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Alternative Proteins and Food Labelling: Is the EU regulatory framework
fit-for-purpose?

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Abstract

Due to environmental, ethical and public health reasons there is a growing need to globally reduce meat consumption and turn to alternative sources of protein. However, their introduction into the market is tied with a number of technological, societal and, most importantly, regulatory challenges. This thesis aims at tackling these challenges, analyzing the EU legislative framework covering alternative proteins and identifying whether it is fit-for-purpose to address their labelling by conducting interdisciplinary research and gathering evidence from legal and other academic sources. The results of the research showed that most aspects related to food safety and consumer protection, except for the names used to market alternative proteins, are adequately covered in the current regulatory regime, while aspects related to sustainability are lacking. Future legislative action on food labelling, environmental and ethical claims, an intervention from the CJEU, targeted research and innovation, international cooperation to increase consumer protection and ensure the smooth functioning of the internal market, adequate incentivization of producers and consumer education can be expected to provide more clarity on the matter, enable the protein transition and facilitate the labelling of alternative sources of protein.

Key words: alternative proteins, consumer protection, food labelling

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Abbreviations

United Nations (UN)
Greenhouse Gas Emissions (GHG emissions)
Farm-to-Fork Strategy (F2F Strategy)
European Union (EU)
European Food Safety Authority (EFSA)
European Commission (EC)
United States of America (USA)
Food and Drugs Administration (FDA)
Generally Recognized as Safe (GRAS)
Food Business Operator (FBO)
Treaty of the Functioning of the EU (TFEU)
Genetically Modified Organism (GMO)
Court of Justice of the EU (CJEU)
Standing Committee on Plants, Animals and Feed (PAFF)
New Genomic Techniques (NGTs)
European Parliament (EP)
Small and Medium Enterprises (SMEs)
Common Agricultural Policy (CAP)
European Vegetarian Union (EVU)
Conseil d'Etat (CE)

Introduction

Background Information & Problem Statement

Over the past decades, a pattern of increasing meat consumption has been noticed globally. For instance, in 1961, the average yearly meat consumption was 23.1 kg per person, while in 2011 the number had almost doubled to 42.2 kg of meat per person.¹ As of 2022, the per capita consumption of meat was still high but showed signs of stagnation, especially in high-income countries.² In low- and middle-income countries, meat consumption is projected to continue rising due to rapid economic growth.³ At the same time, according to the United Nations (UN), the global population is estimated to climb to almost 10 billion people by 2050.⁴ As a result, a huge demand for meat production is created in order to ensure food security and adequately meet the dietary needs of consumers.⁵

On one hand, meat is a staple in human nutrition and is currently highly demanded for several reasons. First and foremost, it has a favorable nutritional profile and its consumption is linked with multiple health benefits. It is a rich source of essential macronutrients, namely protein and fatty acids, and micronutrients such as iron, zinc and B12 vitamins, while also contributing to the normal functioning and development of the human body.⁶ At the same time, it is rich in flavor and texture and is inextricably linked with an array of social and cultural norms.⁷ On the other hand, excessive meat production and consumption have been linked with environmental, ethical and public health concerns.⁸ For instance, the livestock industry is a significant contributor to the total greenhouse gas (GHG) emissions and impacts soil erosion, the overconsumption of processed and red meat has been linked with the occurrence of colon cancer and

¹ P. Sans and P. Combris, 'World meat consumption patterns: An overview of the last fifty years (1961–2011)' [2015] 109 *Meat Science* 106, 106

² OECD/FAO, '*OECD-FAO Agricultural Outlook 2023-2032*' (OECD Publishing 2023), 188

³ Ibid

⁴ M. Henchion and others, 'Review: Trends for meat, milk and egg consumption for the next decades and the role played by livestock systems in the global production of proteins' (2021) 15(100287) *Animal - The international journal of animal biosciences*, 2

⁵ Nayab Fatima and others, 'Recent advances in microalgae, insects, and cultured meat as sustainable alternative protein sources' [2023] 1 *Food and Humanity* 731, 731

⁶ H. Charles J. Godfray and others, 'Meat consumption, health, and the environment' (2018) 361(6399) *Science* eaam5324, 2; Hyun Jung Lee and others, 'Status of meat alternatives and their potential role in the future meat market — A review' (2020) 33(10) *Asian-Australasian Journal of Animal Sciences* 1533, 1533

⁷ Status of meat alternatives and their potential role in the future meat market — A review (n.6) 1533

⁸ Recent advances in microalgae, insects, and cultured meat as sustainable alternative protein sources (n. 5) 731

cardiovascular diseases and certain farming practices are considered cruel and unethical, thus raising issues concerning animal welfare.⁹

Therefore, it has been advocated that it is necessary to globally reduce meat production and consumption and gradually transition to alternative sources of protein in order to mitigate the overall negative impact of the farming industry.¹⁰ As a result, new sources of protein are emerging, with estimates showing that by 2029, 10% of the global protein market will be covered by the alternative protein and meat substitute sectors.¹¹ On an international level, efforts are being made to facilitate this transition from meat products to alternative proteins, with certain initiatives including the EU Farm-to-Fork Strategy (F2F), the UN Sustainable Development Goals, the Canadian food policy and the Healthy China 2030 Plan.¹²

However, many of these alternative proteins are still new and innovative products and are thus facing a myriad of challenges, namely technological, societal and, most importantly, regulatory. In the European Union (EU), there currently is no specific regulatory framework targeting alternative sources of protein, which raises questions concerning their lawful marketing. The main issues lie with their overall labelling, as well as if they should be marketed under denominations traditionally used by the meat industry, or 'meat terms'; topics which have been controversial and heavily debated among political and social circles.

Research Objective & Research Question

In general, this thesis aims at tackling the aforementioned concerns surrounding the labelling of alternative sources of protein. More specifically, its main goals are, firstly, to explore and analyze the extensive EU legislative framework covering the marketing and the labelling of alternative sources of protein; secondly, to identify

⁹ 'Meat consumption, health, and the environment' (n.6) 3; Center for food safety, 'Animal Factories and Animal Welfare' (Center for Food Safety) <<https://www.centerforfoodsafety.org/issues/307/animal-factories/animal-factories-and-animal-welfare>> accessed 2 April 2024; Commission Staff Working Document - Fitness Check of the EU Animal Welfare Legislation [2022] SWD (2022) 328 final, 64

¹⁰ EC, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system' COM/2020/381 final, para 2.4; Antonio Albaladejo Román, 'EU protein strategy' (Briefing Paper No PE 751.426, European Parliamentary Research Service, July 2023) 4

¹¹ Michael Siegrist and Christina Hartmann, 'Why alternative proteins will not disrupt the meat industry' [2023] 203 Meat Science 109223, 1

¹² Océane Duluins and Philippe Vincent Baret, 'A systematic review of the definitions, narratives and paths forwards for a protein transition in high-income countries' [2024] 5 Nature Food 28, 29

whether this legislative framework is fit-for-purpose or if amendments are necessary to properly address their labelling.

Therefore, the main research question of this thesis is:

Is the current EU legislative framework able to address the labelling of alternative proteins and if not, how can it be amended to reflect the growing needs of the market, as well as environmental and ethical concerns surrounding protein consumption?

In order to tackle the main research question and provide a holistic response, several sub-research questions have been formulated and presented below:

1. What are alternative proteins and how are they categorized?
2. How can alternative proteins be marketed in the EU?
3. How can alternative proteins be labelled in the EU?
4. How has the EU dealt with similar situations and what impact does that have on the alternative protein market?
5. How are Member State laws approaching the labelling of alternative proteins? The cases of France, Italy, Germany and the Netherlands
6. Does the use of meat related terms on the labelling of alternative proteins have the potential to mislead the consumers?

Thesis Outline

Each Chapter of the thesis deals with one sub-question. Therefore, in Chapter 1 a categorization, as well as the main characteristics, of alternative proteins are discussed. In Chapters 2 & 3, a deep-dive analysis of the EU legislative framework covering the marketing and labelling of alternative proteins is conducted. In Chapter 4, the position of the EU concerning the labelling of dairy substitutes and its impact on the alternative protein sector is explored and discussed. In Chapter 5, the four case studies are conducted, while in Chapter 6, the potentially misleading effect of 'meat terms' is being explored. Finally, the thesis evaluates the current regulatory, political and societal environment surrounding the labelling of alternative proteins and provides a critical reflection of the issue at hand.

