The personality of personalized nutrition: obtaining consumers' consent in an ethical way



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Abstract

The emerging science of nutriomics applies omics technologies to explore the interaction between diet and biological variation in humans. Personalized nutrition advice based on nutrigenomic information is offered as a direct-to-consumer (DTC) service on the internet. Dealing with sensitive data related to health, personalized nutrition services require consumers' explicit consent according to the General Data Protection Regulation (GDPR). This research discusses how the GDPR could govern DTC personalized nutrition services in an ethical way. Ethical standards for obtaining informed consent in a medical setting are applied to the context of personalized nutrition, according to five essential elements (competence, disclosure, understanding, voluntariness and consent) and three approaches (tiered, layered and staged) related to informed consent. The integration of ethical standards with GDPR requirements shows severe limitations in the current GDPR approach. Within the consent procedure, the GDPR insufficiently assesses consumers' competence, disregards the disclosure of important health-related information, does not facilitate consumers' understanding and allows undesirable positive influencing. On top, the GDPR's broad interpretation of research enables commercial exploitation of nutriomic data. The inadequate consent procedure puts consumers' privacy and health at risk of being harmed. Potential solutions are discussed for a more ethical governance of DTC personalized nutrition services.

Key words: *informed consent, data protection, General Data Protection Regulation, privacy, ethics, direct to consumer, personalized nutrition, nutrigenomics, nutriomics*

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List of Abbreviations

DPD	Data Protection Directive
DTC	Direct-to-consumer
EDPB	European Data Protection Board
EU	European Union
FIR	Food Information Regulation
GDPR	General Data Protection Regulation
GFL	General Food Law
HIPAA	Health Insurance Portability and Accountability Act
IVDMD	In Vitro Diagnostic Medical Devices
NHCR	Nutrition and Health Claims Regulation
UCPD	Unfair Commercial Practices Directive
UCTD	Unfair Contract Terms Directive

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Chapter 1: Introduction

1.1 Background

Personalized nutrition aims to formulate tailor-made dietary and lifestyle recommendations that are more precise than population-level recommendations[1]. It is expected that the personalization of dietary advice will result in more effective behaviour changes[2] and will contribute to the prevention and treatment of diet-related diseases[3]. Personalized nutrition could be based on the analysis of current behaviour (e.g. dietary habits), as well as on the biological characteristics of an individual[4].

One component of personalised nutrition is genomics- and genetics-based ('nutrigenomics'), which focuses on the interactions between nutrients and genes[5]. Relatively small variations in the DNA can significantly change a person's genetic susceptibility to certain complex diseases[6]. While genetics is an important component, it only explains a part of the variation in people's responses to specific food-derived nutrients. The application of other 'omics' technologies, such as epigenomics, transcriptomics, proteomics and metabolomics (Figure 1), is therefore suggested to obtain more comprehensive and accurate recommendations[7,8].

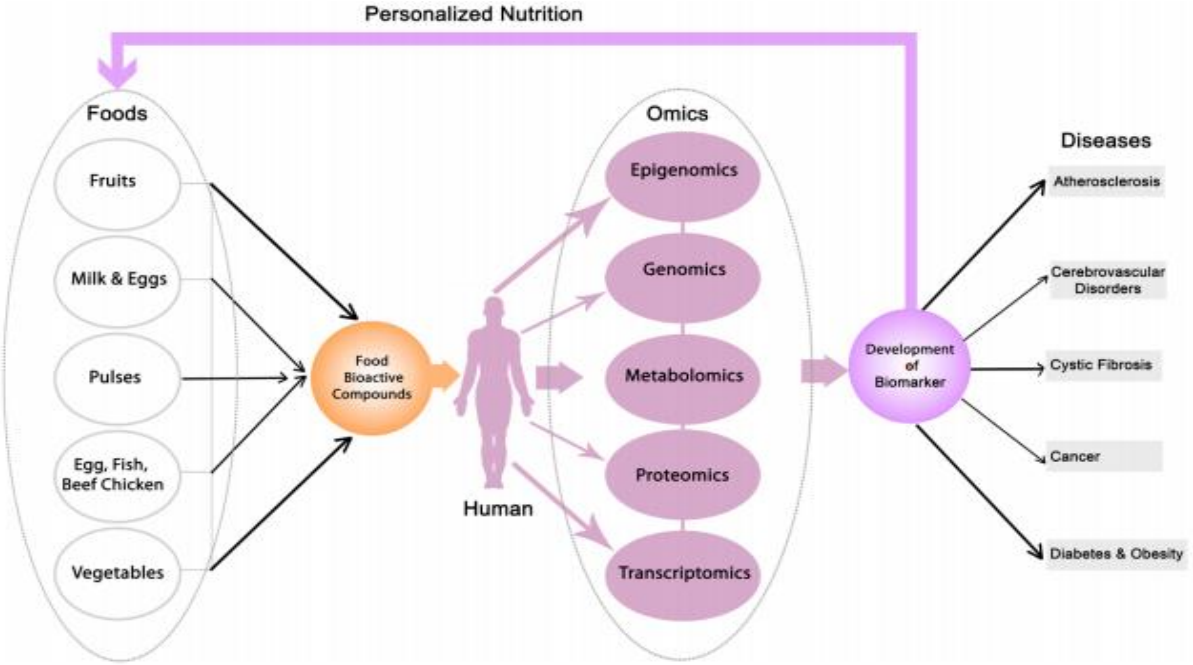


Figure 1: The use of omics technologies in personalized nutrition to study the nutrient-gene interactions with associated biomarkers and diet-related diseases (from Vyas et al, 2018)

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[1] John C Mathers, "Paving the Way to Better Population Health through Personalised Nutrition," *EFSA Journal* 17 (2019).
[2] Carlos Celis-Morales, Jose Lara, and John C Mathers, "Personalising Nutritional Guidance for More Effective Behaviour Change," *Proceedings of the Nutrition Society* 74, no. 2 (2015).
[3] Martin Kohlmeier et al., "Guide and Position of the International Society of Nutrigenetics/Nutrigenomics on Personalized Nutrition: Part 2-Ethics, Challenges and Endeavors of Precision Nutrition," *Lifestyle Genomics* 9, no. 1 (2016).
[4] Jose M Ordovas et al., "Personalised Nutrition and Health," *bmj* 361 (2018).
[5] Jim Kaput, "Nutrigenomics Research for Personalized Nutrition and Medicine," *Current opinion in biotechnology* 19, no. 2 (2008).
[6] Lynette R Ferguson, Martin Philpott, and Matthew PG Barnett, "Nutrigenomics: Integrating Genomic Approaches into Nutrition Research," in *Molecular Diagnostics* (Elsevier, 2010).
[7] Marta Guasch-Ferré, Hassan S Dashti, and Jordi Merino, "Nutritional Genomics and Direct-to-Consumer Genetic Testing: An Overview," *Advances in Nutrition* 9, no. 2 (2018).
[8] Pritesh Vyas et al., "Nutrigenomics: Advances, Opportunities and Challenges in Understanding the Nutrient-Gene Interactions," *Current Nutrition & Food Science* 14, no. 2 (2018).

The field of personalized nutrition is rapidly evolving[9] and it is expected that the advice will increasingly be based on the integration of different omics technologies[10]. This thesis therefore adopts *nutriomics* as a general definition of the discipline, encompassing the integration of nutrition with various omics technologies.

Currently, nutriomics-based personalized nutrition services are often provided in a direct-to-consumer (DTC) model, in which testing can be undertaken without necessarily involving a health care professional[11]. Typically, this model involves a company advertising and selling on the internet. Consumers receive a test kit and send a swab or saliva sample to the company, together with some personal and lifestyle information. The company performs an analysis of the nutriomic information and provides individual nutritional advice to the consumer[12]. While individual nutrition advice seems promising, various legal and ethical obstacles need to be tackled first before nutriomic-based personalised nutrition services can be introduced on a wide scale.

1.2 Problem context

In the context of DTC delivery, personalized nutrition finds itself at the boundary between medicine and consumer culture[13]. On the one hand, it is common for nutriomic companies to add extensive disclaimers to prevent any medical association or liability. The genetic tests are claimed not to be for medical purposes[14]. Health-care professionals are usually not involved and genetic counselling is often not provided[15]. On the other hand, promises are made with pretentious formulations such as 'empowerment' and 'identity', suggesting that consumers would gain major health benefits from the genetic testing[16].

The mixed medical-commercial nature of personalized nutrition creates critical legal and ethical issues. In the delivery of personalized nutrition advice, a company gathers a large quantity of personal information related to the health of the consumer. Promising as the application of omics data may be to contribute to individual health objectives, personalized nutrition comes with risks related to confidentiality, transparency and reliability[17]. The ambiguity of health promises along with a questionable trustworthiness of personalized nutrition services hinders consumers to achieve their health goals[18]. Misinterpretation of the advice may cause harm in the form of confusion, anxiety and

[9] Amber Ronteltap et al., "Nutrigenomics-Based Personalised Nutritional Advice: In Search of a Business Model?," *Genes & nutrition* 8, no. 2 (2013).
[10] Lynnette R Ferguson, *Nutrigenomics and Nutrigenetics in Functional Foods and Personalized Nutrition* (CRC Press, 2016).
[11] David Castle and Nola M Ries, "Ethical, Legal and Social Issues in Nutrigenomics: The Challenges of Regulating Service Delivery and Building Health Professional Capacity," *Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis* 622, no. 1 (2007).
[12] Ibid.
[13] Paula M Saukko et al., "Negotiating the Boundary between Medicine and Consumer Culture: Online Marketing of Nutrigenetic Tests," *Social science & medicine* 70, no. 5 (2010).
[14] Anders Nordgren, "Neither as Harmful as Feared by Critics nor as Empowering as Promised by Providers: Risk Information Offered Direct to Consumer by Personal Genomics Companies," *Journal of community genetics* 5, no. 1 (2014).
[15] Juan María Martínez Otero, "'"Better Not to Know?": Justifiable Limits on the Right to Information in the Realm of Dtc Genetic Testing. An Analysis of the European and Spanish Legal Framework," *European journal of health law* 24, no. 2 (2017).
[16] Jennie Ahlgren et al., "Consumers on the Internet: Ethical and Legal Aspects of Commercialization of Personalized Nutrition," *Genes & nutrition* 8, no. 4 (2013).
[17] Karin Nordström et al., "Values at Stake: Autonomy, Responsibility, and Trustworthiness in Relation to Genetic Testing and Personalized Nutrition Advice," ibid.
[18] Ulf Görman, "Ethical Issues Raised by Personalized Nutrition Based on Genetic Information," ibid.1, no. 1 (2006).

false reassurance[19].The way ethical concerns are addressed largely shapes the public acceptance of personalized nutrition. Consumers consider the ownership and sharing of data with companies as a major ethical issue[20]. The use of branded food products within personalized nutrition advice has been received critically[21]. A normative perspective on personalized nutrition is therefore needed before the adoption of personalized nutrition can be fully embraced.

Getting consent from consumers forms a major challenge in personalized nutrition services, since the consent procedure is decisive for consumers' ability to make informed decisions. In the European Union (EU), companies are obliged to ask consumers consent for the processing of their data according to the rules of the General Data Protection Regulation (GDPR)[22]. Since nutriomic DTC companies are dealing with sensitive data related to health, explicit consent from the consumer needs to be asked. The GDPR, in force since May, 2018, lays down the rules on the good use and confidentiality of data[23].

Currently, the compliance of personalized nutrition services with the GDPR is still in its infancy. The company '23andMe', one of the major personal genomics companies, refrained from asking consumers' consent for data processing outside the context of research activities[24]. Even for the consent to the research part, there was no option to withdraw consent[25]. Consequently, consumers are not aware if their data are sold to third parties, let alone are they able to revoke this development. Potential misuse could lead to sensitive personal data ending up in the wrong hands[26]. This stresses the need of a better understanding of the application of the GDPR to personalized nutrition.

To facilitate adequate consent of nutriomic testing, it is crucial to assess to which extent the GDPR follows ethical standards. An ethical analysis should gather insight into how consumer's consent could be obtained in a morally justified way. Given the medical component of DTC personalized nutrition services, a comparison between consent as defined in the GDPR and informed consent in medical practice is of particular significance[27,28]. The biomedical practice of informed consent is justified by ethical principles of autonomy (self-governance)[29], beneficence (acting in the best interest of the patient) and non-maleficence (avoidance of harm)[30,31,32]. Based on these ethical standards, it is possible

[19] Amanda Singleton et al., "Informed Choice in Direct-to-Consumer Genetic Testing (Dtcgt) Websites: A Content Analysis of Benefits, Risks, and Limitations," *Journal of genetic counseling* 21, no. 3 (2012).
[20] Sonja Wendel, "Situation Variation in Consumer Benefit Salience: Theory and Implications for Consumer-Firm Interaction in the Health Domain" (Maastricht University, 2007).
[21] Ibid.
[22] General Data Protection Regulation.
[23] Ibid.
[24] Kärt Pormeister, "Informed Consent to Sensitive Personal Data Processing for the Performance of Digital Consumer Contracts on the Example of "23andme"," *Journal of European Consumer and Market Law* 6, no. 1 (2017).
[25] Ibid.
[26] Emilia; Kalokairinou Niemiec, Louiza; Howard, Heidi Carmen, "Current Ethical and Legal Issues in Health-Related Direct-to-Consumer Genetic Testing," *Personalized medicine* 14, no. 5 (2017).
[27] Eline M Bunnik, A Cecile JW Janssens, and Maartje HN Schermer, "A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing," *European Journal of Human Genetics* 21, no. 6 (2013).
[28] Cecile JW Janssens; Eline M Bunnik; Wylie Burke; Maartje HN Schermer, "Uninformed Consent in Nutrigenomic Research," ibid.25, no. 7 (2017).
[29] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics* (Oxford University Press, USA, 2001).
[30] Kenneth G Marshall, "Prevention. How Much Harm? How Much Benefit? 4. The Ethics of Informed Consent for Preventive Screening Programs," *CMAJ: Canadian Medical Association Journal* 155, no. 4 (1996).
[31] Neil C Manson and Onora O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge University Press, 2007)., page 186
[32] Julius Sim, "Addressing Conflicts in Research Ethics: Consent and Risk of Harm," *Physiotherapy Research International* 15, no. 2 (2010).

to assess which characteristics of informed consent in medical practice are essential for giving consent in DTC personalized nutrition services. Consequently, the objective of this thesis is to examine how nutriomic-based DTC personalized nutrition services should be governed by data protection regulation at the EU level. This requires an assessment of an ethical benchmark on informed consent and an understanding on which rules are required by GDPR.

1.3 Research questions

The main research question is:

> *How to design the General Data Protection Regulation in order to govern nutriomic-based direct-to-consumer personalized nutrition services in an ethical way?*

The main question is to be answered through three sub-questions:

1. Which ethical standards are appropriate for obtaining informed consent in nutriomic-based direct-to-consumer personalised nutrition services?
2. Which requirements of the General Data Protection Regulation need to be fulfilled for the offering of nutriomic-based direct-to-consumer personalized nutrition services?
3. How do the requirements of the General Data Protection Regulation fulfil the ethical standards on informed consent?

1.4 Research methods

Considering the multidisciplinary scope of this thesis, a combination of legal and ethical research methods will be used to address the research questions.

Question 1 is answered by an assessment of the characteristics of GDPR consent and informed consent in medical practice. This is complemented by applying the principles approach of beneficence, non-maleficence, autonomy and justice[33] to nutriomic-based DTC personalized nutrition services.

Question 2 is answered by applying a doctrinal legal research. The GDPR is interpreted for the application of personalized nutrition. The doctrinal analysis is complemented by guidelines of the Article 29 Working Party (now called European Data Protection Board).

Question 3 is answered by analysing Question (1) and Question (2) , comparing the ethical and legal analysis on governing personalized nutrition services.

1.5 Research outline

The various steps of this thesis are illustrated in Figure 2, providing an overview of the different chapters and their interrelationships.

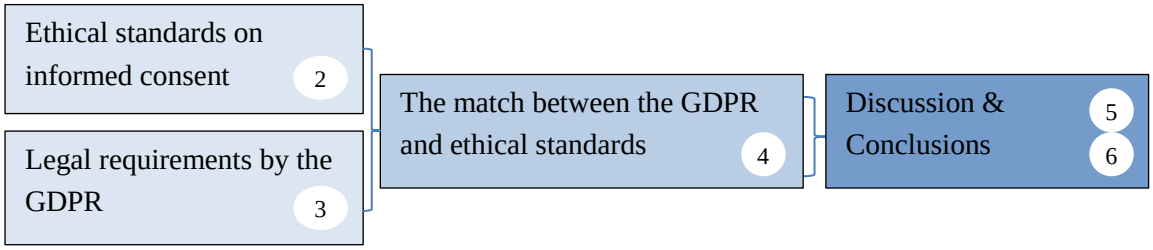


Figure 2: Schematic research outline (numbers corresponding to the chapters)

[33] Tom L Beauchamp, "The 'Four Principles' Approach to Health Care Ethics," in *Principles of Health Care Ethics* (2007).

Chapter 2 is dedicated to an ethical perspective on personalized nutrition services. Insights are drawn from the concept of informed consent in the medical world. An ethical analysis on the justification of using informed consent for nutriomic-based DTC personalized nutrition services, based on principles of beneficence, non-maleficence and autonomy.

Chapter 3 will introduce the legal part of the research. A doctrinal analysis on the General Data Protection Regulation will discuss the processing of data in personalized nutrition services in relation to the scope, the categorization of nutriomic data into genetic and health data, the conditions for consent and the conditions for further processing of nutriomic data under the research exemption.

Chapter 4 will combine the legal and ethical insights by mirroring the GDPR requirements to the ethical standards on personalized nutrition services.

Chapter 5 will discuss possible reasons behind similarities and differences between the GDPR requirements and ethical standards. Possible solutions to overcome the gaps will be explored, along with recommendations for future research on the governance of nutriomic-based DTC personalized nutrition services.

Chapter 6 will summarize the conclusions on how to design the GDPR to govern nutriomic-based DTC personalized nutrition services in an ethical way.

Chapter 2: Towards full informed consent for personalized nutrition

The purpose of this chapter is to assess which ethical requirements are appropriate for obtaining informed consent in nutriomic-based DTC personalised nutrition services. A comparison is made between the legal, data-oriented conception of informed consent (regulated by the GDPR) and the ethical conception on full informed consent in a medical setting. I will first explore the justification for a medical outlook on DTC personalised nutrition services. Then, the justification for full informed consent is assessed. Next, the elements for full informed consent are analysed in the context of personalized nutrition. Finally, a model for getting informed consent for nutriomic-based DTC personalized nutrition services is suggested.

2.1 Justification for a medical outlook on DTC personalized nutrition

Even though commercially-offered personalized nutrition tests strictly fall outside the domain of medicine, the adoption of a medical perspective on these services can be grounded for three reasons. Firstly, the data processed in DTC personalized nutrition has a medical nature, as it can be categorized as genetic data and/or data related to health (see Chapter 2). Advertisement of DTC personalized nutrition emphasizes its medical character, suggesting that major health benefits can be gained[34]. While personalized nutrition can be offered in specific clinical models (e.g. through a health care practitioner, through multidisciplinary health care teams or in a public health model[35]), data handlers in the DTC model do not have to adhere to medical obligations of professional secrecy. Still, the data collected in the commercial model of offering personalized nutrition advice is as health-related and sensitive as in clinical models.

Secondly, several constrains are associated with current regulations governing personalized nutrition services. This can be exemplified by limitations on the GDPR, EU consumer law (on unfair advertisement, terms and business practices), the Food Information Regulation and the regulation on In Vitro Diagnostic Medical Devices (IVDMD). The GDPR is criticized of creating consent transaction overload, information overload and an absence of meaningful choice for consumers[36]. EU consumer law on unfair advertisement, terms and business practices typically stipulates which type of information is not desired (e.g. 'a commercial practice shall be regarded as misleading if it contains false information'[37]), instead of specifying which information should be included. It is thus not compulsory to disclose certain relevant information when advertising personalized nutrition services, such as the risks and limitations of testing. Besides, neither the GDPR nor EU consumer regulations pay attention to the moral standard of ensuring consumers' comprehension of information. Next, it is unclear whether DTC personalized nutrition tests fall under the scope of the Food Information Regulation (FIR), which is directed to food business operators[38]. Food business operators are obliged to conduct fair information practices, including in advertisement and in the presentation of foods[39].

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[34] Jennie Ahlgren et al., "Consumers on the Internet: Ethical and Legal Aspects of Commercialization of Personalized Nutrition."

[35] David Castle et al., *Science, Society, and the Supermarket: The Opportunities and Challenges of Nutrigenomics* (John Wiley & Sons, 2006).

[36] Bart W Schermer, Bart Custers, and Simone van der Hof, "The Crisis of Consent: How Stronger Legal Protection May Lead to Weaker Consent in Data Protection," *Ethics and Information Technology* 16, no. 2 (2014).

[37] Unfair Commercial Practices Directive., Article 6

[38] Food Information to Consumers Regulation., Article 1(3)

[39] Ibid., Article 7

Whether nutriomic companies can be regarded as food business operators may vary per company. Some nutriomic companies may sell specific food products themselves[40], while other companies may limit themselves to the provision of broad dietary advice. The scope of the FIR for nutriomic companies thus remains ambiguous. The testing devices for DTC personalized nutrition (e.g. the kit for the examination of personal samples such as DNA and blood) are subject to the new regulation on In Vitro Diagnostic Medical Devices (IVDMD). The regulation is fully applicable from May 2022 and includes tests regarding the predisposition to a medical condition or a disease[41]. DTC tests for lifestyle purposes - under which personalized nutrition tests can be categorized – will fall under its scope[42]. However, the value of the new regulation for DTC personalized nutrition may be limited, as requirements on genetic information, counselling and informed consent are only directed towards tests in the clinical setting[43].

Thirdly, it can be argued that the nature of personalized nutrition services considerably complicates the effective governance by laws of commerce. This complexity can be captured by the tests that are criticized for their lack of clinical validity and utility[44,45]. Even though evidence of the influence of genetic factors in diet-related diseases has been found, the understanding of the mechanisms is still incomplete and few associations have been tested for causality[46]. The lack of evidence is aggravated by the fact that professional counselling is usually absent or insufficient[47,48]. And even if the information is valid, the tests produce a massive quantity of information with unforeseen future uses.[49] The information is susceptible for misinterpretation by consumers[50] and can cause health and psychological harms[51]. Altogether this severely obstructs the capacity of individuals to oversee the consequences of purchasing personalized nutrition services.

