEU (former Article 95 EC) in the context of the completion of the internal market[471] or measures that support, supplement and monitor the policy pursued by the Member States.[472] Apart from pursuing an active consumer policy, the EU is generally obliged to take into account requirements of consumer protection in defining and implementing all EU policies and activities.[473]

In its judgement in *Tobacco Advertising I,* the CJEU established that Article 168 TFEU does not prevent the EU from regulating public health-related issues under Article 114 TFEU, as long as the harmonising measure in question genuinely aims to improve the conditions for the functioning of the internal market.[474] Accordingly, recourse to Article 114 TFEU as a legal basis must not serve to circumvent the exclusion of harmonisation in Article 168(5) TFEU.[475]

Subsequent case law has further clarified the relationship between Articles 114 and 168 TFEU. According to the CJEU in *Alliance for Natural Health*, Article 114 TFEU can be relied on as a legal basis as long as the conditions for recourse are fulfilled, no matter whether public health protection is of decisive importance for the legislative decisions to be made.[476] Quite on the contrary, as the Court underlined, Article 168(1) TFEU explicitly establishes that "a high level of human health protection shall be ensured in the definition and implementation of all EU policies and activities", whereas 114(3) TFEU requires that in achieving harmonisation a high level of protection of human health be guaranteed.[477]

As far as food advertising to children is concerned, from the outset, the varying levels of protection in the Member States appear to justify recourse to Article 114 TFEU.[478]

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[471] Article 169(2)(a) TFEU.
[472] Article 169(2)(b) TFEU.
[473] Article 12 TFEU.
[474] Case C-376/98 *Germany* v *Parliament and Council* (Tobacco Advertising I), *supra* note 260, para. 84.
[475] *Ibid*, para. 79.
[476] See on Article 95 EC (now Article 114 TFEU) Joined Cases C-154 and 155/04 *Alliance for Natural Health*, *supra* note 466, para. 30.
[477] *Ibid*, para. 31; Case C-380/03 *Germany v Parliament and Council* (Tobacco Advertising II), *supra* note 260, para. 40.
[478] In this respect the Court observed in its judgment in *Spain* v *Council*, *supra* note 260, para. 33-35, that it is sufficient "if the disparities between the laws of the Member States are liable to hinder the free movement of goods". According to the Court in Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco*, *supra* note 260, recourse to Article 114 TFEU is also possible to prevent the heterogeneous development of national laws leading to further disparities or to prevent the emergence of future disparities. See further Weatherill (2011). The Limits of Legislative Harmonization

However, the CJEU established in *Tobacco Advertising I* that recourse to Article 114 TFEU cannot be accepted in relation to means of advertising that have no relation to inter-state trade, whereas a wide-ranging prohibition would effectively limit market access for economic operators wishing to enter the market.[479] Accordingly, harmonisation would most likely be excluded for, e.g. static forms of food advertising like in-store marketing, spots in cinemas and sponsorship of events without a cross-border appeal.[480]

Although the scope of Article 114 TFEU is, thus, not unlimited, the Court's ruling in *Tobacco Advertising II* has made it clear that recourse to Article 114 TFEU does not presuppose the existence of an actual link with the free movement between Member States in every situation.[481] Therefore, when there are obstacles to trade as a result of varying levels of protection in the EU Member States, as is the case for food advertising to children, Article 114 TFEU authorises the EU legislator to intervene by adopting appropriate measures in compliance with Article 114(3) TFEU and with the legal principles in the Treaty or identified in case-law, in particular the principle of proportionality.[482]

6.3.2 Considerations concerning the necessity and proportionality of an advertising ban

A question that remains unanswered after the Court's judgments in *Tobacco Advertising I* and *II* and *Alliance for Natural Health* is whether the EU could restrict commercial statements included in the labelling of foods.

Laws regulating the marketing of foodstuffs may constitute measures having the effect of quantitative restrictions, which are prohibited in Article 34 TFEU. It is settled case law that this prohibition applies not only to national measures, but also to measures adopted by EU institutions.[483]

Ten Years after *Tobacco Advertising*: How the Court's Case Law has become a 'Drafting Guide', *supra* note 254, at p. 834.

[479] Case C-376/98 *Germany* v *Parliament and Council* (Tobacco Advertising I), *supra* note 260, paras 99 and 106.

[480] See Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 84.

[481] Case C-380/03 *Germany v Parliament and Council* (Tobacco Advertising II), *supra* note 260, paras 79 and 80.

[482] See in this sense: Case C-434/02 *Arnold André* [2004] ECR I-11825, para. 34; *Swedish Match*, *supra* note 260, para. 29 and Joined Cases C-154 and 155/04 *Alliance for Natural Health*, *supra* note 466, para. 32.

[483] See, e.g., Case 15/83 *Denkavit Nederland* [1984) ECR 2171, para. 15; Case C-114/96 *Kieffer and Thill* [1997] ECR I-3629, para. 27, *Arnold André*, *supra* note 482, para. 57 and Joined Cases C-154 and 155/04 *Alliance for Natural Health*, *supra* note 466, para. 47.

It is important to bring to mind the distinction between selling arrangements and product requirements resulting from the landmark decision of the CJEU in *Keck and Mithouard*.[484] In accordance with the Court's ruling in this case, measures regulating selling-arrangements, which advertising would generally pertain to, are excluded from the scope of Article 34 TFEU so long as those provisions are applied in a non-discriminatory manner.[485] In contrast, rules that lay down product requirements (such as provisions regulating the designation, form, size, weight, composition, but also the presentation, labelling and packaging of foodstuffs) are the core of the provision.[486]

In accordance with Article 36 TFEU, measures having an equivalent effect can be accepted only to the extent that they are justified on limited grounds such as the protection of health and life of humans and if they are necessary and proportional in relation to this objective.[487] If the protective objective falls outside the scope of Article 36, obstacles to free movement can nonetheless be permissible if they are deemed necessary to satisfy mandatory requirements relating to, e.g., the protection of public health, the fairness of commercial transactions and the defence of the consumer.[488]

Apart from creating a potential barrier to trade, a general prohibition of food advertising to children may also encroach upon, e.g., the commercial freedom of expression and the freedom to conduct a business enjoyed by food operators, thus constituting a human rights violation.[489]