Methodology

This thesis employs an interdisciplinary approach in order to tackle the main research question, as well as the different sub-questions, meaning that research is not limited to one scientific discipline but it integrates inputs and considerations from multiple fields of research, namely life, human and economic sciences. As a result, the broader context surrounding the marketing and labelling of alternative proteins is constructed, understood and evaluated.¹³ As far a legal analysis goes, the thesis employs doctrinal legal research which aims at identifying and critically analyzing the relevant regulatory provisions, as well as established case-law, focusing on both its strengths and shortcomings.¹⁴ Last but not least, case-studies are employed, since they can be a useful tool in order to conduct an in-depth qualitative investigation and assessment of the impact of a complex phenomenon, event or situation on a specific target.¹⁵

More specifically, for Chapters 1 and 6 research was based on social, economic, scientific and legal sources, thus conducting interdisciplinary research, in order to establish the different types of alternative proteins, their technological and nutritional properties, their broad environmental impact, as well as their position within consumer perception. For Chapters 2 and 3, a doctrinal approach was used in order to establish, analyze and evaluate the regulatory framework that surrounds the marketing and the labelling of alternative sources of proteins on an EU level. This means that the main sources of information were regulations, directives and other policy documents that concern the food sector and by extension, alternative proteins. Chapter 4 was mostly written based on a doctrinal research approach and the examination of established EU and Member State case-law. However, reference was also made to news media outlet sources in order to better capture the impact of the *Tofutown* judgement on a societal and political level. Finally, Chapter 5 consists of four distinct case studies.

Concerning Chapter 5, it is important to explain the context and reasoning behind the choice to conduct case studies. In general, the EU is a political and economic entity consisting of 27 Member States. Even though the members of the Union share certain common goals, such as its economic, social and territorial growth and the establishment

¹³ Sally W. Aboelela and others, 'Defining Interdisciplinary Research: Conclusions from a Critical Review of the Literature' (2007) 42(1) Health Services Research 329, 341

¹⁴ Terry Hutchinson, Doctrinal research - Researching the jury. in Dawn Watkins and Mandy Burton (eds), Research methods in law (Routledge, Taylor & Francis Group 2018), 13

¹⁵ Helena Harrison and others, 'Case Study Research: Foundations and Methodological Orientations' (2017) 18(1) Forum Qualitative Sozialforschung, 8

of the internal market, each member is also a sovereign state with different societal values and customs, political and economic motives and aspirations.¹⁶ As a result, they may choose to follow different regulatory pathways in the areas that they are competent to do so, in order to promote and achieve their own independent goals. One of these areas is agriculture and by extension the food sector.¹⁷ In the context of alternative sources of protein and their labelling, opposing views and intents have been presented and, therefore, it is interesting and valuable to assess the position of different Member States from both sides of the spectrum. On one hand, France and Italy were chosen since they are two countries that have chosen to impose regulatory bans and limitations on the labelling of meat substitutes, with Italy being even attempting to ban the production and marketing of lab-grown meat. On the other hand, Germany and the Netherlands were chosen because of their positive approach towards veganism and their choice to adopt guidelines that facilitate the labelling of substitute products and enable the use of 'meat terms'. There are no countries that have implemented national laws allowing the use of 'meat terms' and therefore it was only possible to examine the adopted guidelines.

Data collection was done through multiple web-based sources of legal documents, academic literature, as well as news media outlets (e.g., the BBC, the Guardian). The most used databases were Google Scholar, WUR library and Science Direct, as well as regulatory and legal databases from different EU Member States (e.g., CURIA, EUR-lex, Legifrance).

¹⁶Directorate-General for Communication, 'Aims and values' (*European Union*) <https://european-union.europa.eu/principles-countries-history/principles-and-values/aims-and-values_en> accessed 2 April 2024

¹⁷ Consolidated version of the Treaty on the Functioning of the EU [2012] OJ C 326/47, art 4(2)(d)

Chapter 1: Alternative Proteins

Grasping the concept of alternative proteins and the type of products they refer to can be a challenging task, since it requires the establishment of a baseline under which traditional proteins are clearly defined and juxtaposed to the alternative ones. However, tradition is relative and differs significantly among continents, countries and even regions. What may be viewed as 'traditional' in Western Europe, may be unknown or less popular in South America or Africa.

In the EU, meat is defined in Regulation (EU) 853/2004 as "*the edible parts of an animal [...] including blood*"¹⁸ and refers to, *inter alia*, poultry, lagomorphs, bovine animals and wild game.¹⁹ Meat is currently considered the main source of protein for most adults in the EU.²⁰ Under this context, alternative proteins may be arbitrarily defined as those not included in the aforementioned EU regulatory framework and shall include plant – based substitutes, cultured cells, insects, fungi and algae.²¹ Multiple institutions such as the European Food Safety Authority (EFSA), the European Institute of Innovation and Technology and the Food and Agriculture Organization of the UN provide an almost identical categorization.²² Similarly, descriptions of the term can be found scattered in the provisions of the European Commission (EC)'s F2F Strategy and the EU Protein Strategy, but no clear, legal definition has been provided yet.²³

However, the aforementioned categorization is slightly two dimensional and mainly focuses on drawing a distinction between warm-blooded animals and all other sources of protein without taking into account the multiple aspects associated with the production and consumption of protein. A broader definition, which could pose as potential inspiration for creating a concise legal definition for alternative proteins, has been provided by Grossmann and Weiss and reads as follows:

¹⁸ Regulation (EC) No 853/2004 of the EU and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin [2004] OJ L 139/55, Annex I, 1, 1.1

¹⁹ Ibid Annex I, 1, 1.2 – 1.5

²⁰ EU protein strategy - Briefing Paper No PE 751.426 (n.10) 2

²¹ Lutz Grossman and Jochen Weiss, 'Alternative Protein Sources as Technofunctional Food Ingredients' [2021] 12 Annual Review of Food Science and Technology 93, 94; 'Why alternative proteins will not disrupt the meat industry' (n.11) 1

²² EFSA, 'Novel Food' (EFSA - Science, safe food, sustainability) < <https://www.efsa.europa.eu/en/topics/topic/novel-food#eu-framework> > accessed 2 April 2024; EIT Food, *Protein Diversification – an EIT Food White Paper* (EIT Food, 2022) 7-9; FAO, 'The need for guidance on alternative proteins highlighted to Codex Alimentarius Commission' (8 November 2021, FAO) < <https://www.fao.org/in-action/sustainable-and-circular-bioeconomy/resources/news/details/fr/c/1459357/> > accessed 2 April 2024

²³ A Farm-to-Fork Strategy (n.10) para 2.1, 3.1; EU protein strategy - Briefing Paper No PE 751.426 (n.10) 4-5

*"Alternative proteins are produced from sources that have low environmental impact to replace established protein sources. They can also be obtained from animal husbandry with good animal welfare."*²⁴

This definition's focal point is the environmental and ethical impact of the current protein production regime and seems to be aligned with the main reasons, along with food security, that non-meat protein sources are gaining popularity.²⁵ Similar definitions may have been provided by other scholars and may influence decision making if and when lawmakers decide to create a legal definition for the term. For the time being, it is widely accepted that alternative proteins are all non-meat protein sources, including microbial sources, plants, insects and cultured meat.²⁶

1.1 Plant - based Proteins

Plant-based meat substitutes are constructed from proteins which are derived from plants and are processed to resemble the appearance, texture and flavor of meat.²⁷ Plant proteins date back to, at least, 600 AD Asia, when their consumption was mostly limited to soybean and wheat derivatives produced by simple processing or fermentation techniques.²⁸ In the region, plant-based proteins were a staple in human nutrition for thousands of years, whereas in other parts of the world and throughout the 19th and 20th century, plant-based derivatives were mainly consumed when meat was not available.²⁹ Newer and innovative plant-based proteins were initially introduced during the 1950s to meet the needs of the growing vegetarian and vegan movement.³⁰ However, most of these products did not resemble the composition and flavor of meat, thus limiting their consumption to a niche market. The need to create meat substitutes that would also appeal to non-vegetarian consumers, led food companies to invest more resources in the production of plant-based proteins that mimic conventional meat more

²⁴Alternative Protein Sources as Technofunctional Food Ingredients (n.21) 94

²⁵ The need for guidance on alternative proteins highlighted to Codex Alimentarius Commission (n.22)

²⁶ Ibid

²⁷Jiang He and others, 'A review of research on plant-based meat alternatives: Driving forces, history, manufacturing, and consumer attitudes' (2020) 19(5) Comprehensive Reviews in Food Science and Food Safety 2639, 2640

²⁸ Ishamri Ismail, Young-Hwa Hwang and Seon-Tea Joo, 'Meat analog as future food: a review' (2020) 62(2) Journal of Animal Science and Technology 111, 112; Natalie R. Rubio, Ning Xiang and David L. Kaplan 'Plant-based and cell-based approaches to meat production' [2020] 11 Nature Communications 6276, 2

²⁹János Szenderák, Dániel Fróna and Mónika Rákos, 'Consumer Acceptance of Plant-Based Meat Substitutes: A Narrative Review' (2022) 11(9) Foods 1274, 2

³⁰Ibid

accurately.³¹ These products include not only soy and wheat extracts, but also legume and oilseed proteins.³²