Some of these concerns have been on the table in the (drafting legislative procedure of) the IVDMD regulation. While the regulation demands clinical evidence for all types of devices, the evidence is limited to uses stated by the manufacturer[52]. This may be problematic considering the ubiquitous role of genes in a wide variety of diseases. For example, the manufacturer may only provide evidence for

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[40] Lee Bell, "The Future of Healthy Dining: A Personalized Meal Based on Your Blood," Forbes Media LLC, https://www.forbes.com/sites/leebelltech/2018/07/31/the-future-of-healthy-dining-a-personalized-meal-based-on-your-dna/#683dad874cbe.
[41] IVDMD Regulation., Article 2(2)
[42] Emilia; Kalokairinou Niemiec, Louiza; Howard, Heidi Carmen, "Current Ethical and Legal Issues in Health-Related Direct-to-Consumer Genetic Testing."
[43] IVDMD Regulation., Article 4
[44] Cristiana Pavlidis et al., "Meta-Analysis of Genes in Commercially Available Nutrigenomic Tests Denotes Lack of Association with Dietary Intake and Nutrient-Related Pathologies," *Omics: a journal of integrative biology* 19, no. 9 (2015).
[45] Keith A Grimaldi et al., "Proposed Guidelines to Evaluate Scientific Validity and Evidence for Genotype-Based Dietary Advice," *Genes & nutrition* 12, no. 1 (2017).
[46] Ulf Görman et al., "Do We Know Enough? A Scientific and Ethical Analysis of the Basis for Genetic-Based Personalized Nutrition," ibid.8, no. 4 (2013).
[47] David Castle and Nola M Ries, "Ethical, Legal and Social Issues in Nutrigenomics: The Challenges of Regulating Service Delivery and Building Health Professional Capacity."
[48] Emilia; Kalokairinou Niemiec, Louiza; Howard, Heidi Carmen, "Current Ethical and Legal Issues in Health-Related Direct-to-Consumer Genetic Testing."
[49] Vural Özdemir and Eugene Kolker, "Precision Nutrition 4.0: A Big Data and Ethics Foresight Analysis—Convergence of Agrigenomics, Nutrigenomics, Nutriproteomics, and Nutrimetabolomics," *Omics: a journal of integrative biology* 20, no. 2 (2016).
[50] Karin Nordström et al., "Values at Stake: Autonomy, Responsibility, and Trustworthiness in Relation to Genetic Testing and Personalized Nutrition Advice."
[51] T. Hurlimann et al., "Risks of Nutrigenomics and Nutrigenetics? What the Scientists Say," *Genes & Nutrition* 9, no. 1 (2013).
[52] IVDMD Regulation., Article 56

connection of the APOE gene with cholesterol levels (related to the development of cardiovascular disease), even though the gene is also related to Alzheimer[53]. Furthermore, during the ordinary legislative process the European Parliament had proposed an amendment requiring all genetic tests to come with pre-and post-genetic counselling and explicit, written informed consent[54]. However, objections were raised on account of the infringement of proportionality and subsidiarity[55] and the amendment has not been included in the final regulation. Despite the opposition, the proposals of the European Parliament are in line with the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes[56]. Even though the new IVD regulations shows potential for more effective governance of DTC genetic testing, it can be concluded that the complex features of personalized nutrition are not yet well addressed by EU legislation.

Overall, it can be rationalised that the evident medical character, inadequate regulations of commerce, and the complex features of DTC personalized nutrition services call for medical standards to come into force. The history of medicine has given direction to deal with the complexity of health-related services, drawing insights from the ethical principles of autonomy, beneficence and non-maleficence[57].

2.2 Justification for full informed consent in DTC personalized nutrition

The concept of informed consent in medical practice is of specific relevance for DTC personalized nutrition. The meaning of informed consent within the realm of the GDPR (hereafter: GDPR consent) is mainly focused on information disclosure and specifically related to data use. In contrast, informed consent in medical practice not only looks at disclosure, but also gives emphasis on other aspects, such as the comprehension of information and the nature of intervention. To distinguish between the two forms of consents, the term 'full informed consent' refers to informed consent in medical practice, because it makes more extensive demands on consent than GDPR consent.

Considering the drawbacks of using a data disclosure-oriented concept of consent, it would not harm to see whether nutriomic-based DTC personalized nutrition services are better served by full informed consent. Full informed consent is commonly justified by the respect of patient autonomy (self-governance)[58]. Besides, it is argued that a convincing justification of informed consent is also based on the ethical principles of beneficence (acting in the best interest of the patient) and non-maleficence (avoidance of harm) as well[59,60,61]. Accordingly, the functions of full informed consent can be summarized as (1) increasing the value of personal health decisions[62], (2) restricting potential negative

[53] A Cecile JW Janssens et al., "Uninformed Consent in Nutrigenomic Research," *European Journal of Human Genetics* 25, no. 7 (2017).
[54] Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on in vitro diagnostic medical devices., Amendment 271
[55] Alliance of European Life Science Law Firms, "The Competence of the European Union to Legislate in Relation to Certain Amendments Endorsed by the European Parliament in Connection with a Commission Proposal for an in Vitro Diagnostic Device Regulation.," Lawford Davies Denoon & Axon Lawyers, https://www.eshg.org/fileadmin/eshg/documents/IVD/ESHG_Opinion_19_February_2014_final.pdf.
[56] Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes., Articles 7-9
[57] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics*.
[58] Ibid.
[59] Kenneth G Marshall, "Prevention. How Much Harm? How Much Benefit? 4. The Ethics of Informed Consent for Preventive Screening Programs."
[60] Neil C Manson and Onora O'Neill, *Rethinking Informed Consent in Bioethics*., page 186
[61] Julius Sim, "Addressing Conflicts in Research Ethics: Consent and Risk of Harm."
[62] Susan S Manning and Colleen E Gaul, "The Ethics of Informed Consent: A Critical Variable in the Self-Determination of Health and Mental Health Clients," *Social work in health care* 25, no. 3 (1997).

consequences[63], (3) enabling individuals to take control of their own material(s) and data[64] and (4) limiting possible misuse or manipulation[65]. Accordingly, the justification for full informed consent is assessed by examining how these four functions are relevant for personalized nutrition.

The first function of full informed consent concerns the benefits it can bring in making personal health decisions. Decisions can be critical to the course of one's life and the impact can be difficult to oversee[66]. Full informed consent aims to facilitate the active involvement of the patient in decision-making and thereby increase the chance of a good outcome[67]. Health and lifestyle are key motives to choose for personalized nutrition[68,69]. Personalized nutrition may help people to find a diet that fulfils their nutritional needs and could assist the realization of weight loss and fitness goals[70]. The delivery of personalized nutrition services may thus improve from full informed consent by enabling consumers to achieve their health goals.

A second role of full informed consent is to decrease the risk of harm. This can be done for instance by giving a balanced, complete overview of risks and benefits of a certain health treatment[71]. Negative consequences of personalized nutrition could lie both in direct and indirect harm. Direct harm for personalized nutrition could occur when genes are tested that are associated with susceptibility to diseases. For example, nutrient-gene associations exist for cancer, diabetes, cardiovascular diseases[72] and Alzheimer[73]. Misinterpretation by the consumer can lead to psychological or physical harm, for instance by disregarding medical advice or by eating certain foods instead of taking necessary medication[74]. Arguably, the risk of indirect harm is even more relevant for personalized nutrition. Over- and under-interpretation of disease risks may cause psychological, social and health-related risks, as well as privacy related risks[75]. For example, our social relationship with food may be negatively influenced by personalized nutrition as it blurs boundaries between food and drugs[76,77]. Theoretically, this may cause the transformation of a pleasant activity such as eating into a health hazard[78]. In an extreme scenario, a bio-medicalised view on food may even exacerbate the development of eating disorders such as Anorexia Nervosa and Bulimia Nervosa. Besides, psychological risks may manifest as fears of discrimination and stigmatization, when individuals do

[63] Julius Sim, "Addressing Conflicts in Research Ethics: Consent and Risk of Harm."
[64] David Archard, "Informed Consent: Autonomy and Self-Ownership," *Journal of Applied Philosophy* 25, no. 1 (2008).
[65] Onora O'Neill, "Some Limits of Informed Consent," *Journal of medical ethics* 29, no. 1 (2003).
[66] Susan S Manning and Colleen E Gaul, "The Ethics of Informed Consent: A Critical Variable in the Self-Determination of Health and Mental Health Clients."
[67] Ibid.
[68] Rui Poínhos et al., "Psychological Determinants of Consumer Acceptance of Personalised Nutrition in 9 European Countries," *PloS one* 9, no. 10 (2014).
[69] Audrey Rankin et al., "Food Choice Motives, Attitude Towards and Intention to Adopt Personalised Nutrition," *Public health nutrition* 21, no. 14 (2018).
[70] Audrey Rankin et al., "Public Perceptions of Personalised Nutrition through the Lens of Social Cognitive Theory," *Journal of health psychology* 22, no. 10 (2017).
[71] Julius Sim, "Addressing Conflicts in Research Ethics: Consent and Risk of Harm."
[72] Jose M Ordovas and Dolores Corella, "Nutritional Genomics," *Annu. Rev. Genomics Hum. Genet.* 5 (2004).
[73] A Cecile JW Janssens et al., "Uninformed Consent in Nutrigenomic Research."
[74] Simone RBM Eussen et al., "Functional Foods and Dietary Supplements: Products at the Interface between Pharma and Nutrition," *European journal of pharmacology* 668 (2011).
[75] Eline M Bunnik, A Cecile JW Janssens, and Maartje HN Schermer, "Informed Consent in Direct-to-Consumer Personal Genome Testing: The Outline of a Model between Specific and Generic Consent," *Bioethics* 28, no. 7 (2014).
[76] Franck LB Meijboom, Marcel F Verweij, and Frans WA Brom, "You Eat What You Are: Moral Dimensions of Diets Tailored to One's Genes," *Journal of Agricultural and Environmental Ethics* 16, no. 6 (2003).
[77] Ulf Görman, "Ethical Issues Raised by Personalized Nutrition Based on Genetic Information."
[78] T. Hurlimann et al., "Risks of Nutrigenomics and Nutrigenetics? What the Scientists Say."

not succeed in complying with dietary recommendations. This is especially pertinent when the advice conflicts with social (family, gender) and cultural relationships[79,80]. Finally, indirect risks can occur with regard to the personal data that is collected. Inadequate data governance could lead to privacy issues, with potential harmful consequences for employment or insurance[81,82].

Thirdly, full informed consent brings individuals control on personal materials and data[83]. The GDPR exactly covers this aspect. Data protection as a fundamental right[84] and the importance of individuals to have control of their own personal data[85] are clearly recognized. Hence, it can be argued that the use of full informed consent may have limited added value on this aspect, even with the earlier mentioned drawbacks of the GDPR. Still, full informed consent may mitigate the information overload triggered by the disclosure requirements in the GDPR, by putting emphasis to the relevance of information for consumers.

A fourth aim of full informed consent is to restrict potential misuse or manipulation[86]. This gives patients a say over the amount of information they wish to receive and gives them the possibility to withdraw consent already given[87]. Several features make personalized nutrition services susceptible to deceptive practices: the marketing strategies that are employed, the handling of valuable, personal data and the personalization process through unknown algorithms. The marketing of nutriomic testing shapes the information provided, since its primary aim is to persuade potential customers to purchase their service. Advertisement on personalized nutrition often contains a mixed message: even though there is a disclaimer that the service is not to be used for medical purposes, the health benefits of using personalized nutrition are greatly highlighted. Sometimes, advertisement gives the misleading impression that personalized nutrition would generate medically actionable options, as was observed by the US Government Accountability Office (2010)[88]. Full informed consent emphasises the fairness of information[89] and considers a balanced representation of risks and benefits[90]. Another form of deception could lie in the undesirable circulation of personal data. The data holds valuable health information and there is usually little to no room for consumers to decide upon the terms of data access and use[91]. On top, under the pretext of future research, samples or data may be given to a wide variety of third parties. This could result in indistinct further use of the data that the consumer possibly does not consent of. Consumers generally have no clue how a nutriomic company generates the

[79] Audrey Rankin et al., "Public Perceptions of Personalised Nutrition through the Lens of Social Cognitive Theory."
[80] T. Hurlimann et al., "Risks of Nutrigenomics and Nutrigenetics? What the Scientists Say."
[81] Natalie E Zindorf, "Discrimination in the 21st Century: Protecting the Privacy of Genetic Information in Employment and Insurance," *Tulsa LJ* 36 (2000).
[82] Catherine Heeney et al., "Assessing the Privacy Risks of Data Sharing in Genomics," *Public health genomics* 14, no. 1 (2011).
[83] David Archard, "Informed Consent: Autonomy and Self-Ownership."
[84] General Data Protection Regulation., Recital 2
[85] Ibid., Recital 7
[86] Onora O'Neill, "Some Limits of Informed Consent."
[87] Ibid.
[88] United States Government Accountability Office, "Direct-to-Consumer Genetic Tests Misleading Test Results Are Further Complicated by Deceptive Marketing and Other Questionable Practices," (Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives2010).
[89] David B Resnik, "Ethical Dilemmas in Communicating Medical Information to the Public," *Health Policy* 55, no. 2 (2001).
[90] Amanda Singleton et al., "Informed Choice in Direct-to-Consumer Genetic Testing (Dtcgt) Websites: A Content Analysis of Benefits, Risks, and Limitations."
[91] Edward S Dove, "Biobanks, Data Sharing, and the Drive for a Global Privacy Governance Framework," *The Journal of Law, Medicine & Ethics* 43, no. 4 (2015).

personalized recommendations based on their data[92]. If a company does not use advanced algorithms, the services does not differ from some that were offered 10 years ago[93]. Since algorithms are often protected as intellectual property[94] , the personalization process is non-transparent and thereby prone to fraudulent practices. Consequently, full informed consent would be very welcome in order to prevent or limit deceptive practices related to personalized nutrition services.

All in all, the appropriateness of full informed consent for personalized nutrition is demonstrated in three of its four main functions. Data protection is already sufficiently covered by informed consent requirements in the GDPR, to which full informed consent may offer limited extra value. On the other hand, personalized nutrition services may benefit well from the procedure of full informed consent by enabling consumers to achieve their health goals. Besides, personalized nutrition is prone to deceptive practices (related to the marketing strategies, handling of data and use of unspecified algorithms) and to cause several forms of direct and indirect harms, both health and privacy-related. Hence, as the functions of full informed consent align well with major challenges found in personalized nutrition services, the adoption of full informed consent can be justified.

2.3 Elements of full informed consent in DTC personalized nutrition

From the perspective of biomedical ethics, full informed consent can be defined as a communicative practice in which competent patients are given adequate and clear information. If possible the information is tailored to the patient's needs, the patient's understanding of that information is verified, the patient's decision-making process is free from controlling influences and the consent is asked. Five elements can be distinguished in the definition of full informed consent: (1) competence, (2) disclosure, (3) understanding, (4) voluntariness and (5) consent[95,96]. In comparison, the concept of consent as defined by the GDPR (hereafter: GDPR consent) covers four obligations: it has to be freely given, specific, informed and be an unambiguous indication of wishes by the data subject. Next to the GDPR itself, the Article 29 Data Protection Working Party (hereafter: Art. 29 Working Party) gives guidance on the definition and use of GDPR consent[97]. The differences between the elements of full informed consent and GDPR consent are illustrated in Table 1 below.

[92] National Academies of Sciences Engineering Medicine, *Nutrigenomics and the Future of Nutrition: Proceedings of a Workshop* (National Academies Press, 2018).
[93] Ioannis Arkadianos et al., "Improved Weight Management Using Genetic Information to Personalize a Calorie Controlled Diet," *Nutrition journal* 6, no. 1 (2007).
[94] Nicole Martinez-Martin et al., "Data Mining for Health: Staking out the Ethical Territory of Digital Phenotyping," *NPJ digital medicine* 1, no. 1 (2018).
[95] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics*.
[96] Alan Meisel and Loren H Roth, "What We Do and Do Not Know About Informed Consent," *Jama* 246, no. 21 (1981).
[97] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679," (2018).page 3

Table 1: An overview of the elements of full informed consent (defined by Beauchamp and Childress, 2001[98]) and GDPR consent (defined by the Art. 29 Working Party, 2018[99])

Full informed consent	GDPR explicit consent
- **Competence**: capacity to understand the material information, to make a judgement about the information in light of their values, to intend a certain outcome and to communicate freely their wishes to care givers or investigators	Article 8: Conditions applicable to child's consent in relation to information society services
- **Disclosure**: giving a core set of information, including (1) those facts or descriptions that patients or subjects usually consider material in deciding whether to refuse or consent to the proposed intervention or research, (2) information the professional believes to be material, (3) the professional's recommendation, (4) the purpose of seeking consent and (5) the nature and limits of consent as an act of authorization	- **Specific**: Purpose specification, Granularity in consent requests, Clear separation of information related to obtaining consent for data processing activities from other information - **Informed**: Minimum content requirements
- **Understanding**: a grasp of central facts, at least what a health care professional or researcher believes a patient or subjects needs to understand in order to authorize an intervention	- **Informed**: How to provide information
- **Voluntariness**: willing the action without being under the control of another's influence	- **Freely given**: imbalance of power, conditionality, granularity, detriment
- **Consent**: the decision and authorization to proceed	- **Unambiguous indication of wishes**: an express statement of consent, such as a written and signed statement and/or a two-stage verification

The following section analyses how the elements of competence, disclosure, understanding, voluntariness and consent can be applied for getting consent in personalized nutrition services. This is done by reviewing how the elements of full informed consent are covered by GDPR consent, as guided by the Art. 29 Working Party's interpretation. Subsequently, the added value of an ethical conception of full informed consent for personalized nutrition is discussed.

2.3.1 Competence

Comparison of both forms of consent reveals that the competence element in full informed consent is largely absent in GDPR consent. Article 8 of the GDPR provides some conditions related to the competence of children to give consent. Parents are given the responsibility to consent for children

[98] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics*.
[99] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679."page 1-31

between 13 and 18 years old[100]. This leaves some questions unanswered. Firstly, the minimum age requirement of getting consent remains ambiguous. There is no uniform threshold age of consent, since individual Member States are given the freedom to decide upon a minimum age from 13 to 16 years old[101]. Besides, the enforcement by the GDPR to ensure verifiable age and consent procedures is problematic[102]. Without effective enforcement, non-consensual use by minors (falsifying parents' permission) is inevitable[103].

The question of competence is not further dealt with by the GDPR. Hence, an analysis of competence within full informed consent may provide more clarity. Within full informed consent, competence is defined as the psychological or legal capacity for adequate decision-making[104]. Health care professionals are tasked to make competence judgements. When a patient's incompetence is observed, health care professionals could act by overruling that person's decision or by inquiring surrogate decision makers[105]. The conditions a competence judgement should satisfy may vary according to the context. Grisso and Appelbaum (1998) have thus proposed a sliding-scale approach to competence. This implies that the more risk is involved, the higher the threshold for competence should be[106].

In the context of personalized nutrition advice, the risk for consumers is likely to be found in the process of understanding pertinent information related to the test and the advice. A number of psychological, societal and health-related risks have been mentioned before, often related to the over- or under-estimation of disease risks. For persons with dietary related non-communicable diseases (e.g. obesity, diabetes, cancer) or persons with eating disorders (e.g. Anorexia Nervosa, Bulimia Nervosa), specific risks may arise. For example, nutritional supplements may be recommended that may interfere with disease treatment. Since the risks are related to the details of the testing (e.g. the gene-disease interactions covered) as well as the advice (e.g. nutrition supplements), a better understanding of the specific risks involved is necessary in order to develop a risk-related threshold for competence.

Minors have already been mentioned as a specific case to be taken into account. It can be questioned whether minors should be allowed to undergo DTC genetic testing at all, considering their vulnerability in understanding genetic and genomic information. Negative consequences may include psychological harm (negative effects on self-esteem and self-perception) and the loss of autonomy, privacy and confidentiality[107,108]. Tamir (2010) argues that genetic testing by children may be justified, in the case immediate, medical benefits would outweigh the risks of such tests, and only with the

[100] General Data Protection Regulation., Article 8
[101] Ibid., Article 8(1)
[102] Karen McCullagh, "The General Data Protection Regulation: A Partial Success for Children on Social Network Sites?," *DATA PROTECTION, PRIVACY AND EUROPEAN REGULATION IN THE DIGITAL AGE, EDITED BY TOBIAS BRÄUTIGAM AND SAMULI MIETTINEN* (2016).
[103] Sivan Tamir, "Direct-to-Consumer Genetic Testing: Ethical–Legal Perspectives and Practical Considerations," *Medical law review* 18, no. 2 (2010).
[104] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics*., page 69
[105] Ibid.
[106] Paul S Appelbaum and T Grisso, "Assessing Competence to Consent to Treatment: A Guide for Physicians and Other Health Professionals," (New York: Oxford University Press, 1998).page 139
[107] PJ Malpas, "Predictive Genetic Testing of Children for Adult-Onset Diseases and Psychological Harm," *Journal of Medical Ethics* 34, no. 4 (2008).
[108] Benjamin Wilfond and Lainie Friedman Ross, "From Genetics to Genomics: Ethics, Policy, and Parental Decision-Making," *Journal of pediatric psychology* 34, no. 6 (2008).

involvement and guidance of a genetic counsellor[109]. The Advisory Committee on Genetic Testing[110] and Human Genetics Commission[111] recommend not to offer DTC genetic testing services to those under the age of 16, while the European Society for Human Genetics considers to exclude persons that have not reached the age of legal majority[112].

This calls for strict consent procedures from the side of nutriomic companies. Yet, previous studies on (US-based) DTC genetic testing companies' polices showed that the majority of companies still allow minors to undergo testing, some unconditionally and some upon parental request[113,114]. Besides minors, other individuals may not be capable of making choices or understanding sufficiently the relevant information to undergo testing. This stresses the need for companies to address the appropriate audience for their services, possibly excluding certain persons. This view is supported by the GDPR, that requires a data controller to identify the audience and tailor the information provision to the envisioned audience[115]. With a good understanding of the risks for specific personalized nutrition services, risk-based thresholds for competence could be developed.

Still, the question arises how this competence should be verified in the online context of personalized nutrition services. Health-care professionals will often be able to judge someone's competence on the basis of their personal contact with the patient. In contrast, the online, commercial environment of personalized nutrition services makes competence judgements more complex. Presumably, competence judgements could be performed in the form of pre-test counselling, as this involves face-to-face consultation with a health-care practitioner. Not only could the consumer be supported to understand the health-related information and the actions to undertake, the consumers' competence may be assessed as well by the health-care professional.

2.3.2 Disclosure

Contrary to the competence element, disclosure has a prominent place in GDPR consent. This is determined by the GDPR's obligations that consent should be 'specific' and 'informed'. The 'specific' aspect refers to the data processing purposes. When the purpose of data processing changes, new consent may be needed. The specificity is closely linked to the requirement of 'informed' consent, as it indicates the specificity of information that has to be provided to the individual which consent is needed[116]. This includes the disclosure of the scope and the consequences of data processing. The 'informed' aspect adds to this information requirements on the type of data collected and used, the rights of the data subjects to withdraw consent and the possible risks of data transfers[117].

