Food, Safety and the Behavioural Factor of Risk

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This paper aims to demonstrate that the current application of the concepts of risk and unsafety in Regulation 178/2002 (GFL) 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, i.e., 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 hazard and causes an information gap with respect to how food consumption, eating behaviour and health are interconnected. At the same time, the scope of food safety in the GFL is restricted to what is considered "normal" consumer behaviour in view of the information provided on food labels or generally available in society. In doing so, the legislator 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.

I. 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.

Regulation (EC) 178/2002,[1] which is commonly known as the General Food Law Regulation (GFL) and which provides a general framework for EU food law, does not clarify when food is safe.[2] Instead, it prohibits the placing on the market of *unsafe* foods,[3] thus focusing on ruling out "unsafety" rather than establishing safety.[4] The implications of such negative definition of food safety in the EU will be discussed in this paper.

The concept of unsafety, within the ambit of the GFL, is a legal construction made operational by means of food safety risk analysis.[5,6] Food safety risk analysis, in turn, comprises a systematic way of gath-

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1 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (GFL). The GFL sets out general principles and requirements of EU food law and provides, as such, the general framework on which more detailed food legislation is based.

2 See further on EU food safety regulation and the GFL, e.g.: Alberto Alemanno, *Trade in Food. Regulatory and Judicial Approaches in the EC and the WTO*, (London: Cameron May, 2007); Caoimhín MacMaoláin, *EU Food Law. Protecting Consumers and Health in a Common Market*, (Oxford – Portland Oregon: Hart Publishing, 2007); Bernd van der Meulen and Menno van der Velde, *European Food Law Handbook*, (Wageningen: Wageningen Academic Publishers, 2008); Raymond O'Rourke, *European Food Law*, 3rd ed (London: Sweet & Maxwell, 2005); Anna Szajkowska, *Regulating Food Law* (Wageningen: Wageningen Academic Publishers, 2012).

3 Art. 14(1) GFL.

4 See further on this issue: Bernd van der Meulen, "The Core of Food Law. A Critical Reflection on the Single Most Important Provision in All of EU Food Law", 3 *European Food and Feed Law Review* (2012), pp. 117-125, at p. 118.

5 Art. 3(10) GFL.

6 The main risk-related terms in the GFL are based on those provided by the Codex Alimentarius Commission (CAC), see: Codex Alimentarius Commission, Procedural Manual, 21th edition 2013, available on the internet at: ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_21e.pdf, at p. 121 (last accessed 13 October 2014). The CAC, in turn, was influenced by the terminology in the Agreement on the Application of Sanitary and Phytosanitary Measures under the WTO (SPS-Agreement). See for an

ering and evaluating information relevant for decision-making purposes when dealing with an identified hazard.[7,8] It will be argued, below, that the GFL applies a rather narrow concept of "risk"[9,10] due to a limited focus on chemical, biological and physical hazards.

These legislative choices, which are at the very core of the GFL, result in the emergence of a "grey area" between what is commonly regarded as safe and what is legally accepted as unsafe.[11] 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.[12] Putrid food, for example, is deemed unsafe because it is considered "unfit for human consumption" – whether injurious to health or not.[13] At the same time, foods that pass as "not unsafe" 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 increased risk of coronary heart disease.[14] Although the European Food Safety Authority (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".[15] Despite recognition of the potentially harmful effects of trans fats, so far, the EU has not taken legislative measures in order to restrict their consumption.[16,17]

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 contributing factor to health issues

overview: Charles E. Yoe, *Principles of Risk Analysis, Decision Making Under Uncertainty* (Boca Raton: Taylor & Francis Group LLC, 2012). See further on risk analysis in general: Christopher Hood, Henry Rothstein and Robert Baldwin, *The Government of Risk – Understanding Risk Regulation Regimes*, (Oxford: Oxford University Press, 2001) and specifically with respect to food safety risk analysis, e.g.: Alemanno, *Trade in Food*, *supra* note 2, at pp. 78 *et sqq*.; Giandomenico Majone, "Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform", 1 *European Journal of Risk Regulation* (2010), pp. 5-19; Szajkowska, *Regulating Food Law*, *supra* note 2, at pp. 61 *et sqq*; Ellen Vos, "EU Food Safety Regulation in the Aftermath of the BSE Crisis", 23 *Journal of Consumer Policy* (2000), pp. 227-255.

7 "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".

8 See in this sense: Yoe, *Principles of Risk Analysis, supra* note 6, at p. 4.

9 A definition of "risk" can be found in Art. 3(9) in conjunction with Art. 3(14) GFL.

10 The risk concept in the GFL has been analysed in, e.g.: Alemanno, *Trade in Food, supra* note 2, at p. 82 *et sqq*. and Van der Meulen and Van der Velde, *European Food Law Handbook*, *supra* note 2, at p. 267. See for a more technical angle, e.g.: M.J. Tijhuis, N. de Jong, M.V. Pohjola *et al*, "State of the Art in Risk–Benefit Analysis: Food and Nutrition", 50 *Food and Chemical Toxicology* (2012), pp. 5 *et sqq*, at p. 6. For a more theoretical perspective see, e.g.: Karsten Klint Jensen and Peter Sandøe, "Food Safety and Ethics: The Interplay between Science and Values", (15) *Journal of Agricultural and Environmental Ethics* (2002), pp. 245-253, at p. 245.

11 Bernd van der Meulen, "The Core of Food Law", *supra* note 4, at p. 118; Van der Meulen and Van der Velde, *European Food Law Handbook*, *supra* note 2, at p. 261.

12 Art. 14(2)(b) GFL.

13 Art. 14(2)(b) and (5) GFL. See also: 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)716 final, at p. 11.

14 See, for example, Shyam M. Teegala, Walter C. Willett and Dariush Mozaffarian, "Consumption and Health Effects of Trans Fatty Acids: a Review", 92(5) *Journal of the Associations of Official Analytical Chemists International* (2009), pp. 1250-7.