In accordance with Article 52 of the Charter of Fundamental Rights of the European Union

> any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law and respect the essence of those rights and freedoms. Subject to the principle of proportionality, limitations may be made only if they are necessary and

[484] Joined Cases C-267/91 and C-268/91 *Keck and Mithouard*, *supra* note 296.
[485] *Ibid*, para. 16.
[486] *Ibid*, para. 15.
[487] Article 36 TFEU, see also Joined Cases C-154 and 155/04 *Alliance for Natural Health*, *supra* note 465, para. 51.
[488] Case 120/78, *Rewe-Zentrale AG v Bundesmonopolverwaltung für Brantwein* (Cassis de Dijon), *supra* note 132, para. 8.
[489] The commercial freedom of expression is covered by Article 10(2) of the European Convention on Human Rights, whereas the freedom to conducts a business is protected by Article 16 of the Charter of Fundamental Rights of the European Union, *supra* note 134. Article 6 TFEU grants EU status to both the convention and the Charter. See for a discussion of potential additional violations of (fundamental) rights: Alberto Alemanno and Enrico Benadio (2012). Plain packaging of cigarettes under EU law. In: Tania Voon, Andrew D. Mitchell and Jonathan Libermann (eds). *Public health and plain packaging of cigarettes: legal issues* (Cheltenham UK, Edgar Eltenham Publishing), at pp. 232-233.

genuinely meet objectives of general interest recognised by the EU or the need to protect the rights and freedoms of others.

It is settled case law from the CJEU that the EU legislator must be allowed a broad discretion in areas like human health and consumer protection, which entail political, economic and social choices on its part and in which it is called on to undertake complex assessments.[490] Accordingly, "the legality of a measure adopted in that area can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue."[491]

Here, a potential complication presents itself. It may be difficult to justify the necessity and proportionality of a ban on the commercial promotion of foods to children, because the relationship between food advertising and childhood obesity is, in the words of Sandra Calvert, "by necessity correlational, not causal".[492] Whereas in *Tobacco Advertising I* and *Alliance for Natural Health* the health risks of smoking were not contested, cause-effect relations between the consumption of HFSS foods and obesity, let alone between the marketing and advertising of such foods the prevalence of obesity, continue to be subject to intense scientific debate.[493]

Accordingly, for measures restricting food advertising to children to be accepted as necessary and proportional, a further justification is needed.

The following section will look further into possible justifications of a restriction of food advertising to children. For this purpose, the more traditional risk-based approach to the protection of human

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[490] This large margin of discretion covers both the effects on the free movement of goods and considerations to human rights. See, e.g., Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco*, *supra* note 260, para. 123; Case C-380/03 *Germany v Parliament and Council* (Tobacco Advertising II), *supra* note *260*, para. 125 and Joined Cases C-154 and 155/04 *Alliance for Natural Health, supra* note 466, para. 52.

[491] Case C-380/03 *Germany v Parliament and Council* (Tobacco Advertising II), *supra* note *260*, para. 123. See also Joined Cases C-154 and 155/04 *Alliance for Natural Health, supra* note 466, para. 52. It is important to note that the case law of the CJEU concerning positive harmonisation differs dramatically from its case law in relation to negative harmonisation, where the Court "is sceptical of any restrictions on trade at national level", Unberath and Johnston (2007). The double-headed approach of the ECJ concerning consumer protection, *supra* note 89, at p. 1238.

[492] Sandra L Calvert (2008). Children as Consumers: Advertising and Marketing. 18(1) *The Future of Children*, pp. 205-234, at p. 218. See further for an overview of studies on the correlation between fast food advertising and obesity Jennifer L. Harris, Jennifer L. Pomeranz, Tim Lobstein et al. (2009). A crisis in the marketplace: how food marketing contributes to childhood obesity and what can be done. 30 *Annual Review for Public Health*, pp. 211-225; Sandra Livingstone (2005). Assessing the research base for the policy debate over the effects of food advertising to children. 24(3) *International Journal for Advertising*, pp. 273–296.

[493] Stephanie Lvovich (2002). Advertising and obesity: the research evidence. 4(2) *Young Consumers*, pp. 35-40; David Ashton (2004). *Food advertising and childhood obesity*. 97(2) Journal of the Royal Society of Medicine, pp. 51–52.

health will be weighed against a rights-based approach that offers room to consider the particular vulnerabilities of children-consumers.

6.4 How to establish an advertising ban in the EU legal order?

6.4.1 A risk-based vs. a rights-based approach

The traditional EU approach to consumer protection from the potential negative health effects from food consumption is risk-based. Risk analysis is at the core of, e.g., EU food safety legislation,[494] whereas also EU measures aimed to protect children from, e.g., TV advertising are based on perceived risk.[495] The risk-based approach derives its legitimacy from the existence of scientific evidence of a risk of harm to health. The protective level actually adopted is the result of the weighing and balancing of this risk against other interests at stake, such as the well-functioning of markets and commerce.[496]

In contrast, a rights-based approach detaches from the question of risk and links the question of protection to the very essence of being. It builds on the fundamental rights recognised in, e.g., the United Nations Convention on the Rights of the Child,[497] the right to adequate food[498] and freedom from obesity.[499]

The EU is not a signatory to the UN Conventions and although Articles 2 and 6 of the Treaty on the European Union (TEU) establish that the EU is under a duty to respect human rights, this recognition does not imply that the EU would also have the obligation – or even the authority – to actively protect

[494] Article 6(1) GFL (Regulation (EC) No 178/2002 (GFL), *supra* note 1) requires that, in principle, all food law shall be based on risk analysis.
[495] See in this sense: Helen Stalford and Eleonor Drywood (2009). Coming of Age? Children's rights in the European Union. 46(1) *Common Market Law Review*, pp. 143-172, at p. 149.
[496] Article 6(3) GFL (Regulation (EC) No 178/2002 (GFL), *supra* note 1).
[497] Convention on the Rights of the Child. Geneva, Office of the United Nations High Commissioner for Human Rights, 1989 (http://www.ohchr.org/en/professionalinterest/pages/crc.aspx, last accessed 7 July2015).
[498] General comment 12: the right to adequate food. New York, United Nations, Committee on Economic, Social and Cultural Rights, 1999 (E/C.12/1999/5) (www.unhchr.ch/tbs/doc.nsf/0/3d02758c707031d58025677f003b73b9, last accessed 7 July 2015).
[499] United Nations Standing Committee on Nutrition, Joint Working Groups Statement issued by the Working Groups on Nutrition throughout the Life Cycle, and Nutrition, Ethics and Human Rights (2007). The human right of children and adolescents to adequate food and to be free from obesity and related diseases: the responsibilities of food and beverage corporations and related media and marketing industries. Accessible at the internet at: http://www.unscn.org/files/Statements/Joint_statement_lifecycle_nehr_The_human_right_of_children_and_adolescents_to_adequate_food_and_bee_free_from_obesity.pdf (last accessed 26 August 2015).