Plant-based protein production consists of three basic steps. Firstly, protein extraction and isolation from the plant. Secondly, formulation which includes mixing the protein extract with ingredients like food colorings, flavor enhancers, plant-based fat and flour to emulate the nutritional value and appearance of meat and, finally, further processing, through means of spinning or extrusion, to create a structure that resembles that of meat.³³ By upscaling and improving this production process, it is believed that plant proteins may pose a viable solution to the rising protein demand. For example, according to the EU Protein Strategy, plant proteins can pave the way to a more environmentally friendly and healthy protein consumption, while also positively affecting farmer's incomes and wellbeing.³⁴

The benefits, as well as the pitfalls, of plant-based meat substitutes have been explored in multiple studies and address environmental, nutritional and economic concerns. For instance, studies evaluating the environmental impact of plant protein production and the shift to vegetarian and vegan diets, point to the fact that substituting meat with alternative protein sources has the potential to reduce GHG emissions by 55% and land use demand by 60% but at the expense of energy consumption, which is estimated to be high due to excessive processing.³⁵

From a nutritional perspective, plant proteins are of a lower quality in comparison to animal proteins and have a poorer amino acid and trace element profile, thus requiring some sort of complementation.³⁶ In order to emulate meat structure, the more innovative formulations are occasionally enriched with ingredients to create a 'bleeding' effect on the product.³⁷ Furthermore, these products are usually associated with bitter and stringent off-flavors, thus requiring flavor and aroma enhancers.³⁸ As a result, some

³¹'Meat analog as future food: a review' (n.28) 112; Plant-based and cell-based approaches to meat production (n.28) 2

³² MA Asgar and others, 'Nonmeat Protein Alternatives as Meat Extenders and Meat Analogs' (2010) 9(5) *Comprehensive Reviews in Food Science and Food Safety* 513, 515

³³ Plant-based and cell-based approaches to meat production (n.28) 2

³⁴ Draft Report – European Protein Strategy [2023] 2023-2015(INI) 6

³⁵ A review of research on plant-based meat alternatives: Driving forces, history, manufacturing, and consumer attitudes (n.27) 2641; E Hallstrom, A. Carlsson-Kanyama and P. Börjesson, 'Environmental impact of dietary change: a systematic review' [2015] 91 *Journal of Cleaner Production* 1, 7

³⁶ Plant-based and cell-based approaches to meat production (n.28) 2

³⁷ Felicity Curtain and Sara Grafenauer, 'Plant-Based Meat Substitutes in the Flexitarian Age: An Audit of Products on Supermarket Shelves' (2019) 11(11) *Nutrients* 2603, 1

³⁸ Plant-based and cell-based approaches to meat production (n.28) 4

of these substitutes end up being highly processed, thus deterring consumers, who are sometimes misinterpreting 'natural' products as healthier compared to processed ones.³⁹

To conclude, plant-based proteins originating from, *inter alia*, legumes, soybeans or wheat pose an interesting alternative for consumers who are willing to reduce meat consumption. The market has traditional roots, thus making it easier for their wider introduction into the modern lifestyle compared to lab-grown meat or insects, and is expected to grow more in years to come.⁴⁰ However, further funding and research are required to draw concrete conclusions on their environmental impact, better mimic meat structure to produce more than patties and nuggets and find a balance between creating a product that has an 'original' meat taste and composition while also being minimally processed to appeal to a wider consumer base.

1.2 Cultivated Meat

Cultivated meat is an innovative product manufactured to imitate the structure, texture, taste and smell of conventional meat.⁴¹ The production process starts with stem cells taken from the muscle tissue or the embryos of livestock, which are firstly cultured in a growth medium and differentiated into muscle cells.⁴² The muscle cells are then placed in a suitable bioreactor where they turn into larger muscle fiber and finally meat, through an ageing process.⁴³ In order for cellular agricultural to be successful, it is important to closely monitor and maintain growing conditions that mimic the natural conditions for meat growth in vivo, such as temperature, pressure, pH and glucose levels and cell viability.⁴⁴

Cultured meat is currently viewed as a potential solution to limit excessive animal husbandry while also reaching environmental goals set globally to tackle the effects of the ongoing climate crisis.⁴⁵ It is known that the conventional meat industry is a great

³⁹ Ibid 6

⁴⁰ Meat analog as future food: a review (n.28) 115

⁴¹ Sghaier Chriki, Marie-Pierre Ellies-Oury and Jean-Francois Hocquette, 'Is "cultured meat" a viable alternative to slaughtering animals and a good compromise between animal welfare and human expectations?' (2022) 12(1) *Animal Frontiers* 35, 37

⁴² Nicolas Treich, 'Cultured Meat: Promises and Challenges' (2021) 79(1) *Environmental and Resource Economics* 33, 39

⁴³ Cultured Meat: Promises and Challenges (n.42) 39; Pawar Dnyandeo and others, 'Current and future technologies for monitoring cultured meat: A review' (2023) 173(2) *Food Research International* 113464, 2; Shahida Anusha Siddiqui and others, 'Cultured meat: Processing, packaging, shelf life, and consumer acceptance' (2022) 172(1) *LWT* 114192, 2

⁴⁴ Current and future technologies for monitoring cultured meat: A review (n.43) 2

⁴⁵ Cultured Meat: Promises and Challenges (n.42) 34, 50

contributor to GHG emissions which reach 14,5% of the total anthropogenic emissions.⁴⁶ With the introduction of cultivated meat on the market and the gradual shrinking of the traditional meat industry, it is hypothesized that emissions will be reduced since cultured meat production requires less resources such as land, animals, feed and water.⁴⁷

At the same time, cultured meat is grown in a lab, essentially meaning two things. First of all, it is unaffected by environmental conditions such as heat waves and floods, which creates a sense of security around food production.⁴⁸ A recent example of natural disasters dramatically affecting the meat industry is the storm that hit northern Greece in September 2023 leading to a deadly flood that resulted in almost 200.000 farm animals drowning to death.⁴⁹ Such situations do not have an immediate effect on lab-grown meat, thus mitigating the impact of climate change on its production. Secondly, cultured meat is produced under sterile conditions, thus significantly reducing the risk of foodborne pathogens contaminating the final product.⁵⁰

Furthermore, the production of cultured meat is expected to contribute to animal welfare since it requires minimal animal exploitation besides the initial procedure required to isolate the stem cells.⁵¹ This opens a new door for vegetarian and vegan consumers who abstain from animal products for moral reasons and will potentially be able to taste meat that doesn't involve unethical animal treatment.

However, it is important to note that, at this point, cellular agriculture is at an embryonic stage. Therefore, its efficiency lacks the substantial and robust results that come with large scale production and time. At the moment, the costs associated with cultured meat production are much higher compared to conventional meat.⁵² The main contributor to these high costs is the culture medium used to grow the meat, amounting to almost 55% of the total costs of production.⁵³ In order for the industry to take off

⁴⁶John J Hyland and others, 'The role of meat in strategies to achieve a sustainable diet lower in greenhouse gas emissions: A review' [2017] 132 Meat Science 189, 190

⁴⁷Cultured Meat: Promises and Challenges (n.42) 48; Is "cultured meat" a viable alternative to slaughtering animals and a good compromise between animal welfare and human expectations? (n.41) 38

⁴⁸ Cultured Meat: Promises and Challenges (n.42) 34

⁴⁹ Bethany Bell and Kostas Koukoumakas, 'Storm Daniel: Greek farmers fear they may never recover' (BBC News, 30 September 2023) < <https://www.bbc.com/news/world-europe-66938011> > accessed 2 April 2024

⁵⁰ Cultured meat: Processing, packaging, shelf life, and consumer acceptance (n.43) 3

⁵¹ Cultured Meat: Promises and Challenges (n.42) 52

⁵²Nur Rasyidah Jahir and others, 'Cultured meat in cellular agriculture: Advantages, applications and challenges' [2023] 53 Food Bioscience 102614, 5

⁵³Ibid

and integrate into the market a product similar and comparable to conventional meat, it is important to reduce these costs.