15 EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), "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 2010, at p. 54, available at: www.efsa.europa.eu/en/efsajournal/doc/1461.pdf, last accessed on 7 May 2014.

16 Denmark has successfully applied a maximum level of industrially produced trans fatty acids in processed foods (Order No. 160 of 11 March 2003). In 2005, the EU Commission initiated a lawsuit against Denmark contending that the legislation was a technical hindrance to trade (Commission Decision of 21 March 2005, SG(2005)D/201366). However, in 2007, after having received the scientific justification of the Danish legislation by the Danish authorities, the Commission, by Commission Decision of 21 March 2007, withdrew the lawsuit without specifying its grounds for withdrawal (PV(2007)1781 (see further on this subject the answer to the question of the Danish Parliament to the Ministry of Agriculture of 3 December 2007: http://www.eu-oplysningen.dk/upload/application/pdf/b7300e0d/2837sv2.pdf?download=1 (last accessed 13 October 2014)).

17 In view of Art. 30(7) of Regulation (EU) 1169/2011 of the European Parliament and of the Council 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 (the Food Information Regulation, FIR), it is currently being discussed whether the EU should adopt labelling requirements with respect to trans fats.

such as obesity, non-communicable diseases and dental problems.[18] 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".[19]

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".[20] This gives rise to the question whether food information sufficiently prepares consumers to avoid consumptive behaviour detrimental to their health.[21]

This paper is intended to examine the breadth and scope of the "grey area" between safe and unsafe food. In addition, it will explore the consequences in terms of consumer health protection of EU legislation which allows the marketing of food that is neither entirely risk-free, nor legally unsafe.

The paper commences with an analysis of how, at EU level, perceived risks lead to conclusions about the safety of foods. For this purpose, section II 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.[22] 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.[23] 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 III, 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"[24] versus "risky" behaviour in an average consumer.[25,26] By making this "behavioural factor of

18 Recently, a paper was published in one of the world's most prestigious journals, *Nature*, pointing at a correlation between artificial sweeteners and glucose intolerance: Jotham Suez, Tal Korem, David Zeevi et al, "Artificial Sweeteners Induce Glucose Intolerance by Altering the Gut Microbiota", 514 *Nature* (2014), pp. 181-186. See also: Vasanti Malik, Matthias Schulze and Frank Hu, "Intake of Sugar-Sweetened Beverages and Weight Gain: a Systematic Review", 84 (2) *American Journal of Clinical Nutrition* (2006), pp. 274-288. See also the note addressed to the media by the World Health Organisation in relation to its launching, on 5 March 2014, of a public consultation concerning a revised sugars guideline, in which it 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 available on the internet, at: www.who.int/mediacentre/news/notes/2014/consultation-sugar-guideline/en/, last accessed on 7 May 2014.

19 Commission proposal of a GFL, *supra* note 13, at p. 11.

20 Preamble to the Food Information Regulation, recital 3.

21 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: Alberto Alemanno and Alessandro Spina, "Nudging Legally. On the Checks and Balances of Behavioural Regulation", *Jean Monnet Working Paper* 06/13, available on the internet, at: www.jeanmonnetprogram.org/papers/13/documents/JMWP06AlemannoandSpina.pdf, last accessed on 8 May 2014; Geraint Howells, "The Potential and Limits of Consumer Empowerment by Information", 32(3) *Journal of Law and Society* (2005), pp. 349-370; Jacob Jacoby, "Is it Rational to Assume Consumer Rationality?", 6 *Roger Williams University Law Review* (2000), pp. 81-161; Christine Jolls, Cass R. Sunstein and Richard Thaler, "A Behavioral Approach to Law and Economics", 50(5) *Stanford Law Review* (1998), pp. 1471-1550; Richard Thaler, "Toward a Positive Theory of Consumer Choice", 1 *Journal of Economic Behaviour and Organisation* (1980), pp. 39-60.

22 Artt. 6(1) and 14(1) GFL, respectively.

23 See further, e.g. Alemanno, *Trade in Food*, *supra* note 2, at p. 78 *et sqq*; Majone, "Foundations of Risk Regulation", *supra* note 6; Van der Meulen and Van der Velde, *European Food Law Handbook*, *supra* note 2, at pp. 261 *et sqq*; Szajkowska, *Regulating Food Law*, *supra* note 2, at pp. 28 *et sqq.;* Vos, "EU Food Safety Regulation in the Aftermath of the BSE Crisis", *supra* note 6, at p. 229; Yoe, *Principles of Risk Analysis, Decision Making Under Uncertainty*, *supra* note 6, at pp. 4 *et sqq*.

24 Art. 14(3) GFL. See also Commission proposal, *supra* note 13, at p. 11.

25 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, with regard to foodstuffs: Case C-210/96, Gut Springenheide [1998] ECR I-4657, at para. 31 and Case C-358/01, Commission vs. Spain [2003] I-13145, at para. 53. The average consumer benchmark has been codified in several pieces of EU food legislation, e.g., the Food Information Regulation, (FIR) *supra* note 17, and Regulation (EC) No 1924/2006 of the Parliament and of the Council of 20 December 2006 on nutrition and health claims made on food (Claims Regulation).

26 See for a further discussion of the average consumer benchmark, for example: Stephen Weatherill, "Who is the average consumer?", in: Stephen Weatherill and Ulf Bernitz (eds), *The Regulation of Unfair Commercial Practises under EC Directive 2005/29*, (Oxford: Hart Publishing, 2007) and for an overview of Case Law: Hannes Unberath and Angus Johnston, "The Double-Headed Approach of the ECJ Concerning Consumer Protection", 44 *Common Market Law Review* (2007), pp. 1237 *et sqq*. For a critical note on the average consumer benchmark, see: Amandine Garde, *EU Law and Obesity Prevention*, (The Netherlands: Kluwer Law International B.V., 2010), at p. 156.

risk"[27] one of the determinants in the process of deciding whether or not a food is *safe,* the legislator sets aside a reliance on science as a basis for food safety. 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 IV 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.

