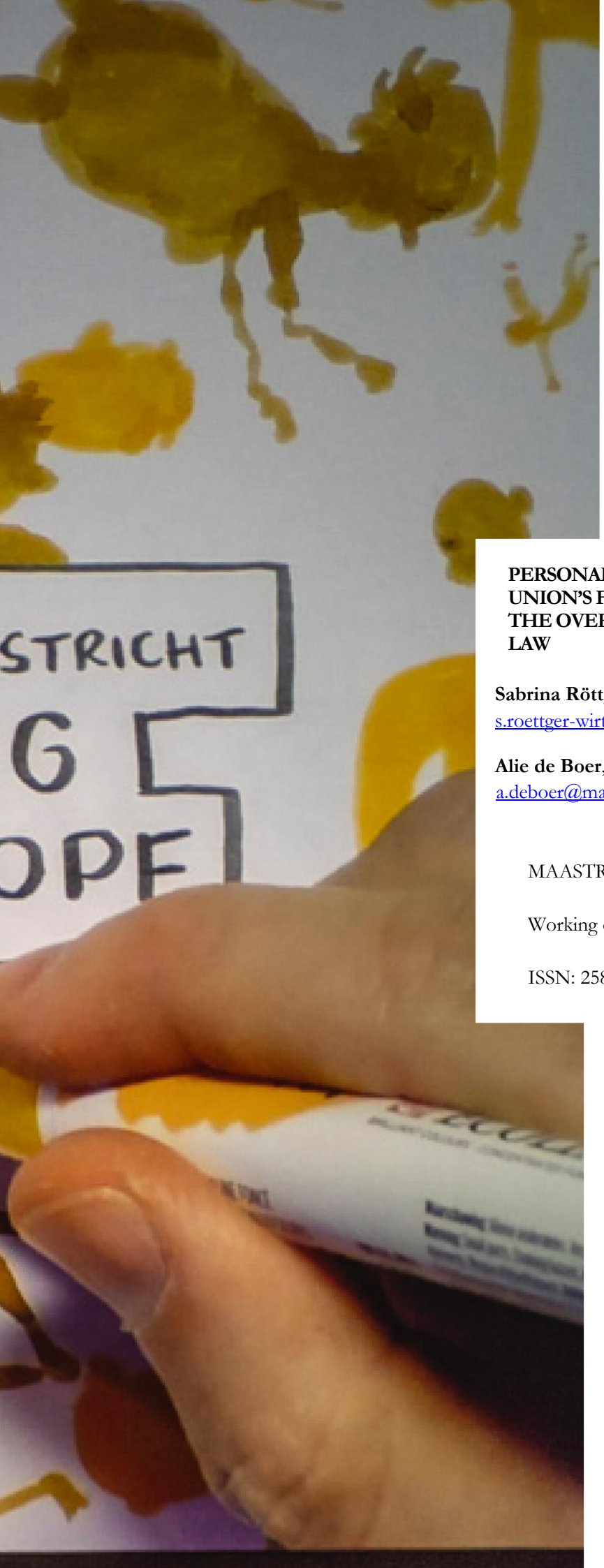

Maastricht University

PERSONALISED NUTRITION: THE EUROPEAN UNION'S FRAGMENTED LEGAL LANDSCAPE AND THE OVERLOOKED IMPLICATIONS OF EU FOOD LAW

Sabrina Röttger-Wirtz, Assistant Professor of EU Law
s.roettger-wirtz@maastrichtuniversity.nl

Alie de Boer, Assistant Professor - Food Claims Centre Venlo
a.deboer@maastrichtuniversity.nl

MAASTRICHT UNIVERSITY

Working on Europe Paper Series - Paper Number *2/2021*

ISSN: 2589-2398

Working on Europe Paper Series (WEPS)

By: Maastricht Working on Europe (MWOE) & Centre for European Research in Maastricht (CERiM)

MAASTRICHT WORKING ON EUROPE

CERiM Centre for European Research in Maastricht

About the Working on Europe Paper Series (WEPS)

The Working on Europe Paper Series is a joint project of the Maastricht Working on Europe (MWoE) research programme and the Centre for European Research in Maastricht (CERiM) at Maastricht University. This series publishes new research on a wide range of topics in European affairs, stimulating theoretical and empirical interdisciplinary academic debate, as well as promoting dialogue with policymakers, stakeholders and citizens from Europe and beyond.

About Maastricht Working on Europe (MWOE) / Studio Europa Maastricht (SEM)

Studio Europa Maastricht is a centre for Europe-related debate and research and was set up at the partners of the Maastricht, Working on Europe programme in 2018: Maastricht University, the Province of Limburg and the municipality of Maastricht. With our broad expertise and wide-ranging activities programme, we aim to encourage the public debate and create a focal point where know-how and skills meet and where vision can be developed. We try to find the best answers for the issues which challenge today's Europe, in collaboration with academics, entrepreneurs, NGOs, policymakers, journalists, cartoonists, students, schools and any other interested parties. Our mission is to stimulate active, critical debate with citizen engagement at its core.

About the Centre for European Research in Maastricht (CERiM)

CERiM is a Jean Monnet Centre of Excellence and an interdisciplinary research venue creating synergies and stimulating joint projects and events in the fields of European law, governance, and their respective history. It brings together researchers from the Faculty of Arts and Social Sciences (FASoS), the Faculty of Law (FL), and the University College Maastricht of Maastricht University (UCM). CERiM links the FASoS research programme Politics and Culture in Europe with the Maastricht Centre for European Law (FL), and the Montesquieu Institute Maastricht (FL with participation of FASoS). At the same time it bundles individual efforts to increase international outreach and to give a substantial input to the Maastricht University's strategic research theme Europe and a Globalising World. CERiM is one of several centres at Maastricht that bring together researchers from the Faculty of Law, FASoS, and UCM. Other such centres are MACIMIDE, a centre that focuses on migration, mobility, citizenship, development and family life, and ITEM, a centre that seeks to facilitate Euregional cross-border mobility and cooperation. CERiM collaborates closely with both centres in the form of common events and funding applications.

Abstract

Personalised nutrition, the tailoring of nutrition products, services or advice to individual characteristics such as genetics, phenotype, nutritional intake and/or exercise routine, is increasingly attracting the interest of industry, consumers and researchers. This working paper provides an overview of the current EU regulatory framework as applying to personalised nutrition, and draws attention to the important role of EU law food in the regulation of this innovative approach to nutrition. It is argued that personalised nutrition challenges the regulatory borderline between health and lifestyle products or services and, furthermore, also pushes the boundaries of current food safety and health claims legislation.

Keywords: Food Law, Personalised Nutrition, Health Claims, Food Safety, European Law

Personalised Nutrition: The European Union's Fragmented Legal Landscape and the Overlooked Implications of EU Food Law

A revised version of this working paper is forthcoming as an article in the European Journal of Risk Regulation. An Open Access First View version is available via: https://doi.org/10.1017/err.2020.79

Table of Contents

I. Introduction

The personalisation of health is a game changer in the health sector at large. Amidst this trend, "personalised nutrition" became a buzzword, both for individual consumers and for the industry. The number of offers for personalised nutrition advice and products are ever-increasing, from a personalised nutrition programme developed on the basis of continuous glucose monitoring and tracking of eating habits,[1] to personalised muesli which is mixed based on an at home blood and/or DNA test.[2] Where historically, nutrition was mainly used to prevent hunger, people nowadays are increasingly interested in using foods to stay healthy, or even prevent diseases.[3] From the scientific perspective, variations in responses to nutrition were already a topic of interest in the 1950s, but advancements in scientific methods such as the possibility of human whole genome sequencing since 2001 have made large contributions to the fields of nutrigenetics (how the genotype, the DNA sequence, affects an individual's response to foods) and nutrigenomics (what the effect of food is on gene expression), and thereby enhanced the development of personalised nutrition.[4]

Nowadays, dietary advice is very general and targets the full population: it gives one-size-fits all advices to address risk factors in the development of chronic diseases including obesity and diabetes type II,[5] with limited impact so far.[6] Personalising such strategies has been suggested as more effective to change behaviour.[7] Therefore, scientists concentrate on the development of methods to analyse inter-individual differences between people in their response to food products and how this can be translated into nutrition advice.[8] In this regard, the personalisation