[109] Sivan Tamir, "Direct-to-Consumer Genetic Testing: Ethical–Legal Perspectives and Practical Considerations."
[110] JC Barber, "" Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public". Advisory Committee on Genetic Testing," *Journal of medical genetics* 35, no. 6 (1998).
[111] Human Genetics Commission, "Genes Direct: Ensuring the Effective Oversight of Genetic Tests Supplied Directly to the Public," (2003).
[112] European Society of Human Genetics, "Statement of the Eshg on Direct-to-Consumer Genetic Testing for Health-Related Purposes," *European Journal of Human Genetics* 18, no. 12 (2010).
[113] Heidi Carmen Howard, Denise Avard, and Pascal Borry, "Are the Kids Really All Right? Direct-to-Consumer Genetic Testing in Children: Are Company Policies Clashing with Professional Norms?," ibid.19, no. 11 (2011).
[114] Pascal Borry et al., "Health-Related Direct-to-Consumer Genetic Testing: A Review of Companies' Policies with Regard to Genetic Testing in Minors," *Familial cancer* 9, no. 1 (2010).
[115] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679.", page 14
[116] Eleni Kosta, *Consent in European Data Protection Law* (Martinus Nijhoff Publishers, 2013).
[117] General Data Protection Regulation., Articles 13 and 14

The disclosure element in full informed consent has a different focus. It emphasises a restriction on the amount of information, concentrating on accurate and relevant information. Individuals would be given the chance to obtain more information if they wish so, so that the information is meaningful for them[118]. This is a valuable view on information disclosure, as GDPR consent is often criticized for creating a culture of information excess[119].

Personalized nutrition services may therefore benefit by a critical assessment of the core information components to be included in informed consent. Other information can be categorized as optional, available upon request of the consumer. Since genetic and genomic testing is one of the most contentious forms of personalized nutrition[120], it may require a more elaborate informed consent process than other forms of testing (e.g. advice based on protein/metabolite values). Consequently, the following part will focus on the information elements for nutriomic testing, assuming it to be adequate as well for other types of personalized nutrition services. The following part will first assess which information should be disclosed according to literature and then integrate this with legal requirements by the GDPR into one list.

The literature on disclosure requirements for informed consent

Several authors have proposed a list of key information components to be included in informed consent for genetic/genomic testing, both in commercial and clinical settings. Ayuso et al. 2013 performed a systematic review of articles and guidelines on the informed consent of whole exome sequencing in the clinical setting between 2006 and 2012[121]. Bunnik, Janssens and Schermer (2014)[122] and Niemiec et al. (2016)[123] concentrate on informed consent for DTC genetic testing, while Henderson et al. (2014)[124] and Jamal et al. (2013)[125] focus on the clinical setting. Table 2 illustrates the similar key information elements described by these scholars.

Table 2: Key elements of information to be disclosed in informed consent for clinical or direct-to-consumer genetic/genomic testing, according to scholars

Key information elements	Wording of key information elements by scholars
1. **Purpose**	• Scope of the test (Ayuso et al., 2013), • Purpose of the test (Bunnik et al., 2013), • Explanation of test (Henderson et al., 2014)
2. **Target group**	• Target group (Bunnik et al., 2013)

[118] Onora O'Neill, "Some Limits of Informed Consent."
[119] Bart W Schermer, Bart Custers, and Simone van der Hof, "The Crisis of Consent: How Stronger Legal Protection May Lead to Weaker Consent in Data Protection."
[120] Ulf Görman et al., "Do We Know Enough? A Scientific and Ethical Analysis of the Basis for Genetic-Based Personalized Nutrition."
[121] Carmen Ayuso et al., "Informed Consent for Whole-Genome Sequencing Studies in the Clinical Setting. Proposed Recommendations on Essential Content and Process," *European Journal of Human Genetics* 21, no. 10 (2013).
[122] Eline M Bunnik, A Cecile JW Janssens, and Maartje HN Schermer, "A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing," ibid., no. 6.
[123] Emilia Niemiec et al., "Content Analysis of Informed Consent for Whole Genome Sequencing Offered by Direct-to-Consumer Genetic Testing Companies," *Human mutation* 37, no. 12 (2016).
[124] Gail E Henderson et al., "The Challenge of Informed Consent and Return of Results in Translational Genomics: Empirical Analysis and Recommendations," *The Journal of Law, Medicine & Ethics* 42, no. 3 (2014).
[125] Seema M Jamal et al., "Practices and Policies of Clinical Exome Sequencing Providers: Analysis and Implications," *American Journal of Medical Genetics Part A* 161, no. 5 (2013).

3. Description of the test process	• Description of the test process (Ayuso et al., 2013), • Description study design (Henderson et al., 2014)
4. Possible benefits and risks	• Possible benefits and risks (Ayuso et al., 2013), • Risks and implications of testing (Bunnik et al., 2013), • Benefits and risks (Henderson et al., 2014), • Potential risks (Jamal et al., 2013), • Expected benefits and possible risks (Niemiec et al., 2016)
5. Limitations	• Limitations of the tests (Bunnik et al., 2013)
6. Availability of alternative tests	• Availability of alternative tests (Ayuso et al., 2013)
7. Voluntary nature	• Voluntary nature of the test (Ayuso et al., 2013)
8. Possibility of refusal	• Possibility of refusal (Ayuso et al., 2013)
9. Future use of the samples and the data / Potential follow-up	• Future use of the samples and the data (Ayuso et al., 2013), • Potential follow-up (Bunnik et al., 2013), • Use of data in other studies and other permissions sought (Henderson et al., 2014)
10. Confidentiality / Data Protection	• Confidentiality of the outcomes (Ayuso et al., 2013), • Data protection (Bunnik et al., 2013), • Privacy / confidentiality (Henderson et al., 2014), • Data sharing and results management (Jamal et al., 2013)
11. Management of incidental findings	• Management of incidental findings (Ayuso et al., 2013), • Categories of results to be returned (or not) (Henderson et al., 2014), Processes for return (Henderson et al., 2014), • Discussion incidental findings (Jamal et al., 2013) • Managements of incidental findings and categorization of genetic information (Niemiec et al., 2016)
12. Pre-test counselling	• Pre-test counselling (Ayuso et al., 2013), • Need for pre-test counselling (Niemiec et al., 2016)
13. Where to find further and independent information	• Where to find further and independent information (Bunnik et al., 2013)
14. Tiers	• Tiers of personal genome testing (Bunnik et al., 2013)

Several observations can be made from Table 2. For example, some information elements are only mentioned by scholars focusing on the clinical setting. This concerns the (3) *description of the test process*, the (6) *availability of alternative tests*, the (7) *voluntary nature of the test* and the (8) *possibility of refusal*. These elements may indeed be less relevant for the setting of DTC tests for personalized nutrition advice. While the description of the test process may be convenient for a consumer, it does not seem to be crucial information to be able to decide upon obtaining the service. Personalized nutrition tests are evidently voluntary, have clear alternatives (e.g. other companies, other sources for dietary advice) and consumers are likely aware of the possibility to refuse to take the test. Besides, these information elements may be regarded as less essential, since they are scarcely brought

up in the papers belonging to the systematic review by Ayuso et al.[126]. Consequently, they are not included as key information disclosure for personalized nutrition services.

Within the context of personalized nutrition, the suitability of three other disclosure elements from Table 2 can be debated: (11) *pre-test counselling*, the (12) *management of incidental findings* and (14) *tiers*. Since the purpose of pre-test counselling is more related to the understanding than to the disclosure of information, it is not included as a key disclosure element. Instead it will be covered in the next section (See paragraph 2.3.3, page 25).

The management of incidental findings is considered to be important by many scholars, especially in the context of whole exome and genome sequencing[127,128]. Incidental findings could be defined as 'results that are outside the original purpose for which a test or procedure was conducted'[129]. The Working Group on the Incidental Findings in Clinical Exome and Genome Sequencing of the American College of Medical Genetics and Genomics (ACMG) speaks of a 'deliberate search' for certain alterations in genes that are not apparently relevant to a diagnostic indication for which the sequencing test was ordered[130]. It is doubtful whether incidental findings are an important issue within personalized nutrition services. Incidental findings are primarily relevant when whole exome or genome sequencing is applied, which is not evident for personalized nutrition services. The disclosure of incidental findings in a clinical setting is based on a strong duty of beneficence towards patients. In the aim of providing personalized nutrition advice, the search for genetic alterations falls out of the scope of the commercial service. Besides, it can be difficult to interpret and to communicate incidental findings. A company probably does not hold the right expertise to perform this in a careful way. It can thus be concluded that it is better not to communicate incidental findings to consumers of personalized nutrition services. Nonetheless, it is necessary to create awareness about the subject, as companies have to take a clear stand in how they deal with incidental findings. The management of incidental findings is thus included with the category of 'Potential follow-up'.

Tiers are brought forward by Bunnik et al. as a separate information element[131]. The tiers – or categories of traits or diseases – enable informed consent to be given for specified categories rather than for a complete package. Arguably, this is not an disclosure element itself, but a way of providing choice to consumers. The notion of tiers is therefore discussed later (See paragraph 2.4, page 32).

Some remarks can be made with regard to the inclusion of other information components mentioned in Table 2. Most authors take benefits and risks in one category, or only mention the disclosure of risks. From Table 2, the paper by Bunnik et al. (2013) is the only one mentioning limitations. Risks focus on possible negative consequences for the consumer, while limitations relate to the uncertainty of the test

[126] Carmen Ayuso et al., "Informed Consent for Whole-Genome Sequencing Studies in the Clinical Setting. Proposed Recommendations on Essential Content and Process."
[127] Ibid.
[128] Emilia Niemiec et al., "Content Analysis of Informed Consent for Whole Genome Sequencing Offered by Direct-to-Consumer Genetic Testing Companies."
[129] Presidential Commission for the Study of Bioethical Issues, "Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts," (2013).
[130] Robert C Green et al., "Acmg Recommendations for Reporting of Incidental Findings in Clinical Exome and Genome Sequencing," *Genetics in Medicine* 15, no. 7 (2013).
[131] Eline M Bunnik, A Cecile JW Janssens, and Maartje HN Schermer, "A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing."

results. Since the clinical validity and accuracy of DTC tests is often a source of criticism[132,133], it can be justified to include the limitation as a separate, key disclosure element. This is supported by Singleton et al. (2012), who emphasizes that DTC genetic companies should better balance their information provision about risks, benefits and limitations[134]. Statements about benefits were 6 times more frequent than information related to risks and limitations. This could severely distort consumers' image of personalized nutrition testing. Consequently, benefits, risks and limitations should be included as three separate information elements to promote a better overview for the consumer and a more balanced representation of relevant information.

In addition, Table 2 shows that only Bunnik et al. (2013) mention the categories of 'target group' and 'where to find further and independent information'. Both can be regarded particularly relevant for personalized nutrition services. It is crucial from an ethical perspective to give individuals the chance to obtain more information if they wish so, so that the information is meaningful for them[135]. Hence, it is important to show what further (independent) information possibilities exist. Besides, as discussed with regard to competence, more awareness is needed from companies to address the appropriate target group for personalized nutrition services. This is necessary to decrease the risk of harm in vulnerable groups, which may include children, pregnant women, individuals with specific (dietary related) diseases (e.g. obesity, diabetes, cancer, cardiovascular diseases) or eating disorders (anorexia, bulimia). It is therefore advised to consider a description for whom the test is not suitable. The element of target group is thus rephrased as 'Exclusion', with the aim of avoiding harm to vulnerable groups.

Taking this into consideration, eight information elements from Table 2 are left: purpose, exclusion, benefits, risks, limitations, optional follow-up, data protection and further information possibilities related to personalized nutrition services.

Disclosure requirements for informed consent in the GDPR

The GDPR legally obliges data controllers to provide specific information with regard to data processing. For a nutriomic company requesting consumers' informed consent, Article 13 lays down this right to information. Not all of the elements in Article 13 have to be mentioned in the process of obtaining consent, as clarified by the Working Party[136]. Minimum content requirements for consent to be informed include the controller's identity, the purpose of each of the processing operations for which consent is sought, what (type of) data will be collected and used, the existence of the right to withdraw consent and information about the use of the data for automated decision-making (where relevant) and on the possible risks of data transfers (where relevant)[137].

Some of the content requirements can directly be categorized under the element of confidentiality / data protection, including the purpose of each of the processing operations for which consent is sought[138] and the nature of data that will be collected and used[139]. In addition, the processors' identity

[132] Cristiana Pavlidis et al., "Meta-Analysis of Genes in Commercially Available Nutrigenomic Tests Denotes Lack of Association with Dietary Intake and Nutrient-Related Pathologies."
[133] Keith A Grimaldi et al., "Proposed Guidelines to Evaluate Scientific Validity and Evidence for Genotype-Based Dietary Advice."
[134] Amanda Singleton et al., "Informed Choice in Direct-to-Consumer Genetic Testing (Dtcgt) Websites: A Content Analysis of Benefits, Risks, and Limitations."
[135] Onora O'Neill, "Some Limits of Informed Consent."
[136] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679.", page 15
[137] Ibid., page 13
[138] General Data Protection Regulation., Art 13(1)(c)
[139] "Opinion 15/2011 on the Definition of Consent," no. WP187 (2011)., page 19

and contact details[140] can be disclosed within the category of 'further information possibilities'. In this way, the consumer would not only have options to obtain further information from independent sources, but also be provided with the means to contact the processor itself.

The intention of data transfers (e.g. to a third country or an international organisation)[141] can be headed under the 'optional follow-up' element, since it concerns the future use of data. Within the category of 'optional follow up', data sharing with other parties can be communicated as well. This fulfils GDPR's requirement to disclose 'the recipients or categories of recipients of the personal data, if any'[142] and potential further processing 'for a purpose other than that for which the personal data were collected'[143]. This is important for further use of nutriomic data by third parties, since the Working Party underscores that when data is to be processed by other controllers that wish to count on the original consent, these organisations should all be named[144].

The existence of the right to withdraw consent[145] is given considerable attention in the GDPR. The data subject should be informed of the right to withdraw consent before actually giving consent[146] and the withdrawal of consent should be equally as easy as giving consent[147]. While the right to withdraw consent is related to the concept of voluntariness, it is recommended to include it also as a disclosure requirement for personalized nutrition services. In this way, companies are stimulated to mention their management with regard to the withdrawal of consent for further uses of nutriomic data. As explained in Chapter 2, the ex-post removal of an individual's data from research may be problematic. Hence, it is better to communicate beforehand how the withdrawal of consent works for (research) uses of personal data by third parties.

Finally, the GDPR mentions a specific disclosure requirement in case of automated decision-making and profiling[148]. Automated decision-making concerns the 'ability to make decisions by technological means without human involvement', while profiling is defined as an automated form of processing carried out on personal data, with the aim of evaluating personal aspects about a natural person[149]. These personal aspects could include the data subject's health, personal preferences, reliability or behaviour, location and movements[150]. Even though profiling is not a contentious issue right now for personalized nutrition services, this may change in the future. Since some nutriomic companies are affiliated with supermarkets or food companies (see Chapter 2), it is likely that nutriomic data could be used to evaluate automatically consumers' food preferences or shopping behaviour. Hypothetically, this may lead to automated food advertising making referrals to one's genetic or blood profile. Since this case of automated decision-making and requires data subject's explicit consent[151], the disclosure requirement should be give attention (where applicable) within the category of data protection.

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[140] General Data Protection Regulation., Art. 13(1)(a)
[141] Ibid., Art.13(1)(f)
[142] Ibid., Art.13(1)(e)
[143] Ibid., Art.13(3)
[144] "Guidelines on Consent under Regulation 2016/679.", page 13
[145] General Data Protection Regulation., Art. 13(2)(c)
[146] Ibid., Art. 7(3)
[147] "Guidelines on Consent under Regulation 2016/679.", page 21
[148] General Data Protection Regulation., Art.13(2)(f)
[149] "Guidelines on Automated Individual Decision-Making and Profiling for the Purposes of Regulation 2016/679," (2017)., page 6-7
[150] Ibid., page 6-7
[151] General Data Protection Regulation., Article 22(2)

Disclosure requirements for informed consent for personalized nutrition services

As a result, the following nine information elements can be regarded as essential for personalized nutrition services: *purpose*, *exclusion*, *benefits*, *risks*, *limitations*, *data use*, *optional follow-up*, *withdrawal of consent* and *further information possibilities*. Most of these are inspired by literature on informed consent[152,153,154,155,156,157], while the GDPR adds the withdrawal of consent and provides more details to the elements of data protection, optional follow-up and further information possibilities. This is illustrated in Figure 3 below.

1. **Purpose**: focus of test, e.g. on vitamin/mineral deficiencies, dietary sensitivities, food allergies and/or genetic susceptibility to dietary-related diseases
2. **Exclusion**: groups not suitable for testing, e.g. children, pregnant women, individuals with specific (dietary related) diseases (e.g. obesity, diabetes, cancer, cardiovascular diseases) or eating disorders (anorexia, bulimia)
3. **Benefits**: potential positive impacts for the consumers, e.g. a better adherence to a healthy diet, knowledge about genetic susceptibility
4. **Risks**: potential negative impacts for the consumer, e.g. psychological, social, health-related and privacy risks, implications for family members
5. **Limitations**: clinical validity and accuracy of the test and link to (national) dietary guidelines, emphasising importance of a varied diet
6. **Data protection**: Type of data collected and used, the translation of data into personalized advice (algorithmic personalization process), purposes of data processing operations, automated decision-making and/or profiling (where applicable)
7. **Optional follow-up**: future use of samples and data, indicating specific further purposes (e.g. related to research and other third parties) and intention of data transfers (where applicable), management of incidental findings
8. **Withdrawal of consent**: rights of the consumer to withdraw consent at any time, also with regards to future use of data
9. **Further information possibilities**: controllers identity and contact details and links to independent information sources about (personalized) nutrition c

Figure 3: Disclosure requirements for informed consent for DTC personalized nutrition services, as inspired by literature (in black) and obligations by the GDPR (in blue)

2.3.3 Understanding

The 'informed' requirement of GDPR consent provides instructions on how to provide information, demanding information to be easily accessible and easy to *understand*. It is specified by a requirement to use 'clear and plain language' for consent[158]. This suggests a difference in the interpretation of

[152] Carmen Ayuso et al., "Informed Consent for Whole-Genome Sequencing Studies in the Clinical Setting. Proposed Recommendations on Essential Content and Process."
[153] Eline M Bunnik, A Cecile JW Janssens, and Maartje HN Schermer, "Informed Consent in Direct-to-Consumer Personal Genome Testing: The Outline of a Model between Specific and Generic Consent."
[154] Emilia Niemiec et al., "Content Analysis of Informed Consent for Whole Genome Sequencing Offered by Direct-to-Consumer Genetic Testing Companies."
[155] Gail E Henderson et al., "The Challenge of Informed Consent and Return of Results in Translational Genomics: Empirical Analysis and Recommendations."
[156] Seema M Jamal et al., "Practices and Policies of Clinical Exome Sequencing Providers: Analysis and Implications."
[157] Amanda Singleton et al., "Informed Choice in Direct-to-Consumer Genetic Testing (Dtcgt) Websites: A Content Analysis of Benefits, Risks, and Limitations."
[158] General Data Protection Regulation., Article 7(2)

understanding in GDPR consent and in full informed consent. While the GDPR focuses on the legibility and readability of the language, the understanding element in medicine considers the *actual comprehension* by the patient. Full informed consent will not be valid without plausible comprehension by patients. Hence, a health care provider has a duty to ensure a patient understands the relevant information. Eventually, GDPR consent might aim for better comprehension, as 'providing information to data subjects prior to obtaining their consent is essential in order to enable them to make informed decisions, understand what they are agreeing to'[159].

The GDPR tries to pursue understanding by stipulating how information should be provided to the data subject. The Working Party's interpretation gives limited guidance on this. It recommends to provide layered and granular information, especially when dealing with small screens or situations with restricted room for information, and emphasizes that information should be tailored to the target audience[160]. Besides, consent should not be tied into contract or general terms and conditions, it has to be separate and distinguishable from other matters[161]. These recommendations all relate to the format of presenting consent and do not consider how the consumer receives this information. Manson and O'Neill would recognize this as an approach of seeing information merely as a means to convey, thereby dismissing the full act of communicating[162].

Full informed consent could add a dimension of taking into account how a consumer understands and responds to the presented information. Beauchamp and Childress state that the nature of understanding within informed consent implies that a person has at least a grasp of the central facts, while complete understanding is not necessary[163]. Instead, adequate understanding should be strived for. In addition, Beskow and Weinfurt regard understanding as a process consisting of four stages: the development of consent materials, the consideration of thresholds for adequate understanding, the assessment of actual comprehension and the decision regarding consequences for lack of understanding[164].

Development of consent materials

The development of consent materials concerns the question which information a person needs to understand in order to give authorization[165]. In a clinical setting, this typically consists of diagnoses, prognoses, the nature and purpose of the intervention, alternatives, risks and benefits, and recommendations[166]. The translation to the DTC context of personalized nutrition advice is not evident, due to a lack of research on the topic. Based on the mentioned aspects in the clinical setting and the disclosure requirements from Figure 1, it is suggested that the purpose of the service, the risks, benefits and limitations and a basic conception of data protection are essential to understand for consumers of personalized nutrition services. A key difference with the aforementioned aspects in the clinical setting would be the understanding of data protection. The importance of including data protection has been acknowledged in specific clinical settings. For example, confidentiality and data

[159] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679.", page 13
[160] Ibid., page 14
[161] Ibid., page 14
[162] Neil C Manson and Onora O'Neill, *Rethinking Informed Consent in Bioethics*.
[163] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics*.
[164] Laura M Beskow and Kevin P Weinfurt, "Exploring Understanding of "Understanding": The Paradigm Case of Biobank Consent Comprehension," *The American Journal of Bioethics* 19, no. 5 (2019).
[165] Ibid.
[166] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics*.

protection are commonly counted in when assessing the understanding of biobank participants[167,168]. Since personalized nutrition services are susceptible to questionable data practices (further explained in Chapter 3), it may be justified to verify consumers' comprehension on this. Consequently, it may for instance be tested whether consumers know which data is collected, whether it is shared with other parties, and if they are aware of the right to withdraw their consent.

Consideration of thresholds for adequate understanding

The idea of setting a threshold for adequate understanding is not without controversy. Opponents of setting a threshold appeal to principles of respect and autonomy, arguing that persons should be allowed to decide for themselves which information is important to understand[169]. At the same time, it can be contended that consumers are only able to make such an evaluation when they have a basic understanding of the information. It can be concluded that the establishment of a threshold of understanding should take consumers' autonomy into consideration. Then, a threshold can be chosen keeping in mind which level of understanding is necessary for using the services.

Assessment of actual comprehension

The assessment of understanding can be facilitated in several ways. Two options for personalized nutrition services are explored: the design of comprehension questions and the option of pre- and post-test counselling. A comprehension quiz may be suitable, as it directly enables a basic assessment of consumers' understanding[170]. Wilbanks (2018) provides some suggestions to facilitate a comprehension quiz in electronic consent. For example, he recommends to combine pictorial and textual elements in the interface and to only ask binary questions (Yes/No, A or B)[171]. Furthermore, Wilbanks offers several ideas for design of consent interactions, for instance using interactive quiz-based games (e.g. with role-play) and investigating consumers' risk-benefit perception[172]. A respect for consumers' autonomy could be strived for by introducing the comprehension quiz in such a way that its purpose falls in line with the purpose of the service. Based on a Sage Bionetworks study on the design of electronic consent[173], this may be formulated as follows: 'To better understand your evolving health and nutritional profile, we will ask you to perform simple activities and respond to the questions'. Taking into account risks of information load, this could be followed by a limited set of comprehension questions, formulated binary (two choice options).