II. The legal framework

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.[28] 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 Union dependent on compliance with the legal requirements protecting these consumer interests.[29]

Within the ambit of the GFL, the potentially conflicting interests of free trade and consumer protection[30] have been balanced and translated into two general principles of EU food law: the principle of food safety[31] and the principle of informed choice.[32,33] The latter can be seen as a context-specific application of the consumer's right to information, guaranteed in the Treaty.[34,35] These principles are founded on the idea that the healthy functioning of the internal market depends on two preconditions: consumer safety and consumer confidence.[36] In this view, the internal market concept simultaneously presupposes that consumers are at liberty to choose and feel safe and confident about the quality of what is on offer.[37]

Although food safety is thus accepted as one of the main objectives of EU food law, the GFL does not contain a legal definition of the concept.[38] From the outset, it appears to have a positive, inclusive connotation in that safety is directly linked to the achievement of "a high level of protection of human life and health".[39] Following this line of argumentation, food safety legislation could be understood as aimed at the optimisation of food production and distribution from a human health point of view; health including food safety, quality and nutrition.[40]

In contrast to the seemingly ambitious objective of food safety legislation, food *information* legislation[41] does not aim to steer, let alone optimise, food

27 See further on the integration of behavioural – or "lifestyle" – factors in risk analysis, e.g.: Simon Planzer and Alberto Alemanno, "Lifestyle Risks: Conceptualizing an Emerging Category of Research", 4 *European Journal of Risk Regulation*, 2010, pp. 335-337; Richard Thaler and Cass R. Sunstein, *Nudge: Improving Decisions About Health, Wealth and Happiness* (London: Penguin Books, 2009).

28 Art. 5(1) and (2) GFL.

29 Bernd van der Meulen, "The Function of Food Law. On the Objective of Food Law, Legitimate Factors and Interests Taken Into Account", 2 *European Food and Feed Law Review* (2010), pp. 83-90, at p. 85.

30 See in this respect, for example, Stefania Negri, "Food Safety and Global Health: An International Law Perspective", 2 *Global Health Governance* (2009), pp. 1-26, at p. 7.

31 Set out in Art. 14 GFL.

32 Set out in Art. 8(1) GFL.

33 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 1975 C 092, at p. 0001, the provision of information to consumers has been a fundamental principle of the EU. See further on EU consumer policy: Hans-W. Micklitz, Norbert Reich and Peter Rott, *Understanding EU Consumer Law* (Antwerp: Intersentia, 2009) and Stephen Weatherill, *EU Consumer Law and Policy*, 2nd ed (Cheltenham: Edward Elgar Publishing Limited, 2013).

34 The consumer right to information is expressly recognised in Art. 169(1) of the Treaty on the Functioning of the European Union (TFEU).

35 See further on the "informed consumer" concept, e.g.: Norbert Reich, Christopher Goddard and Ksenija Vasiljeva, *Understanding EU Law*, 2nd ed (Antwerp: Intersentia, 2005), at pp. 297-298 and Stephen Weatherill, "The Role of the Informed Consumer in EC Law and Policy", 2 *Consumer Law Journal* (1994), pp. 49-62.

36 Preamble to the GFL, recitals 1, 9 and 23.

37 Thomas Wilhelmsson, "The Abuse of the 'Confident Consumer'", 27 *Journal of Consumer Policy (*2004), pp. 317–337, at p. 320. See for an overview of the developments in EU consumer law and policy: Jules Stuyck, "European Consumer Law After the Treaty of Amsterdam: Consumer Policy in or beyond the Internal Market", 37 *Common Market Law Review* (2000), pp. 367-400; Micklitz, Reich and Rott, *Understanding EU Consumer Law*, *supra* note 33; Weatherill, *EU Consumer Law and Policy*, *supra* note 33.

38 Van der Meulen and Van der Velde, *European Food Law Handbook*, *supra* note 2, at p. 261.

39 Art. 1(1) and 5(1) GFL.

40 MacMaoláin 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*, *supra* note 2, at p. 224.

41 The main food information rules are set out in the Food Information Regulation (FIR), *supra* note 17.

and food production.[42] Instead, it embraces the fundamental principle of consumer autonomy[43] and is based on the idea that, where consumer protection is deemed necessary, adequate labelling offers a less intrusive and more flexible alternative to detailed legislation on the nature and composition of foodstuffs.[44] The primary objective of food information is to enable consumers to make informed choices without being misled.[45] For this purpose, food information legislation limits producers' freedom of commercial expression[46] by requiring the provision of certain information particulars, while prohibiting other types of information.[47]

For the purpose of assuring a high level of food safety in the EU, the EU legislator has introduced two main instruments, laid down in Articles 6 and 14 GFL, respectively. Article 14 GFL establishes general "food safety requirements" and is directed at food producers, who are responsible for compliance.[48] The provision bans from the market food that is unsafe and lays down criteria for determining when this is deemed to be the case.[49]

The second instrument, laid down in Article 6(1) GFL, 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", in this context, is defined as any law, regulation or administrative decision at an EU or national level regarding food.[50] Hence, the obligation covers all formal food legislation and day-to-day decision-making with respect to food.[51]

At the same time, Article 6 GFL implies that for food laws that offer protection of consumer interests other than safety, no risk analysis is required. Food legislation providing consumer information or targeting misleading practices, for example, is, as a matter of principle, excluded from this obligation.[52] Apparently, the EU legislator perceives a clear distinction between *risk* regulation and *information* regulation. The latter is directed at effectuating the consumer's right to information and protecting his economic interests rather than eliminating risk.[53] 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, the consumer is left to freely choose his diet, and legislation is limited to ensuring that this freedom remains relatively unimpaired.

The question arises under what circumstances food can be said to pose "a potential safety issue". Who decides when risk analysis is required, and on what basis? The answer to these questions is decisive for the scope of food safety, and, consequently, indicative for the existence of a grey area in EU food law. In search of answers, the following section will look further into the process of risk analysis.