[1] https://www.theclearhealthprogram.com/clear-nutrition-program, last accessed: 11/12/2020.
[2] https://www.mymuesli.com/neuheit/personalised-nutrition/mymicro-vital, last accessed: 11/12/2020.
[3] N. Georgiou, J. Garssen and R. Witkamp, "Pharma–nutrition interface: The gap is narrowing" (2011) 651 *Eur J Pharmacol* 1, p. 2; B. Bigliardi and F. Galati, "Innovation trends in the food industry: The case of functional foods" (2013) 31 *Trends Food Sci Technol* 118, p. 118.
[4] B. de Roos, "Personalised nutrition: ready for practice?" (2012) 72(1) *Proc Nutr Soc* 48; R. Fallaize et al., "An insight into the public acceptance of nutrigenomic-basedpersonalised nutrition" (2013) 26 *Nutr Res Rev* 39; L. Ferguson et al., "Guide and Position of the International Society of Nutrigenetics/Nutrigenomics on Personalised Nutrition: Part 1 – Fields of Precision Nutrition" (2016) *J Nutrigenet Nutrigenomics* 12.
[5] M. Ordovas, L.R. Ferguson, E. Shyong Tai, J.C. Mathers, "Personalised nutrition and health" (2018) *BMJ* 361, p.1; D. Kromhout, C.J.K. Spaaij, J. de Goede, R.M. Weggemans, "The 2015 Dutch food-based dietary guidelines", (2016) 70 *Eur J Clin Nutr* 869.
[6] L. Snyder, "Health Communication Campaigns and Their Impact on Behavior", (2007) 39(2) *J Nutr Educ Behav* 32.
[7] Ordovas supra, note 5, p.1 and 4.
[8] European Food Safety Authorithy, "Scanning the Food Safety Environment - EFSA's Strategic Environmental Scan Report" (2019), available via: https://www.efsa.europa.eu/sites/default/files/EFSA_Environmental_Scan_Report_2019.pdf, last accessed:11/12/2020.

of nutrition indicates a move away from dietary advice for the general public, to more tailored products and services that are offered for groups of people or individuals to meet their nutritional needs.[9]

Therefore, personalised nutrition is not only gaining traction in the more lifestyle and wellness-oriented food industry, but in a public health context personalised nutrition is presented as a promising contributor to alleviating non-communicable diseases which are an ever-increasing problem in the European Union.[10] While currently personalised nutrition is something that is available to a narrow group of highly motivated and financially affluent consumers,[11] or engage in personalised nutrition approaches due to certain specific circumstances like a career in professional sports. Nevertheless, since personalised nutrition could succeed in providing significant and sustainable changes to health, it is argued that it is very desirable to make it accessible to the population at large,[12] especially for low income citizens as the burden of a developing a disease is the highest on them.[13]

The scientific progress in health and nutrition and the way in which it is translated into services and goods also entails challenges from a legal and regulatory perspective. While there is no specific regulatory framework in place for pesonalised nutrition, several existing laws and policies are applicable. This paper will examine the current legal limitations and considerations in place that have to be taken into account in the development of personalised nutrition services and products, while also examining if and how the existing legislation ensures the safety of the products and prevents misleading claims.

So far, research into the regulatory framework for personalised nutrition has mainly focussed on data protection and medical testing devices, as well as the regulation of personalised nutrition services.[14] The aim of this working paper is, therefore, to provide a comprehensive overview of the current regulatory framework established by EU

[9] Ordovas supra, note 5; J. Toro Martin et al., "Precision Nutrition: A Review of Personalized Nutritional Approaches for the Prevention and Management of Metabolic Syndrome" (2017) 9 N*utrients* 913; Food4Me project, "Personalised nutrition: paving a way to better population health - A White Paper from the Food4Me project", (2015) via: https://www.researchgate.net/publication/317012773_White_paper_on_personalised_nutrition_-_paving_a_way_to_better_population_health, last accessed: 11/12/2020.
[10] J. Mathers, "Paving the way to better population health through personalised nutrition", (2019) 17 EFSA Journal 1, p. 7.
[11] S. Adams et al., "Perspective: Guiding principles for the implementation of personalized nutrition approaches that benefit health and function", (2020) 11 Advances in Nutrition 25, p 4.
[12] Ibid.
[13] Ibid., p. 7.
[14] Food4Me project supra, note 9; J. Ahlgren et al., "Consumers on the Internet: ethical and legal aspects of commercialization of personalized nutrition", (2013) 8 *Genes & nutrition* 349; D. Castle and N. Reis, "Ethical, legal and social issues in nutrigenomics: The challenges of regulating service delivery and buildinghealth professional capacity", (2007) 662 *Mutation Research* 138; P. Reilly and R. DeBusk, "Ethical and legal issues in nutritional genomics", (2008) 108 *J Am Diet Assoc* 36.

law as it can be applied to personalised nutrition, and to provide novel insights into to the important role of EU law food in the regulation of this innovative approach to nutrition. After defining the phenomenon of personalised nutrition (section II), this working paper will provide an overview of the most important legal requirements in these areas (section III) by addressing the basic requirements of consumer protection on health and lifestyle advice and the legal requirements for gathering data and information on consumers or patients. However, the role of food law in the regulation of personalised nutrition has only been addressed to a limited extent.[15] Where the advancements in personalised nutrition will also lead to the production and marketing of personalised foods, EU food law and its requirements regarding health protection and consumer information creates significant legal boundaries (Section IV), which so far have not been intensively studied.

II. Personalised nutrition: a definition

Although personalised nutrition is still a relatively young phenomenon, what is already clear is that it's exact contents can be multi-faceted, ranging from testing services, nutrition advice to the personalisation of different kinds of food; with varying '"levels" of personalisation from mere questionnaires to personalisation of advice and products via gene and/or blood tests.[16] What unites these various offerings is the core thinking that personalised nutrition is more effective than general nutrition advice and that individuals are shown to respond differently to dietary advices.[17] Differences that are experienced by individuals can for example related to the individual genetic variation that affects their ability to absorb, distribute, metabolise or excrete a compound (kinetics).[18]

Generally, three layers of information can be used to increase understanding of individual responses to food ingredients, foods and the overall diet: (i) demographic and lifestyle-related information, such as age and frequency of food consumption; (ii) phenotypic information[19] such as BMI and cholesterol levels, all observable characteristics that are the expressed result of how genetic make-up (DNA) interacts with environmental factors (e.g. diet); and (iii) information based on an individual's genotype (the DNA structure in itself),[20] including the

[15] A notable exception is: C. Ballke and A. Meisterernst, "Nutrigenomics - A New Trend from a Legal Perspective", (2014) 7 *Eur Food &Feed L Rev* 14.
[16] Ordovas supra, note 5, p. 1; Toro-Martin supra, note 9.
[17] Fallaize supra, note 4; J. Hesketh, I. Wybranska, Y. Dommels, M. King, R. Elliott, C. Pico, J. Keijer, "Nutrient-gene interactions in benefit-risk analysis", (2006) *Br. J. Nutr* 95.
[18] Ferguson supra, note 4, p. 15.
[19] M.J. Gibney & M.C. Walsh*, "The future direction of personalised nutrition: my diet, my phenotype, my genes"*, (2013) *Proc Nutr Soc* 72, p. 221.
[20] Ferguson supra, note 4.

genetic predisposition for certain diseases or the (in-)capacity to absorb or metabolise a specific nutrient. These three information layers originate from data gathered through different more or less invasive methods: data describing food intake and eating habits via (online) questionnaires, activity tracking via wearables, phenotypic data (gender, weight etc.), measures of blood pressure, sampling of blood or urine such as blood glucose levels, or genetic data, which is usually collected through buccal swabs.[21]

The first type of information, demographics and lifestyle, can be used to provide stratified or tailored advice to specific subgroups of the population. Stratified, tailored or targeted nutrition describes the aim of grouping people together based on their personal information.[22] And even though this first layer of information could already be used to provide more individualised dietary information, the second level of individualisation, "individualised" or "personalised" nutrition mainly refers to the use of phenotypic data. The third level of individualisation, "genotype-directed" nutrition, focusses on using genotypic data of an individual to base their personalised nutrition plan on.[23] These three levels of individualisation can all be used separately to develop personalised nutrition products and services.[24] Interestingly, the potential for integrating data from different sources has resulted in the trend to focus on combining data obtained through all these three layers.[25] The addition of genotypic data to the information obtained through analysing demographics, lifestyle, food behaviour, (deep) phenotyping and metabolomics, is now known as "precision nutrition".[26] It is the combination and blending of the obtained inights and the symbiosis this creates, that provides more insights into individual nutrition benefits.