or promote the rights guaranteed in the United Nations Conventions.[500] However, the protection of the rights of the child is explicitly mentioned as an EU objective in both Article 3(3) and (5) TEU, as well as in Article 24 of the Charter of Fundamental Rights of the European Union, which grants children "the right to such protection and care as is necessary for their well-being".[501] Despite the fact that the Charter does not extend EU competence to matters not included in the Treaties,[502] it does underline the importance of respect for children's rights as a part of overall EU policy.[503] According to Garde, "the tools are therefore in place to promote the rights of the child at the EU level" and, accordingly, to apply a rights-based approach.[504]

6.4.1.1 A risk-based approach of the protection of children from food advertising to children

Whereas it is inevitably impossible to establish a causal link between advertising and human health, in relation to tobacco, the existence of such relationship between advertising and increased consumption is accepted as a fact. Recital 3 of the Preamble to Directive 2003/33/EC (the Tobacco Advertising Directive)[505] states: "The legislation of the Member States to be approximated is intended to protect public health by regulating the promotion of tobacco, an addictive product responsible for over half a million deaths in the EU annually, thereby avoiding a situation where young people begin smoking at an early age *as a result of promotion* and become addicted" (italics added). There is no reason to assume that food advertising would not have a similar effect on consumptive behaviour as tobacco. Indeed, the very purpose of all advertising is increased consumption.

[500] However, the European Commission 2011 Agenda for the rights of the child recalls that the standards and principles of the UN Convention on the rights of the child must continue to guide EU policies and actions that have an impact on the rights of the child. In this respect, the UN Convention on the rights of the child should be used on an equal basis as the EU Treaties and the Charter of Fundamental Rights as a common basis for all EU action relevant to children, *supra* note 134. See in this sense: Margaret Tuite (2013). The way forward: the implementation of the EU Agenda for the rights of the child, 14 *ERA Forum*, pp. 543-556, at p. 544.

[501] Charter of Fundamental Rights of the European Union, *supra* note 134.

[502] Article 6 TEU.

[503] According to Helen Stalford and Eleonor Drywood, the absence of an express legal basis for action provided by the Treaty inevitably results in sporadic, incidental measures spread across certain disconnected areas. But accepting that the EU does not have a dedicated mandate for regulating children's rights supports the need for an even more considered and sensitive rationale to underpin any child-related provision. Stalford and Drywood (2009). Coming of Age? Children's rights in the European Union, *supra* note 495, at p. 149.

[504] Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 230.

[505] Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products, OJ L 152, 20.6.2003, pp. 16-19.

As for the effect of increased consumption on consumers' health, we can only assume that such relation indeed exists. The ever growing body of scientific studies on the consequences of food marketing to children certainly points in the direction of a correlation.[506] Nevertheless, from a risk-based perspective, the EU legislature may well be compelled to resort to the precautionary principle in search of a justification for an advertising ban on the grounds of human health.[507]

The precautionary principle "adds subtlety"[508] to risk analysis by substantially lowering the threshold for action than a solely risk-based approach would prescribe.[509] It is to be applied in cases where a potential adverse impact on human health has been established but where scientific evidence is not complete or where there is ongoing scientific controversy in regard to the probability of harm or the scope or degree of seriousness of the risk.[510] In light of the Commission's Communication on the use of the precautionary principle, conclusive scientific evidence of the reality of risk is not required, so that action can be deemed appropriate even where cause for concern is based on preliminary scientific findings. However, consideration to the free movement of goods requires that the existence of risk must be adequately substantiated by scientific evidence, so that a purely hypothetical risk cannot be accepted.[511, 512]

6.4.1.2 A rights-based approach of the protection of children from food advertising to children

Whereas legislation restricting the commercial promotion of foods to children may ultimately serve to protect human health and well-being, the underlying thought is that children, unlike adults, are generally unable to understand and to appropriately respond to food advertising.

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[506] Harris, Pomeranz, Lobstein et al. (2009). A crisis in the marketplace: how food marketing contributes to childhood obesity and what can be done, *supra* note 492; Tim Lobstein and Sue Dibb (2005). Evidence of a possible link between obesogenic food advertising and child overweight. 6(3) *Obesity Review*, pp. 203-208.

[507] Article 7 of Regulation (EC) No 178/2002 (GFL), *supra* note 1).

[508] See in this sense: Bernd van der Meulen and Anna Szajkowska (2014). The general food law: general provisions of food law. In: Bernd van der Meulen (ed.) *EU Food Law Handbook* (Wageningen: Wageningen Academic Publishers), at p. 246.

[509] See in this sense: René von Schomberg (2006). The precautionary principle and its normative challenges, in: Elizabeth Fisher, Judith Jones and René von Schomberg (eds). *Implementing the precautionary principle: perspectives and prospects* (Cheltenham, UK: Edward Elgar), at p. 23.

[510] Recital 21 of the Preamble to the GFL (Regulation (EC) No 178/2002 (GFL), *supra* note 1). See also René von Schomberg (2006). The precautionary principle and its normative challenges, *supra* note 509.

[511] Communication from the Commission of 2 February 2000 on the precautionary principle, COM(2000) 1, http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf (accessed 9 September 2015). See further, e.g., Case C-236/01, *Monsanto Agricoltura Italia and others* [2003] ECR I-8105, paras 137-138.

[512] See further René von Schomberg (2012). The precautionary principle: its use within hard and soft law. 3(2) *European Journal of Risk Regulation*, pp. 147-156, at p. 152.