Another possibility to test for consumers' understanding for personalized nutrition services is by counselling. Pre- or post-test counselling involves a face-to-face consultation with a health care practitioner prior or after receiving test results. The aim is to make sure that persons are competent to make a choice, understand the information provided and can take a decision suitable for them[174]. While

[167] Laura M Beskow and Kevin P Weinfurt, "Exploring Understanding of "Understanding": The Paradigm Case of Biobank Consent Comprehension."
[168] Kelly E Ormond et al., "Assessing the Understanding of Biobank Participants," *American journal of medical genetics Part A* 149, no. 2 (2009).
[169] Laura M Beskow and Kevin P Weinfurt, "Exploring Understanding of "Understanding": The Paradigm Case of Biobank Consent Comprehension."
[170] Megan Doerr, Christine Suver, and John Wilbanks, "Developing a Transparent, Participant-Navigated Electronic Informed Consent for Mobile-Mediated Research," *Participant-Navigated Electronic Informed Consent for Mobile-Mediated Research (April 22, 2016)* (2016).
[171] John Wilbanks, "Design Issues in E-Consent," *The Journal of Law, Medicine & Ethics* 46, no. 1 (2018).
[172] Ibid.
[173] Ibid.
[174] European Society of Human Genetics, "Statement of the Eshg on Direct-to-Consumer Genetic Testing for Health-Related Purposes."

some are in favour of making counselling mandatory for DTC genetic testing[175,176], concerns about its implementation have been raised as well. A particular challenge is the general lack of genetic knowledge and training by health care professionals[177]. Besides, conflicts of interest could arise when a health care practitioners is hired by (or associated with) a company, undermining the impartiality of the assistance[178].

The necessity for genetic counselling is less disputed. The European Society of Genetics even considers it an essential element of the informed consent process for genetic testing[179]. Especially when test deal with complex disease information, genetic counselling is considered to be indispensable[180,181,182]. This raises the question how suitable pre- or post- genetic counselling is for nutriomic tests. Compared with diagnostic or highly predictive health tests, nutriomic tests may not raise the same need for counselling[183]. Nutriomic tests typically concentrate on genetic variations that only have a limited impact on the risk of disease. While tests in clinical genetics serve as a basis for major life decisions, personalized nutrition advice usually does not directly mention disease risks[184]. Instead, the effects of possessing certain genetic variants on specific dietary-related compounds (e.g. cholesterol, saturated fat, salt, folic acid) are communicated[185]. Therefore, when incidental findings are not mentioned and the impact on disease risk is low, genetic counselling seems to be less relevant for personalized nutrition services[186].

There are situations imaginable that would justify the assistance of genetic counselling in personalized nutrition. Certain personalized nutrition tests and services may involve higher health risks. Genetic counselling is especially relevant when it helps the consumer to get a grip on information necessary for making essential health choices. Whenever the test deals with complex diseases, the need of ensuring consumers' understanding about genetic risks thus becomes more crucial. In particular, it should be considered whether *pleiotropic* genes are included within the test (e.g. when one gene influences two or more seemingly unrelated phenotypic traits). For these genes, the harm of not informing is larger, as consumers may be faced with disease associations later on, in an unexpected way, involuntarily or while not having access to accurate information[187]. A notorious example is the

[175] Emilia Niemiec et al., "Content Analysis of Informed Consent for Whole Genome Sequencing Offered by Direct-to-Consumer Genetic Testing Companies."
[176] Emilia; Kalokairinou Niemiec, Louiza; Howard, Heidi Carmen, "Current Ethical and Legal Issues in Health-Related Direct-to-Consumer Genetic Testing."
[177] Anna Harris, Susan E Kelly, and Sally Wyatt, "Counseling Customers: Emerging Roles for Genetic Counselors in the Direct-to-Consumer Genetic Testing Market," *Journal of genetic counseling* 22, no. 2 (2013).
[178] Heidi Carmen Howard and Pascal Borry, "Is There a Doctor in the House?," *Journal of Community Genetics* 3, no. 2 (2012).
[179] European Society of Human Genetics, "Statement of the Eshg on Direct-to-Consumer Genetic Testing for Health-Related Purposes."
[180] Heidi Carmen Howard and Pascal Borry, "Is There a Doctor in the House?."
[181] Mitchell PB, Meiser B, Wilde A, Fullerton J, Donald J, Wilhelm K,Schofield PR (2010) Predictive and diagnostic genetic testing inpsychiatry. Clin Lab Med 30:829–846
[182] Anna Middleton et al., "Direct-to-Consumer Genetic Testing: Where and How Does Genetic Counseling Fit?," *Personalized medicine* 14, no. 3 (2017).
[183] Mark Weir et al., "Canadian Health Care Professionals' Knowledge, Attitudes and Perceptions of Nutritional Genomics," *British journal of nutrition* 104, no. 8 (2010).
[184] Ulf Görman et al., "Do We Know Enough? A Scientific and Ethical Analysis of the Basis for Genetic-Based Personalized Nutrition."
[185] Ibid.
[186] Cecile JW Janssens; Eline M Bunnik; Wylie Burke; Maartje HN Schermer, "Uninformed Consent in Nutrigenomic Research."
[187] Ibid.

APOE gene, which is related to cholesterol level, but also to Alzheimer disease. The act of not informing individuals about the influence of an APOE variant on the risk on Alzheimer disease in personalized nutrition studies[188,189] has been regarded as a 'major omission that invalidates the informed consent'[190]. Besides the APOE gene, other genes that have strong associations with both diet and disease risks have been proposed, such as F5 (thrombophilia), HFE (hemochromatosis), and HLA (autoimmune diseases)[191]. Accordingly, the European Nutrigenomics Organisation states that 'genotyping that will allow predicting *high disease susceptibility* is only acceptable to be disclosed in a research context if it is subjected to appropriate genetic counseling' [emphasis added][192].

Another situation in which genetic counselling for personalized nutrition services seems appropriate is in the case of particular vulnerable groups. As has been mentioned before (see paragraph 2.3.1, page 17), minors form a specific risk group that may validate the involvement of a genetic counsellor[193]. The counselling could fulfil two functions: the health care practitioner would verify that the minor has sufficient psychological capacity for adequate decision-making (a competence judgement) and would ensure adequate understanding of the relevant gene-diet interactions.

Decision regarding consequences for lack of understanding

In case it is assessed that a consumer has an insufficient understanding of essential information related to nutriomic testing, a company should act upon this in an adequate way. The decision for an appropriate follow-up depends on the method of assessment. In a comprehension quiz, understanding may be assessed in a summative (requiring a perfect score before the consent procedure can be continued) or in a formative way (an incorrect answer leads to more education and guidance)[194]. Considering the aim of full informed consent to achieve adequate understanding (as opposed to complete understanding), a formative assessment may be more appropriate. In this way, consumers' learning could be facilitated, without obstructing much the continuity of the consent procedure. When prospective consumers would not be able to complete the quiz adequately, a company may suggest more assistance online (e.g. on a platform with questions and answers) or to give personal genetic counselling to the consumer. As concluded from above, genetic counselling does not seem to be essential for every type of personalized nutrition service. It can be offered optionally, e.g. after the comprehension quiz. Some conditions can be imagined that would justify compulsory genetic counselling, for instance when personalized nutrition services test for complex diseases (involving pleiotropic genes) or test specific vulnerable persons such as minors. In an extreme scenario, when a health care professional would still have doubts with a person's comprehension of essential details of the test, it may be decided to advise someone against undergoing a personalized nutrition test.

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[188] Celis-Morales C Fallaize R, Macready AL, Marsaux CF, Forster H, O'Donovan C, Woolhead C, San-Cristobal R, Kolossa S, Hallmann J, Mavrogianni C, Surwillo A, Livingstone KM, Moschonis G, Navas-Carretero S, Walsh MC, Gibney ER, Brennan L, Bouwman J, Grimaldi K, Manios Y, Traczyk I, Drevon CA, Martinez JA, Daniel H, Saris WH, Gibney MJ, Mathers JC, Lovegrove JA; Food4Me Study., "The Effect of the Apolipoprotein E Genotype on Response to Personalized Dietary Advice Intervention: Findings from the Food4me Randomized Controlled Trial," *The American journal of clinical nutrition* 104, no. 3 (2016).

[189] H-L Hietaranta-Luoma et al., "Erratum To: Using Apoe Genotyping to Promote Healthy Lifestyles in Finland–Psychological Impacts: Randomized Controlled Trial," *Journal of genetic counseling* 25, no. 6 (2016).

[190] Cecile JW Janssens; Eline M Bunnik; Wylie Burke; Maartje HN Schermer, "Uninformed Consent in Nutrigenomic Research."

[191] Ibid.

[192] European Nutrigenomics Organisation, "The Nugo Bioethics Guidelines on Human Studies," (2007).

[193] Sivan Tamir, "Direct-to-Consumer Genetic Testing: Ethical–Legal Perspectives and Practical Considerations."

[194] John Wilbanks, "Design Issues in E-Consent."

2.3.4 Voluntariness

The aspect of 'freely given' consent resembles the element of 'voluntariness'. In GDPR consent 'freely given' is defined as data subjects 'having a real choice'[195]. Freely given consent includes no imbalance between the controller and the data subject, no occurrence of conditionality (e.g. tying consent into contracts) and granularity (e.g. the possibility to give separate consent for different personal data processing operations). Besides, consent should be given without detriment. Consent without detriment implies that consent can only be valid if it does not lead to extra costs for the data subject and that there is no risk of deception, intimidation, coercion or significant negative consequences if a data subject does not consent'[196]. For example, it should be possible for the consumer to withdraw consent without negative consequences, such as the performance of the service being reduced[197].

While GDPR's freely given consent focuses on the unwanted, negative influence from others, full informed consent defines voluntariness as an action without being under the control of another's influence. This includes coercion, persuasion and manipulation, but also positive influencing (e.g. rewards, offers, encouragement; such as offering discounts on services)[198]. GDPR consent does not mention positive influencing. Consequently, it has been suggested that positive pressure does not invalidate GDPR consent, to the degree that the individual has been given the necessary information relating to the data processing and has been given a real choice to decide[199]. Still, it is imaginable to positive influences can be harmful. Within the context of personalized nutrition services, specific offers and rewards related to shopping preferences may be proposed to the consumer, in case nutriomic data is shared with supermarkets and/or food companies. Therefore, it is recommended to give more attention to positive influencing, by including it as a standard for informed consent for personalized nutrition services.

Chapter 2 already highlighted the susceptibility of personalized nutrition tests for involuntary testing by third parties. Without consumers being aware of it, their data may be used by third parties for other (research) purposes than that of the original company. Hence, to avoid involuntary testing resulting from using personalized nutrition services, a fair data follow up procedure is crucial. While disclosure of further data use was already recommended as disclosure requirement (within 'optional follow-up, see paragraph 3.3.2), the perspective of voluntariness may add to this an emphasis on consumers having a choice to decide. Thus, besides informing of consumers what could happen with their data, nutriomic companies are encouraged to provide more choice in further data use.

2.3.5 Consent

The 'unambiguous indication of wishes' and the concept of 'explicit consent' can be associated with the element of 'consent' within full informed consent. They specify the way of giving authorization to proceed. In this case, full informed consent does not provide many details about how to give consent, whereas GDPR consent gives clear direction. Informed consent in a health care context is often given

[195] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679.", page 5
[196] Ibid., page 10
[197] Ibid., page 10
[198] Tom L Beauchamp and James F Childress, *Principles of Biomedical Ethics*.
[199] Eleni Kosta, *Consent in European Data Protection Law*.

implicitly, which is possible in personal communication[200]. In an electronic environment such as personalized nutrition services, explicit consent becomes more important.

The unambiguous indication of wishes entails that consent should be validated by the data subjects' statement or 'clear affirmative action'[201]. This can be done written or (recorded) oral, including by electronic means[202]. When providing consent by electronic means - which personalized nutrition services is likely to do - the request for consent should not be unnecessarily disruptive to the use of the service[203]. At the same time, it is not allowed to use opt-out or pre-ticked opt-in boxes[204].

Explicit consent – necessary for processing nutriomic data – goes beyond the unambiguous indication of wishes[205]. An express statement of consent is necessary. In an online context, this may be achieved by filling in an electronic form, by sending an email, by uploading a scanned document carrying the signature of the data subject, or by using an electronic signature[206]. A two-stage verification of consent is recommended, e.g. first agreeing in one way, then confirming by an extra verification link or code[207]. With the advice of two-stage verification of consent, the GDPR sets a high standard for validating consumers' consent in personalized nutrition services.

2.3.6 Essential elements of informed consent for personalized nutrition services

Following the comparison between full informed consent and GDPR consent, the supposed one-element focus of GDPR consent on information disclosure seems to be somewhat exaggerated. A closer look at the stipulations of the GDPR reveals ambition towards a definition that beholds more than only disclosure. Freely given consent aspires to voluntariness, while the unambiguous indication of wishes and the explicit consent give guidance on the way of giving authorization. Even so, several ways were shown in which full informed consent may add value to the consent procedure of personalized nutrition services.

GDPR consent mainly focuses on which information should be disclosed. Full informed consent brings a limit on the amount of information, focusing only on accurate and relevant information. The disclosure elements also need to be in balance: for a fair representation of information, the consent procedure should provide information about risks, benefits and limitations. Furthermore, the concept of voluntariness within full informed consent brings for personalized nutrition services the suggestions to give more attention to a fair data follow up procedure and to explicitly manage influences of rewards, offers and encouragement. Competence and understanding elements of full informed consent are clearly absent in GDPR consent. While 'easy understanding' is mentioned by the GDPR, it mainly refers to the legibility of the text, instead of enabling real comprehension by the consumer. Two options for assessing consumers understanding were explored: a comprehension quiz for essential information to be understood and optional pre- and/or post-test counselling.

Overall it can be concluded that personalized nutrition services could benefit from the explicit inclusion of competence, disclosure, understanding, voluntariness and consent within its informed

[200] Neil C Manson, "Consent and Informed Consent," in *Principles of Health Care Ethics* (2006).
[201] General Data Protection Regulation., Art.4(11)
[202] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679.", page 17
[203] General Data Protection Regulation., Recital 32
[204] Ibid., Article 7(2)
[205] Ibid., Article 9
[206] "Guidelines on Consent under Regulation 2016/679.", page 18-19
[207] Ibid.

consent procedure. Figure 4 shows an integration of the elements of full informed consent and GDPR consent within personalized nutrition services.

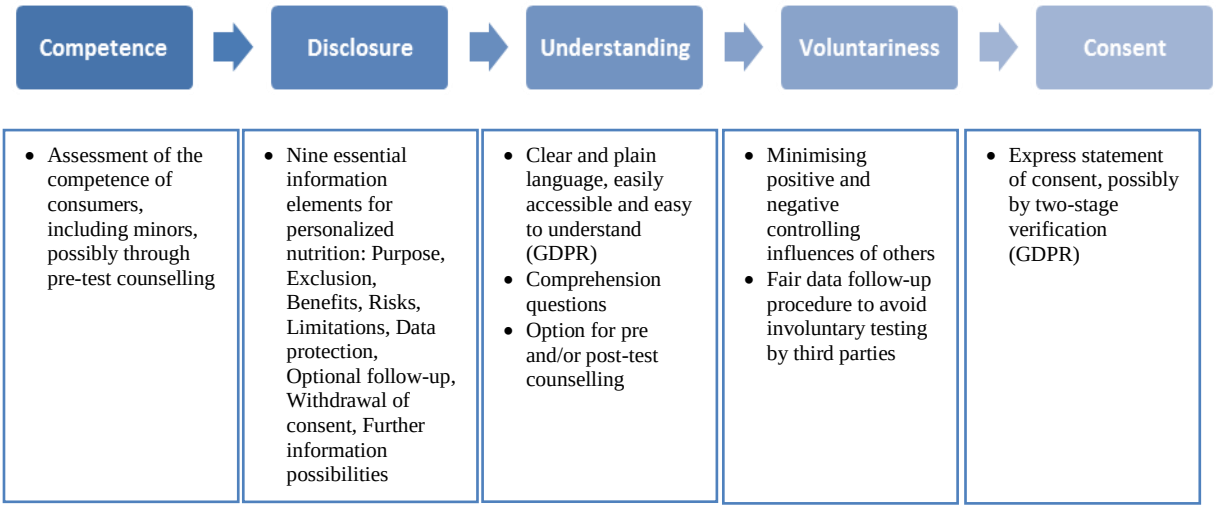


Figure 4: Ethical foundations of informed consent for DTC personalized nutrition services

2.4 A model for informed consent in DTC personalized nutrition services

The previous sections established the fundamental elements of informed consent for personalized nutrition services. The next part focuses on the integration of these elements within a model for informed consent. As a specific model for DTC personal genome testing has already been proposed[208], this section assesses how this model can be tailored to the context of personalized nutrition.

For DTC genetic testing informed consent should not be too generic, but also not be too specific[209]. With too specific information, the complexity and volume of information would make an information overload unavoidable, undermining consumers' autonomous choice. With too generic information, consumers are not sufficiently protected against harms, as they would have insufficient idea of the different options for testing and the consequences. The authors therefore propose a model in between generic and specific consent by integrating three approaches on informed consent: a tiered, layered and staged model[210].

2.4.1 Tiered approach to informed consent

The *tiered* approach implies a differentiation of the testing offer, so that consumers are able to make choices between different categories with regard to the information they would or would not like to receive[211,212]. The differentiation may be made on the basis of test characteristics (e.g. purpose of the test, clinical validity and utility) or disease characteristics (e.g. severity, actionability, age of onset and

[208] Eline M Bunnik, A Cecile JW Janssens, and Maartje HN Schermer, "A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing."
[209] "Informed Consent in Direct-to-Consumer Personal Genome Testing: The Outline of a Model between Specific and Generic Consent."
[210] Ibid.
[211] "A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing."
[212] Angela R Bradbury et al., "Development of a Tiered and Binned Genetic Counseling Model for Informed Consent in the Era of Multiplex Testing for Cancer Susceptibility," *Genetics in Medicine* 17, no. 6 (2015).

the somatic or psychiatric nature of the disease), as they are connected with different clinical, psychological and social consequences for consumers[213].

For personalized nutrition services, a differentiation based on test characteristics is probably more suitable, as disease risks are rarely directly communicated to consumers[214]. Instead, it seems more appropriate to offer choices with regard to different purposes of obtaining personalized nutrition advice. Some consumers may specifically want to take personalized nutrition advice to lose weight, to achieve fitness goals[215] or to manage food allergies[216]. Other consumers may want a more general check-up to make their food choices healthier[217,218]. The tiered approach emphasizes that it is important to distinguish choices with different clinical, psychological and social impacts for consumers[219]. As mentioned before, the inclusion of genes with a high disease susceptibility (in particular when related to complex diseases) can be associated with a higher likelihood of harm within personalized nutrition services[220]. Therefore, when a nutriomic company would like to include these types of genes within their tests, it may be better to offer this within a separate group. Consequently, it can be imagined that a personalized nutrition company would differentiate between 4 relevant tiers: (1) a general dietary advice for the improvement of food choices, (2) a general dietary advice + inclusion of genes with a high disease susceptibility, (3) a focus on weight loss or fitness goals and (4) a focus on food allergies.

Beside a differentiation based on test and disease characteristics, another relevant criterion for personalized nutrition services may be data protection, as test choices could involve different privacy implications for consumers. In this light, the concept of tiers can be related to the GDPR's concept of granularity. Granularity means that when data processing is done in pursuit of several purposes, consent should be obtained for each purpose separately[221]. Hence, a nutriomic company may also opt to provide choices based on different data processing purposes.

2.4.2 Layered approach to informed consent

The *layered* approach makes a distinction between several levels of information: a first layer with minimal basic information that is essential for all consumers, and extra layers with more detailed information that is available upon request[222]. For personalized nutrition services, the first layer may include the 9 information elements that have earlier been characterized as essential, as well as the associated comprehension questions. The first layer could present the different group (tiers) from which consumers can choose. The second and further layers could present specific and detailed

[213] Eline M Bunnik, Maartje HN Schermer, and A Cecile JW Janssens, "The Role of Disease Characteristics in the Ethical Debate on Personal Genome Testing," *BMC medical genomics* 5, no. 1 (2012).
[214] Ulf Görman et al., "Do We Know Enough? A Scientific and Ethical Analysis of the Basis for Genetic-Based Personalized Nutrition."
[215] Audrey Rankin et al., "Public Perceptions of Personalised Nutrition through the Lens of Social Cognitive Theory."
[216] Enza D'Auria et al., "Personalized Nutrition Approach in Food Allergy: Is It Prime Time Yet?," *Nutrients* 11, no. 2 (2019).
[217] A Ronteltap, JCM Van Trijp, and RJ Renes, "Consumer Acceptance of Nutrigenomics-Based Personalised Nutrition," *British Journal of Nutrition* 101, no. 1 (2008).
[218] Rosalind Fallaize et al., "An Insight into the Public Acceptance of Nutrigenomic-Based Personalised Nutrition," *Nutrition research reviews* 26, no. 1 (2013).
[219] Eline M Bunnik, A Cecile JW Janssens, and Maartje HN Schermer, "A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing."
[220] Cecile JW Janssens; Eline M Bunnik; Wylie Burke; Maartje HN Schermer, "Uninformed Consent in Nutrigenomic Research," ibid.25, no. 7 (2017).
[221] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679." Page 11
[222] Angela R Bradbury et al., "Development of a Tiered and Binned Genetic Counseling Model for Informed Consent in the Era of Multiplex Testing for Cancer Susceptibility."

information about the tiers. Additional general information can be provided upon request, such as information on the sampling and testing procedure, the laboratory analysis, references to the scientific literature[223]. The concept of layered information is also captured in the disclosure element of 'further information possibilities', as consumers are in this way supported to reach out for more information, in case they desire to do so. By creating options for genetic counselling, another possibility is added to make additional information available based on consumers' needs.

2.4.3 Staged approach to informed consent

The *staged* approach recognizes informed consent as a process that takes time, as the passing of time improves understanding and decision-making[224,225]. This could be facilitated by distributing information to consumers over different stages of the process and by regularly updating test results based on new scientific developments[226]. In this way, informed consent is appreciated as a learning process, opposed to the GDPR's approach of seeing consent as a once-and-for-all-time transaction.

The step-wise provision of information could be achieved by distinguishing informational stages in the process of informed consent for DTC personalized nutrition services. Three different phases relate to the (1) pre-test information (2) the information before receiving the test results and (3) the information before receiving updates of the test results[227]. In the first phase consumers can choose a certain tier(s), while the second and third phase would give layered information per tier[228].

With regard to the different elements of full informed consent for personalized nutrition, some information may be suitable to be spread over different phases. Logically, options for pre-test counselling are relevant to present before testing (related to *Further information possibilities*), while options for post-test counselling are best to present prior to or shortly after receiving the test results. In addition, general limitations can be mentioned in the first phase, while specific limitations related to the test results can be discussed in the second phase. Similarly, information related to the optional further use of data (related to *Optional follow-up*) can be extended to the second phase.