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

42 See for a commentary on the FIR: Olaf Sosnitza, "Challenges of the Food Information Regulation: Revision and Simplification of Food Labelling Legislation?", 1 *European Food and Feed Law Review* (2011), pp. 16-26. See further on EU food information legislation, e.g.,: Ilona Cheyne, "Consumer Labelling in EU and WTO law", in Sanford Gaines, Brigitte Egelund Olsen and Karsten Engsig Sørensen ed, *Trade in the EU and the WTO, A Legal Comparison* (Cambridge: Cambridge University Press, 2012), pp. 310 *et sqq*.

43 Tatiana Klompenhouwer and Henk van den Belt, "Regulating Functional Foods in the European Union: Informed Choice Versus Consumer Protection?", 16 *Journal of Agricultural and Environmental Ethics* (2003), pp. 545-556, at p. 546.

44 After the acceptance of the principle of mutual recognition in the seminal Cassis de Dijon judgment (Case 120/78, Rewe-Zentrale AG v Bundesmonopolverwaltung für Brantwein [1979] ECR 649), the Commission left the idea of adopting detailed "recipe legislation" in favour of a well-developed and clear system of labelling, presentation and advertising of foodstuffs, see: Commission Communication of 8 November 1985 on the completion of the internal market: Community legislation on foodstuffs, COM(85) 603 final, at p. 8.

45 Art. 3(1) Food Information Regulation, *supra* note 17. See also the Regulation's preamble, recital 4.

46 Art. 11(1) of the Charter of Fundamental Rights of the European Union.

47 See further: Van der Meulen and Van der Velde, *European Food Law Handbook*, *supra* note 2, at p. 371.

48 Art. 17(1) GFL.

49 Art. 14(1) and (2) GFL.

50 Art. 3(1) GFL.

51 For an interpretation of the scope of Art. 6 GFL see: Van der Meulen and Van der Velde, *European Food Law Handbook*, *supra* note 2, at p. 269. See further: Alemanno, *Trade in Food*, *supra* note 2, at pp. 78 *et sqq*; Ellen Vos and Michelle Everson, *Uncertain Risks Regulated*, (Oxon: Routledge-Cavendish, 2009), at pp. 96-97.

52 Commission proposal for a GFL, *supra* note 13, at p. 9.

53 This does not mean that consumer information cannot be opted for as a means to regulate risks. In those situations food information legislation is a risk management tool rather than (just) an information tool.

communication".[54,55] Risk assessment is a scientific process, undertaken by an independent risk assessor[56] – generally EFSA[57] – and is aimed at risk characterisation.[58] Risk management is the political process of weighing policy alternatives in view of the outcome of risk assessment.[59]

The components of risk analysis are distinct in that EU food law is based on the fundamental separation of risk assessment from risk management.[60,61] At the same time, they are interconnected in a regulatory process that demands full and interactive exchange of information – risk communication.[62]

With respect to the second component, risk management, Alemanno further distinguishes two stages, contained in the legal definition. During what could be referred to 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 or the appropriate level of protection in society. Hereafter, in the "policy stage", the risk manager decides upon a specific measure to achieve that protective level.[63]

In deciding upon an appropriate reaction in view of 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"[64] and the precautionary principle may play a role.[65] Whereas the precautionary principle may only be invoked in order to justify the adoption of provisional measures in case of scientific uncertainty about the seriousness of an identified risk,[66] other legitimate factors may be called upon in order to justify risk management decisions that are not (fully) in line with the outcome of scientific risk assessment.[67] Relevant considerations could be societal, economic, traditional, ethical or environmental in nature.[68]

The risk 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 as to "how safe is safe" – or rather: how unsafe is unsafe.[69] Although other legitimate factors may play a role, as a result of the primacy of science in the GFL, the outcome of scientific risk assessment is of overriding importance for that decision.[70]

Contrary to the process of risk assessment, which is generally depicted as evidence-based and value-

54 Art. 3(10) GFL.

55 See further on the phases of risk analysis , e.g. Alemanno, *Trade in Food*, *supra* note 2, at p. 78 *et sqq*; Van der Meulen and Van der Velde, *European Food Law Handbook*, supra note 2, at pp. 261 *et sqq*; Szajkowska, *Regulating food law*, *supra* note 2, at pp. 28 *et sqq;* Vos, "EU Food Safety Regulation in the Aftermath of the BSE Crisis", *supra* note 6, at p. 229; Yoe, *Principles of Risk Analysis*, *supra* note 6, at pp. 4 *et sqq*. See further on risk analysis from an international perspective: FAO and WHO, *Food safety risk analysis: A guide for national food safety authorities*, 87 FAO Food and Nutrition Paper (2006), available on the internet at: www.who.int/foodsafety/publications/micro/riskanalysis06.pdf?ua=1, last accessed 13 October 2014.

56 Art. 6(2) GFL.

57 Art. 22 and 23 GFL.

58 Art. 3(11) GFL.

59 Art. 3(12) GFL.

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

61 See on the question whether risk assessment and risk management can indeed be viewed as separate processes, e.g.: Sheila Jasanoff, "Relating Risk Assessment and Risk Management. Complete separation of the two processes is a misconception", 1 *EPA Journal* (1993), pp. 35-37; Majone, "Foundations of Risk Regulation", *supra* note 6, at p. 18; Erik Millstone, "Science, Risk and Governance: Radical Rhetorics and the Realities of Reform in Food Safety Governance", 38 *Research Policy* (2009), pp. 624-636, at p. 626.

62 Art. 3(13) GFL, see also the Commission proposal for a GFL; *supra* note 15, at p. 9.

63 Alemanno, *Trade in Food*, *supra* note 2, at p. 86.

64 See also: Alberto Alemanno, "Risk vs Hazard and the Two Souls of EU Risk Regulation - A reply to Ragnar Löfstedt", 2 *European Journal of Risk Regulation* (2011), pp. 169-171, at p. 171; Alemanno, *Trade in Food*, *supra* note 2, at pp. 395 *et sqq*.; Szajkowska, *Regulation Food Law*, *supra* note 2, at pp. 125 *et sqq*. See for a US perspective on the role of "other legitimate factors" in EU and US legislation: Marsha A. Echols, "Food Safety Regulation in The European Union and the United States: Different Cultures, Different Laws", 4 *Colombia Journal of European Law* (1998), pp. 525-543.