This approach is supported by an International Obesity Taskforce (IOTF) Working Group in the "Sydney principles",[513] which promotes a rights-based approach, drawing from children's intrinsic vulnerability their right to be protected from commercial exploitation – no matter the actual impact on their health.[514]

On a Member State level, Sweden is the sole EU Member State to have embraced a rights-based approach to protecting children from commercial marketing messages, whereas several EU Member States, such as France and the United Kingdom, have opted for a risk-based approach.[515]

Despite the fact that the Swedish Marketing Practices Act (MPL) (1995:450)[516] does not expressly address marketing to children, a prohibition against advertising directly addressing children under the age of 16 has been established in the case law applying the act.[517] According to Swedish view, particular honesty and trustworthiness is required in relation to consumer groups that can be regarded as less critical, such as children. Specific rules regulating TV advertising have been laid down in the Swedish Radio and TV Act (RTVA) (1996:844) that expressly prohibits advertising to children under the age of 12 years on national radio and TV before and during children's programmes.[518] In addition, people associated with children's radio or TV programmes are not allowed to take part in advertising targeted at children under the age of 12 years.[519]

Contrary to a risk-based approach, the rights-based approach focuses on protection beyond the risk of physical harm, thus allowing for the underlying determinants of health to be addressed, as well. It

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[513] The Sydney principles are a set of seven principles developed in 2007 by an International Obesity Taskforce (IOTF) Working Group to guide action on changing food and beverage marketing practices that target children. The Principles state that actions to reduce marketing to children should: (i) support the rights of children; (ii) afford substantial protection to children; (iii) be statutory in nature; (iv) take a wide definition of commercial promotions; (v) guarantee commercial-free childhood settings; (vi) include cross-border media; and (vii) be evaluated, monitored and enforced. See further: Boyd Swinburn, Gary Sacks, Tim Lobstein et al. (2007). The 'Sydney Principles' for reducing the commercial promotion of foods and beverages to children. 11(9) *Public Health Nutrition*, pp. 881–886.

[514] *Ibid*.

[515] The UK prohibits food advertising in relation to children's TV programmes, whereas the French Public Health Code prescribes the inclusion of health messages in certain types of advertisements.

[516] Marknadsföringslag (2008:486), http://www.riksdagen.se/sv/Dokument-Lagar/Lagar/Svenskforfattningssamling/sfs_sfs-2008-486 (accessed 19 August 2015), available in English at: http://www.wipo.int/wipolex/en/text.jsp?file_id=236789 (accessed 19August 2015).

[517] Lena Olsen (2007). Children and Advertising, Some perspectives on the Relevant Legal Arguments. In: Peter Wahlgren (ed.) *What is Scandinavian law: Social private law* (Stockholm: Stockholm Institute for Scandinavian Law, 2007), pp. 435-461, at p. 439.

[518] Radio- och TV-lag (1996:844), http://www.notisum.se/rnp/sls/lag/19960844.htm (accessed 19 August 2015).

[519] Section 7(4) of the Radio and TV Act.

is argued by Naomi Priest, Boyd Swinburn and Elizabeth Waters that, accordingly, government action in this area can be justified on the basis that obesity is now widely recognised as a societal problem, challenging individual responsibility.[520] This way, the rights-based approach permits the EU legislature to take into account children's cognitive inability to grasp the bias and self-interest of marketing messages, as a result of which children tend to accept such statements as truthful and accurate.[521]

6.4.2 A future role for the FIR?

The rules regulating the provision of food information to consumers are based on the assumption that the average consumer is generally able, on the basis of the mandatory particulars included in the labelling of a food, to make informed and unconstrained dietary choices.[522] On the basis a growing body of scientific evidence, however, it can be concluded that children, in this sense, are not average. Nevertheless, although the case law from the CJEU follows an allowance for children's particular vulnerability in individual situations, the FIR does not generally regard children to be in need of special consideration.[523]

According to Samantha Graff, Dale Kunkel and Seth E. Mermin, children under a certain age – presumably four or five – do not at all distinguish commercials from other media content. Moreover, children do not grasp the full intent of advertising until they are at least 11-12 years of age.[524] Accordingly, children do not possess the critical ability of most adults to assess the information provided, filter out obvious exaggerations and weigh and balance advantages against disadvantages. More importantly, children cannot predict the longer-term consequences of their today's choices,

[520] Naomi Priest, Boyd Swinburn and Elizabeth Waters (2010). A human rights approach to childhood obesity prevention. In: Elizabeth Waters, Boyd Swinburn, J.C. Seidel et al (eds). *Preventing childhood obesity: evidence policy and practice* (Oxford: Wiley-Blackwell), at p. 43.
[521] *Ibid.* See also Gerard Hastings, Martine Stead, Laura McDermott et al (2003). *Review of Research on the Effects of Food Promotion to Children. Final Report prepared for the Food Standards Agency*, http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.134.1856&rep=rep1&type=pdf, pp. 33-36 (accessed 30 October 2015).
[522] See in this sense Recitals 3 and 4 of the Preamble to Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[523] Case C-210/96 *Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirekto des Kreises Steinfurt – Amt für Lebensmittelüberwachung* (Gut Springenheide), *supra* note 88, para. 34.
[524] Samantha Graff, Dale Kunkel and Seth. E. Mermin (2012). Government can regulate food advertising to children because cognitive research shows that it is inherently misleading, 2(31) *Health Affairs*, pp. 392-398, at p. 395.

such as the effects of excess bodyweight not only during childhood, but also later in life.[525] Therefore, children are more susceptible than adults to being manipulated into making choices that may well affect their health and well-being in the longer or shorter run.[526]

Against this background it appears possible to adopt a more restrictive attitude towards the provision of voluntary information aimed or particularly suited to appeal to children, who lack the cognitive and decisional skills to take in and balance commercial outings against mandatory particulars. A similar attitude has been already adopted towards, e.g., food information attributing to any food with the property of preventing, treating or curing human disease, no matter whether such information is truthful or not.[527]

An often-heard counterargument is that children's pattern of consumption is a parental responsibility, because it is the child's parent who purchases and pays for whatever the child consumes. This argument not only underestimates the consumptive power of children, but also overlooks the fact that foods – particularly HSSF foods – continue to be designed to appeal to children, strongly suggesting that such marketing techniques are, indeed, effective.[528]