Moreover, the positive environmental impact of the mass production of cultured meat is currently based on assumptions and predictions. For example, a 2011 study comparing conventional and cultured meat, hypothesized that the transition to cellular agriculture could lead to 78–96% lower GHG emissions, 99% lower land use, and 82–96% lower water use.⁵⁴ However, these, and similar, numbers involve high uncertainty and are currently debated. More recent studies point to a bigger environmental impact which relates to high energy consumption and the excessive use of components like glucose and amino acids during production.⁵⁵

Another major challenge is the way food companies will be able to create a product that resembles conventional meat on a nutritional and compositional level. Obtaining the complex structure of the muscle tissue and the distribution of fat, otherwise known as marbling, is a difficult task that requires more research and time.⁵⁶ Therefore, it is believed that minced meat - type products are likely to enter the market way before cultured steaks or fillets.⁵⁷ Furthermore, the lack of myoglobin in cultured meat, a protein responsible for the natural color of meat, leads to a pale pigmentation that can also negatively affect consumer perception.⁵⁸ Currently, consumer acceptance is low and is occasionally tied to the aforementioned notion that 'unnatural' products are unhealthy and dangerous.⁵⁹

Finally, the regulatory implications of introducing cultured meat into the market play a major role in its large-scale funding and production. From a legal standpoint, cultivated meat most likely falls within the EU definition of a novel food as described in Regulation (EU) 2015/2283, since it "[...] *was not used for human consumption to a significant degree within the Union before 15 May 1997*"⁶⁰. Therefore, before entering

⁵⁴ Cultured Meat: Promises and Challenges (n.42) 47

⁵⁵ Ibid 48

⁵⁶ Is "cultured meat" a viable alternative to slaughtering animals and a good comprise between animal welfare and human expectations? (n.41) 37

⁵⁷ Cultured Meat: Promises and Challenges (n.42) 39

⁵⁸ Is "cultured meat" a viable alternative to slaughtering animals and a good comprise between animal welfare and human expectations? (n.41) 37

⁵⁹ Cultured Meat: Promises and Challenges (n.42) 41; Luis Arango, Felix Septianto and Nicolas Pontes, 'Challenging cultured meat naturalness perceptions: The role of consumers' mindset' [2023] 190 *Appetite* 107039, 1

⁶⁰ Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 [2015] OJ 2 327/1, art 2(1)

the market it shall go through a lengthy authorization procedure, which is further expanded in Chapter 2.⁶¹ Similarly, other countries demand that cultured meat follows their own regulatory requirements. For instance, Singapore's food safety authority, which has given the clear to cultured chicken meat since 2020, has issued guidance documents specifying all the requirements and conditions under which cultured meat may be marketed.⁶² In the United States of America (USA), which has also allowed the production of cultured chicken since 2023, lab-grown meat falls under the joint jurisdiction of the Food and Drugs Administration (FDA) and the Food Safety and Inspection Service and the process includes a pre-market consultation to verify the safety of the product in question, as well as regular inspections to ensure that cultured meat does not violate any of the withstanding laws concerning food products.⁶³ Other countries, like Japan and Australia, are also open to the idea of cultured meat.⁶⁴

In conclusion, cultured meat shows promise as an alternative protein source but its manufacture is still evolving. Before being accepted as a safe and nutritious food product, it is important to optimize its large-scale production process to match the nutritional, ethical, environmental, regulatory and economic demands of the current market and be a viable alternative to conventional meat products.

1.3 Fungi

Fungi are classified as one of the five kingdoms of life and include multiple categories of organisms such as mushrooms, yeasts and molds.⁶⁵ They are extremely common in nature, hence their wide application range in human life.⁶⁶ They have been utilized for thousands of years, not only as a food source in the form of edible mushrooms, but also as feed, pharmaceutical ingredients and functional foods.⁶⁷

Certain fungi, namely yeasts and filamentous fungi, have the ability to produce mycoproteins, which pose as promising candidates for the substitution of conventional

⁶¹ Ibid art 6(2)

⁶² Yuxiang Gu and others, 'Risk assessment of cultured meat' [2023] 138 Trends in food science & technology 491, 497

⁶³ FDA, 'Human Food Made with Cultured Animal Cells' (FDA, 21 March 2023) < <https://www.fda.gov/food/food-ingredients-packaging/human-food-made-cultured-animal-cells> > accessed 2 April 2024

⁶⁴ Challenging cultured meat naturalness perceptions: The role of consumers' mindset (n.59) 1

⁶⁵ Amro A. Amara and Nawal Abd El-Baky, 'Fungi as a Source of Edible Proteins and Animal Feed' (2023) 9(1) Journal of Fungi 73, 73; Ute Schweiggert-Weisz and others, 'Food proteins from plants and fungi' [2020] 32 Current Opinion in Food Science 156, 159

⁶⁶ Fungi as a Source of Edible Proteins and Animal Feed (n.65) 73

⁶⁷ Marilyn G. Wiebe, 'Quorn™ Myco-protein - Overview of a successful fungal product' (2004) 18(1) Mycologist 17, 17; Tyler J. Barzee and others, 'Fungi for future foods' (2021) 1(1) Journal of Future Foods 25, 25

proteins for a number of reasons.⁶⁸ First of all, after processing they can imitate the structure of meat.⁶⁹ Edible fungi also have a protein content ranging from 9% to 45% depending on the species, are high in fiber and low in saturated fats and are a good source of vitamins and other micronutrients.⁷⁰ Finally, they are considered safe for short- and long- term consumption based on toxicological studies and the FDA has included them in the list of food ingredients "*Generally Recognized as Safe*" (GRAS) since 2002.⁷¹

One fungus belonging to the aforementioned category that has been extensively researched and has been dominating the edible fungi market since 1985 under the trade name Quorn™, is *Fusarium venenatum*.⁷² Its manufacturing technology was patented upon release, therefore significantly reducing competition. The patent has now expired in the EU, thus allowing other food companies to enter the market.⁷³ In general, mycoproteins are produced in bioreactors under controlled temperature, pH and substrate composition to ensure optimal growth, while the following steps include RNA reduction through heat treatment, steaming, forming and texturizing the final product which, depending on the processing method, can mimic meatballs, chicken nuggets or minced meat.⁷⁴ Recently, efforts have been made to produce more complex meat structures from mycoproteins, such as bacon and steak.⁷⁵

Mycoproteins have gained popularity as a potential solution to the excessive need for alternative protein sources, not only due to their nutritional profile but also due to their lower environmental impact compared to meat protein.⁷⁶ Studies have shown that mycoprotein-producing fungi can be cultivated in enclosed bioreactors, thus

⁶⁸ Fataneh Hashempour-Baltork and others, 'Mycoproteins as safe meat substitutes' [2020] 253 Journal of Cleaner Production 119958, 8; Fernanda Stoffel and others, 'Production of edible mycoprotein using agro-industrial wastes: Influence on nutritional, chemical and biological properties' [2019] 58 Innovative Food Science & Emerging Technologies 102227, 9

⁶⁹ 'Meat analog as future food: a review' (n.28) 114

⁷⁰ Dana Chezian, Orla Flannery and Ajay Patel, 'Factors affecting consumer attitudes to fungi-based protein: A pilot study' (2022) 175(1) Appetite 106043, 1; Food proteins from plants and fungi (n.65) 159; Fungi for future foods (n.67) 26

⁷¹ Michael F. Jacobson and Janna DePorter, 'Self-reported adverse reactions associated with mycoprotein (Quorn-brand) containing foods' (2018) 120(6) Annals of Allergy, Asthma & Immunology 626, 626; Mycoproteins as safe meat substitutes (n.68) 2,8

⁷² Fungi for future foods (n.67) 27

⁷³ Factors affecting consumer attitudes to fungi-based protein: A pilot study (n.70) 1

⁷⁴ 'Meat analog as future food: a review' (n.28) 114; MG Wiebe, 'Myco-protein from *Fusarium venenatum*: a well-established product for human consumption' (2002) 58(4) Applied Microbiology and Biotechnology 421, 422; Plant-based and cell-based approaches to meat production (n.28) 4

⁷⁵ Fungi for future foods (n.67) 27

⁷⁶ Mycoproteins as safe meat substitutes (n.68) 5

significantly reducing land requirements and can thrive in low-value substrates, such as agricultural byproducts, thus efficiently utilizing waste.⁷⁷

In regards to consumer acceptance, studies are showing mixed results with consumers either being willing to try mycoproteins or expressing discomfort and even disgust towards them.⁷⁸ For example, a 2022 study evaluating the factors affecting consumer behavior towards fungi, showed that a portion of respondents were associating them with mold and expressed concerns regarding their safety, while others provided negative opinions on their taste and smell.⁷⁹ On another note, studies have also shown that consumers have rated mycoproteins positively due to their lower environmental impact.⁸⁰

Last but not least, the regulatory aspect of producing fungal protein shall be taken into account. Products such as Quorn™ have been deemed as safe for human consumption and have been circulating the global market for decades. For example, the United Kingdom, the USA and New Zealand have made the product available since 1986, 2001 and 2010, respectively.⁸¹ Other countries such as Norway, Canada, Japan and Malaysia have also authorized the use of mycoprotein as a food source.⁸² Even though said authorizations exist, it does not negate the fact that similar products, depending on their status as a novel food, their manufacturing technology and their intended use, may need to go through different types of authorizations depending on the regulatory framework of the country they are meant to be marketed in.⁸³ At the same time, it is necessary to adhere to the relevant food safety requirements since mycoproteins have been linked with severe allergic reactions, their high RNA content may lead to health issues such as gout if not reduced effectively and, finally, certain mycoprotein producing fungi are known to also produce mycotoxins.⁸⁴

⁷⁷ Ibid 5, 8

⁷⁸ Factors affecting consumer attitudes to fungi-based protein: A pilot study (n.70) 9