65 See further on the role of the precautionary principle in EU food safety law: Alemanno, *Trade in Food*, *supra* note 2, at pp. 407 *et sqq;* Van der Meulen and Van der Velde, *European Food Law Handbook*, *supra* note 2, at pp. 269 *et sqq*; Szajkowska, *Regulating Food Law*, *supra* note 2, at pp. 61 *et sqq*. See for an overview of the origin and functioning of the precautionary principle: Helle Tegner Anker and Margaret Rosso Grossman, "Authorization of Genetically Modified Organisms: Precaution in US and EC Law", 1 *European Food and Feed Law Review* (2009), pp. 3-22.

66 Art. 7(1) GFL lays down the conditions for the application of the precautionary principle.

67 Szajkowska, *Regulating Food Law*, *supra* note 2, at pp. 125 *et sqq*.

68 Preamble to the GFL, recital 19.

69 Alemanno, *Trade in Food*, *supra* note 2 at p. 89.

70 *Ibid*. See further: Szajkowska, *Regulating Food Law*, *supra* note 2, at p. 91.

free,[71,72] the decision whether a risk analysis is required is, by its very nature, rather subjective. Article 6(1) GFL leaves it up to the risk manager to decide whether risk analysis is appropriate or not. In general, it is, therefore, the risk manager who, in search of a scientific foundation for a policy initiative, initiates the process by posing questions to the risk assessor concerning a perceived hazard.[73] In doing so, the risk manager makes value judgements and normative choices with respect to the putative hazard to be assessed.[74] It is from these value-judgments and choices that the grey area appears.

In section III.2, below, this stratum of the grey area will be further explored by means of an analysis of the interpretation and application of "risk" within the context of the GFL. First, another aspect of the grey area will 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.

3. The prohibition against unsafe foods

Article 14 GFL, described by Van der Meulen as "the single most important provision of food law",[75] introduces a negative concept of safety that departs from the positive definition adopted by the Codex Alimentarius Commission,[76] as well as from the Commission's original proposal.[77] The negative formulation of Article 14(1) GFL does not in itself imply a limitation of the seemingly wide scope of safety, inferred from the regulation's objectives. It merely indicates that the legislator at the time sought to reduce the burden of proof on food producers to demonstrating that their products are "not unsafe" rather than "safe".[78]

Although the practical implications of the adoption of a negative rather than a positive concept of food safety appear to be limited, it has symbolic significance in that it prioritises legal certainty for food producers over the protection of consumers' health and safety. 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.[79]

Article 14(7) and (9) GFL add to the negative definition of food safety a presumption of safety of compliant foods. In view of these provisions, food that is in accordance with specific EU or – in absence thereof – national food safety legislation, is deemed safe insofar as the by those laws covered aspects are concerned. Since food is densely regulated in the EU,[80] 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.[81]

Article 14(2) GFL lays down the determinants of unsafety. It establishes that food is deemed unsafe if it is considered to be "injurious to health" or "unfit for human consumption". From the outset, the legislator appears to have opted for a rather broad interpretation of unsafety, according to which, in principle, any potentially harmful effect on human health – albeit it acute, short-term, long-term or accumulated – renders the food in question unsafe.[82] Article

71 Alemanno, *Trade in Food*, *supra* note 2, at p. 88.

72 Numerous scholars have contested that risk assessment can ever be value-free, e.g., Alemanno, "Risk vs Hazard and the Two Souls of EU Risk Regulation", *supra* note 64; Sheila Jasanoff, "Contested Boundaries in Policy-Relevant Science", 17 *Social Studies of Science* (1987), pp. 195-230; Jensen and Sandøe, "Food safety and Ethics", *supra* note 10, at p. 247; Millstone, "Science, Risk and Governance", *supra* note 61.

73 However, EFSA may also issue scientific opinions on its own initiatives (Art. 29 (1)(b) GFL).

74 Jensen and Sandøe, "Food Safety and Ethics", *supra* note 10, at p. 247. See further: Jasanoff, "Contested Boundaries in Policy-Relevant Science", *supra* note 72; Millstone, "Science, Risk and Governance", *supra* note 61, at p. 626.

75 Van der Meulen, "The Core of Food Law", *supra* note 4, at p. 117.

76 Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969), available on the internet at: http://www.codexalimentarius.org/standards/list-of-standards/en/?provide=standards&orderField=fullReference&sort=asc&num1=CAC/RCP, last accessed 14 October 2014.

77 Commission proposal for a GFL, *supra* note 13. The Commission's amended proposal for a GFL of 7 August 2001, COM(2001) 475 final, does not give a reason for this shift, nor is the amendment based on an amendment from the European Parliament. See also Van der Meulen, "The Core of Food Law", *supra* note 4, at p. 118.

78 *Ibid*.

79 *Ibid*, at p. 119.

80 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. Hersey and Jean V. McHale, *Health Law and the European Union*, (Cambridge: Cambridge University Press, 2004), at p. 348; MacMaoláin, *EU Food Law, supra* note 2; Van der Meulen and Van der Velde, *European Food Law Handbook*, *supra* note 2; O'Rourke, *European Food Law*, *supra* note 2.

81 See on the "presumption of safety" and its limits: Van der Meulen, "The Core of Food Law." *supra* note 4, at p. 122-124.

82 Art. 14(4) GFL.

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 this fault does not pose a threat to human health. This way, the legislator 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".[83]

Nevertheless, the scope of unsafety is by no means unlimited. Article 14(3) GFL provides that in determining whether a food is unsafe, regard shall be had to (a) "the normal conditions of use of the food" and (b) "the information provided to the consumer". Arguably, almost any food can become harmful if stored or prepared in the wrong way. 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".[84]

Here, the grey area comes into view: Although food consumption outside of what is considered "normal conditions of use" can be harmful to health, these risks do not necessarily render the food in question unsafe in a legal sense. For the purpose of Article 14 GFL, the legislator has thus drawn the line between safety and unsafety – between no risk and an unacceptable level of risk – at the point of "normality", i.e., "normal" consumer behaviour.[85] In other words, the consequences of the incorrect handling of food and of unusual consumption patterns are placed outside the scope of (un)safety, the determining factor being whether the way the food in question is handled by the consumer can be deemed average, or "normal".