If it is recognised that children cannot be subjected to the informed choice-mechanism that underlies the FIR in the same way as adults, the conclusion drawn by Graff, Kunkel and Mermin that advertising directed at children is "inevitably misleading", seems all the more acceptable.[529] Following this line of reasoning the marketing of foods targeting – or particularly suited to appeal to – children would be deemed innately inaccurate, unclear and difficult to understand in the sense of

[525] Lobstein, Parn and Aikenhead (2011). A junk-free childhood: Responsible standards for marketing foods and beverages to children, *supra* note 419, at p. 3.
[526] See in this sense: Boyd Swinburn, Gary Sacks, Tim Lobstein et al. (2007). The 'Sydney Principles' for reducing the commercial promotion of foods and beverages to children, *supra* note 513, at p. 882.
[527] Article 7(3) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.
[528] According to Gerard Hastings and Georgina Cairns, children represent an important target group for marketers because of their independent purchasing power, their influence on household purchase decisions and because they represent tomorrow's brand-loyal adult consumer. Gerard Hastings and Georgina Cairns (2010). Food and beverage marketing to children. In: Elizabeth Waters, Boyd Swinburn, J.C. Seidel et al. (eds). *Preventing Childhood Obesity: Evidence Policy and Practice*, (Oxford: Wiley-Blackwell), pp. 120-128.
[529] Graff, Kunkel and Mermin (2012). Government can regulate food advertising to children because cognitive research shows that it is inherently misleading, *supra* note 524, at p. 396.

Article 7(2) FIR or indeed considered inherently misleading as to the "nature, identity, properties, composition" and/or effects of the food in question, as prohibited by Article 7(1) FIR.[530]

6.5 Conclusion

In recent years, the impact of food advertising on the attitudes, behaviour and health of children has been much debated. Increasing demands for action have led to a number of policy initiatives both at the EU and at the Member State level. The scope and effect of the measures currently in force appear however rather limited, while food continues to be marketed and advertised to attract the attention of children.

Against that background, this chapter poses the question whether the EU legislator could step in and ban food advertising to children. Moreover, it examines what would be the appropriate legal context for the enactment of such ban.

In light of the existing differences on a Member State level, it can be expected that recourse to Article 114 TFEU would be accepted as an appropriate legal basis. It is settled case law from the CJEU that the EU legislator must be allowed a broad margin of discretion in regard to the type and scope of the provisions chosen.

Accordingly, in a traditional risk-based approach, the question whether restrictions to food advertising to children could be accepted essentially boils down to establishing a probable and serious harmful impact on human health. However, whereas there is no doubt that food advertising indeed affects children, a causal relationship between advertising and health-related issues such childhood obesity is hard to establish. From a public health perspective, the EU will therefore be compelled to resort to the precautionary principle in search of a justification for an advertising ban on the grounds of human health, which may present issues in regard to the probability of risk.

However, in light of the recent embedding of children's rights in the EU Treaty, there may be room for a rights-based approach based on children's assumed inherent age-related vulnerability and that is not hampered by the limitations associated with a risk-based approach.

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[530] Article 7(1) of Regulation (EU) No 1169/2011 (FIR), *supra* note 6.

Within the existing EU legal framework, such alternative approach could be accommodated in the FIR. The FIR is encompassing both in scope and purpose, covering food advertising and food labelling. Moreover, it awards equal importance to the protection of consumers' health and other interests. Despite the fact that the regulation does not explicitly acknowledge the particularly vulnerable position of children-consumers, it is open to agreeing individual entitlement to special protection on a case-by-case basis.

The rules regulating the provision of food information to consumers are based on the assumption that the average consumer is generally able, on the basis of the mandatory particulars included in the labelling of a food, to make informed and unconstrained dietary choices. The acceptance of a rights-oriented approach, however, would allow the rejection of the applicability of the concept of informed choice to minors on an equal basis as for adults. This approach would agree to the general denunciation of food marketing to children on the basis of the assumption that children's cognitive inability to grasp the intent of marketing messages would render it inherently misleading, ambiguous and/or confusing to them as prohibited in Article 7 FIR.

6.6 Recommendation

This chapter argues that Article 7 FIR on fair information practices can be interpreted to prohibit food marketing and advertising to children because it is inherently ambiguous and misleading to them.

It would, however, be helpful to clarify the FIR by including in Article 7 an explicit prohibition in line with Article 7(3) FIR, which prohibits food information that attributes to any food to property of preventing, treating or curing a human disease.

Accordingly, it is recommended that a new subsection be included in Article 7 FIR, which will explicitly prohibit the provision of food information, including advertising and presentation, which is targeted at or particularly suited to attract the attention of children.

7 Conclusion

7.1 Main findings

The objective of the thesis was to examine EU regulation of *food health* as opposed to food safety to establish where the legislature has drawn the line between food safety and non-safety issues. The ultimate purpose was to determine the extent to which consumers are entitled to legal protection from foods that are deemed safe in a legal sense, but that may nevertheless affect human health in a negative way. The central question was formulated as follows:

To what extent does EU food law offer consumer protection from foods that are not deemed unsafe in a legal sense, but that may compromise human health due to other factors, e.g., their nutritional composition?

The thesis was set up as an analysis of the scope and protective purpose of both EU food safety and EU food information legislation based on the interpretation of relevant legal provisions, and the examination of policy documents, relevant case law from the CJEU and legal doctrine.

The study has led to five scientific papers, four of which have been published in scientific journals or conference proceedings. The fifth paper is currently being processed for submission for publication in a scientific journal. The papers were reproduced in the substantive chapters 2-6 of this thesis. They focused on the following principal research questions:

1. **To what extent does EU food law address consumer protection from non-safety health risks? (Chapter 2)**
2. **Is the EU competent to regulate consumer protection from non-safety health risks? (Chapter 3)**
3. **How does EU food law deal with the seeming conflict between the freedom of choice and a high level of consumer (health) protection? (Chapter 4)**
4. **Has EU food information legislation become more protective of consumers in recent times? (Chapter 5)**
5. **To what extent does the EU legislature address protection of the most vulnerable consumers: children? (Chapter 6)**

The main contribution of this thesis is the further articulation and qualification of the grey area of regulation in EU food law. The grey area marks the void between what legally comprises a food safety risk and what could in fact pose a threat to human health, i.e. non-safety health threats. The growing prevalence of obesity and non-communicable diseases are examples of contemporary challenges that are difficult to fit into the rather narrow concept of food safety in the GFL and that are therefore considered to be non-safety issues.