The third phase considers the possibility to re-interpret test results according to new developments in science. The importance of updating test results has been emphasised in the context of DTC genetic testing companies[229], and also specifically for nutriomics[230]. Some DTC genetic companies (such as 23andme) indeed update their consumers routinely when test results could be reinterpreted and when

[223] Eline M Bunnik, A Cecile JW Janssens, and Maartje HN Schermer, "A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing."
[224] Anne L Angiolillo et al., "Staged Informed Consent for a Randomized Clinical Trial in Childhood Leukemia: Impact on the Consent Process," *Pediatric blood & cancer* 42, no. 5 (2004).
[225] John B Tebbetts, Terrye B Tebbetts, and Mark Gorney, "An Approach That Integrates Patient Education and Informed Consent in Breast Augmentation," *Plastic and reconstructive surgery* 110, no. 3 (2002).
[226] Eline M Bunnik, A Cecile JW Janssens, and Maartje HN Schermer, "A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing."
[227] Ibid.
[228] Ibid.
[229] Amanda Singleton et al., "Informed Choice in Direct-to-Consumer Genetic Testing (Dtcgt) Websites: A Content Analysis of Benefits, Risks, and Limitations."
[230] Engineering National Academies of Sciences, and Medicine, "Nutrigenomics: Regulatory, Ethical, and Science Policy Considerations," in *Nutrigenomics and the Future of Nutrition: Proceedings of a Workshop* (National Academies Press, 2018).

the testing offer could be expanded with new genetic variants or associations[231,232]. As nutriomics is an emerging, rapidly evolving science[233], new research using omics technologies will inevitably alter the associations between biological and dietary characteristics. This may lead to a different risk pattern and test advice for a person[234]. In this way, the re-adjusting of test information contributes to the accuracy to the test results. Besides, it supports consumers' autonomy by allowing consumers to decide for each update whether they would desire to receive the new information and by giving more opportunity for verification whether the information provided makes sense[235].

2.4.4 A tiered, layered, staged model for DTC personalized nutrition services

By integrating the essential elements of informed consent for personalized nutrition services with tiered, layered and staged approaches to informed consent, a model is constructed (Figure 5). The elements of competence, disclosure, understanding and consent come back in the age verification, the 9 information elements, the comprehension quiz and the consent authorization by two-stage verification. The voluntariness element is linked with the information related to further use of data, striving for a fair data follow-up procedure to avoid involuntary testing by third parties. The model illustrates three informational stages within the informed consent process, gives freedom of choice in the testing offer of personalized nutrition services by the creation of tiers and presents layered information with a separation of essential and additional information.

Pre-test information

- **9 information elements**: Purpose, Exclusion, Benefits, Risks, Limitations, Data use, Optional follow-up, Withdrawal of consent, Further information possibilities (Layered information, Option for pre-test counselling)
- **Comprehension questions,** after (A) Benefits, Risks, Limitations; (B) Data use and (C) Optional follow-up elements
- **Choice for certain tier(s)** (for example: (1) general dietary advice (2) general dietary advice + inclusion of genes with a high disease susceptibility, (3) a focus on weight loss or fitness goals, (4) focus on food allergies)
- **Consent authorization** by two-stage verification, **age verification** to decide necessity of compulsory genetic counselling for minors

Information prior to receiving the test results

- **Information per tier**, each tier could contain layered information
- Options for **post-test counselling**
- Information related to **optional follow-up** (further use of data)
- Information related to the possibility of receiving subsequent **updates of test results**

Information related to updated test results

- Information related to **updates of test results per tier**, each tier could contain layered information

Figure 5: A tiered, layered and staged model for informed consent in DTC personalized nutrition services

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[231] Eline M Bunnik, A Cecile JW Janssens, and Maartje HN Schermer, "A Tiered-Layered-Staged Model for Informed Consent in Personal Genome Testing."
[232] Engineering National Academies of Sciences, and Medicine, "Nutrigenomics: Regulatory, Ethical, and Science Policy Considerations."
[233] Kathryn M Camp and Elaine Trujillo, "Position of the Academy of Nutrition and Dietetics: Nutritional Genomics," *Journal of the Academy of Nutrition and Dietetics* 114, no. 2 (2014).
[234] Raluca Mihaescu et al., "Evaluation of Risk Prediction Updates from Commercial Genome-Wide Scans," *Genetics in Medicine* 11, no. 8 (2009).
[235] Engineering National Academies of Sciences, and Medicine, "Nutrigenomics: Regulatory, Ethical, and Science Policy Considerations."

Chapter 3: The requirements by the GDPR for personalized nutrition

This chapter assesses the requirements of the General Data Protection Regulation for the offering of nutriomic-based DTC personalized nutrition services. It describes how the personalized nutrition services fall under the material and territorial scope of the GDPR, followed by an analysis on nutriomic data as personal data categories. Then, the conditions for getting explicit consent for nutriomic data are analysed. Finally, the further use of nutriomic data under the GDPR's research exemption is examined.

3.1 Personalized nutrition under the scope of the GDPR

The personalisation of nutrition based on a person's biological characteristics makes extensive use of 'omics' technologies. These include genetics, genomics, epigenomics, proteomics and metabolomics (see Figure 1, page 6)[236], which can be captured in the umbrella term 'nutriomic' data. Nutriomic data needs to be processed to turn raw data in (clinically) relevant outcomes. This happens often by so called next-generation sequencing technologies. Next-generation sequencing technologies enable the generation of massive amounts of omics data (ranging from megabases to gigabases) sets from individuals in a quick and inexpensive way[237]. This creates challenges for data processing and puts pressure on data tracking, data storage, and quality control[238]. The 'big data' character of personalized nutrition necessitates efficient data sequencing[239,240]. For this purpose, algorithms are often used in order to incorporate a larger data set of multiple persons[241,242].

In the EU, the processing of personal data is regulated by the GDPR, which is directed towards the protection of identifiable natural persons (called data subjects)[243]. Both personal data processed by automated means (e.g. digital databases) and part of a filing system (e.g. manually processed) fall under the scope of the GDPR[244]. Consequently, the processing of personal data by automated means in DTC personalized nutrition services makes it subject to the material scope of the GDPR[245].

Furthermore, the data processing requirements for personalized nutrition depends on the geographical origin of the consumer. Next to nutriomic companies established in the EU, companies from non-EU countries processing personal data of individuals in the EU are also included in the territorial scope of the GDPR[246]. This may lead to situations in which non-EU nutriomic companies would have to comply with different data processing regimes at the same time. For example, while the GDPR is considered to be applicable to all sectors (with data protection grounded in human rights principles),

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[236] Jose M Ordovas et al., "Personalised Nutrition and Health."
[237] Jason M Rizzo and Michael J Buck, "Key Principles and Clinical Applications of "Next-Generation" DNA Sequencing," *Cancer prevention research* 5, no. 7 (2012).
[238] Wim Pinxten and Heidi Carmen Howard, "Ethical Issues Raised by Whole Genome Sequencing," *Best Practice & Research Clinical Gastroenterology* 28, no. 2 (2014).
[239] Daniel McDonald, Gustavo Glusman, and Nathan D Price, "Personalized Nutrition through Big Data," *Nature biotechnology* 34, no. 2 (2016).
[240] Vural Özdemir and Eugene Kolker, "Precision Nutrition 4.0: A Big Data and Ethics Foresight Analysis—Convergence of Agrigenomics, Nutrigenomics, Nutriproteomics, and Nutrimetabolomics."
[241] Jason R Miller, Sergey Koren, and Granger Sutton, "Assembly Algorithms for Next-Generation Sequencing Data," *Genomics* 95, no. 6 (2010).
[242] David Zeevi et al., "Personalized Nutrition by Prediction of Glycemic Responses," *Cell* 163, no. 5 (2015).
[243] General Data Protection Regulation., Article 1.1
[244] Ibid., Article 2.1
[245] Ibid., Article 2.1 and Article 2.2
[246] Ibid., Article 3.2

the Health Insurance Portability and Accountability Act (HIPAA) in the US only applies to the health sector[247]. Consequently, a nutriomic company might not have to adhere to the HIPAA, but should still comply with the GDPR when serving a consumer from the EU. In some sectors companies have approached this variety in legal data regimes by extending the requirements of the GDPR to all customers, including the company Microsoft[248]. It is not clear whether nutriomic companies will follow these examples.

3.2 The categorization of nutriomic data into genetic and health data

Having established that data processing by nutriomic companies is subject to the scope of the GDPR, this subsection assesses under which categories 'nutriomic' data would fall. This is necessary, since the classification of personal data influences further obligations for data processing. Nutriomic data can be considered personal data, since it holds information relating to an identified or identifiable natural person (the consumer of the personalized nutrition service)[249]. The GDPR distinguishes different categories of personal data, including genetic data and 'data concerning health'.

Whenever genomics, genetics, epigenomics and/or transcriptomics technologies are used for personalized nutrition advice, the nutriomic data collected can be considered 'genetic data'. The category of genetic data is new in EU's data protection regulation. The Data Protection Directive 95/46/EC (DPD, the precursor of the GDPR) only contained a general category of 'data concerning health'[250] to which genetic data would belong to[251]. Instead, the GDPR specifically defines genetic data as the ''inherited or acquired genetic characteristics of a natural person which give *unique information* about the *physiology or the health of that natural person* and which result, in particular, from an analysis of a biological sample from the natural person in question'' (emphasis added) [252]. In addition, Recital 34 indicates that genetic data result from the 'chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis', or 'from the analysis of another element enabling *equivalent information* to be obtained'[253] (emphasis added). Consequently, it can be inferred that the nutriomic data obtained by DNA analysis (genetics), chromosomal DNA analysis (genomics), changes in DNA methylation (epigenomics) and RNA analysis (transcriptomics) can be considered 'genetic data'.

Yet, it is not clear if proteomics and metabolomics could be regarded as genetic data as well. Proteomic and metabolomic data might be interpreted to be of 'equivalent information' to data coming from DNA and RNA analysis[254]. It could be argued that like genes, proteins and metabolites are biomarkers suitable to determine health and disease susceptibility and to provide information on diet-disease interactions. Protein biomarkers can be linked to nutrient metabolism and function[255] and

[247] Edward Dove, "Collection and Protection of Genomic Data," *Routledge Handbook of Genomics, Health and Society* (2018).
[248] D. Kawamoto, "Tech Companies Embrace Some Gdpr Privacy Practices Outside of Europe," Government Technology, https://www.govtech.com/policy/Tech-Companies-Embrace-Some-GDPR-Privacy-Practices-Outside-of-Europe.html.
[249] General Data Protection Regulation., Article 4(1)
[250] Data Protection Directive., Article 8
[251] Article 29 Data Protection Working Party, "Working Document on Genetic Data," ed. Article 29 Data Protection Working Party (2004)., page 5
[252] General Data Protection Regulation.
[253] Ibid., Recital 34
[254] Ibid.
[255] Robert N Cole et al., "The Plasma Proteome Identifies Expected and Novel Proteins Correlated with Micronutrient Status in Undernourished Nepalese Children," *The Journal of nutrition* 143, no. 10 (2013).

metabolomics allows the identification and validation of biomarkers of dietary intake[256]. This biomarker role would favour the equivalency referred to in Recital 34[257].

On the other hand, proteins and metabolites are characterized by a higher variability compared to DNA and RNA. The chemical structure, concentration, spatial and temporal distribution of proteins is considerably more diverse than DNA and RNA, while for metabolites the diversity is even larger. This complicates the conformance to the aspects of ***unique information*** about the physiology or the health of ***that natural person*** in the definition of genetic data[258] (emphasis added). Conclusively, besides the similar function as health biomarker, it can be contended that information from DNA and RNA is more 'unique' and related to a specific person than information from proteins and metabolites.

Alternative to genetic data, the nutriomic data from proteins and metabolites could belong to the category of 'data concerning health'. This relates to the physical or mental health of a natural person, revealing information about the health status[259]. Data concerning health includes the 'information derived from genetic data and biological samples'[260]. Hence, the metabolomic and proteomic data may be regarded as providing information derived from biological samples. Consequently, nutriomic data may be classified differently in the GDPR, depending on the 'omics' technology used. While the genomics, genetics, epigenomics and transcriptomics can be regarded as genetic data, proteomic and metabolomic data may be either genetic data (similar their role as biomarker) or data concerning health (proteomic/metabolomic information as less 'unique' than DNA/RNA information).

The difference between genetic data and data concerning health is subtle in the GDPR. It is unclear what distinguishes 'genetic data' from 'information derived from genetic data', since raw data is practically always interpreted further. It is disputed whether genetic data truly offers unique information, as it also reveals (physiological or health) information about a person's related groups (e.g. same family, ethnic group, or geographical origin)[261]. For a consumer of personalized nutrition services, this could create a situation in which nutriomic data may contain information highly significant for family members of the consumer. Nevertheless, the data would not be treated as personal data under the GDPR, which has a clear focus on the individual and defines personal data only as identifiable data[262]. Shared, 'non-unique' data from genomic analyses is thus not treated as personal data[263,264]. Not only does the 'non-unique' nature of genetic data confuse the data protection rights of related groups, it also blurs the distinction between genetic and health data even further.

The ambiguity in classification supports the claim that the categorization between genetic and health data is unnecessary. Both categories derive information about a persons' health[265]. Besides, the requirements on data processing for genetic data and data concerning health are similar. Both data are

[256] Silke S Heinzmann et al., "Metabolic Profiling Strategy for Discovery of Nutritional Biomarkers: Proline Betaine as a Marker of Citrus Consumption," *The American journal of clinical nutrition* 92, no. 2 (2010).
[257] General Data Protection Regulation., Recital 34
[258] Ibid., Article 4(13)
[259] Ibid., Article 4(15)
[260] Ibid., Recital 35
[261] Dara Hallinan and Paul de Hert, "Genetic Classes and Genetic Categories: Protecting Genetic Groups through Data Protection Law," in *Group Privacy* (Springer, 2017).
[262] General Data Protection Regulation., Article 4(1)
[263] Heather Widdows, *The Connected Self: The Ethics and Governance of the Genetic Individual* (Cambridge University Press, 2013).
[264] Mark Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection*, vol. 16 (Cambridge University Press, 2012).
[265] Edward Dove, "Collection and Protection of Genomic Data."

considered to have a particularly sensitive nature and therefore belong to a special category of data that are only allowed to be processed under specific conditions[266].

One therefore wonders the reasoning behind the categorization. Under the DPD, it was necessary to establish a link between genetic data and the health status of an individual, in order to classify genetic data as sensitive data[267]. With the GDPR in force, this is not necessary anymore, as genetic data is automatically regarded as sensitive data[268]. The recognition of genetic data as a stand-alone category of the GDPR is therefore thought to support the notion of genetic exceptionalism[269], which advocates a special protection of genetic data, differentiating it from other types of health data[270,271]. Nevertheless, it is argued that the use of 'bounded' categories of personal data only leads to confusion and an 'increased risk of regulatory failure to protect against the harms'[272]. Accordingly, the benefit of having a specific category for genetic data is probably limited for the context of nutriomic data. While data collected in personalized nutrition services may be divided under different headings of personal data under the GDPR, all nutriomic data can be regarded as sensitive personal data.

3.3 Conditions for getting explicit consent for nutriomic data processing

Since personalized nutrition services deal with sensitive personal data, the data processing of nutriomic data is only allowed when it is performed according to one of the exceptions stated in Article 9(2). Among these exceptions, two legal grounds are of relevance for personalized nutrition services: explicit consent of the data subject[273] and the processing of sensitive personal data for scientific research purposes[274]. This section will discuss the GDPR's conditions for getting explicit consent from consumers of personalized nutrition services.

Explicit consent for nutriomic data processing should be freely given, specific, informed and be an unambiguous indication of wishes by the data subject (See also Table 1, page 17)[275]. In addition, valid consent needs to fulfil some additional requirements set out by Article 7 and 8, such as conditions on children's consent[276], the obligation of the controller to demonstrate consent[277] and the data subject's right to withdraw consent at any time[278]. In the context of DTC personalized nutrition services, these conditions could provide certain challenges.

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[266] General Data Protection Regulation., Recital 51, Article 9

[267] Article 29 Data Protection Working Party, "Advice Paper on Special Categories of Data ('Sensitive Data')," (2011).

[268] Paul Quinn and Liam Quinn, "Big Genetic Data and Its Big Data Protection Challenges," *Computer law & security review* 34, no. 5 (2018).

[269] Dara Hallinan, Michael Friedewald, and Paul De Hert, "Genetic Data and the Data Protection Regulation: Anonymity, Multiple Subjects, Sensitivity and a Prohibitionary Logic Regarding Genetic Data?," *Computer Law & Security Review* 29, no. 4 (2013).

[270] Amy L McGuire et al., "Confidentiality, Privacy, and Security of Genetic and Genomic Test Information in Electronic Health Records: Points to Consider," *Genetics in Medicine* 10, no. 7 (2008).

[271] James P Evans and Wylie Burke, "Genetic Exceptionalism. Too Much of a Good Thing?," ibid.

[272] Edward Dove, "Collection and Protection of Genomic Data."

[273] General Data Protection Regulation. Article 9(2)(a)

[274] Ibid., Article 9(2)(j)

[275] Ibid., Recital 32, Article 4(11).
Note: 'Freely given' refers to the real choice and control by the data subject, 'specific' to the specification of purpose(s) and having a choice in relation to each of them, 'informed' to the minimum content requirements and how to provide information and 'unambiguous indication' to the way of giving content

[276] Ibid., Article 8

[277] Ibid., Article 7(1)

[278] Ibid., Article 7(3)

Generally, the regulation of consent by the GDPR is likely to result in 'consent desensitisation' (consumers not making active, informed consent choices). Consent has a prominent role in the GDPR[279]. Minimum information requirements are stipulated ('informed' consent) and granularity and specificity of information to the data processing purposes are asked ('specific' consent) [280,281]. Besides, for explicit consent two stage verification is asked, setting a high standard for validating consumers' consent. These requirements are likely to aggravate the overload of information and the overload of consent requests. Furthermore, as personal data is a crucial aspect of the business strategy of nutriomic services, there is probably little to no room for negotiation on the use of the data. The absence of meaningful choice is likely to exacerbate consent desensitisation[282]. The GDPR's Working Party briefly touches upon the issue, hailing the 'click fatigue' - the diminishing warning effect mechanisms of consent[283]. Yet, it does not provide guidance to limit this development and merely shifts responsibility to data controllers to deal with this[284].

Furthermore, it is doubtful how well GDPR's notion of informed consent matches with the nature of DTC personalized nutrition. GDPR's 'informed' aspect of consent asks for a high clarity and accessibility of information. Clear and plain language has to be used and the message should be easily understandable[285]. This creates two challenges: (1) the conversion of the complex nature of data processing into simplified terms and (2) the probable outcome that consumers still do not adequately understand the simplified information. With regard to the first challenge, it is sometimes argued that complex concepts such as data necessitate the use of sophisticated language[286]. Still, nutriomic companies could make an effort to simplify legal texts by applying readability tests such as the Flesch Reading Ease or the Flesch-Kincaid test[287]. When the information requirements of consent are delivered in a clear format and language, it is still questionable whether the consumers understand the risks and consequences of data processing within personalized nutrition services. Simplified information does not directly lead to an improved comprehension, as is exemplified by studies on information provision in a clinical setting[288,289]. Risks of inadequate data protection are abstract and may therefore be hard to be envisioned by consumers[290]. Besides, the consequences of using personalized nutrition services may be especially difficult to oversee. Various uncertainties are attached to the field of nutriomics, for instance related to the validity of scientific evidence on nutriomics, the interactions between genetic and environmental factors and the design of nutriomics

[279] Benjamin Bergemann, "The Consent Paradox: Accounting for the Prominent Role of Consent in Data Protection" (paper presented at the IFIP International Summer School on Privacy and Identity Management, 2017).
[280] General Data Protection Regulation., Article 4(11)
[281] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679."
[282] Bart W Schermer, Bart Custers, and Simone van der Hof, "The Crisis of Consent: How Stronger Legal Protection May Lead to Weaker Consent in Data Protection."
[283] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679.",page 17
[284] Ibid., page 17
[285] General Data Protection Regulation., Article 7(2), Recital 39
[286] Omri Ben-Shahar and Adam Chilton, "Simplification of Privacy Disclosures: An Experimental Test," *The Journal of Legal Studies* 45, no. S2 (2016).
[287]Shmuel I Becher and Uri Benoliel, "Law in Books and Law in Action: The Readability of Privacy Policies and the Gdpr," *CONSUMER LAW & ECONOMICS, Klaus Mathis & Avishalom Tor, eds., Springer (forthcoming, 2019)* (2019).
[288] Terry C Davis et al., "A Polio Immunization Pamphlet with Increased Appeal and Simplified Language Does Not Improve Comprehension to an Acceptable Level," *Patient Education and Counseling* 33, no. 1 (1998).
[289] Terry C Davis et al., "Informed Consent for Clinical Trials: A Comparative Study of Standard Versus Simplified Forms," *JNCI: Journal of the National Cancer Institute* 90, no. 9 (1998).
[290] Glen J Nowak and Joseph E Phelps, "Understanding Privacy Concerns: An Assessment of Consumers' Information-Related Knowledge and Beliefs," *Journal of Direct Marketing* 6, no. 4 (1992).

products and services[291]. Altogether, these factors could complicate the effective regulation of personalized nutrition services by GDPR's informed consent.

Another challenge for personalized nutrition services lies in the GDPR's conditions applicable to children's consent (as explained in Chapter 2). The GDPR recognizes the specific protection that children merit with regard to their personal data[292]. Still, it permits minors under 16 to undergo nutriomic testing, on the condition that parental consent is given[293]. Member states are allowed to apply a certain age limit, but not lower than 13 years[294]. This may create various undesirable consequences for personalized nutrition services. Chapter 2 already mentioned the challenges of variable minimum age limits across Member States and the complex enforcement of verifying age and consent procedures[295,296]. Against this, it can be argued that the controller still has to make *reasonable* efforts to verify that consent is given by the holder of parental responsibility over the child[297]. Yet, the meaning of 'reasonable' is vague – leaving the question unanswered how much effort a nutriomic company should put into a verification procedure. Besides falsifying parental consent, a child may also pretend to be an adult, bypassing the need of parent's consent. In this way, non-consensual use by children is hard to avoid. This may lead to serious emotional harm, e.g. related to loss of privacy or the finding of undesirable genetic information, or physical harm, e.g. related to wrong follow-up of personalized nutrition advice[298]. In other applications of DTC genetic testing than nutriomics, studies on companies policies have showed that a majority of them do perform genetic testing in minors[299,300]. This is in conflict with many professional norms for DTC genetic testing services, for example stating that minors can be tested for adult-onset disorders only if therapeutic or preventative measures are available[301]. The specific relation between minors and personalized nutrition services has barely received any attention. This is surprising, considering the vulnerability of minors, the sensitivity of the personal data, the low validity of nutriomic testing and the uncertain risks associated with it. In this light, it can be concluded that GDPR's regulation of minors' consent is inadequate and may lead to harmful situations.

To conclude, the requirements of the GDPR's on explicit consent may provide a few obstacles for the delivery of personalized nutrition services. The consent requirements lack strict obligations on minors' accessibility, are likely to exacerbate consent desensitisation, and will probably not facilitate the adequate understanding by consumers of personalized nutrition services.