It will be discussed in section III.3 below that the legislator, under the influence of this "behavioural factor of risk", has limited the responsibility of food producers by placing on consumers the duty to behave "normally", i.e., in line with custom and available food information.

Moreover, by accepting the behavioural factor of risk as one of the determinants of food (un)safety, the legislator makes an interesting U-turn from science to non-science-based decision-making with respect to consumer health.

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:

- Fall outside the scope of risk in the GFL, and/or
- Are avoidable by normal human 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, the following section (III) will discuss the causes and implications of the existence of a grey area.

III. Exploring the causes and implications of the grey area

1. Example: The case of aspartame

In the previous section it was argued that some foods fall outside the scope of food safety, despite the fact that they may have a negative impact on consumer health. Where legislation governing food appears to be, figuratively speaking, "black and white" (foods are unsafe or safe), these foods fall somewhere between the two. They are "grey area foods", falling in a grey area of regulation. In the following sections it will be argued that aspartame is one such food.

Aspartame is chosen as an example because of its ubiquity in "light" or "diet" food products, popular with the weight conscious public.[86,87] As will be dis-

83 Commission proposal for a GFL, *supra* note 13, at p. 11.

84 *Ibid*.

85 See also: Van der Meulen, "The Core of Food Law", *supra* note 4, at p. 120.

86 According to De la Peña, the weight conscious public often considers foods containing artificial sweeteners to be "healthy food": Carolyn de la Peña, "Artificial Sweetener as a Historical Window to Culturally Situated Health", 1190 *Annals of the New York Academy of Science* (2010), at pp. 159-65. See also Dirk J.G. Bakker, "Consumer Behaviour and Attitudes toward Low-Calorie Products in Europe", 85 *World Review of Nutrition and Dietics* (1999), pp. 146-158 and Kirtida R. Tandel, "Sugar Substitutes: Health Controversy over Perceived Benefits", 2(4) *Journal of Pharmacology & Pharmacotherapeutics* (2011), pp. 236-243, at p. 237.

87 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 in order to lose weight. Of the respondents, 39% had opted to reduce sugar-intake, while 38% ate fewer calories. European Commission, 246/Wave 64.3 Special Eurobarometer, Health and Food (2006), at pp. 36 *et sqq*, available on the internet, at: http://ec.europa.eu/health/ph_publications/eb_food_en.pdf, last accessed on 22 May 2014.

cussed below, there is evidence which 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.

a. 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 European (and global) market.

Following safety evaluations by the Scientific Committee for Food (SCF) in 1984[88] and 1988,[89] aspartame was authorised as an additive in the EU in 1994. In subsequent years, it was re-assessed six times and found not unsafe.[90] 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".[91]

At the same time, scientific research with respect to 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.[92] Some even found a positive correlation between artificial sweetener use and weight gain and type 2-diabetes,[93,94] while others found no correlation at all.[95] In view of the scientific uncertainty as to 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.[96]

In accordance with Article 8(1) in conjunction with the Annex of the Claims Regulation,[97] 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. Since sugary foods are generally perceived to be unhealthy by EU consumers,[98] claims referring

88 Scientific Committee for Food, Sweeteners, Reports of the Scientific Committee for Food, (Sixteenth Series) EUR 10210 EN, Commission of the European Communities, Luxembourg.

89 Scientific Committee for Food, Sweeteners, Reports of the Scientific Committee for Food, (Twenty-first Series) EUR 11617 EN, Commission of the European Communities, Luxembourg.

90 Scientific Committee for Food, 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, Opinion of 4 December 2002 holding an Update on the Safety of Aspartame, SCF/ADD/EDUL/222/ Final, available on the internet, at: http://ec.europa.eu/food/fs/sc/scf/out155_en.pdf, last accessed on 21 October 2014; EFSA Panel of Food additives, flavourings, processing aids and materials in contact with food (AFC), Opinion of 3 May 2006 related to a new long-term carcinogenicity study on aspartame, 356 EFSA Journal (2006), at pp. 1-44; EFSA Panel on Food Additives and Nutrient Sources added to Food, 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 (2009), at pp. 1-18; EFSA ANS Panel, Statement of 8 February 2011 on two recent scientific articles on the safety of artificial sweeteners, 9(2):1996 EFSA Journal (2011); EFSA ANS Panel, 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.

91 EFSA Scientific Opinion on the re-evaluation of aspartame, *supra* note 90, at p. 152.

92 See, e.g.: Christopher Gardner, Judith Wylie-Rosette, Samuel S. Giddings *et al*, "Nutritive Sweeteners: Current Use and Health Perspectives, A Scientific Statement from the American Heart Association and the American Diabetes Association", available on the internet, at: http://circ.ahajournals.org, DOI: 10.1161/CIR.=b=13e31825c42ee, last accessed on 19 May 2014.

93 See, e.g., Sharon P. Fowler, Ken Williams, Roy G. Resendez *et al*, "Fueling the Obesity Epidemic? Artificially Sweetened Beverage Use and Long-term Weight Gain". 16 *Obesity* (2008), pp. 1894-1900.

94 See further: Qing Yang, "Gain Weight by 'Going Diet?' Artificial Sweeteners and the Neurobiology of Sugar Cravings", 83 *Yale Journal of Biology and Medicine* (2010), pp. 101-108, at p. 104.

95 V. van Wymelbeke, M.E. Béridot-Thérond, V. de la Guéronnière et al, "Influence of Repeated Consumption of Beverages Containing Sucrose or Intense Sweeteners on Food Intake", 58 *European Journal for Clinical Nutrition* (2004), pp. 425-34. See for an overview, Tandel, "Sugar substitutes: Health Controversy over Perceived Benefits", *supra* note 86. Tandel suggests that well-designed large-scale studies in the general population are necessary in order to settle the controversy.