The analysis concludes that EU food law does not address the grey area directly, but places the ultimate responsibility for non-safety health threats with consumers, who are expected to protect their own health and well-being by making informed and rational food choices on the basis of available food information. At present, grey area foods are, therefore, predominantly a food information issue **(Chapter 2).**

From a risk management perspective, it appears both reasonable and efficient to hold consumers responsible for the health consequences of consumptive behaviour that is regardless of information provided on food labels or otherwise. However, in regard to grey area foods, this division of responsibilities can lead to compromising situations for consumers.

In accordance with the average consumer benchmark developed by the CJEU, requirements for consumer information are based on a rather low denominator for protection. To protect themselves, consumers are therefore expected to be able to decipher often quite technical data on the nature and composition of foodstuffs and to predict the shorter and longer-term effects on their health and well-being of their overall dietary and lifestyle-related choices (**Chapter 4**).

The question arises whether the EU legislature could step in and regulate grey area foods. Although the TFEU does not provide for a specific legal basis to adopt food health law and explicitly prohibits the harmonisation of public health legislation, there appears to be room for the adoption of harmonising measures to facilitate the protection of consumer health at the EU level (**Chapter 3**).

In recent years, the EU legislature has adopted several rather restrictive measures in an area where consumer safety is not directly at stake. Not only have the rules on mandatory labelling been supplemented with nutrition information, but additional rules have also been introduced with respect to voluntary food information that could impede the intelligibility of the mandatory particulars. In general, the consumer image that emerges from these legal adjustments is that of a person who may

well be oriented towards a nutritionally well-balanced diet, but who does not necessarily possess the relevant knowledge to make discriminating choices in this respect.

Whereas these developments illustrate an increased commitment from the EU legislature to empower consumers in pace with the advancement of modern manufacturing and advertising techniques, they do not indicate the departure from the average consumer benchmark for protection in food information legislation. On the contrary, the reinforcement of food information legislation as a tool for consumer protection reaffirms the EU legislature's basic assumption that consumers, once provided with sufficient accurate food information, are capable of protecting their health and well-being by means of making informed food choices (**Chapter 5**).

Arguably, to make appropriate food choices is difficult for any consumer and even more so for the weaker, more gullible kind. Consumers are subjected to advanced marketing techniques, and their choices are not always driven only by rationality. A much-debated question in this context is what role the EU should play in relation to children, particularly in the field of food marketing and advertising to this age group.

From a traditional, risk-based perspective, the legitimacy of adopting restricting legislation depends on scientific proof of a risk to human health. However, whereas there is no doubt that food advertising indeed affects children, a causal relationship between advertising and health-related issues such as childhood obesity has not been – and probably cannot be – established.

A rights-based approach, on the contrary, derives from children's inherent age-related vulnerability their entitlement to special protection. The application of such rights-based focus in EU food law would allow for the rejection of the applicability to minors of the concept of informed choice and the prohibition of food advertising to children as inherently misleading, ambiguous and confusing to them. Following this line of reasoning, marketing techniques that convey messages about foods that are directly targeted or particularly suited to appeal to children would be prohibited pursuant to Article 7 FIR (**Chapter 6**).

7.2 The grey area between risk and safety

The research question that was in focus in Chapter 2 was

> **To what extent does EU food law address consumer protection from non-safety health risks?**

It was concluded that the legal choices that are at the basis of the GFL result in the emergence of a grey area between what is commonly regarded as harmless and what is legally accepted to be safe food. This grey area comprises foodstuffs that may present a threat to human health on grounds that fall outside the legal definition of risk.

The grey area results from the definition of risk in the GFL, which is rather narrow due to its interlinkage with only chemical, biological and physical hazards. Other threats to human health, like those related to the nutritional composition of food, are excluded from the definition. By consequence, food safety risk assessment in the EU is essentially confined to classic food toxicology, while other research areas such as epidemiology and behavioural sciences are not systematically taken into account. The result is an information gap with respect to how food composition and consumer behaviour are related and how they may affect human health.

In the phase of risk management following a food safety risk assessment this information gap is not necessarily addressed either. For the purpose of risk management, grey area foods are not considered to be unsafe if the negative effects of their consumption are avoidable by what is considered normal" consumptive behaviour in light of the food information provided on the label or generally available to the consumer.

Accordingly, the EU legislature has introduced a subjective element in distinguishing between safe and unsafe food by instituting a relationship between food safety and consumer behaviour in light of the normal conditions of use of a food and the information made available to consumers. This behavioural factor of risk results in rather high standards for what is expected from consumers in terms of the avoidance of negative health consequences from food consumption.

Chapter 2.3.1 illustrated the consequences of this system based on the food safety risk assessment of aspartame. Because of the application of the rather narrow definition of risk in the GFL, scientific evidence questioning the benefits of aspartame as an alternative to sugar and suggesting that its consumption may in fact be related to the prevalence of obesity and NCDs, was deemed irrelevant for the purpose of the safety assessment of aspartame.

Because of its subsequent classification as safe, aspartame is widely used as a replacement for sugar in foods that are marketed to target a diet and health-conscious public, whereas it may in fact be unfit as a diet option.

In regard to grey area foods the legislative choices in the GFL can thus lead to rather compromising situations for consumers. They are expected to exhibit appropriate consumptive behaviour, but the potential dietary and behavioural pitfalls associated with these foods are not properly addressed by EU food law.

7.3 Food Health Law and the EU Treaty

The EU has developed a detailed, stringent set of food safety rules that aim to limit or contain the risk that people experience negative health consequences from the consumption of food. In doing so, the legislature has focused on food safety in a relatively narrow sense, not including the potential risks for human health of foods with, e.g., negative nutritional features.

While EU food safety legislation seems successful in preventing food-borne illnesses, public focus has shifted to the growing prevalence of lifestyle-related illnesses. There is convincing scientific evidence of a correlation between obesity and non-communicable diseases on the one hand, and unhealthy food on the other. EU initiatives to tackle the root causes of these public health challenges focus on guiding consumer choice rather than regulating the composition and nutritional value of foods.