These levels of individualisation can be marketed to consumers in various forms. The umbrella-term personalised nutrition can be used to refer to products, services and advice.[27] In this definition, personalised nutrition "products" refers to food products that can be or are already personalised by or for consumers, based on specific individual data. "Service" concerns the gathering and analysis of personal data, to obtain information that allows for the individualisation of the diet. The most common example of such a service is carrying out a genetic test,

[21] Food4Me project supra, note 9, p. 22; Adams supra, note 11
2.; H. Forster, M.C. Walsh, M.J. Gibney, L. Brennan, E.R. Gibney, "*Personalised nutrition: the role of new dietary assessment methods",*(2016) *Proc Nutr Soc* 75.
[22] Ordovas supra, note 5, p.1; Toro-Martin supra, note 9.
[23] Toro-Martin supra, note 9; Ferguson supra, note 4.
[24] Food4Me project supra, note 9, p.3, p.58.
[25] Mathers supra, note 10, p.6; Food4Me project supra, note 9; Ordovas supra, note 5; Adams supra, note 11.
[26] Toro-Martin supra, note 9; Ordovas supra, note 5, p.1; Ferguson supra, note 4, Adams supra, note 11, p. 3.
[27] Ordovas supra, note 5, p.1, Adams supra, note 11.

however, it may also include other or additional sources of personal data such as a questionnaire-based analysis of dietary habits. Even though personalised nutrition advice can be addressed separately,[28] the line between service and advice is not clear cut. "Advice" is generally considered to entail the advice provided after providing some type of information (based on the service), and how to optimise the diet based on the analysed results.[29] Both "service" and "advice" can therefore be grouped together, to relate to all steps in offering, identifying, processing and advising upon the obtained information.[30] Finally, at least certain personalised nutrition products, in their development and production, will be based on or combined with prior services and advices as described above.

III. The fragmented regulation of personalised nutrition

Having described the multi-faceted definition of what constitutes personalised nutrition in the section above, it is not surprising that the phenomenon raises various legal and regulatory concerns. Personalised nutrition entails risks for consumers that go beyond the traditional general nutrition advices: personalisation *per se* requires data including very sensitive health data that deserves adequate protection; this data might be collected through at home tests without professional supervision; consumers might be more likely to believe false, not scientifically substantiated claims, if the advice and products are personalised. Subsequently, the question arises if personalised nutrition products are safe when consumed by someone to whom they were not targeted.

Currently, on EU level, personalised nutrition and the risks it entails are not regulated in a *sui generis* form such as a specific Regulation or Directive. This seems to also hold true for the legislation of the Member States.[31] The European Commission in 2016 conducted a workshop on "smart personalised nutrition" (SPN) and concluded that it is necessary to: 'establish a legal and ethical framework for SPN and promote its international harmonization. This should encompass data sharing frameworks, privacy laws, information law and food legislation.'[32] Nevertheless, the absence of a specific regulatory framework does not mean that the phenomenon is unregulated. On the contrary, personalised nutrition falls within the scope of various existing legal instruments, the application of which will differ with regard to the type of personalised nutrition product, service or advice in question. Next to the EU law applying to the provision of personalised nutrition services and general consumer protection

[28] Ibid.
[29] Ibid.
[30] Adams supra, note 11; Toro-Martin supra, note 9.
[31] Food4Me project supra, note 9, p. 72.
[32] https://ec.europa.eu/research/bioeconomy/pdf/spn_quo_vadis_final.pdf, last accessed: 11/12/2020.

measures, also the risk associated with the gathering of personalised nutrition data and the development of food products are subject to existing EU law.

When examining the legislation applicable to gathering data for the personalisation of nutrition, the providing of nutrition advice and services on the internal market and the marketing of personalised nutrition, it becomes evident in the analysis is that personalised nutrition can be categorised between healthcare and lifestyle related products and services,[33] which affects the question which legal framework will be applicable.

a. Gathering Data: Data Protection and Privacy

The whole premise of personalised nutrition – the personification of nutrition advice, services and products – depends on obtaining information about individuals. The ever-increasing ability to process data is a catalyst for the personalisation of nutrition and it is very likely that online tools (such as apps)[34] will play a big role in this development for collecting information and for providing services to consumers.[35] The legal and ethical questions of data protection and privacy in the context of personalised nutrition are extensive, which is why this section only provides an overview.[36]

In the European Union, the rights to privacy and data protection are fundamental rights: Article 7 of the Charter of Fundamental Rights of the European Union grants the right to resect for private and family life, while Article 8(1) of the Charter and Article 16(1) of the Treaty on the Functioning of the European Union (TFEU) provide the correlated right to the protection of personal data. Concrete norms on how to handle data can be found in the General Data Protection Regulation (GDPR)[37], which applies when personal data is processed, which includes collecting, storing, disseminating and combining data.[38]

[33] F. Lucivero and B. Prainsack, "The lifestylisation of healthcare? 'Consumer genomics' and mobile health as technologies for healthy lifestyle", (2015) 4 *Applied & Translational Genomics* 44; Food4Me project supra, note 9, p. 89; Ahlgren supra, note 14, p. 352f.
[34] This can then fall under 'mobile health' (mHealth). See further: European Commission, Green Paper on mobile Health ("mHealth"), COM(2014) 219 final, Brussels, 10.4.2014.
[35] Food4Me project supra, note 9, p. 79.
[36] See further: Ahlgren supra, note 14; Castle and Reis supra, note 14.
[37] Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119, pp. 1-88. (Hereafter GDPR.)
[38] Art. 4(2) GDPR.

Information constitutes personal data if it relates to an identified or identifiable natural person,[39] which in times of big data and technological process becomes an increasingly broad category, as it becomes more and more likely that through a combination of available data certain information can be traced back to an individual.[40] Personalised nutrition depends on the processing of personal data: obviously the name of a person is personal data, but also information like height and weight can be personal data if they can – for example when combined with other data – lead to identifying a person. It is also important to stress that DNA can constitute personal data in itself (person X has this DNA), while it may also establish a link between another piece of information and the individual, as the individual DNA is specific to an individual and may be used to identify the person.[41] Also for human tissue samples, it has been made clear that extracting information from samples constitutes collection of personal data.[42]

Where in the context of personalised nutrition personal data is processed, several protection mechanisms apply. The GDPR in Article 5 lays down several key principles applying to the processing of personal data, such as lawfulness, fairness and transparency; purpose limitation and data minimization. The lawfulness in terms of the grounds of the processing can be based on freely given, informed, specific, and unambiguous consent, or on several other grounds, to be found in Article 6 of the GDPR.[43] Next to the responsibility the GDPR assigns to companies which control the data in accordance with these principles, the GDPR also gives rights to the data subject (the person who's data is processed), including rights of information, access, rectification, erasure, object, data portability, and a protection against certain types of automated decision-making.[44] The GDPR in Chapter IV also places several other obligations on companies that would process personal data in the context of offering personalised nutrition.