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[291] Michiel Korthals and Rixt Komduur, "Uncertainties of Nutrigenomics and Their Ethical Meaning," *Journal of agricultural and environmental ethics* 23, no. 5 (2010).
[292] General Data Protection Regulation., Recital 38
[293] Ibid., Article 8(1)
[294] Ibid., Article 8(1)
[295] Milda Macenaite, "From Universal Towards Child-Specific Protection of the Right to Privacy Online: Dilemmas in the Eu General Data Protection Regulation," *New Media & Society* 19, no. 5 (2017).
[296] Karen McCullagh, "The General Data Protection Regulation: A Partial Success for Children on Social Network Sites?."
[297] General Data Protection Regulation., Article 8(2)
[298] Sivan Tamir, "Direct-to-Consumer Genetic Testing: Ethical–Legal Perspectives and Practical Considerations."
[299] Heidi Carmen Howard, Denise Avard, and Pascal Borry, "Are the Kids Really All Right? Direct-to-Consumer Genetic Testing in Children: Are Company Policies Clashing with Professional Norms?."
[300] Pascal Borry et al., "Health-Related Direct-to-Consumer Genetic Testing: A Review of Companies' Policies with Regard to Genetic Testing in Minors."
[301] Pascal Borry et al., "Predictive Genetic Testing in Minors for Adult-Onset Genetic Diseases," *Mount Sinai Journal of Medicine: A Journal of Translational and Personalized Medicine: A Journal of Translational and Personalized Medicine* 75, no. 3 (2008).

3.4 Further processing of nutriomic data under the research exemption

Besides the option of asking consumers' explicit consent for personalized nutrition services, another legal ground for processing nutriomic data is the so-called research exemption. The research exemption is relevant when processing of nutriomic data is necessary for scientific research purposes[302]. This section will discuss the applicability of the GDPR's research exemption for nutriomic services. After discussing the relation between the research exemption and explicit consent the section explores how third parties of nutriomic companies fall within the meaning of scientific research as defined by the GDPR, followed by an overview of the possible exemptions that are covered by the research exemption. Lastly, it is analysed how the research exemption is limited by stronger data protection measures.

3.4.1 The relation between research exemption and consent

As different legal grounds may be used for the processing of nutriomic data, the relation between the research exemption and explicit consent needs to be clarified. Since it can safely be assumed that research is not a primary objective of a company providing personalized nutrition services, one expects consumers' explicit consent is typically obtained in order to collect the personal data. The question arises whether the consent would have to include an approval for potential *further* processing of nutriomic data for research purposes (e.g. by third parties). The question can be answered looking at GDPR's Recitals 50 and 33.

The option of further processing for scientific research purposes is mentioned in Recital 50. It specifies the need of compatibility between the purposes for which the personal data were initially collected and the research purposes. To enable further processing for scientific research purposes, a nutriomic company has to make sure that the research purposes align with the purposes of their service. To evaluate this compatibility it should take into consideration inter alia 'the context in which the personal data have been collected' and the 'consequences of the intended further processing for data subjects'[303].

Recital 33 recognizes that it is often not possible to fully specify the research purpose. For this reason it is allowed that data subjects offer their consent to 'certain areas of scientific research'. This implies that nutriomic companies can ask for a broad type of consent, enabling a permission request for an undefined use for future research[304]. Two conditions should be met: the scientific research should comply with recognised ethical standards and the consent should only be given to research in the extent allowed by the intended purpose[305].

Consequently, a nutriomic company needs to specifically ask data subjects their consent for further processing for scientific research purposes. While a broad type of consent is endorsed, purpose compatibility and adoption of recognised ethical standards need to be ensured.

3.4.2 The meaning of scientific research for third parties of nutriomic companies

To determine which third parties for the further processing of nutriomic data would be covered under the research exemption, it is worth exploring the meaning of scientific research. This section will first

[302] General Data Protection Regulation., Article 9(2)(j)
[303] Ibid., Recital 50
[304] Luca Marelli and Giuseppe Testa, "Scrutinizing the Eu General Data Protection Regulation," *Science* 360, no. 6388 (2018).
[305] General Data Protection Regulation., Recital 33

assess to which third parties nutriomic companies are connected and then analyse how these could fit within the meaning of scientific research as defined by the GDPR.

Third parties connected to nutriomic companies

Nutriomic companies are affiliated with a wide range of partners. To begin with, numerous agreements have been made with the food and health industry. For example, Campbell Soup Company invested 32 million dollars in 2016 in Habit[306], a prominent US-based personalized nutrition company[307]. Habit was recently sold to Viome to complement Habit with artificial intelligence and data based on a person's microbiome[308]. Another example is Royal DSM, a Dutch company active in the domains of health, nutrition and materials, which has become the largest stakeholder of Mixfit, a personalized nutrition start-up company based in Boston[309].

The investments in nutriomic companies are not limited to the food industry. Deals have also been struck with food service providers and retailers. The provision of personalized meal boxes is exemplified by agreements in the UK between Thriva (blood health test company) and Vita Mojo (restaurant & software company)[310] and in the Netherlands between Mijnlabtest (DNA & blood testing company) and Ekomenu (meal boxes by Ekoplaza supermarket). Supermarkets have shown interests as well. The British 'DNAnudge' smartphone app determines the suitability of food items from the supermarket Waitrose with the customer's DNA and metabolism[311]. Dutch supermarket Jumbo partners with soccer club PSV in a personalized nutrition app, eventually wishing to extend the app to regular consumers[312]. Canadian supplement maker AOR, partner of the company 'DNA labs', even speaks of a 'retail-ready DNA kit'[313] – at the same time promising to the client never to share or sell its data[314].

In addition, the international research consortium of TNO & Wageningen University on personalized nutrition & health demonstrates that the variety of interested partners goes beyond food industries and services: from employers, consumer electronics to ICT industry[315]. Omnigen represents a company that works together with a wide diversity of partners, including a medical centre, biotechnology

[306] Kenneth Hilario, "Campbell's Investing $32m in San Francisco Company Set to Launch in 2017," American City Business Journals, https://www.bizjournals.com/philadelphia/news/2016/10/25/campbells-invests-in-personalized-nutrition-habit.html.

[307] Grand View Research, "Personalized Retail Nutrition and Wellness Market Size, 2018 - 2025," in *Biotechnology*, ed. Grand View Research (2018).

[308] Viome, "Viome Acquires Habit from Campbell Soup Company to Become the Undisputed Leader in Personalized Health," PR Newswire, https://www.prnewswire.com/news-releases/viome-acquires-habit-from-campbell-soup-company-to-become-the-undisputed-leader-in-personalized-health-300790252.html.

[309] DSM, "Dsm Becomes Largest Shareholder in Mixfit Inc. To Enter B2c Personalized Nutrition," https://www.dsm.com/corporate/media/informationcenter-news/2018/07/22-18-dsm-becomes-largest-shareholder-in-mixfit-inc-to-enter-b2c-personalized-nutrition.html.

[310] Lee Bell, "The Future of Healthy Dining: A Personalized Meal Based on Your Blood".

[311] Caroline Brogan, "DNA Test and Phone App to 'Nudge' Waitrose Shoppers Towards Healthier Food," Imperial College London, https://www.imperial.ac.uk/news/188593/dna-test-phone-nudge-waitrose-shoppers/.

[312] PSV, "Jumbo Foodcoach in Toekomst Ook Voor Consument Beschikbaar," https://www.psv.nl/nieuwspagina/artikel/jumbo-foodcoach-in-toekomst-ook-voor-consument-beschikbaar-.htm.

[313] Adi Menayang, "Canadian Supplement Maker Aor Launches 'Retail-Ready' DNA Test Kit," Nutraingredients USA, https://www.nutraingredients-usa.com/Article/2019/03/20/Canadian-supplement-maker-AOR-launches-retail-ready-DNA-test-kit.

[314] Advanced Orthomolecular Research, "The Myblueprint Privacy Pledge - an Industry First," Advanced Orthomolecular Research, https://myblueprintdna.us/.

[315] Personalized Nutrition & Health, "Public Private Partnership," Personalized Nutrition & Health, https://www.personalisednutritionandhealth.com/en/personalisednutritionandhealth/Partners.htm.

companies, a greenhouse horticulturalist and a food business platform[316]. Altogether, this shows the wide variety of partners linked to nutriomic companies that may have an interest in using the research exemption for further possibilities of processing nutriomic data.

Meaning of scientific research in the GDPR

The research exemption is only to be used when processing is necessary for archiving purposes in the public interest, *scientific* or historical research purposes[317]. Although no definition is given by the GDPR, Recital 159 provides an interpretation to what is understood as scientific research: 'For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and *privately funded research* [emphasis added]'[318].

The reason why privately funded research is included in scientific research can be traced back to Article 179 of the Treaty of the Functioning of the EU where it is emphasized that the objective of promoting research is a way for the EU to become more competitive in the global market, including in its industry[319]. The Article argues that the involvement of private actors is essential for promoting innovation, but that it also creates opportunities for misuse at the same time[320].

Since the notion of 'privately funded research' is not explained in more detail, it is unclear in which case commercial research aligns with the scientific research purposes of the GDPR. Pormeister questions if the existence of a research department in a private company would be sufficient in order to benefit from the research exemption, or whether a separate research entity would be required[321].

Another open question relates to the link between scientific research and public interest. The GDPR is not explicit on this aspect. Van Veen (2018) observes that the GDPR only mentions public interest and research with a comma in between, giving the suggestion of two separate legal bases[322]. Recommendations are therefore made to express more clearly in the GDPR that scientific research would need to contribute to the public interest[323].

The meaning of scientific research for third parties of nutriomic companies

It can be concluded that commercial research is included within the definition of scientific research, while it remains unclear how research-oriented a private company needs to be and whether public interests need to be pursued. Considering the abundant variety of third parties working together with nutriomic companies, the interpretation of research in the GDPR may open up a broad leeway for those third parties to take advantage of the research exemption. This could include public institutions such as universities and research organisations, and also private parties such as food industry, food service providers, supermarkets and biotechnological companies.

316 Omnigen, "Partners Omnigen," Omnigen, https://consument.omnigen.nl/nl/partners/.
317 General Data Protection Regulation.
318 Ibid., Recital 159
319 TFEU, Article 179
320 Mahsa Shabani and Pascal Borry, "Rules for Processing Genetic Data for Research Purposes in View of the New Eu General Data Protection Regulation," *European Journal of Human Genetics* 26, no. 2 (2018).
321 Kärt Pormeister, "The Gdpr and Big Data: Leading the Way for Big Genetic Data?," *Annual Privacy Forum* (2017).
322 Evert-Ben van Veen, "Observational Health Research in Europe: Understanding the General Data Protection Regulation and Underlying Debate," *European Journal of Cancer* 104 (2018).
323 Ibid.

3.4.3 Possible derogations for further data processing of nutriomic data

Having established the diversity of third parties of nutriomic companies that may benefit from the research exemption, this section will analyse which possibilities the research exemption may give to them. When it is recognized that data is being processed for research purposes, the GDPR grants derogations from certain data processing principles and rights. Some of them are applicable in all Member States, while other derogations are country specific.

Union-wide exemptions when processing further for research purposes

The performance of research activities may influence some principles relating to the processing of personal data (storage and purpose limitations) and some rights of the data subject (informational rights and right to erasure).

Derogations from storage and purpose limitations

Generally, the GDPR puts limits to the purpose of data processing (e.g. data should not be processed when it is incompatible with the specific, explicit and legitimate purposes of collection) and to the storage of data (e.g. no longer than is necessary for the purposes for which the personal data are processed)[324]. The research exemption provides a relief from both these principles. Hence, further processing for research purposes is not considered to be 'incompatible with the initial purposes'[325] and personal data can be kept for longer periods necessary for research purposes[326]. This derogation seems to put a double standard between primary and secondary data controllers. A nutriomic company collecting the data still has to ensure purpose compatibility with the intended research activity[327] – even if it could remain ambiguous in terms of the type of research[328]. Once the personal data has been allocated to a third partner, purpose compatibility would be assumed and practically any activity for research purposes could be performed - for as long as would be deemed necessary.

Derogations from informational rights

The supposed double standard between the nutriomic company and its partners may also be true with regard to informational rights. Information rights are different for situations in which data has been collected (Article 13) or has not been obtained (Article 14) from the data subject. A data controller from a nutriomic company (collecting the data) needs to give information about further research activities[329]. The purpose of the further processing should be provided[330] and other information whereas relevant (*inter alia* the period of storage and the existence of certain rights)[331]. For a third party of nutriomic company, Article 14 comes in play. For further processing for research purposes the information requirements do not apply where 'the provision of such information proves *impossible* or would involve a *disproportionate effort'* or 'in so far as the obligation referred to in paragraph 1 of this Article is likely to *render impossible* or *seriously impair* the achievement of the objectives of that processing' [emphasis added] [332].

[324] General Data Protection Regulation., Article 5
[325] Ibid., Article 5(b)
[326] Ibid., Article 5(e)
[327] Ibid., Recital 50
[328] Ibid., Recital 33
[329] Ibid., Article 13(3)
[330] Ibid.
[331] Ibid., Article 13(2)
[332] Ibid., Article 14(5)

The assessment of what constitutes a '*disproportionate effort'* should take into account three factors: the number of data subjects, the age of the data and any appropriate safeguards adopted[333]. Nutriomic research typically requires the processing of a large groups of data subjects, necessary to establish reliable evidence for nutrient-gene interactions. Consequently, the large volume of nutriomic data may prompt a researcher of a third party to claim a disproportionate effort to inform. Art.14(5)(b) has thus been named as the 'big data exception' to the obligation to inform[334]. Additionally, with no storage limitation the data can be kept as long as considered necessary for the research. As the age of the data increases, the disproportionate effort will only become larger. Once the sensitive personal data is transferred from a nutriomic company to a researcher, information requirements thus lose significance. Still, Art.14(5)(b) requires appropriate measures to be taken by the data controller in order to 'protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available'[335]. However, it is unclear whether this would facilitate the understanding of data subjects on how their sensitive data are being used in research activities. Consequently, data subjects may not be aware of their rights related to further processing[336].

Derogations from rights to erasure

In addition to information rights, the performance of research activities could have implications for the data subject's right to erasure (also called right to be forgotten). Again, a derogation is only granted 'in so far as the right referred to in paragraph 1 when likely to *render impossible* or *seriously impair* the achievement of the objectives of that processing'[337] [emphasis added]. One possibility of using the exemption of the right to erasure is linked to the withdrawal of consent[338]. When research has already been performed, it may be difficult to follow-up on a withdrawal of a data subject's consent. The ex-post removal of an individual's data from research might be interpreted as a 'serious impairment of the achievement of the research objectives'. On the other hand, it may still be manageable to prevent the use of personal data in future research. It is unclear where the boundary of this 'serious impairment' lies. For instance, a research partner could argue that the objectives of *ongoing* research projects are also seriously impaired if a data subject would withdraw their consent in the meantime. This stresses the need for nutriomic companies to make clear agreements with their research partners to determine the consequences of a consumers' withdrawal of consent on the right to be forgotten.

Country specific exemptions when processing further for research purposes

Next to Union-wide exemptions, individual Member States are allowed to derogate from certain rights. Art. 89(2) allows derogations from the rights of access, rights to rectification, rights to restriction of processing and rights to object[339]. An even longer list is given by Recital 156, which also authorizes Member States to provide specifications and derogations related to information rights, rights to erasure and data portability[340]. Again, the derogations should only be applied when they are

[333] Ibid., Recital 62
[334] Kärt Pormeister, "The Gdpr and Big Data: Leading the Way for Big Genetic Data?."
[335] General Data Protection Regulation., Article 14(5)
[336] Ibid., Article 21(6)
[337] Ibid., Article 17(3)
[338] Ibid., Article 17(1)(b)
[339] Ibid., Article 89(2)
[340] Ibid., Recital 156

necessary for the fulfilment of the research purposes and to the extent that the rights would 'render impossible or seriously impair the achievement' of the research purposes[341].

The fact that a high degree of flexibility is given to Member States could have consequences for the delivery of personalized nutrition services. Third parties of nutriomic companies may be incentivized to perform their research activities in the countries with the most derogations[342]. Such 'forum-shopping' behaviour inevitably weakens the protection of nutriomic data. Besides, it may confuse consumers of personalized nutrition services with regard to the applicable data principles and data rights. This is alarming, since it violates the *informed* or *disclosure* element of consent and obstructs the GDPR's core mission to protect data as a fundamental right. This stresses the need for stronger data protection measures on the research exemption.

3.4.4 Stronger data protection measures for research by Member States

While third parties of nutriomic companies may be allowed to derogate from certain data rights and principles, the GDPR directs Member States to put limitations to the breadth of the research exemption. Member State are allowed to install further conditions on sensitive data processing and they are expected to install safeguards with respect to the minimization of data. This underlines the necessity of assessing which stronger data protection measures might be installed with regard to personalized nutrition services.

Further conditions on sensitive data processing by Member States

In theory, the scope of the research exemption could be limited by Article 9(4), which allows Member States to introduce further conditions, including limitations with regard to the processing of genetic data, biometric data or data concerning health[343]. Stricter rules on processing nutriomic data for research purposes are thus possible on a national level. It is imaginable that Art. 9(4) could be used to apply a stricter alignment of research purposes with the public interest, or a limit to certain types of research. Another possibility is giving a more precise definition of research, e.g. when privately funded research can be included. This may have a considerable influences on the range of third parties that can make use of the research exemption. In a strict interpretation of the meaning of scientific research, commercial parties may even be excluded from taking advantage of the research exemption.

However, such requirements may not be effective in ensuring individuals control over their sensitive personal data, as data can easily be transferred to other countries[344]. Next to that, collaborative genetic research is often reliant on the cross-border processing of data[345]. On the same line, Recital 53 emphasizes that the national measures should not 'hamper the free flow of personal data within the Union' when cross-border processing applies. Hence, in practice the usefulness of Art.9(4) and the flexibility on Member-State level may be limited to achieve a stricter protection of nutriomic data.

Safeguards to be installed by Member States

Next to the possibility of installing further conditions, Member States are assigned to introduce certain technical and organisational measures, in particular to ensure respect for the principle of data

[341] Ibid., Article 89(2)
[342] "Genetic Data and the Research Exemption: Is the Gdpr Going Too Far?," *International Data Privacy Law* (2017).
[343] General Data Protection Regulation., Article 9(4)
[344] "The Gdpr and Big Data: Leading the Way for Big Genetic Data?."
[345] Mahsa Shabani and Pascal Borry, "Rules for Processing Genetic Data for Research Purposes in View of the New Eu General Data Protection Regulation."

minimisation (Art.89(1))[346]. It is left to Member States to determine which measures are to be installed and how data minimisation should be achieved. The principle of data minimization states that personal data shall be 'adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed'[347]. When research is performed on a large dataset of nutriomic data, this may be a challenging task. Since research on big genetic data often depends on the maximisation of data[348], it is unclear how the principle of data minimisation would resonate with this type of research[349].

It is not evident whether the recommended pseudonymisation[350] would be a suitable safeguard for protecting nutriomic data. Pseudonymisation is a form of de-identification that removes or replaces direct identifiers from a data set, but still keeps in place indirect identifiers[351]. Additional information needs to be stored separately and technical and organisational measures should be installed to prevent unwanted re-identification[352]. The application of pseudonymisation as a safeguard may be problematic in the case of nutriomic data processing. Some weaknesses that have been perceived with anonymization may also occur with the pseudonymisation of genomic data. Before the GDPR era, anonymization was regarded as the only way to bypass consent[353]. Yet, this led to the objection that it is not feasible to anonymize genomic data[354]. Even from seemingly anonymous data it is possible to identify individuals, e.g. through the use of advanced statistical techniques and by drawing upon other forms of publically available data[355]. The inclusion of pseudonymisation in the GDPR has thus been be praised for bringing more nuance in de-identification[356]. In practice the distinction between pseudonymous and anonymous data cannot always be made[357]. In comparison with anonymization, pseudonymisation just renders the identification more difficult – yet not impossible[358]. Considering the 'unique' nature of genomic data, it is questionable whether the removal of direct identifiers would be a useful security measure. Besides, it is likely that the ability of re-identifying individuals from pseudonymized data will only increase over time. A data controller of a pseudonymized data set could also intentionally take actions to allow the re-identification of the data subjects, e.g. by connecting data to other (public) datasets[359]. Besides, pseudonymized data may be vulnerable to re-identification by adversary third parties[360]. Hence, it is questionable whether pseudonymisation would be an effective safeguard for the protection of nutriomic data.

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346 General Data Protection Regulation., Article 89(1)
347 Ibid., Article 5(1)(c)
348 Eun Pyo Hong and Ji Wan Park, "Sample Size and Statistical Power Calculation in Genetic Association Studies," *Genomics & informatics* 10, no. 2 (2012).
349 Quinn and Quinn, 'Big genetic data and its big data protection challenges'
350 General Data Protection Regulation., Article 89(1)
351 Mike Hintze and Khaled El Emam, "Comparing the Benefits of Pseudonymisation and Anonymisation under the Gdpr," *Journal of Data Protection & Privacy* 2, no. 2 (2018).
352 General Data Protection Regulation., Article 4(5)
353 Edward Dove, "Collection and Protection of Genomic Data."
354 Harald Schmidt and Shawneequa Callier, "How Anonymous Is 'Anonymous'? Some Suggestions Towards a Coherent Universal Coding System for Genetic Samples," *Journal of medical ethics* 38, no. 5 (2012).
355 Paul Quinn and Liam Quinn, "Big Genetic Data and Its Big Data Protection Challenges."
356 Mike Hintze and Khaled El Emam, "Comparing the Benefits of Pseudonymisation and Anonymisation under the Gdpr."
357 Nayha Sethi, "The Promotion of Data Sharing in Pharmacoepidemiology," *European journal of health law* 21, no. 3 (2014).
358 Francis Aldhouse, "Anonymisation of Personal Data–a Missed Opportunity for the European Commission," *Computer Law & Security Review* 30, no. 4 (2014).
359 Paul Quinn, "The Anonymisation of Research Data—a Pyric Victory for Privacy That Should Not Be Pushed Too Hard by the Eu Data Protection Framework?," *European Journal of Health Law* 24, no. 4 (2017).
360 Khaled El Emam and Cecilia Álvarez, "A Critical Appraisal of the Article 29 Working Party Opinion 05/2014 on Data Anonymization Techniques," *International Data Privacy Law* 5, no. 1 (2014).

Other possible safeguards have been proposed, such as an opt-out registration, in which citizens can confidentially decide upon the inclusion of their sensitive data in research[361]. Another possibility is a controlled access model, in which researchers need to ask approval from ethics or data access committees, in order to ensure research is only performed where the benefits for data subjects prevail over the risks[362]. While these measures would probably allow more appropriate guidelines for DTC nutriomic companies and their third (research) parties, it is left to the Member States to decide upon this. Art.89(1) thus leaves up room for different interpretations, which may undermine the harmonization of the data protection across the EU.

3.4.5 The applicability of the research exemption for nutriomic services

To sum up, the applicability of the GDPR's research exemption for nutriomic services is specified by the foundation in Art. 9(2)(j), the interpretation of scientific research, the permission of derogations from certain principles and rights and the limitations to be installed by Member States. An overview of the relevant GDPR articles and recitals is given in Figure 6 (see next page).