The observation in Chapter 2 that EU food law leaves open a grey area between risk and safety prompts the question whether the EU legislature could step in and adopt legislation. A preliminary question in that regard is whether the EU legislature would at all be competent to regulate food beyond the protection of consumers' health from unsafe products. Accordingly, the main research question to guide the analysis in Chapter 3 was

> **To what extent is the EU legislature competent to regulate "food health"?**

The analysis in Chapter 3 demonstrated that, although Article 168(5) TFEU explicitly prohibits the adoption of harmonising measures in the area of public health, it simultaneously contains elements that justify the conclusion that EU competence to regulate food health is not affected.

A first indication was found in the Treaty, itself. As discussed in Chapter 3.2.1, Article 168(1) TFEU contains a so-called mainstreaming provision. It establishes that "a high level of human health protection shall be ensured in the definition and implementation of all EU policies and activities". In

addition, Article 114(3) TFEU requires that in achieving harmonisation a high level of protection of human health be guaranteed.

As described in Chapter 3.2.2, a second argument for an extensive interpretation of EU competence in this area can be found in the CJEU's judgement in *Tobacco advertising I.*[531] The CJEU established that Article 168 TFEU does not prevent the EU from regulating public health-related issues under Article 114 TFEU as long as the harmonising measure in question genuinely pursues to improve the conditions for the functioning of the internal market. Accordingly, recourse to Article 114 TFEU, possibly in conjunction with Article 169(2)(a) TFEU, must not serve to circumvent the prohibition of harmonisation in Article 168(5) TFEU and it shall comply with the legal principles in the Treaty or identified in case-law, in particular the principle of proportionality. Subsequent case law has further clarified the relationship between Articles 114 and 168(5) TFEU.

The CJEU has been more or less systematically disqualifying Member States' legislative interventions aimed at protecting consumers' health and other interests as disproportionate in relation to the free movement of goods and other interests at stake. It appears more acceptant of intervention at the EU level, where it consistently holds that the EU legislator "must be allowed a broad discretion in areas that involve political, economic and social choices on its part".[532] Because the Court has found such discretion to be appropriate in the case of tobacco advertising, it may also accept recourse to Article 114 TFEU as a legal basis for the adoption of harmonising measures in the area of food health.

7.4 The impact of the informed-choice paradigm on the protection of consumers from grey area foods

From Chapter 4 onward, the focus of the thesis shifted from risk regulation to consumer information with the aim to establish the extent to which consumer information legislation offers consumers protection from foods that fall in the grey area between risk and safety.

The main objective of EU food law is to pursue a high level of consumer protection by ensuring food safety and by providing a basis for informed consumer choice. The information paradigm that

[531] Case C-376/98 *Germany* v *Parliament and Council* (Tobacco Advertising I), *supra* note 260, paras 76-79.
[532] Case C-344/04 *International Air Transport Association v Department of Transport*, *supra* note 271, at para 80.

underlies the principle of informed choice presupposes that consumers possess both the will and the necessary intellectual skills to understand and apply food information. At the same time it acknowledges that consumers need a minimum amount of information to be able to make rational and sound food choices.

Chapter 4 analysed the consumer image that prevails throughout EU food law. Furthermore, it looked into the concept of informed choice and the seeming conflict between the freedom to choose and right to a high level of consumer (health) protection. Accordingly, it posed the question whether it is indeed possible to adequately protect consumers while, at the same time, guaranteeing them a genuine freedom of choice of what they eat, and *vice versa*. This question appears particularly relevant in relation to weaker consumers, whose choices may be at risk of turning out less "informed" than one could hope for. The central question was formulated as follows:

What is the impact of the informed-choice paradigm on consumer health protection from grey area foods?

This thesis found that while usually the impetus for legal protection is the will to balance an unequal relationship in favour of the weaker party, the benchmark for protection in food information legislation is not the weaker, gullible consumer.

The way the objectified EU food consumer is perceived depends on the characterisation of the health threat from a particular food. In the face of health and safety challenges – i.e., food safety risks – consumers are generally perceived as vulnerable, and in need of protection. Where safety risks are not deemed present, however, consumers are seen as rational, cautious and well-informed and, therefore, expected to be able to take care of themselves by making subjective choices that maximise their personal benefit.

As was described in Chapter 2, grey area foods are characterised by a certain potentially negative features, which are not governed by food safety legislation. The consequential applicability of the informed choice paradigm as a standard for consumer protection from these foods reveals a frailty within the EU legal framework and the split consumer benchmark that it has brought about.

To appreciate the potential health impact from grey area foods, consumers must decipher often quite technical messages on food labels to comprehend the possible effects of food on his health and well-being in the shorter or longer run and in light of their overall diet and lifestyle. Moreover, they are

expected to respond rationally, in spite of all the potentially contradictory messages that no doubt are sent their way. It is clear that this is a challenge for any consumer and particularly for the weaker kind.

It is concluded that, in practice, consumers' freedom to choose what they eat is limited only in relation to food safety issues. If food is safe, freedom rules out protection, no matter how difficult it may be for consumers to make appropriate, balanced choices and how multifaceted the potential effect on consumers' health and well-being.

7.5 Consumer information legislation: From informed to educated choice?

Chapter 5 further explored the concept of informed choice and its consequences for consumers, focusing on the question what level of food information is deemed necessary to ensure that consumers are adequately protected, while at the same time ensuring that their autonomy remains relatively unimpaired.

Chapter 5.1 noted that some authors have claimed that EU food information legislation has become so protective of the consumer that it shows paternalistic tendencies in setting aside the principle of informed choice in favour for more intrusive educational motives. These assertions led to the following research question:

Has EU food information legislation become more protective of consumers in recent times?

An analysis of the development of EU food information legislation showed an increase over time in the amount of information deemed necessary to sufficiently empower consumers to make efficient food choices. This is particularly clear with regard to nutrition, where labelling has transitioned from a voluntary framework to becoming mandatory on all foods. The framework for mandatory food information has therefore changed quite dramatically. At the same time, the EU legislature has become increasingly active in regulating the voluntary provision of food information to consumers, with particular regard to misleading advertising.