The personalisation of nutrition products, advice and services will not only require the processing of personal data, but might also presuppose the processing of data concerning the health of a person. Such data is sensitive data and subject to the even stricter protection of Article 9 of the GDPR. According to Article 4(15) of the GDPR data concerning health is defined as: 'personal data related to the physical or mental health of a natural person, including

[39] Art. 4(1) and Recital 26 GDPR.
[40] For a detailed discussion: N. Purtova, "Health data for common good: Defining the boundaries and social dilemmas of data commons", in S. Adams, N. Purtova, & R. Leenes (Eds.), *Under observation: : The interplay between eHealth and surveillance* (Springer International, 2016), pp. 177-210.
[41] Article 29 Working Party, Letter to the European Commission, Annex, 5 Feburary 2015.
[42] Ibid.
[43] The definition of consent is to be found in Art. 4(11) GDPR.
[44] Art. 12-23 GDPR Art. 12-23.

the provision of health care services, which reveal information about his or her health status.' This applies to data which 'reveal information relating to the past, current or future physical or mental health status of the data subject'[45] and the Recital 35 explicitly mentions 'information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples (…) and any information on, for example, a disease, disability, disease risk (…).'[46]

This type of data, as well as genetic data and biometric data,[47] cannot be processed unless this is authorised under the conditions of Art. 9(2). Article 9(2) then lists several circumstances under which the processing is allowed, the most important in the context of personalised nutrition being: explicit consent (Art. 9(2)(a)) and the processing for purposes of preventive or occupational medicine, carried out by a professional subject to the obligations of profession secrecy (Art. 9(2)(h) jo. 9(3)). Notably, the necessity for performance of a contract is not an acceptable exception in the processing of health data. The GDPR does not further specify which additional requirements apply to explicit consent as opposed to regular consent, which has to be 'freely given, specific, informed and unambiguous' as defined in Article 4(11) GCPR. Guidelines by the Article 29 Working Party indicate that 'explicit' is referring to the way that consent is given, in the sense that it must be an express statement of consent, preferably in writing and potentially even signed or via two staged-verification in the digital context.[48] In the processing of data in the context of personalised nutrition offerings, the extend of data protection – and the corresponding rights and duties – depend not only on the nature of the data processed but also on the question how they are combined. It does not matter whether for example an app is marketed more as lifestyle app than making explicit health benefit claims, it still might process health data.

b. Gathering Data: Medical Devices and the Regulation of Genetic Testing

Offering personalised nutrition can require the use of devices, like the tools used to collect samples for blood or buccal cell swabs. Some of the equipment and technology used in the personalisation of nutrition will qualify as medical device and, therefore, will be subject to EU law. In this regard, medical device refers to a broad range of products such as instruments, appliances or software, which are produced with the intention of medicinal use, thus

[45] Recital 35 GDPR.
[46] Ibid.
[47] The definitions of genetic and biometrict data are to be found in Art. 4(13) and (14) GDPR.
[48] Article 29 Working Party, Guidelines on consent under Regulation 2016/679, As last Revised and Adopted on 10 April 2018, WP259 rev.01, pp. 18-20.

for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease.[49] The additional category of *in vitro* diagnostic devices, which are devices such as test kits, intended for the collection and examination of specimens (including tissue and blood) taken from the human body to examine the physiological state of someone or monitor therapeutic treatment, is subject to a separate piece of legislation with specific requirements.[50] While the medical devices used in genetic testing are regulated on EU level, this does not hold true for the different methods in which genetic testing can be offered or by whom it is offered. Questions relating to medical supervision or informed consent are subject to national legislation and hardly harmonised on EU level.[51]

Therefore, the manufacturing and marketing of medical devices is subject to EU harmonisation.[52] However, the legislation itself is limited to establishing essential requirements regarding the safety and performance of the devices, containing minimum requirements concerning the reduction of risks to patients and the efficiency of the products. In order to demonstrate that a medical device conforms with these essential requirements, it will have to fulfil the technical specifications, which are adopted in the form of harmonised standards by private standardization bodies. The compliance will be assessed by so-called notified bodies. Manufacturers must apply for assessment with a notified body in order to obtain certification, while some low risk products can even be self-certified. A product that has shown compliance with the standards – and therefore the essential requirements in the legislation – will be certified, can bear the CE-mark and subsequently can be sold in the EU.

As personalised nutrition services will often take place outside the classical healthcare setting the defining question for the qualification of equipment or technology as medical device, will be whether the personalisation of nutrition in a general or specific case would qualify as medical purpose, or would be seen as lifestyle related. This is especially difficult to determine with regard to software such as apps or algorithms to support the dietary advice, which can constitute medical devices, but this depends very much on its intended use. A similar problem in the distinction

[49] Art. 1(2)(a), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993, p. 1–43.
[50] Art. 1, Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJ L 331, 7.12.1998, p. 1–37.
[51] L. Kalokairinou et al., "Legislation of direct-to-consumer genetic testing in Europe: a fragmented regulatory landscape", (2018) 9 *J Community Genet* 117.
[52] For an introduction to medical device regulation: N. Chowdhury, *European Regulation of Medical Devices and Pharmaceuticals – Regulatee Expectations of Legal Certainty* (Heidelberg, 2014); C. Altenstetter and G. Permanand, "EU Regulation of Medical Devices and Pharmaceuticals in Comparative Perspective", (2007) 24 *Review of Policy Research* 390.

health vs. lifestyle is also present with regard to genetic testing kits.[53] Nevertheless, this characterisation problem is partially addressed by a recent revision of the medical device legislation. Currently the EU is in a transition phase between the three old Medical Device Directives,[54] which have been replaced in April 2017 by two new regulations.[55] The two new Regulations were meant to apply after a transition period in May 2020 (medical devices) and May 2022 (*in vitro* diagnostic devices), however, this is now delayed by one year called into question by due to the COVID-19 crisis.[56] The new Medical Device Regulation includes the prediction of diseases as medical purpose and, therefore, means that tools use in personalised nutrition services will be covered by the legislation if they are used to predict the disease predisposition of a person.[57] Moreover, the new IVDD Regulation also includes devices aimed at 'providing information (…) concerning the predisposition to a medical condition or a disease'[58] in its definition. The IVDD Regulation also specifically addresses genetic testing in Article 4 and required informed consent of the person being tested. Thus, under the new legislation, also tests that are performed outside the classical health setting, but which are aimed at providing information on disease predisposition, are qualified as (*in vitro*) medical device and will have to be manufactured and marketed in accordance with the applicable Regulation.

c. Offering Advice and Services on the Internal Market

EU law also affects who can offer personalised nutrition services, such as carrying out tests regarding nutrition deficits, gene tests or the provision of nutrition advice, and under which conditions. Thus, on a case-by-case basis, depending on the nature of the service and the professional providing it, either the Services Directive[59] or the Patient Rights Directive[60] will be applicable, but only where the service is provided cross-border, as otherwise the national legislation will govern the provision of the service. The main importance of EU law in this regard is that

[53] See further: Food4Me project supra, note 9, p.82ff. For an overview of the developments in direct-to-consumer genetic testing see: A. Phillips, "Only a click away — DTC genetics for ancestry, health, love…and more: A view of the business and regulatory landscape", (2016) 8 *Applied & Translational Genomics* 16.
[54] Council Directive 93/42/EEC; Directive 98/79/EC; Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, OJ L 189, 20.7.1990, p. 17–36.
[55] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; *OJ L 117, 5.5.2017,* p. 1–175; Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, 5.5.2017, p. 176–332.
[56] Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions, OJ L 130, 24.4.2020, p. 18–22.
[57] Art. 2(1), Regulation (EU) 2017/745.
[58] Art. 1(2)(c), Regulation (EU) 2017/746.
[59] Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market, OJ L 376, 27.12.2006, p. 36–68.
[60] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45–65.

it simplifies offering personalised nutrition services outside the Member State where the service provider is established by guaranteeing the freedom to provide services.[61] This is further specified in the Services Directive, which minimises administrative burdens on service providers. From a consumer protection perspective the Directive is relevant because it entails certain rights for the recipient of a service, and minimum information to be provided to the customer and rules on professional liability.[62]

However, personalised nutrition can, under certain circumstances, fall outside the Services Directive, and into the remit of the Patients Rights Directive which applies to cross-border healthcare.[63] According to Article 3(a) of the Patient Rights Directive, healthcare is defined as 'health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices'. Therefore, depending on who is involved in the provision of personalised nutrition services this might qualify as healthcare. In this regard, doctors and nurses fall under the definition of health professionals, so as regulated professions in the healthcare sector.[64] Notably, many countries have regulated the profession of dieticians, which means that the title can only by carried and the respective tasks only be executed by persons who have obtained the required professional qualification.[65] In Germany for example a 'Diätassitent(in)' is someone who '(a)dministers dietary and nutritional therapies as prescribed by or upon prescription of a medical practitioner; helps prevent and treat medical conditions; offers nutritional advice to patients and runs courses on nutrition; accepts full responsibility for his/her work.'[66] Thus, providers of personalised nutrition services will carefully have to examine if they can offer their specific service in a Member State that might regulate dietary advice. The Patient Rights Directive mostly concerns questions of facilitating cross-border healthcare and