Scope of the research exemption for third parties of nutriomic companies

Nutriomic companies need to ask data subjects their consent for further processing for scientific research purposes. A broad type of consent is endorsed, while purpose compatibility and adoption of recognised ethical standards need to be ensured. So far, there are no restrictions on how research oriented a third party needs to be and whether commercial research has to pursue public interests. Hence, a wide variety of third parties working together with nutriomic companies (including universities, food industry, food service providers, supermarkets and biotechnological companies) could possibly benefit from the research exemption.

Possible derogations for further data processing of nutriomic data

Research partners of nutriomic companies might benefit from numerous derogations under the research exemption. This could result in a situation that sensitive data is used for an indefinite time for practically any research purpose, while data subjects are not aware of the research activities, neither of their rights related to this, while their rights to be forgotten could prove ineffective. When the scale of data sets in research increases, the effectiveness of enforcing individual's rights would be even more difficult. This is alarming considering the vulnerable character of nutriomic data and the consequences on privacy.

[361] Knut W Ruyter et al., "From Research Exemption to Research Norm: Recognising an Alternative to Consent for Large Scale Biobank Research," *Medical Law International* 10, no. 4 (2010).
[362] Mahsa Shabani and Pascal Borry, "Rules for Processing Genetic Data for Research Purposes in View of the New Eu General Data Protection Regulation."



Figure 6: Schematic overview of the implications of the GDPR research exemption on the further processing of sensitive personal data, with its foundation (in orange), stronger data protection measures (in green) and derogations (in blue)

Stronger data protection measures by Member States

It is unclear how suitable the potential further conditions by Member States will be for research on data obtained by nutriomic companies. In theory, Art. 9(4) could be applied to ensure a contribution of research to the public interest, a limit to certain types of research or a more exact interpretation when privately funded research can be included. Yet, the creation of further conditions is limited by the easy transfer of data and the recognition for a free flow of data within the Union.

Furthermore, the instalment of pseudonymisation as a safeguard might face similar disadvantages as was seen with the anonymization of genomic data. When re-identification of data is occurring, either by the data controller or by malevolent third parties, sensitive personal data may be exposed in an undesirable manner. Technical and organisational measures ought to respect the principle of data minimization, but this may be complicated for research on big genetic data. Alternatively, safeguards such as an opt-out register or a controlled access model might be appropriate to protect against misuse of the research exemption. Still, a high level of harmonisation on the conditions of research exemption is not likely, as it is left to Member States to decide upon the safeguards. Since derogations could also be enacted by Member States, a situation may arise in which third parties of nutriomic companies move their research activities to the countries with the most derogations.

Chapter 4: The match between the GDPR requirements and ethical standards on personalized nutrition

The integration of ethical standards on informed consent (Chapter 2) with GDPR requirements (Chapter 3) in personalized nutrition services allows an answer to the question whether the GDPR is up to the ethical challenges that are at stake in the consent process of nutriomic-based personalized nutrition services. I will argue that the imprecise definition of research within the GDPR is a major obstacle that needs to be tackled first. Secondly, I will draw conclusions on the comparison between GDPR consent with full informed consent based on ethical considerations.

The analysis of the GDPR revealed a crucial issue for personalized nutrition services: the GDPR does not clearly define the meaning of scientific research. Scientific research is interpreted in a broad way. The GDPR includes privately funded research and does not require any contribution of scientific research to the public interest. This has various consequences for the delivery of personalized nutrition services. The broad interpretation of research allows for commercial exploitation of nutriomic data, which may encourage food industries, food service providers, supermarkets and biotechnological companies to use sensitive data with less strict processing requirements. These derogations include the storage of data for an unlimited time (no storage limitation), its use for practically any research purpose (no purpose limitation) and weakened data subject's rights (informational rights and rights to be forgotten). Member States can even introduce extra derogations which may stimulate companies to move to the country with the most exceptions.

While the adoption of recognised ethical standards needs to be ensured, these have not been established for the further processing of sensitive data by commercial research - let alone specifically for the context of personalized nutrition services. Member States have to install safeguards and further conditions. It is unclear how suitable these will be for the processing of nutriomic data. The instalment of further conditions is limited by the cross-border character of genetic data processing and EU's emphasis on ensuring a free flow of data. The suggested safeguard of pseudonymisation does not rule out the possibilities of data re-identification of nutriomic data. The aim of data minimization may be complicated for personalized nutrition services as research on big genetic data often depends on data maximisation. Consequently, the limitations to the research exemption for third parties of nutriomic companies prove to be neither precise or solid.

An analysis of the ethical standards of informed consent indicated further aspects at which the GDPR is missing out. Five elements within full informed consent were assessed: competence, disclosure, understanding, voluntariness and consent. These were related to the elements of GDPR's definition of explicit consent: specific, informed, freely given and the unambiguous declaration of wishes. The comparison demonstrated that the GDPR lacks guidance on the assessment of consumers' competence. To be more specific, GDPR's regulation of minors' accessibility to personalized nutrition services is alarming. Minors under 16 are allowed to undergo nutriomic testing with parental consent. With variable minimum age limits across Member States and the challenging enforcement of age and consent verification, non-consensual use by children seems inevitable. Personalized nutrition services process sensitive data, come with many uncertainties and still have a low scientific validity. As a result, emotional or physical harms could easily manifest in a vulnerable group such as minors. GDPR's way of testing competence within consent is thus insufficient.

The element of disclosure could be considered the core of GDPR consent, with both specific and informed aspects referring to content requirements. Consent should minimally include information on the *right to withdrawal of consent*, the *controller's identity*, the *purpose of each of the processing operations for which consent is sought* and *what data will be collected and used*. A literature review on essential information in a clinical and DTC context showed a different picture on minimum disclosure. Nine key disclosure elements for personalized nutrition services were recommended: *Purpose, Exclusion, Benefits, Risks, Limitations, Data protection, Optional follow-up, Withdrawal of consent* and *Further information possibilities*. Of these elements, the GDPR only touches upon the *Data protection*, *Optional follow-up* and *Withdrawal of consent*. While this can be explained by the GDPR's emphasis on data protection, it was argued that the health character of personalized nutrition services justifies more health-related information disclosure in consent. Personalized nutrition services may tend to exaggerate information related to the benefits of testing, while disregarding the risks and limitations of testing. Information in the consent process should thus be disclosed in a balanced way.

The GDPR's notion of consent does not live up to the ethical standard of assessing whether consumers of personalized nutrition services sufficiently understand the consent information. The GDPR stipulates information to be easily accessible and easy to understand and aims to achieve this by demanding the use of clear and plain language. However, simplified information does not ensure consumers' comprehension. From an ethical perspective, understanding can be seen as a process of four stages, with the *development of consent materials*, the *consideration of thresholds for adequate understanding*, the *assessment of actual comprehension* and the *decision regarding consequences for lack of understanding*. I suggest that consumers of personalized nutrition services should at least understand the purpose of the service, the risks, benefits and limitations and a basic conception of data protection. A possible assessment method is a comprehension quiz and/or pre- and post-test counselling. In some specific cases with more risks at stake (e.g. testing minors, tests involving complex diseases), mandatory genetic counselling may be justified to ensure adequate understanding.

The GDPR's requirement of having freely given consent partially resembles the element of voluntariness within full informed consent. Both interpretations of consent emphasize that there should not be deception, intimidation, coercion or significant negative consequences if a data subject does not consent. Voluntariness within full informed consent differs on another aspect from freely given consent. It specifically adds an absence of positive influencing (e.g. the effects of rewards, offers, encouragement). Positive influences within personalized nutrition services may be harmful, for instance when consumers are financially encouraged to share sensitive data with dubious third parties. Nevertheless, GDPR's consent can still be valid when such positive pressure is applied. This may lead to harmful consequences in the follow-up of data processing.

The last element of the consent process is the expression of consent as an authorization to proceed. The GDPR tackles this aspect well. An unambiguous indication of wishes is required from the consumer, validated by a statement or clear affirmative action. For nutriomic-based personalized nutrition services explicit consent is required. This can be done with two-stage verification of consent, in which consumers first agree in one way and then have to confirm with an extra verification step.

Finally, I concluded that informed consent for personalized nutrition services should be not too generic, but also not too specific. An ethical model has been described integrating tiered, layered and staged approaches to informed consent. It can be concluded that the GDPR does not incorporate the

tiered and *staged* approaches sufficiently within its consent requirements. The GDPR does not encourage data controllers to offer consumers different choices or *tiers* with regard to data use or data processing purposes. The GDPR mainly sees consent as a one-time transaction, rather than as a learning process with different *stages*. Staged consent allows the passing of time to improve understanding and decision-making. Especially for the field of personalized nutrition, frequent updates of test results are crucial to keep up with the rapid scientific developments. At the same time, the GDPR does promote a *layered* concept of information. Within the Art. 29 Working Party's guidelines on transparency, data controllers are stimulated to prioritise information and to present information in different layers with appropriate level of detail. Hence, while the GDPR acknowledges the layered approach, it would benefit from adopting tiered and staged approaches to informed consent.

Chapter 5: Discussion

This thesis showed severe limitations in the current GDPR approach with respect to informed consent in nutriomic-based DTC personalized nutrition services. In this section, I will assess the reasons behind the inadequate match between GDPR requirements and ethical standards. For a well-informed discussion on consent, empirical evidence needs to be discussed as well. I will thus provide context on the current data practices of nutriomic companies and assess the inherent risk of privacy concerns. Then I will discuss alternative approaches to govern personalized nutrition services as inspired by legal considerations. Finally, I will propose directions for future research on the governance of personalized nutrition services.

5.1 Explaining the gap between GDPR requirements and ethical standards

To explain the inadequacy of GDPR consent, it is necessary to clarify the different backgrounds of GDPR consent and full informed consent. An obvious difference between the two forms of consent is a focus on data use versus a focus on a medical intervention. The GDPR was designed to harmonize data privacy requirements[363]. The function of privacy is to give individuals control and rights over their data and sets obligations to prevent the misuse of others' personal information[364]. In contrast, full informed consent prioritises the protection and well-being of patients, who will undergo treatment to improve their health. Data protection only has a secondary function in the clinical setting.

The protection of privacy comes with different values and perceptions than the pursuit of health goals. While health is ubiquitously important to all humans, contributing to happiness and well-being, many people do not perceive privacy as an intrinsic value[365]. Consumers notoriously ignore privacy statements and easily provide their personal data[366]. This contrasting attitude stems from the specific character of privacy, less observable and more abstract than health. The likelihood of a privacy breach is often unknown (as many privacy problems remain unnoticed)[367], while health issues have better measurable manifestation. Besides, the impact of a privacy breach is less visible than health outcomes, which are more directly felt by a person.

The emphasis on both privacy and health objectives has consequences for the interpretation of consent. The way of looking at competence and understanding in GDPR consent turned out to be particularly unsatisfactory. With consent as a way to establish informational rights, the GDPR focuses on the information content and disclosure. In contrast, seeing consent as an interpersonal act of communication, clinical practice also takes into account how well the information is received. Manson and O'Neill illustrate the GDPR approach with a *conduit and container* metaphor[368]. According to this narrative, the GDPR typically sees information as content to be transferred and conveyed. This is

[363] Yves Poullet, "Is the General Data Protection Regulation the Solution?," *Computer Law & Security Review* 34, no. 4 (2018).
[364] Neil C Manson, "Consent and Informed Consent."
[365] Lawrence O Gostin, "Health Information: Reconciling Personal Privacy with the Public Good of Human Health," *Health Care Analysis* 9, no. 3 (2001).
[366] Patricia A Norberg, Daniel R Horne, and David A Horne, "The Privacy Paradox: Personal Information Disclosure Intentions Versus Behaviors," *Journal of consumer affairs* 41, no. 1 (2007).
[367] Md Mahmud Hossain, Maziar Fotouhi, and Ragib Hasan, "Towards an Analysis of Security Issues, Challenges, and Open Problems in the Internet of Things" (paper presented at the 2015 IEEE World Congress on Services, 2015).
[368] Neil C Manson, "Consent and Informed Consent."

problematic, since it disconnects consent from the full needs of successful communicative transactions.

The function of communication is especially important for data protection, since many misunderstandings are associated with the concept of privacy. A common misunderstanding about privacy is that 'I have got nothing to hide and nothing to lose'[369]. This exemplifies the false notion that privacy is an individual matter. It is often forgotten that people who are careless about their data not only reveal information about themselves, but also about others. Public harms may be done to the person whose data was taken, to other individuals and to social and political environments[370]. The confusion around privacy is even reflected within the GDPR. The GDPR puts the ones whose data is collected in the centre, instead of prioritising the harms that may be done to the data subject and to others. It thereby ignores the 'public good' aspect of privacy.

The online provision of personalized nutrition services further complicates effective communication. Health care is often delivered by personal interaction, facilitating the verification of patients' competence and understanding. The request of consent in an electronic environment without personal contact brings additional challenges[371]. People approach legal choices differently in a digital setting: it is culturally common to accept legal statements without reading them[372]. The reading process on a screen is also different than on paper. Screen text is usually read less meticulously in a skimming process[373]. Since many consent requests are offered in an online setting, there is a strong need to pay more attention to the role of communicative action in GDPR consent.

5.2 An empirical perspective: the current data practices of nutriomic companies

Privacy in personalized nutrition services is not just theory. Essential questions for empirical work are: How many companies are involved in personalized nutrition? How many consumers are using personalized nutrition services now? How many consumers are interested in using personalized nutrition services? And: What is the threat to privacy when using personalized nutrition services?

While the questions are obvious and provide important context to the discussion in this thesis, the answers are not straightforward. We do know that DTC genetic tests are increasing in popularity. The company 23andme, a general personal genomics company, has over 10 million customers[374]. Specific data for personalized nutrition is scarce. A Google search in 2011 has resulted in 76 examples of companies involved in personalised nutrition[375]. Since the field of personalized nutrition is rapidly evolving, this number cannot be taken as a realistic representation of the current market. The fact that the data are in private hands severely limits accurate analysis. While the current amount of consumers of personalized nutrition remains unknown, it can be established that there is an enormous interest in personalized nutrition by the European public[376]. According to Blue (2019), the era of personalized

[369] Daniel J Solove, "I've Got Nothing to Hide and Other Misunderstandings of Privacy," *San Diego L. Rev.* 44 (2007).
[370] Joshua AT Fairfield and Christoph Engel, "Privacy as a Public Good," *Duke LJ* 65 (2015).
[371] Enrico Coiera and Roger Clarke, "E-Consent: The Design and Implementation of Consumer Consent Mechanisms in an Electronic Environment," *Journal of the American Medical Informatics Association* 11, no. 2 (2004).
[372] John Wilbanks, "Design Issues in E-Consent."
[373] Ibid.
[374] 23andMe, "About Us," 23andMe, https://mediacenter.23andme.com/company/about-us/.
[375] Amber Ronteltap et al., "Nutrigenomics-Based Personalised Nutritional Advice: In Search of a Business Model?."
[376] Barbara Stewart-Knox et al., "Personalized Nutrition: Making It Happen," in *Trends in Personalized Nutrition* (Elsevier, 2019).

nutrition has started and the market is 'quickly gaining scale, momentum, and consumer visibility'[377]. Consumer interest is reflected in the willingness to pay. In a European-wide study, around 30% of participants reported a higher willingness to pay for personalized nutrition advice, with an average of 150% of the reference price of non-personalized nutrition advice[378]. The huge investments from the personalized nutrition industry[379,380] and the wide variety of partners involved[381] further suggest that the market is quickly rising.

What are the actual privacy risks of using personalized nutrition services? This question can be answered by assessing the current data practices of nutriomic companies, the privacy risk of these data practices, and the risk of harm following from privacy violations[382]. Empirical evidence is even more limited here. Data practices of nutriomic companies have not been investigated yet. Since misuse of nutriomic data has not been revealed, statements about the magnitude of harm from privacy violations remain speculative.

With lacking empirical evidence, it is only possible to assess the likely risk of privacy issues in personalized nutrition. The widespread interest from industry and consumers already indicates the magnitude of the risk, suggesting that the problem is not limited to a very specific group of citizens. From the analysis of this thesis we also know that it is easy for a company to bypass adequate informed consent, putting public goals seriously at stake. Another consideration is consumers' perception towards privacy. At the one hand, it has been found that privacy is a major obstacle for consumers to accept personalized nutrition[383,384]. This might stimulate companies to improve their data protection management. On the other hand, the privacy paradox has shown that consumers' perception of privacy is completely different from consumers' behaviour in privacy[385]. Together with the many misunderstandings around privacy, I can safely assume that the privacy risk is fairly widespread. I can equally assume that most citizens and regulators are much left in the dark with respect to informed consent. While data has not yet exposed privacy issues in personalized nutrition, I can conclude that there is a serious risk.

5.3 Solutions to overcome the gap between GDPR requirements and ethical standards

It is clear that consumers of personalized nutrition services are at risk of being harmed by the lack of appropriate data protection. While having identified specific bottlenecks for the sector of personalized nutrition, some of the challenges may ask for overarching policies. A balance is therefore needed between general and sector-specific (e.g. ethical standards for personalized nutrition) solutions. I propose five legal options that improve the design of the GDPR for a better governance of DTC personalized nutrition services. I thereby assume that an improved informed consent procedure

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[377] Tom Blue, "Charting the Course to Success in the Era of Personalized Nutrition," *Integrative Medicine: A Clinician's Journal* 18, no. 1 (2019).
[378] Arnout RH Fischer et al., "Willingness to Pay for Personalised Nutrition across Europe," *The European Journal of Public Health* 26, no. 4 (2016).
[379] Grand View Research, "Personalized Retail Nutrition and Wellness Market Size, 2018 - 2025."
[380] DSM, "Dsm Becomes Largest Shareholder in Mixfit Inc. To Enter B2c Personalized Nutrition".
[381] Personalized Nutrition & Health, "Public Private Partnership".
[382] Ryan Calo, "The Boundaries of Privacy Harm," *Ind. LJ* 86 (2011).
[383] Zoltán Szakály, András Fehér, and Marietta Kiss, "Consumer Acceptance of Personalized Nutrition," in *Trends in Personalized Nutrition* (Elsevier, 2019).
[384] Aleksandra Berezowska et al., "Consumer Adoption of Personalised Nutrition Services from the Perspective of a Risk–Benefit Trade-Off," *Genes & nutrition* 10, no. 6 (2015).
[385] Patricia A Norberg, Daniel R Horne, and David A Horne, "The Privacy Paradox: Personal Information Disclosure Intentions Versus Behaviors."

through the GDPR will also benefit other sectors. The options include: the exercise of delegated acts, a major reform on the research exemption in 2020, a strengthened role of the European Data Protection Board, the interpretation and enforcement of the GDPR by EU consumer law, the development of sector-specific code of conducts and the introduction of ethics committees as organizational safeguards. The following section explains these suggestions in more detail.

1. Delegated acts by the European Commission to improve transparency requirements

A first idea is to start a reform process of the GDPR at EU level. For example, the European Commission may adopt delegated acts to amend non-essential elements of regulations[386]. The GDPR recognizes the power of delegation[387] and specifically foresees delegation possibilities with regard to the transparency requirements in Article 12[388]. An amendment of Article 12(1) might provide a leeway to strengthen transparency obligations in consent. For example, Article 12(1) may be altered to clarify the meaning of 'concise, transparent, intelligible and easily accessible form, using clear and plain language'[389]. The element of 'in particular for any information addressed specifically to a child' could be elaborated to strengthen the role of competence in informed consent[390]. However, a delegated act on Article 12 would not be suitable to introduce radically new concepts or approaches. It will therefore not solve major issues, such as the ill-defined meaning of research. Hence, possibilities for more substantive changes to the GDPR should be explored.

2. A major revision of the research exemption

A better option may be to focus on a revision of the research exemption. Above all, it is crucial that minimum measures and limitations are installed to prevent the (commercial) misuse of weakened protection measures of sensitive data. This may be achieved by introducing a clearer definition of research, a limit to certain types of research or a more exact clarification when commercial research can be included. For example, a condition can be installed that scientific research should contribute to the public interest. A good opportunity for a reform of the research exemption may be in May, 2020, when the GDPR will be evaluated and reviewed by the European Commission[391]. Věra Jourová, Commissioner for Justice, Consumers and Gender Equality, already stated that the 'work needs to continue for the new data protection regime to become fully operational and effective'[392]. The GDPR itself mentions 'the developments in information technologies' and the state of progress in the information society' as valid justifications for amendments to the regulation[393]. The rapid development of omics technologies, the corresponding advancement in processing possibilities of omics data and the commercialisation and monetization of data may together validate amendments to the research exemption in May, 2020.

3. New guidelines, recommendations and best practices by the European Data Protection Board

Another solution is to strengthen the position of the European Data Protection Board (EDPB). The European Commission already acknowledged its important role in data protection[394]. The EDPB

[386] TFEU., Article 290
[387] General Data Protection Regulation., Article 92
[388] Ibid., Article 12(8)
[389] Ibid., Article 12(1)
[390] Ibid., Article 12(1)
[391] Ibid., Article 97
[392] European Commission, "General Data Protection Regulation Shows Results, but Work Needs to Continue," news release, 2019, https://ec.europa.eu/commission/presscorner/detail/en/IP_19_4449.
[393] General Data Protection Regulation., Article 97(5)
[394] "General Data Protection Regulation Shows Results, but Work Needs to Continue."

ensures the consistent application of the GDPR, has the power to advise the European Commission on issues related to the protection of personal data and can issue guidelines, recommendations and best practices on its own initiative[395]. This provides possibilities to release new guidelines, in which the role of communication in consent could be specified and a tiered and staged approach to consent could be recommended. The EDPB could give clearer guidance on the role of understanding in informed consent by elaborating on the Article 29 Data Protection Working Party's notion on informed decisions, that data subjects should understand what they are agreeing to in consent[396]. It could establish best practices on consent and suggest a standard consent model, for which Figure 5 may serve as inspiration. It could also specify the possible safeguards of the research exemption, e.g. specifications on the use of pseudonymisation technologies for omics data and suggestions of alternative safeguards[397].

Besides, the EDPB could suggest solutions to deal with the issue of consent overload and information overload, by emphasizing that information should be relevant for data subjects. The principle of proportionality comes in play here. Some of the GDPR information requirements seemed clearly over the top, such as the questionable value of information about the use of the data for automated decision-making and on the possible risks of data transfers. The industry was exposed to information requirements that were costly and rather meaningless to consumers, outweighing the efficiency gains[398]. What is needed is an approach that strikes the balance between achieving the protection of privacy as a fundamental right and administrative burden. A focus on the prevention of consumer harm seems therefore more adequate than strict, narrow obligations on data management.

4. Make GDPR in line with consumer protection law

Since the prevention of consumer harm should get more priority in the GDPR, a logical solution is to interpret the GDPR in the perspective of EU consumer law. While the interplay between data protection and consumer law is not yet clearly defined, consumer law and data protection law could positively complement each other[399]. Consumer law may inform the interpretation and development of the GDPR, by adding balance and fairness in the relationship between consumers and data controllers[400]. Three suggestions are explored how this could look like: the fairness of information practices through the lens of the Unfair Commercial Practices Directive (UCPD) and of the Food Information Regulation (FIR) respectively, as well as an option to enforce data protection through consumer law mechanisms.