96 EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), 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 (2011), pp. 26, at p. 11.

97 *Supra* note 25.

98 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 87.

to a food product's low sugar content may further enhance the positive image that consumers have of "light" foods in which sugar is replaced by a sweetener, such as aspartame.[99]

b. The food safety risk assessment of aspartame

When evaluating the safety 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.[100] 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.[101]

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

2. The scope of risk in the GFL

The example of aspartame illustrates that some foods, which are legally deemed "safe", can have negative effects on health that are not covered by EFSA's food safety risk assessment. In the case of aspartame, critical scientific evidence on the relationship between consumption and altered consumptive behaviour was excluded from safety risk assessment. Apparently, such potential cause and effect was not regarded as a "risk" within the context of the GFL.

So what is risk? 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 described as "a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect".[102] Within the context of EU food law, a food safety risk can, in other words, be described as the likelihood that a biological, chemical or physical agent present in a food causes an unacceptable effect on human health.[103]

Clearly, biological, chemical and physical hazards are not the only possible dangers to human health from food consumption. Human health may also be jeopardised by threats 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 shows that foods that are high in sugar, fat or sodium, for example, possess the intrinsic potential to cause harm to human health.[104] 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 many times greater than damage, illness or injury attributable to biological, chemical and physical hazards.[105]

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99 See in this respect: Bakker, "Consumer Behaviour and Attitudes toward Low-Calorie Products in Europe, *supra* note 86; De la Peña, "Artificial Sweetener as a Historical Window to Culturally Situated Health", *supra* note 86; Tandel, "Sugar Substitutes", *supra* note 86.

100 EFSA Scientific Opinion on the re-evaluation of aspartame, *supra* note 90, at p. 151.

101 *Ibid*, at p. 100.

102 Article 3(14) GFL. The GFL definitions of "risk" and "hazard" are based on the Codex Alimentarius definition of 2003, see: Codex Alimentarius Commission, Procedural Manual, 21th edition 2013, *supra* note 6.

103 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, *Trade in Food*, *supra* note 2, at p. 81 *et sqq;* Ulrich Beck, *Risk Society: toward a New Modernity*, (London, Sage ,1992), at p. 21; Sheila Jasanoff, "Bridging the Two Cultures of Risk Analysis", 13(2) *Risk Analysis* (1993), pp. 123-129, at p. 124; Ortwin Renn, "The Role of Risk Perception for Risk Management", 59 *Reliability Engineering and System Safety* (1998), pp. 49-62, at p. 51.

104 WHO, "Global status report on noncommunicable diseases 2010", April 2011, available on the internet at <www.who.int/nmh/publications/ncd_report2010/en/>, at p. vi (last accessed on 26 May 2014).

105 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". Tijhuis, De Jong, Pohjola *et al*, "State of the Art in Risk–Benefit Analysis: Food and Nutrition", *supra* note 10, at p. 6.

The former hazards, however, fall outside the definition of risk within the GFL.[106,107]

It is rather interesting that the legislator 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 is essentially focused on determining 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.[108] In view of the seemingly ambitious objectives that appear to be at the core of the GFL, a broader, more inclusive notion of hazard 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.[109] Millstone supports the co-evolutionary model for risk analysis, in which scientific and non-scientific considerations are interdependent; socio-economic and political considerations are integrated in the framing assumptions for risk assessment.[110] Alemanno argues in favour of enhanced transparency and preservation of the "two souls of EU risk regulation"[111] and Van Asselt and Renn propose a paradigm shift towards holistic "risk governance".[112] What these submissions have in common is that they are founded on the fundamental acknowledgement that risk assessment is not and cannot be an objective, scientific process[113] and that it is, therefore, necessary to clarify where "scientific evidence stops and where other concerns kick in".[114]

However, within the current EU framework for risk analysis, the narrow definition of a hazard does not single-handedly result in a limited scope of food safety. As discussed in section II.2, risk management is not bound by the outcome of risk assessment, but allows for other legitimate factors to be taken into account. This safety net allows for more non-traditional, less scientifically-defined potential hazards to be taken into consideration on a risk management level – at least in theory.

In practice, however, the likelihood of food being declared unsafe on the basis of other legitimate factors, alone, appears negligible. The EU legislator 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 play a "precautionary" role.[115]

Another determining factor in this respect may prove to be the behavioural factor of risk, as a result of which negative health effects that are deemed to result from "abnormal" consumer behaviour are excluded from the scope of unsafety. This factor will be further discussed in the following section.

3. The impact of the behavioural factor of risk

Section II.3 found that Article 14(3) GFL excludes from the scope of unsafety, health risks that can be

106 Van der Meulen and Van der Velde, *European Food Law Handbook*, *supra* note 2, at p. 269; Szajkowska, *Regulating Food Law*, *supra* note 2, at p. 100.

107 In 2003, the Codex Alimentarius Commission added to its Procedural Manual, which is one of main guidance documents for EFSA (see: Technical report of EFSA prepared by the Secretariat of the Scientific Committee on List of guidance documents, 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, p. 120). This is, however, not reflected in the GFL.

108 Tijhuis, De Jong, Pohjola *et al*, "State of the Art in Risk–Benefit Analysis: Food and Nutrition", *supra* note 10, at p. 7.

109 Jasanoff, "Bridging the Two Cultures of Risk Analysis", *supra* note 103, at pp. 123 and 130.

110 Erik Millstone, "Science, Risk and Governance": *supra* note 61, at p. 627 *et sqq*.

111 Alemanno, "Risk vs Hazard and the Two Souls of EU Risk Regulation", *supra* note 64, at p. 171.

112 Marjolein B.A. van Asselt and Ortwin Renn, "Risk Governance", 14(4) *Journal of Risk Research* (2011), pp. 431-449, at pp. 442 *et sqq*.