[61] Arts. 56-62 Treaty on the Functioning of the European Union (TFEU), Consolidated Version, OJ C 326, 26.10.2012, p. 47–390.
[62] Arts. 19-23 Directive 2006/123/EC.
[63] For a more detailed analysis on the implications of either the Services Directive or the Patients Righsts Directive applying, see: Food4Me project supra, note 9, pp. 73-77.
[64] Art. 3(f) Directive 2011/24/EU.
[65] The European Commission has created a database on regulated professions, which provides an overview over which Member States regulate the profession of dieticians and which rules apply: https://ec.europa.eu/growth/tools-databases/regprof/index.cfm?action=profession&id_profession=1380&from=regprof&id_regprof=919; last accessed: 11/12/2020.
[66] Diätassistentengesetz vom 8. März 1994 (BGBl. I S. 446). The translation is derived from: https://ec.europa.eu/growth/tools-databases/regprof/index.cfm?action=regprof&id_regprof=919&id_profession=1380&tab=countries&quid=2&mode=asc&pagenum=1, last accessed: 11/12/2020.

regulating its reimbursement, for consumers/patients it is mainly relevant due to the minimum information it requires to be provided in order to enabled informed decision-making.[67]

d. Marketing: Contracts and Advertising

Finally, EU law also places limits and conditions on the marketing of personalised nutrition services and products, and grants certain consumer protection rights. First of all, Directive 2005/29/EC on unfair business-to-consumer commercial practices, the enforcement of which currently has been strengthened, prohibits misleading commercial practices, including deceiving information.[68] As argued by Ballke and Meisterenst, if a personalised nutrition product or service offered would for example fall short of providing the state-of-the-art genetic analysis concerning predisposition for certain diseases that the consumer would legitimately expect through the information provided about the product, this would be a misleading practice.[69] In such cases, the Directive grants rights to proportionate and effective remedies, which might be in the form of damages, but the exact nature of this is dependent on national law.[70]

Additionally, Directive 2011/83/EU on consumer rights harmonises the protection of consumers in contacts between them and traders, also including distance sales contracts but excluding contracts for healthcare.[71] It provides for minimum information that needs to be given to the consumer before the conclusion of a contract and grants a 14 days withdrawal right for distance contracts.[72] In case a personalised nutrition product or service is offered via the internet, the E-Commerce Directive 2000/31/EC applies as *lex specialis*, also requiring for certain information to be provided and regulating contractual matters.[73] Article 8 of the Directive especially specifies that services provided by members of regulated professions needs to be performed in accordance with the applicable regulations for this profession.

---

[67] Art. 4(2)(b) Directive 2011/24/EU.

[68] Arts. 6 and 7, 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.

69 Ballke and Meisterenst supra, note 15, p. 18.

[70] Art. 11, Directive 2005/29/EC.

[71] Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights; OJ L 304, 22.11.2011, p. 64–88.

[72] Arts. 5-16, Directive 2011/83/EU.

[73] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market, OJ L 178, 17.7.2000, p. 1–16.

IV. The Missing Piece: Developing and Selling a Food Product - Safety and Consumer Protection

The discussion of personalised nutrition in the literature often focusses on the technical and technological regulation whih we discussed in the previous section, however, it fails to address the regulation of personalised nutrition products: foods, which are personalised by or for the consumer, like the muesli mentioned in the introduction. As will be discussed in the following, the development of such products challenges the existing legal framework for foods which is aimed at ensuring a balance between internal market values including the free movement of goods, while guaranteeing a high level of human health and maintaining consumer protection against misleading practices.

a. Pushing the boundaries: Safety – For whom?

First and foremost, like any other food, also personalised nutrition products may not be injurious to health and not unfit for human consumption (for example through decay), according to Article 14 of the General Food Law.[74] While food safety is generally concerned with the safety of food for the general population,[75] how does it adress a situation where a personalised nutrition product is beneficial for a person or groups of persons, while potentially unsafe for the public at large?

In case a product is created to serve the nutritional needs of a certain individual or group of individuals, it might be possible that its consumption by the average consumer would have negative effects on health. This is exemplified by plant sterols, which are added to products like margarine, and can claim to lower cholesterol and this reduces a risk factor in the development of coronary heart disease.[76] However, at the same time, consumption can also lead to an increase in plasma concentrations of phytosterols (for which the consequences on cardiovascular risk are unknown) and a reduction in plasma concentrations of β-carotene (which is likely to increase cardiovascular

[74] Art. 14 General Food Law.

[75] Article 14 of the General Food Law refers to health and human consumption in a general way, while only Article 14(4)(c) addresses the case of marketing a food to specific consumers groups.

76 European Food Safety Authority, Scientific Opinion on the substantiation of a health claim related to 3 g/day plant sterols/stanols and lowering blood LDL-cholesterol and reduced risk of (coronary) heart disease pursuant to Article 19 of Regulation (EC) No 1924/2006, (2012) 10 *EFSA Journal* 2693.

risk).[77] In this case, the EU introduced a mandatory warning label stating that the product is not intended for people that do not need to control their blood cholesterol level.[78] Especially pregnant and breastfeeding women and children are recommended to not consume food fortified with phytosterols.[79]

When examining whether the GFL would cover a situation where a personalised nutrition product would be harmful if consumed by someone else than the intended consumer, it should be considered that the GFL does not require a food to be safe, but rather requires is not to be unsafe.[80] Generally, European Food Law operates on the presumption that food is safe and that by controlling hazards in the supply chain (through food safety management systems), risks are minimised.[81] This changes where a food business operator realises or has reason to believe that food is unsafe (Art. 19(1) GFL). Moreover, for specific foods where the legislator deemed the presumption of safety not to exist, like novel foods where no history of consumption would vouch for the safety, the food business operator will have to prove the safety of the food.[82] Therefore, certain studies need to be conducted (such as sub-chronic toxicity studies) or specific endpoints need to be reported to show that such foods are safe for the general population.[83]

What is essential when assessing the (un-)safety of food are the conditions of normally to be expected use.[84] A personalised food which is specifically made for one person could therefore presumably be expected to be consumed by this person or a group of consumers sharing specific similarities, and no one else. Where a food is intended for a certain category of consumers, the health sensitivities of this specific consumer segment such as infants or elderly people, need to be taken into account.[85] However, when such a product would be sold in a

[77] See information provided by the French Agency for Food, Environmental and Occupational Health & Safety (ANSES): https://www.anses.fr/en/content/foods-fortified-phytosterols-and-prevention-cardiovascular-disease, last accessed: 08/06/2020.
[78] Commission Regulation (EU) No 718/2013 of 25 July 2013 amending Regulation (EC) No 608/2004 concerning the labelling of foods and food ingredients with added phytosterols, phytosterol esters, phytostanols and/or phytostanol esters Text with EEA relevance, OJ L 201, 26.7.2013, p. 49–50.
[79] ANSES supra, note 99.
80 A. Meisterernst, *Lebensmittelrecht* (München, 2019), p. 26.