In order to assess the fairness of informed consent for personalized nutrition services from a consumer law perspective, the applicable consumer legislation should be found. This is not evident: depending on the type of nutriomic company, this may be either the UCPD or the FIR. While normally the fairness of information practices in the food area is covered by the Food Information Regulation (FIR), personalized nutrition services do not evidently fall under the scope of the FIR. The FIR is directed

[395] General Data Protection Regulation., Recital 139, Article 70
[396] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679.", page 13
[397] General Data Protection Regulation., Article 89
[398] Stéphane Ciriani, "The Economic Impact of the European Reform of Data Protection," *Communications & Strategies*, no. 97 (2015).
[399] Natali Helberger, Frederik J Zuiderveen Borgesius, and Agustin Reyna, "The Perfect Match? A Closer Look at the Relationship between Eu Consumer Law and Data Protection Law," *Common Market Law Review* 54 (2017).
[400] Ibid.

towards food business operators[401]. A food business has been defined by the General Food Law (GFL) as '*any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food*'[402]. Many nutriomic companies are partnered with food companies or retailers, which may try to steer the personalized advice towards certain food products. Depending on the agreement between the partners, the extent to which nutriomic companies can be considered food business operators could vary.

Some nutriomic companies are clearly involved in the production or distribution of food, for example in the delivery of personalized meal boxes by Thriva and Vita Mojo[403]. The FIR would then apply, since food is obviously offered for sale. However, this is not necessarily the case for all nutriomic companies. A crucial question remains whether the promotion of certain food products, without directly offering the food products for sale, can be considered as 'distribution of food' within the definition of a food business[404]. A careful conclusion is that in the case of advice for specific food products, the FIR would apply, but in the case of generalised dietary advice (e.g. drink less coffee; eat more whole wheat), the UCPD would be applicable. Hence, I will assess the added value of both the UCPD and the FIR to the meaning of information practices in the GDPR.

The interpretation of the UCPD to information practices

When assuming that nutriomic companies only provide broad dietary advice (e.g. without references to specific food products), the UCPD seems the applicable consumer legislation to assess the fairness of information practices. The UCPD's focus on the economic transaction between consumers and traders may facilitate a check-up of relevant consumer information, by asking the question: what is essential information for consumers in order to make a transaction decision for personalized nutrition services? At least, consumers should be aware of the purpose for which a company will collect their personal data. This may include the aspect whether more personal data are captured than necessary to provide the service and whether those data are monetized or shared with other companies[405]. Especially the monetization of data seems a crucial, but hidden issue for personalized nutrition services. The commercialization of omics data is a valuable additional revenue stream for several DTC genetic testing companies[406,407,408]. The sharing of data thus becomes an important part of their business model[409]. We have already seen the variety of commercial partners of nutriomic companies. Data monetization is therefore likely a common phenomenon in personalized nutrition services, while completely invisible for consumers. This urges the exposure of commercial prospects in the sale of nutriomic data. The UCPD may thus inspire the GDPR by emphasizing that consumers need to know certain information in the consent procedure in order to make an informed, transactional decision.

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401 Food Information to Consumers Regulation., Article 1(3)
402 General Food Law., Article 3(2)
403 Lee Bell, "The Future of Healthy Dining: A Personalized Meal Based on Your Blood".
404 General Food Law., Article 3(2)
405 Natali Helberger, Frederik J Zuiderveen Borgesius, and Agustin Reyna, "The Perfect Match? A Closer Look at the Relationship between Eu Consumer Law and Data Protection Law."
406 Alex Philippidis, "Dtc-Marketed Tests Look to Clinical Studies for Growth: Developers Tap into Data Deluge from Research, Clinical Collaborations," *Clinical OMICs* 3, no. 9 (2016).
407 Emilia; Kalokairinou Niemiec, Louiza; Howard, Heidi Carmen, "Current Ethical and Legal Issues in Health-Related Direct-to-Consumer Genetic Testing."
408 Dennis Grishin, Kamal Obbad, and George M Church, "Data Privacy in the Age of Personal Genomics," *Nature biotechnology* (2019).
409 Brendan Seward, "Direct-to-Consumer Genetic Testing: Finding a Clear Path Forward," *Therapeutic innovation & regulatory science* 52, no. 4 (2018).

The interpretation of the FIR to information practices

In case a nutriomic company offers specific food products for sale with their dietary advice, the FIR would bring additional content for the GDPR's interpretation of consent. The FIR may provide a clearer view on the meaning of the 'informed' aspect of consent, since it takes into account the differences in the perception of consumers and their information needs[410]. This may give the GDPR a basis to develop a more behavioural interpretation on information, in particular with regard to *competence* and *understanding* elements of informed consent. Besides, the FIR specifically strives for social desirable goals, by providing a basis for final consumers to make informed choices[411]. This may give a leeway for the GDPR to emphasize the importance of informed decisions more clearly[412] and to make a plea for scientific research to contribute to consumer interests.

Data protection enforcement through consumer law mechanisms

Consumer law may also contribute to a better enforcement of the GDPR. An infringement of data protection measures may simultaneously result in a consumer law infringement, which could be enforced through consumer organisations. For example, the Unfair Contract Terms Directive (UCTD) may be applied to assess unfair situations arising from personal data processing[413]. Consumer and trade organizations could bring cases for infringements through the EU regulation on consumer protection cooperation[414]. The UCTD is explicitly included in the scope of the regulation[415]. Arguably, the regulation may also provide room for the enforcement of the UCPD. The UCPD has not yet been included as a 'law that protect consumer' interests'[416]. This is remarkable, since the UCPD is evidently part of EU consumer law with its purpose to achieve a high level of consumer protection[417]. Hence, the regulation on consumer protection cooperation may provide an extra mechanism to enforce data protection law through the UCTD, and perhaps the UCPD.

5. Develop sector-specific codes of conduct within the GDPR framework

Another regulatory solution for more ethical data protection regulation can be found in the realm of soft law instruments. The GDPR provides for the compliance with codes of conduct[418] and ethical standards[419]. The establishment of ethical standards specifically concerns data processing for scientific research purposes. Unlike the code of conducts, the call for ethical standards is not founded in any Article of the GDPR, but is solely recognized in a recital[420]. Since recitals mainly have an interpretative function in EU regulations, the establishment of a code of conduct may be a stronger mechanism to promote ethical data behaviour. Article 40 of the GDPR acknowledges the sector-specific element of code of conducts and specifies topics that the code of conducts may cover[421]. Considering the challenges that personalized nutrition services bring for data protection, relevant applications of the code of conduct may include: 'fair and transparent processing', 'information

[410] Food Information to Consumers Regulation., Article 1
[411] Ibid., Article 3(1)
[412] Article 29 Data Protection Working Party, "Guidelines on Consent under Regulation 2016/679."page 13
[413] Natali Helberger, Frederik J Zuiderveen Borgesius, and Agustin Reyna, "The Perfect Match? A Closer Look at the Relationship between Eu Consumer Law and Data Protection Law."
[414] Regulation on consumer protection cooperation.
[415] Ibid., Article 3(a), Annex
[416] Ibid., Article 3(a), Annex
[417] Unfair Commercial Practices Directive., Article 1
[418] General Data Protection Regulation., Article 40
[419] Ibid., Recital 33
[420] Ibid., Recital 33
[421] Ibid., Article 40

provided to the public and to data subjects', 'exercise of the rights of data subjects' and 'information provided to, and the protection of, children, and the manner in which the consent of the holders of parental responsibility over children is to be obtained'[422]. It can be assumed that the possibilities for code of conducts are not limited to the list of topics presented in Article 40(2) ('...may prepare codes of conduct...for the purpose of specifying the application of this Regulation, *such as* with regard to...')[423]. Hence, a code of conduct could also be developed for a clarification on the research exemption, in order to promote an ethical way of processing data when performing scientific research. Recital 33 may be interpreted to support such code of conduct as a form of ethical standard[424].

The adoption of a code of conduct requires a consultation with relevant stakeholders, accreditation by a supervisory authority and approval by the European Commission[425]. Some initiatives already exist, such as a code of conduct for health research[426,427] and a draft code of conduct on privacy for mobile health applications[428]. The idea for a code of conduct for genomics and health has also been proposed[429], which may be particularly suitable for the context of personalized nutrition. A limitation of a code of conduct may be that it only provides an evidence of compliance with the GDPR, but cannot be regarded as a proof of compliance with the GDPR[430]. Nonetheless, a code of conduct would offer practical guidance to nutriomic companies on the application of the GDPR in the specific context of omics technologies and health.

6. Introduce ethics committees as an organisational safeguard

Besides pseudonymisation, the GDPR does not suggest any other form of technical or organisational safeguard to ensure the adequate application of the research exemption[431]. An organisational safeguard that may be particularly suitable for the context of personalized nutrition services is the establishment of independent ethics committees. The option to use nutriomic data for future research has implicit implications. Consumers may assume that there is a governing body deciding what is permitted as research, that there is a general program of research or an account of the general objectives of research. Since this is not the case, consumers' consent to future research becomes an open form of consent, while the research does not necessarily contribute to public goals. While informed consent may be appropriate to enable informed decisions on medical matters, it is not evident whether it is sufficient for privacy issues. Since data processing remains abstract and privacy harms are not necessarily private, it can be questioned whether decisions for further data usage can be left to consumers. An accredited ethics committee may be better equipped to check what research can be permitted and what data behaviour is ethically admissible. The committee can take into account the potential risks of data processing and it can assess the quality of informed consent (e.g. the balance of

[422] Ibid., Article 40(2)
[423] Ibid., Article 40(2)
[424] Ibid., Recital 33
[425] Ibid., Recital 33
[426] Anastassia Negrouk and Denis Lacombe, "Does Gdpr Harm or Benefit Research Participants? An Eortc Point of View," *The Lancet Oncology* 19, no. 10 (2018).
[427] BBMRI-ERIC, "A Code of Conduct for Health Research," http://code-of-conduct-for-health-research.eu/.
[428] Eugenio Mantovani et al., "Towards a Code of Conduct on Privacy for Mhealth to Foster Trust Amongst Users of Mobile Health Applications," in *Data Protection and Privacy:(in) Visibilities and Infrastructures* (Springer, 2017).
[429] Mark Phillips, "International Data-Sharing Norms: From the Oecd to the General Data Protection Regulation (Gdpr)," *Human genetics* 137, no. 8 (2018).
[430] Ibid.
[431] General Data Protection Regulation., Article 89(1)

risks and benefits). In this way, nutriomic data can only be used for future research when privacy considerations are sufficiently covered and clear (public) benefits exist.

5.4 Recommendations for future research

While this thesis specifically looked at the GDPR and the ethics on informed consent, inspiration can be found in other ethical and legal areas to realize a better governance of DTC personalized nutrition services. Several recommendations for future research are proposed, linked to the familial aspect of genetic data, the use of nutriomic data for further research, the application of other laws to the context of personalized nutrition and the strong need for empirical evidence.

Within the GDPR framework, the familial aspect of genetic data clearly deserves more attention. In interpreting the Data Protection Directive, the Art. 29 Working Party has acknowledged the familial dimension of data in its Working Document on Genetic Data. Family members would have a 'right to information that may have implications for their own health and future life'[432]. The legal consequences of a such shared ownership of genetic data remain indecisive. Two possibilities are sketched by the Art. 29 Working Party, either treating family members equally as data subjects, or only granting rights where personal interests are directly affected. Nevertheless, this interpretation seems not have grounded in the definition of genetic data in GDPR. The GDPR has a clear focus on the individual, treating personal data only as identifiable data[433]. Even though a strengthened protection of genetic groups brings out challenges on its own[434], it could be argued that shared, non-unique data from genomic analyses should be treated as personal data[435,436]. Hence, **further analysis should explore the familial aspect of data and its consequences on (informed) consent.**

The use of nutriomic data for further research is a returning issue in the GDPR, which can be approached from different research angles. **A crucial question is whether GDPR's broad interpretation of consent in research can be regarded as full informed consent from an ethical perspective**[437]. In order to answer this question, consent for research in personalized nutrition services may be compared with broad consent in biobanks. Biobank requirements can perhaps be extended to the context of personalized nutrition services. The differences and similarities between these two applications of broad consent may provide insight in how the research of nutriomic data is best governed.

While the introduction of an ethics committee as an organizational safeguard has already been proposed as a solution, the implementation is limited by Member States decisions to decide upon the type of safeguards. It is possible that not all Member States are in favour of installing an ethics committee, which might lead to a fragmented framework on GDPR's research exemption throughout the EU. An alternative is the establishment of an ethics committee as a private label. In this way, nutriomic companies could consumers' privacy concerns, increasing the public acceptance of personalized nutrition services among consumers. Consequently, **the possibilities for self-regulation**

[432] Article 29 Data Protection Working Party, "Working Document on Genetic Data.", page 8
[433] General Data Protection Regulation., Article 4(1)
[434] Dara Hallinan and Paul de Hert, "Genetic Classes and Genetic Categories: Protecting Genetic Groups through Data Protection Law."
[435] Heather Widdows, *The Connected Self: The Ethics and Governance of the Genetic Individual*.
[436] Mark Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection*, 16.
[437] Mark Sheehan, "Can Broad Consent Be Informed Consent?," *Public Health Ethics* 4, no. 3 (2011).

of a controlled data access model should be further explored. Inspiration can be drawn from initiatives currently developed, such as the MyHealthMyData network on biomedical information[438].

Beyond the GDPR, the application of other legislation to personalized nutrition services should be examined in more detail. The possible interplay between the UCPD and the FIR in the context of personalized nutrition should play a pivotal role. With a growing public demand for personalized insights in health and recent initiatives of companies to combine personalized nutrition with tailored food products and supplements, there is a strong need to protect consumers from potentially misleading advertising. **When and how these information practices are regulated by either the UCPD or the FIR should be the central focus of attention**. **A further research question could assess the role of choice architecture, how the marketing of personalized nutrition services would influence consumer decision making**.

In addition, personalized nutrition services are prone to make unsubstantiated health claims under the FIR and the Nutrition and Health Claims Regulation (NHCR). As noted before, personalized nutrition finds itself at the boundary between medicine and consumer culture, aspiring the prevention and treatment of diet-related diseases. At the same time, the FIR prohibits claims or suggestions that food can treat, prevent or cure diseases[439], while the NHCR strictly specifies the conditions for certain 'reduction of disease risk claims' [440]. **This prompts the research questions whether personalized nutrition services are at risk of making health claims, and whether certain types of health claims might be allowed under the FIR and the NHCR.**

Next to the UCPD, FIR and NHCR, the possible application of other relevant EU legislation should be considered as well, including the In Vitro Diagnostic Medical Devices Regulation on the testing devices for DTC personalized nutrition. In any case it is crucial to relate the application of the legislation on personalized nutrition with empirical research. There is a strong need to analyse current practices within DTC personalized nutrition services, and to see whether these practices satisfy legal and ethical standards. **It is recommended to perform a content analysis on the websites of providers of personalized nutrition services, to conduct interviews on their form of consent, the third-party interpretation services, health claims and marketing strategies, and to compare the advice from several providers in order to test the validity of personalized nutrition advice**.

When the additional legal and ethical challenges of governing personalized nutrition services have been identified and substantiated with empirical evidence, new regulatory solutions could be explored. Inspiration may be drawn from other legal systems (e.g. the US, with a rich history in DTC genetic testing services) and from the legislation of individual Member States within the EU, including the role of national consumer authorities on privacy issues. The possibilities of other governance mechanisms beyond informed consent should be taken into account. Perhaps, these findings will justify the design of separate legislation on personalized nutrition services, possibly in the framework of food law. This may allow a concrete ethical and legal solution to the challenges that the personality of personalized nutrition brings.

[438] MyHealthMyData, "Why Mhmd?," http://www.myhealthmydata.eu/why-mhmd/.
[439] Food Information to Consumers Regulation., Article 7(3)
[440] Nutrition and Health Claims Regulation., Article 14

Chapter 6: Conclusions

The main question of this research was:

> *How to design the General Data Protection Regulation in order to govern nutriomic-based direct-to-consumer personalized nutrition services in an ethical way?*

This question was answered through three sub-questions:

1. ***Which ethical standards are appropriate for obtaining informed consent in nutriomic-based direct-to-consumer personalised nutrition services?***

The medical character, the inadequate regulations of commerce and the complex features of DTC personalized nutrition services justify the come-into-play of medical standards. The adoption of informed consent in a medical context (*full informed consent*) is particularly appropriate. The functions of full informed consent align well with the challenges observed in personalized nutrition: to empower consumers to achieve their health goals, to prevent deceptive practices and to avoid various forms of harm.

Five elements of full informed consent can be distinguished: competence, disclosure, understanding, voluntariness and consent. In the context of nutriomic-based DTC personalized nutrition services, the assessment of consumers' **competence** is crucial. It is argued that children should not be permitted to undergo nutriomic testing, or only with the involvement and guidance of a genetic counsellor. Nine key **disclosure** elements were recommended for personalized nutrition services: *Purpose, Exclusion, Benefits, Risks, Limitations, Data protection, Optional follow-up, Withdrawal of consent* and *Further information possibilities*. The major risks involved with personalized nutrition services are related to the **understanding** of information, often arising from an over- or under estimation of disease risks. I conclude that consumers of personalized nutrition services should at least understand the *purpose of the service, the risks, benefits and limitations and a basic conception of data protection*. Appropriate assessment methods may be a comprehension quiz and/or pre- and post-test counselling. The **voluntariness** of consent ensures the absence of both negative and positive forms of influencing. To avoid involuntary testing resulting from using personalized nutrition services, a fair data follow up procedure is essential. The electronic environment of personalized nutrition services stresses an explicit way of giving **consent** - the authorization to proceed with nutriomic testing.

The five elements of full informed consent can be embedded in an ethical model for personalized nutrition. This model gives freedom of choice in the testing offer by the creation of **tiers**, presents **layered** information with a separation of essential and additional information, and sees informed consent as a process with different **stages** to improve consumers' understanding and decision-making.

2. ***Which requirements of the General Data Protection Regulation need to be fulfilled for the offering of nutriomic-based direct-to-consumer personalized nutrition services?***

Personalized nutrition services fall under the material **scope** of the GDPR, since data processing is necessary to turn the omics data into dietary advice. The GDPR covers both nutriomic companies in the EU, as well as companies from non-EU countries processing personal data of individuals from the EU. The **categorization of nutriomic data** under the GDPR has shown to be unclear. When metabolomics and proteomics technologies are used in personalized nutrition advice, it is unclear

whether the data belongs to *genetic data* or *data concerning health*. The bounded categories of personal data could lead to confusion, as the GDPR may give the impression that genetic data are protected in a different way than health data. However, both types of data are characterised as sensitive and fall under the same data processing obligations.

Since nutriomic is regarded as sensitive personal data, **explicit consent** should be obtained for nutriomic data processing. This should be *freely given, specific, informed* and be *an unambiguous indication of wishes by the data subject*. It is doubtful how well GDPR's notion of informed consent matches with the character of personalized nutrition. Two main challenges are: the conversion of the complex nature of data processing into simplified terms and the probable outcome that consumers still do not adequately understand the simplified information. In addition, the conditions on children consent are clearly insufficient to limit minors accessibility to personalized nutrition services. The age and consent verification is problematic and the minimum age limits may vary among Member States.

Nutriomic companies need to ask data subjects their consent for **further processing for scientific research purposes**. Since research is interpreted in a broad way, a wide variety of third parties affiliated with nutriomic companies (universities, food industry, food service providers, supermarkets) could benefit from the research exemption. The research exemption comes with soft data processing requirements: data can be stored for an unlimited time and can be used for practically any research purpose, while data subject's informational rights and rights to be forgotten are significantly weaker. Member States can introduce extra derogations which may stimulate companies to move to the country with the most exceptions. Member States can introduce stronger data protection measures, but these are limited (e.g. by necessity of a free flow of data) or associated with various disadvantages (e.g. pseudonymisation).

3. ***How do the requirements of the General Data Protection Regulation fulfil the ethical standards on informed consent?***

Before the GDPR is measured with ethical standards, the GDPR itself poses a severe problem that needs to be tackled first. The broad interpretation of research within the GDPR has several unwanted implications for the delivery of personalized nutrition services. The GDPR allows commercial research without setting conditions, disregarding a possible contribution to the public interest. Hence, commercial exploitation seems hardly unavoidable, weakening data protection rights and obligations.

A comparison between the ethical conception of *full informed consent* and the legal conception of *GDPR consent* led to more bottlenecks. The GDPR lacks strict obligations on the accessibility of minors to personalized nutrition services. They are allowed to undergo nutriomic testing, while the parental consent is easy to avoid and hard to verify. The disclosure of GDPR consent misses out on several important health-related elements, disabling a balanced representation of risks, benefits and limitations. GDPR's consent requirements are not likely to lead to improved comprehension of consumers of personalized nutrition services, as the GDPR merely looks at the legibility and readability of information. While GDPR's element of *freely given* consent focuses on negative influencing, the undesirable positive influencing needs to be part of valid consent as well. Although the GDPR does recognize the importance of a layered approach to informed consent, it still needs to incorporate a tiered and staged approach to informed consent.

How to design the General Data Protection Regulation in order to govern nutriomic-based direct-to-consumer personalized nutrition services in an ethical way?

Six solutions were proposed to design the GDPR for a more ethical governance of nutriomic-based direct-to-consumer personalized nutrition services:

1. *Delegated acts by the European Commission to improve transparency requirements*

An amendment of Article 12 could strengthen the transparency requirements in consent, by explaining the meaning of 'concise, transparent, intelligible and easily accessible form, using clear and plain language' and the 'information addressed specifically to a child'. This would facilitate stronger roles of competence, disclosure and understanding in informed consent.

2. *A major revision of the GDPR in 2020*

More substantive changes can be implemented in May, 2020, when the GDPR will be evaluated and reviewed by the European Commission. This provides an opportunity to revise the research exemption, reinforcing minimum measures and limitations and clarifying the definition of research.

3. *A stronger role for the European Data Protection Board: New guidelines, recommendations and best practices*

The European Data Protection Board should issue new guidelines, recommendations and best practices on informed consent. It should specify how consent could enable data subjects' understanding beyond readability requirements, recommend a tiered and staged approach, establish best practices on consent, specify the possible safeguards of the research exemption, and provide solutions to deal with the issue of consent overload and information overload.

4. *Make GDPR in line with consumer protection law*

The GDPR should give more attention to the protection of privacy as a prevention of consumer harm. Depending on whether nutriomic companies can be considered food business operators, the fairness of information practices can be interpreted by the UCPD or the FIR. The UCPD allows consumers to visualize the monetization of data in personalized nutrition services. The FIR enables the GDPR to better take into account differences in the perception of consumers and their information needs. Consumer law also provides an option for a stronger enforcement of data protection through the regulation on consumer protection cooperation.

5. *Develop sector-specific codes of conduct within the GDPR framework*

Sector-specific code of conducts could be developed on the fairness and transparency of processing, information requirements, the protection of children and a clarification on the research exemption. A code of conduct for genomics and health may be particularly suitable for personalized nutrition.

6. *Introduce ethics committees as an organisational safeguard*

The GDPR should suggest the introduction of ethics committees as an organisational safeguard. The committee can assess the potential risks of data processing and the quality of informed consent, so that nutriomic data is only used for future research when ethical standards are sufficiently met.

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