113 Jasanoff, "Bridging the Two Cultures of Risk Analysis", *supra* note 103, at p. 123.

114 Alemanno, "Risk vs Hazard and the Two Souls of EU Risk Regulation", *supra* note 64, at p. 171.

115 See for example the "case of BPA": in Alemanno, "Risk vs Hazard and the Two Souls of EU Risk Regulation", *supra* note 64, at p. 172 and the "Hormones case": Szajkowska, *Regulating Food Law*, *supra* note 2, at p. 128. According to Tegner Anker and Rosso 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: Tegner Anker and Rosso Grossman, "Authorization of Genetically Modified Organisms", *supra* note 65, pp. 3-22, at p. 21-22. See for the role of the WTO SPS-Agreement in this respect, e.g.: James Flett, "If In Doubt, Leave It Out? EU Precaution in WTO Regulatory Space", 1 *European Journal of Risk Regulation* (2010), pp. 20-31.

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 an application of the average consumer benchmark in that consumers are expected to eliminate certain risks by avoiding exposure to potential hazards, based on their accordance with product information provided (on the label) or generally available.

Food information requirements with respect to safe and hygienic food use and preparation, handling, storage and recommended shelf life are based on such considerations of avoidable risk.[116] 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. Since 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 cooked. In situations like these, food safety risks are generally managed by means of providing consumer information on how to handle the food.

Interestingly, in its proposal, the Commission stretched its interpretation of what may be expected of the average consumer even further, where it considered:

> 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.[117]

From a risk management point of view, it may appear reasonable to hold consumers responsible for the health consequences of consumptive behaviour that is regardless of consumer information provided on food labels or otherwise. 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.[118,119]

The situation becomes even more diffuse where consumers are expected to appropriately respond to "information generally available". Here, consumers are expected to evaluate and manage the potential health risks of their consumptive behaviour by not only understanding and complying with information available on food labels, but also by assimilating a certain level of general knowledge about food consumption and its potential consequences for 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 that are marketed as "low in sugars" or "sugar-free".[120] 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 III.1.b above, scientific evidence submits that artificial sweeteners may bear directly on the prevalence of obesity and NCDs,[121] suggesting that foods, in which sugar is replaced by artificial sweeteners, may in fact be unfit as a diet option. However, this evidence was deemed to fall outside the scope of the food safety risk assessment of aspartame.

Nevertheless, consumers are expected to be able to distil the 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 risks and what not?

In view of the principles of risk analysis that are at the basis of the GFL, ideally, a sound judgment of what is safe and sound behaviour in relation to food

116 Art. 4(b)(ii) FIR, *supra* note 17.

117 Commission proposal of a GFL, *supra* note 13, at p. 11.

118 See for a study on how nutrition labelling affects consumer choice: George Baltas, "The Effects of Nutrition Information on Consumer Choice", March/April *Journal of Advertising Research* 2001, at pp. 57-63.

119 See further on the subject of consumer understanding of food information: Howells, "The Potential and Limits of Consumer Empowerment by Information", *supra* note 21, pp. 349-370; Garde, *EU Law and Obesity prevention*, *supra* note 26, at pp. 12-14 and 155-157; Thaler, "Toward a Positive Theory of Consumer Choice", *supra* note 21, pp. 39-60.

120 Annex to the Claims Regulation, *supra* note 25.

121 Fowler, Williams, Resendez *et al*, "Fueling the Obesity Epidemic?", *supra* note 93. See further: Tandel, "Sugar Substitutes", *supra* note 86; Yang, "Gain Weight by 'Going Diet?'", *supra* note 94.

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, essentially, hazards of a chemical, biological and physical nature, the legislator has excluded the systematic scientific evaluation of, e.g., behavioural risks.

As discussed in section II.1 above, food information legislation cannot fully compensate for this deficit, because, in view of the Commission's interpretation in its proposal for the GFL, food information legislation is *a priori* excluded from the requirement of risk analysis.[122]

IV. Conclusion

This paper demonstrates how EU food safety regulation calls into being a grey area of foods that can be harmful to health without rendering them unsafe in a legal sense.

Section II describes the general legal framework and shows that "grey area foods" fall outside the scope of "risk" in the GFL, as a result of which they are excluded from scientific risk assessment. It furthermore explains how, 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 "normal" consumer behaviour in view of the food information provided on the label or generally available to the consumer.

On the basis of the food safety risk assessment of aspartame, in section III, the consequences of this legal system are illustrated. When assessing the safety of aspartame, EFSA applied the rather narrow definition of "risk" prescribed in the GFL. As a result, scientific evidence questioning the benefits of aspartame as an alternative to sugar and suggesting that its consumption may in fact cause changes in consumptive behaviour, were deemed irrelevant for the purpose of the safety assessment of aspartame.

Section III.2 looks further into the definition of risk in the GFL as a function of a biological, chemical or physical hazard. Because of its narrow scope, other hazards that can jeopardize human health, such as those related to the nutritional composition of food, are excluded from food safety risk analysis in the EU. Within such a framework, food safety risk assessment is essentially confined to classic food toxicology and 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.

In section III.3 it is 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 legislator has added to the equation an element which is not science-based. By instituting a relationship between food safety and consumer behaviour in view of the normal conditions of use and food information available to consumers, the legislator introduces a subjective element in distinguishing 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 shows how this can lead to rather compromising situations for consumers. Consumers are expected to be able 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 can, therefore, be called into question whether consumers in general are capable of correctly interpreting and applying the sometimes rather technical information on food labels. In view of the information gap that results from a narrow concept of risk in the GFL, to effectively translate something as diffuse as "general knowledge" into appropriate or "normal" consumer behaviour, is clearly even more difficult.

In order 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 for the findings of other research disciplines than classic food toxicology to be taken into account for the purpose of risk assessment, resulting in an overall better understanding of risk. Also for the purpose of risk management greater consideration to other legitimate factors, including aspects of consumer behaviour, would help to add the necessary flexibility

122 Commission proposal of a GFL, *supra* note 13, at p. 11.

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