[81] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, OJ L 95, 7.4.2017, p. 1–142.
[82] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, OJ L 327, 11.12.2015, p. 1–22.
[83] An example of such required studies is the repeated dose 90-day oral toxicity study, that is required in the scientific dossier of GM foods and crops but is also highly suggested in guidance documents for other foods for which sub-chronic toxicity needs to be established, including Regulation (EU) No 2015/2283.
[84] This also means that cases of misuse and excessive consumption are not covered. Meisterenst supra, note 81, p. 138.
[85] Art. 14(4) (c), General Food Law.

normal supermarket, it could be expected that someone else would buy it (much like in the fortified margarine example above). Where a product is harmful to a group of people with health sensitivities that it was not marketed for, it is not automatically injurious in the sense of Art. 14.[86]

Finally, also the information provided to consumers is taken into account in determining the potential unsafety of food (Art. 14(3)(b)). Overall, if a personalised nutrition product is accessible to the public at large, products which have known unwanted side effects in the general population or any non-target group, additional information on the packaging is probably necessary. For specific sensitive groups of the population, those suffering from allergies, this additional information is already provided: on foods that contain one of the 14 specified allergens, or could be contaminated with such allergen, need to carry a warning on their label or the related information on the food.[87] Also other specific food legislation recognises the need to inform vulnerable groups about risk (as exemplified for non-intended consumer segments for fortified margarine), however, not classifying such foods as unsafe.[88]

In summary, although personalised nutrition pushes at the boundaries of the rules regarding food safety, personalised nutrition does not seem to raise safety risks that would be so new that they are either not adequately addressed in the current legal framework or could not already be contained by existing risk mitigation measures like adequate labelling.

b. Pushing the boundaries: claims made on personalised nutrition

In addition to food safety, EU food law also aims to protect consumers against false claims, such as unsubstantiated statements about the health effect of a food product. In this regard, most important in the context of the debate

---

[86] Standing Committee on the Food Chain and Animal Health, Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19, and 20 of Regulation 178/2002, p. 9, via: https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf, last accessed: 11/12/2020.

[87] The Food Information to Consumers Regulation lists allergens as mandatory particulars to be inserted on the food label: Art. 9(1)(c), 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, OJ L 304, 22.11.2011, p. 18–63. Hereafter FIC Regulation.

[88] An example is the Nutrition and Health Claims Regulation (Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404, 30.12.2006, p. 9–25, hereafter NHCR). The NHCR focusses on health benefits of foods, however, it does stipulate the need to inform vulnerable groups for whom the food is not intended about potential risks on the label of such products. (Art. 10(2)(c) NHCR and Art. 6(c) Commission Regulation (EC) No 353/2008 of 18 April 2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council, OJ L 109, 19.4.2008, p. 11–16.) Also when the excess consumption of a product that bears a health claim could lead to health risks, a warning needs to be included on the label, or the food's presentation and advertising. (Article 10(2)(d) NHCR; Reg 353/2008 Art 6(d,e)).

surrounding personalised nutrition - the sometimes unproven claims made[89] - is the obligation that the labelling, advertising and the presentation including packaging and information provided shall not be misleading.[90]

This is further specified in the FIC Regulation, which covers any information that is provided to the final consumer concerning a food, including the label and packaging but also any other accompanying material, advertising and tech tools (such as QR codes, apps or websites).[91] The Regulation not only prohibits information that is misleading consumers concerning the characteristics of the food such as its composition or quantity of the product, but also entails prohibitions on 'attributing to the food effects or properties which it does not possess' and most importantly in the area of personalised nutrition it prohibits any information that will 'attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties'.[92] This provision reinforces the food-medicines-borderline, and, as explained by Ballke and Meisterernst, will significantly limit the marketing options, especially in areas such as personalised nutrition products based on nutrigenomics, which are (allegedly) meant to prevent diseases to which the person in question is genetically predisposed.[93]

The only viable route to making a health-related statement on food is through a so-called health claim, which has to comply with the requirements of the Nutrition and Health Claims Regulation.[94] This Regulation was introduced in the early 2000s, in the wake of the rising trend of functional foods, i.e. foods which have a positive effect on one or more body functions beyond nutritional effects, to harmonise national regulation and to ensure that consumers are protected against false claims and given sufficient information to make an informed choice.[95] The use of health claims is prohibited unless it concerns an authorised claim and conforms to the additional requirements of the Regulation.

The Regulation distinguishes between nutrition claims (beneficial nutritional properties, given a foods energy and calorific value or the quantity, presence or absence of nutrients),[96] and health claims (which either explicitly or

[89] Ordovas supra, note 5, p. 5.
[90] Art. 16, General Food Law.
[91] Art. 2(2), FIC Regulation.
[92] Art. 7, FIC Regulation.
[93] Ballke and Meisterenst supra, note 15, p. 19.
[94] NHCR supra, note 107.
[95] See further: H. Verhagen et al., "Status of nutrition and health claims in Europe", (2010) 501 *Arch Biochem Biophys*.
[96] Art. 2(2)(4), NHCR.

implicitly links a food/food category/one of the foods constituents with health effects)[97]. An example of a nutrition claim is 'fat-free', whereas a health claim would be 'includes vitamin C, which supports your immune system'. Any of these claims will only be acceptable where the nutritionally or physiologically positive effect has been proven by generally accepted scientific evidence, where the nutrient or substance in question is actually present (or absent) in the final food in a quantity that allows for the beneficial effect; that the nutrient or substance is contained in a form that is bioavailable and, also, that it can reasonably expected from a consumer to actually ingest enough of the food to generate the positive effects.[98]

For most personalised foods, health claims would be the most commercially interesting statement to make as personalised nutrition is aimed at maintaining or improving health of an individual.[99] The legislation makes a distinction between different types of health claims, which either are function claims (Art. 13), disease risk reduction claims (Art. 14(1)) or children's development claims (Art. 14(1)). Any information to final consumers referring the impact of a nutrient or substance contained in the food on (a) growth, development and functions of the human body; (b) any psychological as well as behavioural functions; and (c) loosing or controlling bodyweight or hunger reduction/suppression, as well as reduction of energy (in the sense of caloric value); will constitute function claims under Article 13. These claims can only be used where they are contained in the list of authorised health claims,[100] while inclusion of additional claims has to be applied for on the basis of newly generated scientific evidence (Article 13(5)).

Disease risk reduction claims (Art. 14(1)), are claims which explicitly or implicitly attribute the significant reduction of a risk factor to the development of a human disease to consuming a food (ingredient).[101] Especially with regard to these disease risk reduction claims, one has to again regard the borderline to medicinal products: since most diseases are multifactorial – they are likely to be caused by a combination of factors – a food or functional ingredient can only be claiming to positively affect one risk factor in disease development. The positive effect on this risk factor for the development or progress of the disease can then be connected to the reduced risk of

[97] Art. 2(2)(5), NHCR.
[98] Art. 5, NHCR.
[99] Adams supra, note 11; Ordovas supra, note 5., p. 1.
[100] Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and ot children's development and health, OJ L 136, 25.5.2012, p. 1–40.
[101] Art. 2(2)(6), NHCR.

developing the disease itself. Thus, coming back to the plant sterol example, the claim may not be 'plant sterols prevent heart disease', but 'plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.'[102] If the consumption of the food (ingredient) would be immediately suggested to reduce the risk on disease (without clearly stipulating the single risk factor affected by the food), the product would be seen as a medicinal product by presentation. Related to that food-medicine borderline is the requirement for any disease risk reduction claim to be accompanied by a statement which clarifies that a disease is always multifactored and that changing one of these factors can, but does not necessarily have a beneficial effect.[103]

The use of a nutrition or health claim is only possible in a specifically delimited setting, providing that a health claim cannot be 'false, ambiguous or misleading', but also comparative statements about other food cannot be made in a way that makes consumers question the safety or nutritional value of other food.[104] In addition to the requirements stated above, for health claims specifically, it is prohibited to imply that not consuming the food in question would negatively affect health, to indicate an amount of rate of weight loss and, finally, to make claims referring to statements of individual doctors or other health professionals.[105] Further requirements include that the following needs to be included on the label: a statement on the importance of a varied and balanced diet; how much of and in which way the food in question needs to be consumed in order to reach the effects claimed; if applicable, information on who should not consume the food; and, finally also a statement on potential health risks.[106] Any reference to benefits of the product to health in general (such as "good for you" or "healthy") or health-related well-being, can only be made where they are accompanied by a health claim included in the list.[107] Thus, with regard to personalised food the remit to make claims on positive health effects is severely limited. Overstepping these limits would mean that the claims made would be illegal, or might even push the product over the borderline which then needs to be regulated as medicinal product. Moreover, whereas personalised foods can already make use of currently authorised health claims, and for specific nutrients that affect bodily functions or a risk factor for disease in the general population an authorisation request can be submitted under Article 13(5) or

[102] Commission Regulation (EU) No 384/2010 of 5 May 2010 on the authorisation and refusal of authorisation of certain health claims made on foods and referring to the reduction of disease risk and to children's development and health, *OJ L 113, 6.5.2010, p. 6–10.*
[103] Art 14(2), NHCR.
[104] Art. 3(a) and Art. 3(b) NHCR, jo. Art. 9 NHCR.
[105] Art. 12 NHCR.
[106] Art. 10 NHCR.
[107] Art. 10(3) NHCR.