⁷⁹ Ibid 8

⁸⁰David Dean and others, 'Understanding Key Factors Influencing Consumers' Willingness to Try, Buy, and Pay a Price Premium for Mycoproteins [2022] 14 nutrients 3292, 11; Factors affecting consumer attitudes to fungi-based protein: A pilot study (n.70) 9

⁸¹Food Standards Australia New Zealand, 'Quorn (mycoprotein) ' (Food Standards Australia New Zealand (FSANZ), 2011) <<https://www.foodstandards.gov.au/consumer/our-safe-food-supply/quorn-mycoprotein>> accessed 2 April 2024

⁸²Farhan Saeed and others, 'Role of mycoprotein as a non-meat protein in food security and sustainability: a review' (2023) 26(1) International Journal of Food Properties 683, 684

⁸³ Food proteins from plants and fungi (n.65) 160

⁸⁴ Self-reported adverse reactions associated with mycoprotein (Quorn-brand) containing foods (n.71) 630

In conclusion, fungi are another promising alternative protein even though they have yet to take over the market. Further studies are currently required to optimize their processing methods, evaluate their safety and environmental impact in comparison to other protein sources, increase consumer acceptance and reduce production costs.⁸⁵

1.4 Insects

The consumption of insects, or entomophagy, has been practiced for thousands of years.⁸⁶ For example, it has been documented that, during the reign of the Roman Empire, people regularly consumed moth larvae fattened in wine and flour.⁸⁷ In more recent years, entomophagy has been a debatable practice. On one hand, more than 2000 insect species are being consumed in over 113 countries.⁸⁸ In certain parts of the world, mainly central Africa, around 50% of protein intake is based on insects and in Kenya and Burkina Faso insects are treated as delicacies. In Thailand, entomophagy has even been used as an effective measure for pest control during a locust outbreak in 1978.⁸⁹

On the other hand, entomophagy has been met with great skepticism, especially in western countries, where collective efforts are constantly being made to eliminate insects from crops, plantations and daily life.⁹⁰ Insect consumption has also been viewed more as a short-term solution to battle starvation and poverty in the less developed parts of the world and less than a viable option to meet our protein intake needs.⁹¹

From a nutritional perspective, insects are a good source of protein, fats, minerals and vitamins, with protein content occasionally reaching 60% of the total dry matter.⁹² Their protein content is comparable to that of animals and the amino-acids present in

⁸⁵ Food proteins from plants and fungi (n.65) 160

⁸⁶ Chufei Tang and others, 'Edible insects as a food source: a review' (2019) 1(8) Food Production, Processing and Nutrition, 1; S. Belluco and others, 'Edible Insects in a Food Safety and Nutritional Perspective: A Critical Review' (2013) 12(3) Comprehensive Reviews in Food Science and Food Safety 296, 296

⁸⁷ Edible Insects in a Food Safety and Nutritional Perspective: A Critical Review (n.70) 307

⁸⁸ D. Dobermann, J.A. Swift and L.M. Field, 'Opportunities and hurdles of edible insects for food and feed' (2017) 42(4) Nutrition Bulletin 293, 293

⁸⁹ Ibid 293, 294

⁹⁰ A.T. Dossey, J.T. Tatum, W.L. McGill, Chapter 5: Modern Insect-Based Food Industry: Current Status, Insect Processing Technology, and Recommendations Moving Forward. in Dossey and others (eds), *Insects as Sustainable Food Ingredients* (Academic Press 2016) 113, 114

⁹¹ Edible insects as a food source: a review (n.86) 5; Opportunities and hurdles of edible insects for food and feed (n.88) 294

⁹² Edible Insects in a Food Safety and Nutritional Perspective: A Critical Review (n.70) 302

insects are easily digestible.⁹³ Insects are also very efficient in converting feed into edible biomass.⁹⁴ However, all these factors vary depending on the species, the insect's developmental stage, the feed and processing method used.⁹⁵

At the same time, farming insects is believed to promote animal welfare and environmentally friendly practices. By mimicking their natural habitat, which includes multiple insects being cramped in small spaces, causing stress and spreading disease is easily avoided.⁹⁶ Before further processing, insects are usually put into a state of deep sleep, through exposure in freezing temperatures, which leads to a painless death.⁹⁷ Moreover, insect farming is less water and energy intensive and is giving off less GHG emissions than cow farming.⁹⁸

As already mentioned, insect consumption has not been an indigenous practice in most western societies. Consequently, they usually require pre-market authorizations to ensure their safety. For instance, in the EU, insects are required to adhere to the provisions of the Novel Foods Regulation and in Canada and the USA approval must come from the relevant government bodies.⁹⁹ However, the regulatory framework surrounding insect consumption needs refining on a global level since there are limited considerations concerning marketing and farming obligations.¹⁰⁰

However, an important barrier in the mass production of edible insects is consumer acceptance, especially in western countries where insects are associated with feelings of fear and disgust. A 2021 systematic review of consumer acceptance of alternative proteins showed that insects were ranked last in comparison to other non-conventional proteins with psychological, product – related, cultural and social factors affecting consumer decision making.¹⁰¹ Therefore, in order to successfully industrialize entomophagy, it is important to invest in appropriate production and marketing strategies to increase consumer acceptance.

⁹³Edible insects as a food source: a review (n.86) 1

⁹⁴Chapter 5: Modern Insect-Based Food Industry: Current Status, Insect Processing Technology, and Recommendations Moving Forward (n.90) 122

⁹⁵Edible Insects in a Food Safety and Nutritional Perspective: A Critical Review (n.70) 301; 'Why alternative proteins will not disrupt the meat industry' (n.11) 3

⁹⁶Chapter 5: Modern Insect-Based Food Industry: Current Status, Insect Processing Technology, and Recommendations Moving Forward (n.90) 114

⁹⁷ Ibid 125

⁹⁸Chapter 5: Modern Insect-Based Food Industry: Current Status, Insect Processing Technology, and Recommendations Moving Forward (n.90) 114

⁹⁹ Ibid 304

¹⁰⁰ Ibid 305

¹⁰¹M.C. Onwezen and others, 'A systematic review on consumer acceptance of alternative proteins: Pulses, algae, insects, plant-based meat alternatives, and cultured meat' (2021) 159(1) *Appetite* 105058, 9

1.5 Algae

Algae can be divided in two categories, macro- and micro- algae and include multiple different species.¹⁰² Macroalgae are larger in size and more easily collectible and have been traditionally consumed by people inhabiting coastal areas, especially in Asia.¹⁰³ For instance, macroalgae are consumed as seaweed flakes and in sushi.¹⁰⁴ Due to their nutritional profile they are also used as emulsifiers, thickeners and stabilizers in products mimicking meat texture.¹⁰⁵

Microalgae consumption, on the other hand, has been limited to very few species due to high levels of toxin accumulation.¹⁰⁶ The most commonly used species, which have been proven to not have a toxicogenic effect on humans, are *Chlorella* sp. and *Spirulina* sp.¹⁰⁷ They are commonly used as foaming, emulsifying and gelling agents, resembling egg white proteins.¹⁰⁸

In general, algae are rich in protein and contain quantities of all essential amino acids in levels comparable to those of plants like soy and corn.¹⁰⁹ They also contain certain antioxidants and lipids crucial for the normal functioning of humans, such as omega-3 fatty acids.¹¹⁰ Therefore, due to their composition they show potential as a substitute in vegan or vegetarian diets.¹¹¹

The mass cultivation and production of algae as an innovative source of protein is also a promising way to address the current need for environmentally friendly and ethical production of protein since they can be grown in arable and non-arable land using multiple sources of water such as non-potable water, saltwater and wastewaters that would otherwise be disposed in the environment.¹¹²

¹⁰²Kathleen Hefferon, 3.15 - Algae as a Meat Alternative. in Pasquale Ferranti (ed), Sustainable Food Science - A Comprehensive Approach (Elsevier 2023) 195

¹⁰³Jose Lucas Perez-Illorens, 'Microalgae: From staple foodstuff to avant-garde cuisine' [2020] 21 International Journal of Gastronomy and Food Science 100221, 1; Philip Thornton, Helen Gurney-Smith and Eva Wollenberg, 'Alternative sources of protein for food and feed' [2023] 62 Current Opinion in Environmental Sustainability 101277, 2

¹⁰⁴ Alternative sources of protein for food and feed (n.103) 2

¹⁰⁵ 3.15 - Algae as a Meat Alternative (n.102) 196

¹⁰⁶ Microalgae: From staple foodstuff to avant-garde cuisine (n.103) 1

¹⁰⁷ 3.15 - Algae as a Meat Alternative (n.102) 195, 196; E.W. Becker, 'Micro-algae as a source of protein' (2007) 25(2) Biotechnology Advances 207, 208

¹⁰⁸ 3.15 - Algae as a Meat Alternative (n.102) 196

¹⁰⁹ Alternative sources of protein for food and feed (n.103) 2; Micro-algae as a source of protein (n.107) 209; Anu Lahteenmaki-Uutela and others, 'Alternative proteins and EU food law' [2021] 130 Food Control 1083364, 1

¹¹⁰ Alternative sources of protein for food and feed (n.103) 2

¹¹¹ Ibid

¹¹²Alternative sources of protein for food and feed (n.103) 4; Yasin Torres-Tijji and others, 'Microalgae as a future food source' [2020] 41 Biotechnology Advances 107536, 1

Furthermore, as already mentioned, a great number of algae has been traditionally consumed in many parts of the world such as Asia, South America and West Africa.¹¹³ Therefore, many of them have received, for example, GRAS status in the USA and authorization for use in the EU based on historical evidence of their consumption. Depending on their species, algae have also been considered safe in multiple countries such as China, Japan and Canada.¹¹⁴ Therefore, their legal status is highly dependent on multiple factors and differs across the world.