Instead, the recent legislative developments signal a growing understanding of the complexity of food choices and of the need to actively provide all consumers with enough, adequate food information to enable them to make informed food choices. This development cannot be said to have altered the

standard for protection in contemporary EU food information legislation, which continues to be based on the average consumer benchmark in misleading advertising.

7.6 The case of food advertising to children

There are increasing demands for action against food advertising to children because of its correlation with the growing prevalence of obesity and non-communicable diseases among this age group. This gives rise to the following question:

> **To what extent does the EU legislature address protection of the most vulnerable consumers: children?**

From the traditional risk-based perspective that is at the core of EU food law, the adoption of restrictions that go beyond the prohibition of misleading food information would be acceptable only in case of a risk to human health. However, whereas there is no doubt that food advertising affects children, a causal relationship between advertising and health-related issues such childhood obesity is hard to establish.

In light of the recent embedding of children's rights in the EU Treaty, there may be room for an alternative approach that takes into account children's assumed inherent age-related vulnerability and that is not hampered by the limitations associated with a risk-based approach.

Within the existing EU legal framework, a rights-based approach could be accommodated in the FIR. The FIR is encompassing both in scope and purpose and covers both food advertising and food labelling. Moreover, it awards equal importance to the protection of consumers' health and other interests. Despite the fact that the regulation does not explicitly acknowledge the particularly vulnerable position of children-consumers, it is open to accepting the need for special protection on a case-by-case basis.

7.7 Summary of conclusions and recommendations

As one of its main achievements, this thesis mapped the grey area of regulation between risk and safety. It has drawn its contours, explained the cause for its existence and examined its consequences.

It was concluded that the grey area comprises foods that pose threats to human health that fall outside the narrow scope of risk in the GFL. Because traditional food safety risk assessment considers only biological, chemical or physical hazards, findings from other scientific disciplines, such as behavioural science and epidemiology, are systematically disregarded.

It was demonstrated that the resulting information gap has implications for consumer health protection from grey area foods. The responsibility for avoiding exposure to these threats remains with the consumer, who is expected to be relatively knowledgeable and to exhibit rational, appropriate consumptive behaviour in light of the food information provided on the label or generally available.

The main conclusion is:

Within the current legislative framework, EU food consumers are not adequately protected from grey area foods as a result of

a. A narrow scope of risk in the GFL, which confines food safety risk assessment to biological, chemical and physical hazards, systematically excluding the findings from other scientific disciplines, such as behavioural science and epidemiology.
b. The influence of the behavioural factor of risk, as a result of which the potential negative health consequences from consumptive patters that are not deemed "normal" remain the responsibility of the consumer.

There is, in other words, a need for the development of EU food health law. Food health law should become an integral part of EU food law by incorporating in the current legal set-up the risks to human health from the consumption of foods that fall outside the scope of food safety risk assessment but that can nevertheless pose a threat to consumers' health for reasons that fall outside the current, narrow definitions of risk and safety.

Chapter 2.2.2 indicated that several scholars have criticised the limitation of food safety risks assessment to a restricted scientific context focusing mainly on classic food toxicology.[533] They have argued in favour of a more integrated approach to risk, allowing a wide scope of traditional and less-traditional scientific considerations to come into play.

There are two possible ways forward to better integrate food health into EU food law. First, the scope of food safety risk analysis could be broadened by allowing the findings of other scientific disciplines

[533] Jasanoff (2013). Bridging the two cultures of risk analysis, *supra* note 190, at pp. 123 and 130; Millstone (2009), Science, risk and governance: Radical rhetorics and the realities of reform in food safety governance, *supra* note 149, at p. 627. Alemanno (2011). Risk vs Hazard and the Two Souls of EU Risk Regulation: A Reply to Ragnar Lofstedt, *supra* note 152, at p. 171; Van Asselt and Renn (2011). Risk Governance, *supra* note 199, at pp. 442.

to play a role in risk assessment. The result would be a more comprehensive appreciation of the potential health consequences of food consumption and a possible lessening of the information gap on how food composition, eating behaviour and health are interconnected.

A second possibility would be to accept that consumers do not have a common understanding of what is normal consumptive behaviour, so that food information legislation should facilitate a better comprehension of this notion and its implications. A proper response would require a general revision of food information legislation to include due consideration to weaker, vulnerable consumers and, quite possibly, the finalisation of nutrition profiles to be able to distinguish between lower and higher quality food products.

Future research could focus on ways to implement these recommendations by addressing the following queries:

- Could the scope of food safety risk assessment be broadened to include research from scientific disciplines such as epidemiology and behavioural science?
- Would a broader definition of risk in the GFL be compatible with EU law?

In this context, it appears highly relevant to also address the compatibility of a broader concept of risk with international standards (i.e., *Codex Alimentarius*) and WTO trade law:

- Would a broader definition of risk in the GFL be compatible with WTO trade law?
- To what extent could the precautionary principle be invoked in case of scientific uncertainty concerning non-safety health risks?

Much has been written on the right to adequate food, mainly from the perspective of global development. In EU food law, however, the potential role of human rights appear to have been overshadowed by the strong focus on the fundamental EU principle of the free movement of goods.[534]

Particularly in regard to children, Garde has argued that the tools are in place to "promote the rights of the child at the EU level and for the EU to develop policies that take the best interest of the child

[534] See in this sense: MacMaoláin (2007), *EU food law: protecting consumers and health in a common market*, *supra* note 3. See further on a potential future role of human rights in EU food (labelling) law Bernd van der Meulen and Eva van der Zee (2013). 'Through the Wine Gate.' First steps towards Human Rights Awareness in EU Food (Labelling) Law. 8(1) *European Food and Feed Law Review*, pp. 41-52.

into account".[535] On the information side of the equation, this thesis has contributed by demonstrating that the FIR could accommodate a rights-based approach to food advertising targeting children. Future research could embrace a broader focus and examine the potential overall role of human rights in EU food legislation:

- To what extent is a rights-based approach to consumer (health) protection compatible with EU (food) law?

Or even:

- What role should human rights play in EU food law?

This broader perspective could address the global relevance of "food health", while placing the results from this thesis in an international trade context.

[535] Garde (2010). *EU law and obesity prevention*, *supra* note 65, at p. 230.

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