Article 14(1)(a), some questions with regard to the approval of health claims remain, specifically related to single effects highlighted in claims, the use of genetic predisposition as risk factor for disease development, and target groups for claims.

Firstly, personalised nutrition focusses on developing foods that are tailored to positively affect a group of consumers or an individual, based on their personal needs, which are therefore expected to not just affect one but rather multiple biomarkers. However, health claims can only address one relationship between a single nutrient and a single effect currently.[108] Whereas personalised nutrition should make use of a combination of different insights, into for example genetic, phenotypic, clinical and dietary information[109], it can thus be questioned whether such information can be transferred to consumers within one health claim.

Health claims can address how an ingredient can positively affect a bodily function or how it can reduce a single risk factor in the development of a disease. To substantiate the effect of a personalised nutrition product on a bodily function under an Article 13(5) claim, scientific evidence should be generated into how an ingredient would affect genes in such a way that normal functions are maintained or supported.[110] For disease risk reduction claims (Article 14(1)) on personalised nutrition, the effect of a nutrient on the genetic predisposition for a disease would need to be accepted as a risk factor for disease development. Other, currently authorised disease risk reduction claims focus on the role of a nutrient in affecting the nutritional status of an individual (such as the bone mineral density) or blood plasma levels of nutrients (lowering LDL cholesterol), both seen as risk factors in the development of a specific disease. No claim has yet been submitted which suggests that a nutrient can affect the genetic predisposition to the development of a specific disease, and it thus unkown whether this will fall within the remit of disease risk reduction claims or again will be interpreted as a medicinal claim. However, as put forward by Ballke & Meisterernst, communicating the health benefits of a product based on this nutrigenomic information seems to be essential for the success of such personalised products.[111]

---

[108] Art. 2, Commission Regulation 353/2008.

[109] K. Grimaldi et al., "Proposed guidelines to evaluate scientific validity and evidence for genotype-baseddietary advice", (2017) 12(35) *Genes & Nutrition* 1, pp. 2-3.

[110] For further analysis: I. Pravst et al., "Recommendations for successful substantiation of new health claims in the European Union", (2018) 71 *Trends in Food Sci Technol* 259; A. de Boer, E. Vos and A. Bast, "Implementation of the nutrition and health claim regulation – The case of antioxidants", (2014) 68 *Regul. Toxicol. Pharmacol* 475.

[111] Ballke and Meisterenst supra, note 15, p. 18.

Furthermore, personalised products are meant for specific individuals (or groups of individuals with similar traits) that would benefit from a product. Importantly, for any food it is prohibited to explicitly state or in some form imply that sufficient nutrients cannot be derived from a balanced and varied diet, unless it concerns nutrients which have been identified as lacking – for example in a specific region - in the context of the Regulation.[112] Meisterernst, however, describes that this prohibition refers to the required quantities of nutrients in a balanced and varied diet in general, but that claims of nutritional deficiency or 'extra needs' may be permissible in special situations.[113] This would open the door for such claims in the context of personalised nutrition, for people in specific situations like sports people or pregnant women.

This relates to the use of target groups for claims: When the described health benefit is not necessarily beneficial for the general population but merely addresses a specific subgroup, this needs to be specified in the conditions of use of a proposed claim.[114] The Member State to whom the authorisation request is submitted is responsible for reviewing whether a certain subgroup of the population can be seen as target population for a claim.[115] Neither in the Nutrition and Health Claims Regulation, nor in any other legislative documents, specifications are however provided for when a certain subpopulation would be admissible as target group for a claim.

When in a claim's conditions of use a target group is specified, it affects the assessment of its scientific substantiation. In those cases where the health effect is deemed relevant for a specific target population, based on age, sex, lifestyle or physiological conditions, the scientific evidence for the claim must be gathered by studying the proposed health effect in individuals that are representative of this subpopulation.[116] Only when health effects are reported in the subpopulation, or when the results can be extrapolated to this subpopulation, the findings can be used to support a proposed claim.[117] EFSA's guidance seems to imply that a subgroup can be based on different characteristics or traits. Various references to subgroups relate to demographics (including age), lifestyle characteristics (being an athlete) and sometimes phenotypic traits (suffering from mild to moderate hypercholesterolaemia). Nonetheless, there is no indication of whether (and when) individual differences such as

[112] Art. 3(2)(d), NHCR.
[113] A. Meisterernst, *Health & Nutrition Claims* (Berlin, 2010), p. 69.
[114] Art. 6(a), Commission Regulation 353/2008.
[115] Art. 7(a), Commission Regulation 353/2008; European Food Safety Authority, "General scientific guidance for stakeholders on health claim applications", (2016) 14 *EFSA Journal* 4367, p. 8.
[116] European Food Safety Authorithy supra, note 116, p. 7 & 15.
[117] Ibid., p. 18.

genotypic traits would be accepted as basis for a subgroup by the risk manager. Claims that are even more personalised, purely individual health claims, do not seem to be foreseen by the current regulation at all.

The Nutrition and Health Claims Regulation therefore places strict conditions on the communication of health benefits of foods. While personalised foods could use health claims relating to single nutrients, targetting larger subgroups of the population, it can be questioned to what extent the actual health benefits of a fully personalised product can be communicated to individual consumers. In this regard, further regulatory and sceintific clarification is required on the possibility to communicate effects on multiple biomarkers and genetic predisposition to diseases. Moreover, uncertainty persist concerning the definition of potential target groups.

V. Conclusions and Outlook

Personalised nutrition is a multi-faceted phenomenon that encompasses testing services, nutrition advice as well as the personalisation of different kinds of food, and sometimes even a combination of all these components. Moreover, the personalisation can follow varying "levels" of individualisation, using demographic and lifestyle-related, phenotypic and/or genotypic information. The broad definition of personalised nutrition and the fact that a wide range of activities and products come into play in personalised nutrition, has resulted in quite fragmented legislation. Many legal requirements address the separate aspects that fall within the remit of personalised nutrition: consumer protection on health and lifestyle advice is dealt with in distinct legal acts, and the gathering and handling of data and information on consumers (and patients) is regulated by separate regulations and directives. In the dimension of personalised nutrition advice and services (and the data and information required for that), the boundaries between health and lifestyle start to blur. This leads to uncertainty for those working in the field, for whom it might not necessarily be clear which rules and regulations to follow. In the gathering of data needed for personalised nutrition, the GDPR applies and introduces a special regime for health data which is deemed to be sensitive data. Nevertheless, producers, service providers and also consumers might not be as vigilant as in a more lifestyle related context than a clearly medical one. Moreover, with an increase in personal data shared, processed, and combined, more and more information allows for drawing conclusions about a person's health status and, therefore, constitutes health data. Also for the medical devices used to gather information, even if they are extensively regulated, the characterisation as medical device hinges on an intended medical use, which creates a grey area for devices used in personalised nutrition.

Overall, it became clear that the absence of a specific regulatory framework does not mean that the phenomenon is unregulated. On the contrary, personalised nutrition falls within the scope of various existing legal instruments, the application of which will differ with regard to the type of personalised nutrition product, service or advice in question. However, in general, the regulatory requirements are stricter for health than for lifestyle products and services, which creates grey areas, not only for personalised nutrition but also for other areas like the gathering of health data in wellness apps or the marketing of genetic testing to consumers. This increasingly blurred borderline requires attention of policy-makers in order to provide clear regulatory structures for businesses as well as consumers.