However, it is believed that their introduction to the market on a global level is currently difficult for multiple reasons. First of all, production costs are very high, which turns their production into a less profitable business compared to conventional protein sources.¹¹⁵ At the same time, algae's powdery texture after processing, their dark green color and fish-like smell, paired with their low digestibility reduce their appeal and negatively affect consumer acceptance.¹¹⁶ Their high water content is also an inhibiting factor due to rapid quality deterioration and spoilage.¹¹⁷ Overcoming technological difficulties and enhancing production and processing methods while also improving consumer perception may prove as solution to meet the global protein needs.¹¹⁸

¹¹³ Microalgae: From staple foodstuff to avant-garde cuisine (n.103) 2-4

¹¹⁴ Microalgae as a future food source (n.112) 3

¹¹⁵ Micro-algae as a source of protein (n.107) 209

¹¹⁶ Ibid

¹¹⁷ Food proteins from plants and fungi (n.65) 158

¹¹⁸ 3.15 - Algae as a Meat Alternative (n.102) 198

Chapter 2: The Marketing of Alternative Proteins in the EU

As established in Chapter 1, the umbrella term 'alternative proteins' covers a wide range of products originating from plants, animals and animal cells. Each type of product is strictly bound to EU law and shall follow the rules and principles laid down in the relevant regulatory framework in order to be lawfully marketed within its territory.

2.1 General Food Law

The main regulation that applies to all meat substitutes is Regulation (EC) 178/2002, hereinafter referred to as the General Food Law (GFL), since they are "*intended to be [...] ingested by humans*"¹¹⁹ and therefore fall within the definition of food. All foods produced outside the domestic level have to adhere to the GFL which serves as a baseline for all subsequent Union and national measures concerning food safety.¹²⁰ The GFL establishes, *inter alia*, the main responsibilities and obligations of food business operators (FBOs) in order to ensure food safety.¹²¹ Decisions on food safety shall be taken on a risk-based approach with the objective of ensuring a high level of consumer protection and the "*effective functioning of the internal market*"¹²². Another common denominator in all food law provisions is the precautionary principle which is embedded in the Treaty of the Functioning of the EU (TFEU).¹²³ Initially, the precautionary principle referred to environmental concerns alone but it has evolved to apply to food related matters as well and grants the right to temporary and proportionate regulatory action when food safety cannot be assured due to scientific uncertainty.¹²⁴

The cornerstone of the GFL is food safety. All alternative proteins may only be placed on the market when they are safe, regardless of origin or production method.¹²⁵ The Regulation specifies the conditions under which food is considered to be unsafe and mandates that FBOs ensure they take all measures necessary to protect human health and fulfil the requirements of the GFL.¹²⁶

¹¹⁹ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the EFSA and laying down procedures in matters of food safety [2002] OJ 2 031/1, art 2

¹²⁰ Ibid art 1(3), art 4(2)

¹²¹ Ibid art 1(2)

¹²² Ibid art 6(1), art 5(1), art 1(1)

¹²³ Treaty on the Functioning of the EU (n.17) art 191(2)

¹²⁴ Treaty on the Functioning of the EU (n.17) art 191(2); Jale Tosun, 'How the EU handles uncertain risks: Understanding the role of the precautionary principle' (2013) 20(10) Journal of the European Public Policy 1517, 1518; Regulation (EC) No 178/2002 (n.119) art 7(1)-(2)

¹²⁵ Regulation (EC) No 178/2002 (n.119) art 14(1)

¹²⁶ Ibid art 14(2)-(5), art 17 (1)

2.2 Novel Foods Regulation

After establishing the general rules surrounding food law, it is important to navigate Regulation (EU) 2015/2283, hereinafter referred to as the Novel Foods Regulation (NFR), which plays an essential role in the introduction of certain alternative protein sources in the internal market.¹²⁷

Novel foods are defined as those “*not used for human consumption to a significant degree [...] before 15 May 1997*”¹²⁸ and shall fall within at least one of the categories described in Art. 2(a)(i)-(x) of the NFR. It is important to note that the NFR excludes genetically modified foods from its scope.¹²⁹ Therefore, if a food product contains genetically modified organisms (GMOs) and is novel simultaneously, the NFR does not apply and the FBO shall consult with the GMO legal framework to ensure compliance with all its provision and lawfully market their product within the EU.¹³⁰ Novel foods require pre-market authorization by the EC and inclusion in the list of authorized novel foods i.e. the Union list, before they can be consumed in the EU.¹³¹

Plant-based proteins that are currently produced from soybeans or chickpeas to imitate the structure of meat, “*have a history of safe use within the Union*”¹³² and are, therefore, exempted from the provisions of the NFR.¹³³ However, when traditionally used plant proteins are extracted, treated or produced with novel technologies, which result in significant compositional or structural changes, then the final product is considered a novel food.¹³⁴

Other alternative proteins, such as those originating from microorganisms, fungi or algae, may also fall within the scope of the NFR even if they have been a staple in human nutrition outside the EU before May 1997.¹³⁵ A prominent example is algae which have been consumed for millennia in Asian countries but are not so widespread in the EU.¹³⁶ Such products may fall within the scope of the NFR and thus require an authorization to enter the Union market but applicants may follow a simplified procedure

¹²⁷Regulation (EU) 2015/2283 (n.60)

¹²⁸Ibid art 3(2)(a)

¹²⁹Ibid art 2(2)(a)

¹³⁰EC, 'GMO legislation' (European Commission - Food, Farming, Fisheries) <https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-legislation_en> accessed 2 April 2024

¹³¹Regulation (EU) 2015/2283 (n.60) art 6(1)-(2)

¹³²Ibid art 2(a)(iv)

¹³³Alternative proteins and EU food law (n.109) 4

¹³⁴ Regulation (EU) 2015/2283 (n.60) art 2(a)(iv)

¹³⁵ Ibid art 2(a)(ii)

¹³⁶ Alternative proteins and EU food law (n.109) 5

described in Art. 14-20, if they can demonstrate that the particular food has “a history of safe food use in a third country”¹³⁷.

The NFR also specifies that “food consisting of, isolated from or produced from cell culture or tissue culture of animals [...]”¹³⁸ is considered a novel food and thus, it can be assumed that lab-grown meat also falls within its scope. A reluctance to definitively include cultured meat within this category has been expressed by the EC in its response to a written question concerning the potential risks of cultured meat, which stated that “cultured meat may fall in this category”¹³⁹, meaning Art. 3(2)(a)(vi). Despite the unclear categorization of lab-grown meat, it is safe to conclude that it had not been consumed before May 1997 in the EU and it shall not be considered as having a history of safe food use in a third country, since the first authorization for its manufacturing and marketing was granted in Singapore in 2020.¹⁴⁰ Therefore, it is a novel food within the meaning of EU law and shall comply with the provisions of the NFR. As of September 2023, EFSA had yet to provide their scientific opinion concerning its safety, essentially meaning that no authorization applications had been submitted at the time.¹⁴¹ As a result, cultured meat is currently not allowed for human consumption in the EU.