Our food law analysis shows that even though safety of products could be of concern for specific non-target groups of personalised foods, the information requirements currently established in EU food law should be able to ensure that "health sensitive" and vulnerable consumers are sufficiently informed. Information is also key when ensuring that the communicated health benefits are sufficiently targeted to those groups that have been proven to benefit from consuming the product, but the risk of misleading health claims is highly reduced by the claims regulation already in place. However, our analysis also reveals that although the regulatory framework itself sets clear delimitations concerning the efficacy of personalised nutrition and the potential use of health claims for such products, the approach to the underlying scientific evidence required to obtain health claims needs to be developed further and adjusted to the unique challenges of personalised nutrition. To ensure that these innovative insights from nutritional and health sciences can be translated into actual consumer benefits, such clarifications and adjustments will be key. While consumers do not need to be protected by specific regulation for personalised nutrition, clearer guidance on the limits of potential claims would enable to increase the potential postitive effects of personalised nutrition on public health, yet ensuring that consumers are not mislead. Thus, there seems to be no need for legislative action, but rather for further scientific and regulatory guidance within the existing legislative framework. This approach of "recombinant regulation"[118] as Ellen Stokes calls it, is not a rare occurrence in risk regulation in the European Union, an often can provide a adequate framework to deal with innovative technologies and current societal challenges by applying existing legislation.

[118] E. Stokes, "Recombinant Regulation: EU Executive Power and Expertise in Responding to Synthetic Biology" in M. Weimer and A. de Ruijter, *Regulating Risks in the European Union: The Co-production of Expert and Executive Power* (Oxford, 2017), pp. 59-79.

Reference list

S. Adams et al., "Perspective: Guiding principles for the implementation of personalized nutrition approaches that benefit health and function", (2020) 11 *Advances in Nutrition* 25.

J. Ahlgren et al., "Consumers on the Internet: ethical and legal aspects of commercialization of personalized nutrition", (2013) 8 *Genes & nutrition* 349.

C. Altenstetter and G. Permanand, "EU Regulation of Medical Devices and Pharmaceuticals in Comparative Perspective", (2007) 24 *Review of Policy Research* 390.

C. Ballke and A. Meisterernst, "Nutrigenomics - A New Trend from a Legal Perspective", (2014) 7 *Eur Food &Feed L Rev* 14.

B. Bigliardi and F. Galati, "Innovation trends in the food industry: The case of functional foods" (2013) 31 *Trends Food Sci Technol* 118.

A. de Boer, E. Vos and A. Bast, "Implementation of the nutrition and health claim regulation – The case of antioxidants", (2014) 68 *Regul. Toxicol. Pharmacol* 475.

D. Castle and N. Reis, "Ethical, legal and social issues in nutrigenomics: The challenges of regulating service delivery and buildinghealth professional capacity", (2007) 662 *Mutation Research* 138.

N. Chowdhury, *European Regulation of Medical Devices and Pharmaceuticals – Regulatee Expectations of Legal Certainty* (Heidelberg, 2014).

L. Ferguson et al., "Guide and Position of the International Society of Nutrigenetics/Nutrigenomics on Personalised Nutrition: Part 1 – Fields of Precision Nutrition" (2016) *J Nutrigenet Nutrigenomics* 12.

H. Forster, M.C. Walsh, M.J. Gibney, L. Brennan, E.R. Gibney, "*Personalised nutrition: the role of new dietary assessment methods",*(2016) *Proc Nutr Soc* 75.

N. Georgiou, J. Garssen and R. Witkamp, "Pharma–nutrition interface: The gap is narrowing" (2011) 651 *Eur J Pharmacol* 1.

M.J. Gibney & M.C. Walsh*, "The future direction of personalised nutrition: my diet, my phenotype, my genes"*, (2013) *Proc Nutr Soc* 72, p. 221.

Grimaldi et al., "Proposed guidelines to evaluate scientific validity and evidence for genotype-baseddietary advice", (2017) 12(35) *Genes & Nutrition* 1.

J. Hesketh, I. Wybranska, Y. Dommels, M. King, R. Elliott, C. Pico, J. Keijer, "Nutrient-gene interactions in benefit-risk analysis", (2006) *Br. J. Nutr* 95.

L. Kalokairinou et al., "Legislation of direct-to-consumer genetic testing in Europe: a fragmented regulatory landscape", (2018) 9 *J Community Genet* 117.

D. Kromhout, C.J.K. Spaaij, J. de Goede, R.M. Weggemans, "The 2015 Dutch food-based dietary guidelines", (2016) 70 *Eur J Clin Nutr* 869.

F. Lucivero and B. Prainsack, "The lifestylisation of healthcare? 'Consumer genomics' and mobile health as technologies for healthy lifestyle", (2015) 4 *Applied & Translational Genomics* 44.

J. Mathers, "Paving the way to better population health throughpersonalised nutrition", (2019) 17 EFSA Journal 1, p. 7.

A. Meisterernst, *Lebensmittelrecht* (München, 2019).

M. Ordovas, L.R. Ferguson, E. Shyong Tai, J.C. Mathers, "Personalised nutrition and health" (2018) *BMJ* 361, p.1.

A. Phillips, "Only a click away — DTC genetics for ancestry, health, love…and more: A view of the business and regulatory landscape", (2016) 8 *Applied & Translational Genomics* 16.

I. Pravst et al., "Recommendations for successful substantiation of new health claims in the European Union", (2018) 71 *Trends in Food Sci Technol* 259.

N. Purtova, "Health data for common good: Defining the boundaries and social dilemmas of data commons", in S. Adams, N. Purtova, & R. Leenes (Eds.), *Under observation: : The interplay between eHealth and surveillance* (Springer International, 2016), pp. 177-210.

P. Reilly and R. DeBusk, "Ethical and legal issues in nutritional genomics", (2008) 108 *J Am Diet Assoc* 36.

B. de Roos, "Personalised nutrition: ready for practice?" (2012) 72(1) *Proc Nutr Soc* 48; R. Fallaize et al., "An insight into the public acceptance of nutrigenomic-basedpersonalised nutrition" (2013) 26 *Nutr Res Rev* 39.

L. Snyder, "Health Communication Campaigns and Their Impact on Behavior", (2007) 39(2) *J Nutr Educ Behav* 32.

E. Stokes, "Recombinant Regulation: EU Executive Power and Expertise in Responding to Synthetic Biology" in M. Weimer and A. de Ruijter, *Regulating Risks in the European Union: The Co-production of Expert and Executive Power* (Oxford, 2017), pp. 59-79.

J. Toro Martin et al., "Precision Nutrition: A Review of Personalized Nutritional Approaches for the Prevention and Management of Metabolic Syndrome" (2017) 9 N*utrients* 913.

H. Verhagen et al., "Status of nutrition and health claims in Europe", (2010) 501 *Arch Biochem Biophys*.

Other sources:

European Food Safety Authorithy, "Scanning the Food Safety Environment - EFSA's Strategic Environmental Scan Report" (2019), available via: https://www.efsa.europa.eu/sites/default/files/EFSA_Environmental_Scan_Report_2019.pdf, last accessed:11/12/2020.

European Food Safety Authority, Scientific Opinion on the substantiation of a health claim related to 3 g/day plant sterols/stanols and lowering blood LDL-cholesterol and reduced risk of (coronary) heart disease pursuant to Article 19 of Regulation (EC) No 1924/2006, (2012) 10 *EFSA Journal* 2693.

Food4Me project, "Personalised nutrition: paving a way to better population health - A White Paper from the Food4Me project", (2015) via: https://www.researchgate.net/publication/317012773_White_paper_on_personalised_nutrition_-_paving_a_way_to_better_population_health, last accessed: 11/12/2020.

Standing Committee on the Food Chain and Animal Health, Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19, and 20 of Regulation 178/2002, p. 9, via: https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf, last accessed: 11/12/2020.

PERSONALISED NUTRITION: THE EUROPEAN UNION'S FRAGMENTED LEGAL LANDSCAPE AND THE OVERLOOKED IMPLICATIONS OF EU FOOD LAW

Sabrina Röttger-Wirtz, Assistant Professor of EU Law
s.roettger-wirtz@maastrichtuniversity.n

Alie de Boer, Assistant Professor - Food Claims Centre Venlo
a.deboer@maastrichtuniversity.nl

MAASTRICHT UNIVERSITY

Working on Europe Paper Series - Paper Number *2/2021*

ISSN: 2589-2398

Website: www.maastrichteurope.nl/research/working-papers

MWOE / Studio Europa: www.maastrichteurope.nl

CERiM: https://cerim.maastrichtuniversity.nl/

Contact us: papers@maastrichteurope.nl

Working on Europe Paper Series (WEPS)