Art. 2(a)(v) of the NFR states that “food consisting of, isolated from or produced from animals or their parts [...]” falls within its scope, thus requiring a pre-market authorization. The regulation excludes animals produced with traditional breeding practices that have been recognized within the EU as being historically safe and widely exercised prior to May 15, 1997.¹⁴² According to the EC, insects fall within the meaning of this definition since there is no data to support that insects were consumed within the Union to a “significant degree” before May 15, 1997.¹⁴³ Therefore, whole insects and their parts or extracts are subject to the provisions of the NFR and FBOs are required to follow the extensive authorization procedure.¹⁴⁴ However, prior to the adoption of the current NFR, the regulatory framework was not so detailed concerning

¹³⁷ Regulation (EU) 2015/2283 (n.60) art 14(e)

¹³⁸ Ibid art 3(2)(a)(vi)

¹³⁹ Question for written answer E-004200-18 to the European Commission from Mara Bizzotto (ENF) (30 July 2018)

¹⁴⁰ Alternative proteins and EU food law (n.109) 4

¹⁴¹ Wolfgang Gelbmann, ‘Science on the menu – Episode 10 – From lab to fork’ (20 September 2023, 05:02:24) < <https://www.efsa.europa.eu/en/podcast/episode-10-lab-fork> > Accessed 2 April 2024

¹⁴² Regulation (EU) 2015/2283 (n.60) art 2(a)(v)

¹⁴³ EC, ‘Approval of fourth insect as a Novel Food’ (European Commission - Food, Farming, Fisheries) < https://food.ec.europa.eu/safety/novel-food/authorisations/approval-insect-novel-food_en > accessed 31 March 2024

¹⁴⁴ Alternative proteins and EU food law (n. 109) 5

the type of products that belong in this category, thus creating discrepancies between Member States and even leading to legal proceedings. The previous NFR, or Regulation (EC) 258/97, only stated that novel foods are those "*isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use*"¹⁴⁵, thus creating a legal gap and allowing for different interpretations of the text. Certain Member States, such as Finland, the Netherlands and Denmark, approached the definition literally and read it as excluding whole insects from the regulation and thus allowed the marketing of whole insects without a pre-market authorization.¹⁴⁶ Others followed a teleological interpretation of the provision and concluded that the former NFR not only included ingredients isolated from insects, but also whole insects.¹⁴⁷ The idea behind this train of thought was that the cornerstone of the NFR was, *inter alia*, to "*protect public health*"¹⁴⁸ and ensure the safety of foods that were not traditionally consumed within the Union. Therefore, it was considered inconsistent with the essence of the regulation to exclude whole insects from the requirements of the NFR.

For instance, France was one of the Member States that initially adopted this less lenient approach to the marketing of whole insects, which led to the legal proceedings between the company Entoma SAS on one hand and the French Ministries for the Economy and Finances and for Agriculture and Food on the other hand.¹⁴⁹ Prior to the proceedings, the company was marketing mealworms, locusts and crickets as whole insects.¹⁵⁰ In 2016, the French government ordered Entoma SAS to suspend the circulation of these products with immediate effect on the grounds that they were violating the provisions of Regulation (EC) 258/97 which required a pre-market authorization for said products.¹⁵¹ After multiple rejected appeals brought before higher courts by the company, the French Council of State requested a preliminary ruling from the Court of Justice of the EU (CJEU) concerning the interpretation of Art. 1(2)(e) of Regulation (EC) No 258/97.¹⁵² Finally, the CJEU ruled that whole insects, did not fall

¹⁴⁵ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1997] OJ 2 043/1, art 1(2)(e)

¹⁴⁶ Alternative proteins and EU food law (n. 109) 5; Valeria Paganizza, 'Are Insects Novel Foods?' [2020] 15(6) European Food and Feed Law Review 579 (note), 580

¹⁴⁷ Are Insects Novel Foods? (n.133) 580

¹⁴⁸ Regulation (EC) 258/97 (n.145) rec. 2

¹⁴⁹ Case C - 526/19 *Entoma SAS v Ministre de l'Économie et des Finances, Ministre de l'Agriculture et de l'Alimentation* [2020] ECLI:EU:C:2020:769, para 2

¹⁵⁰ Ibid para 14

¹⁵¹ Ibid para 15

¹⁵² Ibid para 16-21

within the scope of that regulation; thus essentially annulling the original decisions of the local courts which were suspending the marketing of the aforementioned products.¹⁵³

According to today's standards, this ruling by the CJEU seems rather insignificant in the sense that the current NFR incorporated whole insects in the list of foods falling within its scope and therefore, all FBOs who have been eager to market any type of insect product within the EU after January 1st, 2018 are obligated to follow the pre-market authorization procedure.¹⁵⁴ However, the ruling of the CJEU had a major impact on companies marketing whole insects prior to the adoption of the current NFR. Since these products did not fall within the scope of Regulation (EC) 258/97 but are now subject to Regulation (EU) 2015/2283, FBOs were granted a transitional period where they were allowed to market their products while awaiting the final decision of the EC regarding their authorization application which had to be filed by January 1st, 2019.¹⁵⁵ As a result, certain products are currently on the market while their authorization is still pending.¹⁵⁶ As of March 2024, the EC has already authorized 4 insect species as foods and 8 more applicants are in line for their safety evaluation from EFSA.¹⁵⁷

After evaluating whether their product is a novel food or not, FBOs shall submit the application portfolio to the EC in accordance with Art. 10 of the NFR. Afterwards, the EC may request EFSA's opinion on the safety status of the food. EFSA has 9 months to provide their opinion and within 7 months of its publication, the EC shall forward a draft implementing act authorizing the novel food to the Standing Committee on Plants, Animals and Feed (PAFF).¹⁵⁸ The implementing act shall only be adopted after PAFF has provided a positive opinion.¹⁵⁹ Similarly, in cases of traditional foods from third countries, FBOs may follow the notification procedure described in Art. 14-19 of the NFR. The Regulation also allows for the proprietary protection of data used in an application for a period of five years under certain requirements, which means that

¹⁵³ Ibid para 46

¹⁵⁴ Regulation (EU) 2015/2283 (n.60) art 6(2)

¹⁵⁵ Ibid art 35(2); Approval of fourth insect as a Novel Food (n.130)

¹⁵⁶ Ibid

¹⁵⁷ Whitney Vale-Hagan and others, 'Edible insects in mixed-sourced protein meals for animal feed and food: An EU focus' [2023] 1 Food and Humanity 1180, 1184; Approval of fourth insect as a Novel Food' (n.143)

¹⁵⁸ Regulation (EU) 2015/2283 (n.60) art 11(1), art. 12 (1)

¹⁵⁹ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [2011] OJ 2 55/13, art 5(2)-(4)

these data may not be used for the benefit of subsequent applications without the agreement of the original applicant.¹⁶⁰

2.3 Genetically Modified Foods Regulation

GMOs are defined in Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms as those organisms "*in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*"¹⁶¹. In an effort to ensure, *inter alia*, the adequate protection of human life and health, Regulation (EC) 1829/2003, hereinafter referred to as the GMO Regulation, states that foods containing GMOs are required to go through a safety assessment procedure before entering the EU market.¹⁶² The regulation further specifies that it applies to foods "*containing or consisting of GMOs*" and foods "*produced from or containing ingredients produced from GMOs*"¹⁶³ but excludes foods that are manufactured with genetically modified processing aids.¹⁶⁴ These are exempted from the provisions of the GMO Regulation and do not require a pre-market authorization.

FBOs who wish to market any of the aforementioned products are required to submit an authorization application to the national competent authority who is then responsible to notify EFSA.¹⁶⁵ EFSA has six months to publish their opinion to the EC and the Member States, who also have to capacity to get involved in the process.¹⁶⁶ After taking into account the considerations of all involved parties, including those of the PAFF Committee, the EC shall make their final decision in accordance with Art. 35(2) of the GMO Regulation. It is important to note that authorization is not permanent and lasts for 10 years, with the possibility of renewal.¹⁶⁷ The final product shall adhere to specific labelling rules which require a clear indication of the presence of genetic modification, except in cases where the food includes GM ingredients in a proportion lower than 0,9% and it can be scientifically backed that its presence is "*adventitious or*

¹⁶⁰ Regulation (EU) 2015/2283 (n.60) art 26(1)-(2)

¹⁶¹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2001] OJ 2 106/1, art 2(2)

¹⁶² Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2003] OJ 2 268/1, rec. 3

¹⁶³ Ibid art 3(1)(b)-(c)

¹⁶⁴ Ibid rec 16

¹⁶⁵ Ibid

¹⁶⁶ Astrid Seehafer Marvin and Bartels, 'Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat' (2019) 14(4) Eur Food & Feed L Rev 323, 327

¹⁶⁷ Regulation (EC) No 1829/2003 (n.162) art 7(5), art 11

*technically unavoidable*¹⁶⁸. Similarly, FBOs are required to follow the procedures laid down in Directive 2001/18/EC, which require that all new GMO products should be accompanied by a "*case-by-case environmental risk assessment*"¹⁶⁹, and Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.¹⁷⁰

Foods coming from alternative protein sources may require a GMO authorization. Concerning plant-based products, two GM ingredients that have attracted attention and are being used in the manufacturing of meat substitutes are genetically modified soybeans and soy leghemoglobin.¹⁷¹ The first ones made up 77% of the total soybean cultivation worldwide in 2017 and are widely produced in the USA, Brazil and Argentina.¹⁷² In the EU, GM soybean has received several authorizations for use in food and feed, which can be found in the register of authorized GMOs.¹⁷³ On the contrary, soy leghemoglobin is currently at a limbo state concerning the type of authorization that is required.¹⁷⁴ Leghemoglobin is a naturally occurring protein that transfers oxygen to the root nodules of leguminous plants and has been used by food companies in their plant-based patties as a food colorant in an effort to imitate the function of hemoglobin which results in the vibrant red color of uncooked meat.¹⁷⁵ On a large-scale manufacturing level, soy leghemoglobin is produced by the GM yeast *Pichia pastoris* in fermenters, which causes uncertainty concerning its GMO status.¹⁷⁶ On one hand, if the GMO is categorized as a processing aid and the leghemoglobin can be isolated from the genetically modified yeast before being added to the food recipe, then the final product

¹⁶⁸ Ibid art 12(2)-(3), art 13

¹⁶⁹ Directive 2001/18/EC (n. 161) rec 19

¹⁷⁰ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC [2003] OJ 2 268/24

¹⁷¹ Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat (n.166) 327

¹⁷² ISAAA, Global Status of Commercialized Biotech/GM Crops in 2017: Biotech Crop Adoption Surges as Economic Benefits Accumulate in 22 Years. ISAAA Brief No 53 (ISAAA: Ithaca NY 2017), 102; Joshua Hadi and Gale Brightwell, 'Safety of Alternative Proteins: Technological, Environmental and Regulatory Aspects of Cultured Meat, Plant-Based Meat, Insect Protein and Single-Cell Protein' (2021) 10(6) Foods 1226, 1233

¹⁷³ EC, 'EU Register of authorized GMOs' (European Commission - Food, Farming, Fisheries) < <https://webgate.ec.europa.eu/dyna2/gm-register/> > accessed 3 April 2024

¹⁷⁴ Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat (n.166) 327

¹⁷⁵ Michael Zeece, Chapter Eight - Food colorants. in Michael Zeece (ed), Introduction to the Chemistry of Food (Academic Press 2020) 334; Alternative proteins and EU food law (n. 109) 4

¹⁷⁶ Safety of Alternative Proteins: Technological, Environmental and Regulatory Aspects of Cultured Meat, Plant-Based Meat, Insect Protein and Single-Cell Protein (n.172) 1233; Alternative proteins and EU food law (n. 109) 4

shall be excluded from the provisions of the GMO Regulation as per Rec. 16. On the other hand, if the meat substitute is treated as "*food produced from or containing ingredients produced from GMOs*"¹⁷⁷, then the FBO is obligated to follow the relevant authorization and marketing procedure.

Besides plant-based alternative proteins, cultured meat is another product that has the potential to be manufactured through genetic engineering of the original animal cells used, in order to reduce the number of biopsies needed, accelerate the cell cultivation process and eliminate the use of fetal bovine serum as a nutrient medium.¹⁷⁸

However, meat substitutes produced from GMOs might not become very popular in the near future within the EU. First of all, the regulatory framework towards GMOs is highly demanding, time consuming and costly for food companies.¹⁷⁹ At the same time, consumers are skeptical not only towards the consumption of GMOs, but also towards Novel Foods in general, and are more inclined to purchase GM-free foods.¹⁸⁰ Finally, there is a widespread structural negativity towards GMOs since many EU Member States, namely Greece, Austria, Bulgaria, Germany, Hungary, Italy, Luxembourg and Poland, have banned GM crop cultivation in their respective territories, thus perpetuating prejudices against GMOs even if their safety has been ensured by EFSA.¹⁸¹

2.4 New Genomics Techniques Regulation

Directive 2001/18/EC clarifies which techniques fall within its scope and which ones are exempted.¹⁸² Concerning the exemptions, a point of disagreement and heavy criticism rose among European scholars and scientists after the 2018 Judgement of the CJEU on new mutagenesis techniques used to produce weed-resistant plant varieties.¹⁸³

¹⁷⁷ Regulation (EC) No 1829/2003 (n.162) art. 3(1)(c)

¹⁷⁸ Neil Stephens, 'Bringing cultured meat to market: Technical, socio-political, and regulatory challenges in cellular agriculture' [2018] 78 Trends in food science & technology 155, 157; Alternative proteins and EU food law (n. 109) 327

¹⁷⁹ Alternative proteins and EU food law (n. 109) 327

¹⁸⁰ Montserrat Costa-Font, José M. Gil and Bruce Traill, 'Consumer acceptance, valuation of and attitudes towards genetically modified food: Review and implications for food policy' (2008) 33(2) Food Policy 99, 100; Michael Siegrist and Christina Hartmann, 'Consumer acceptance of novel food technologies' [2020] 1 Nature Food 343, 347-348; Consumer acceptance, valuation of and attitudes towards genetically modified food: Review and implications for food policy (n.180)107

¹⁸¹ EP, 'Q&A: GMO cultivation in the EU' (News - European Parliament, 12 January 2015) <<https://www.europarl.europa.eu/news/en/headlines/society/20140902STO57801/q-a-gmo-cultivation-in-the-eu> > accessed 3 April 2024

¹⁸² Directive 2001/18/EC (n.161) Annex I(A) – (B)

¹⁸³ Juan Antonio Vives-Vallés and Cécile Collonnier, 'The Judgment of the CJEU of 25 July 2018 on Mutagenesis: Interpretation and Interim Legislative Proposal' [2020] 10 Frontiers in Plant Science, 4; Case C-528/16 Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt [2018] ECLI:EU:C:2018:583

Even though Annex I B(1) of Directive 2001/18/EC states that mutagenesis is excluded from its provisions, the CJEU ruled that organisms obtained through mutagenesis are considered GMOs and that plant varieties produced with new genome editing techniques that do not have a "*long safety record*"¹⁸⁴ and have not "*conventionally been used in a number of applications*"¹⁸⁵ are not exempted from the provisions of Directive 2001/18/EC.¹⁸⁶

In the aftermath of the CJEU's judgement on Case C-528/16, the EC was asked by the Council of the European Union to conduct a study regarding New Genomic Techniques (NGTs) and their standing within Union law.¹⁸⁷ The study was published in April 2021 and focused on, *inter alia*, their safety, their legal status within the GMO legislative framework and their application range.¹⁸⁸ As part of the aforementioned study, the EC defined NGTs as "*techniques that can alter the genetic material of an organism and have been developed after the adoption of Directive 2001/18/EC*"¹⁸⁹. They refer to a wide variety of techniques that may lead to minor genetic changes that could also occur in nature or to more significant and complex modifications.¹⁹⁰ Compared to conventional breeding practices, they are more targeted and precise and lead to the desired results faster.¹⁹¹ The three main techniques that are of interest in the context of the European regulatory framework are mutagenesis, cisgenesis and transgenesis. Mutagenesis refers to techniques that lead to targeted mutations without using genetic material, while cisgenesis refers to the genetic modification of an organism through the

¹⁸⁴ Directive 2001/18/EC (n. 161) rec 17

¹⁸⁵ Ibid

¹⁸⁶ Case C-528/16 (n.183) para 86(1)-(2)

¹⁸⁷ EC, 'Questions and Answers: Study on New Genomic Techniques' (European Commission - Food, Farming, Fisheries) <https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques/questions-and-answers_en> accessed 3 April 2024

¹⁸⁸ EC, 'EC study on new genomic techniques' (European Commission - Food, Farming, Fisheries) <https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en> accessed 3 April 2024

¹⁸⁹ Questions and Answers: Study on New Genomic Techniques (n.187)

¹⁹⁰ Ibid; EC, 'Frequently Asked Questions: Proposal on New Genomic Techniques' (European Commission - Press Corner, 5 July 2023) <https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_3568> accessed 3 April 2024

¹⁹¹ Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 [2023] COM (2023) 411, 1

use of a genetic sequence from a sexually compatible organism.¹⁹² Transgenesis concerns the introduction of genetic material from alien, non-crossable species.¹⁹³

After thorough examination of Member States', stakeholders' and experts' considerations, the EC concluded that NGTs are a promising way to meet the objectives of the EU Green Deal and the UN's sustainable development goals.¹⁹⁴ However, the EC figured that this cannot happen under the current GMO regulatory framework since it is outdated regarding NGTs and may lead to disruptions of the internal and international market.¹⁹⁵ The main legal gap that needed to be addressed was the lack of a proper detection method for NGT products that contain no foreign genetic material, thus causing "*implementation and enforcement challenges*".¹⁹⁶ On their safety, EFSA's assessment led to the conclusion that targeted mutagenesis and cisgenesis do not bear more danger compared to conventional breeding techniques and, therefore, risk assessment and authorization procedures shall be adapted accordingly to facilitate their use in the agri-food sector.¹⁹⁷ However, EFSA's assessment was limited to NGTs targeted at plants and no other forms of life, such as animals and fungi, since scientific knowledge on them is currently limited.¹⁹⁸

Following the publication of the study, the EC submitted in July 2023 a proposal for a new regulation on plants obtained by certain new genomic techniques and their food and feed.¹⁹⁹ The main goal of the Regulation is to facilitate the authorization procedure of products obtained through the use of NGTs, promote innovation, ensure consumer protection and food security and reach environmental goals set by Union and international agreements.²⁰⁰

¹⁹² EFSA, 'FAQ: Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis' (EFSA, 18 October 2022) <<https://www.efsa.europa.eu/en/news/faq-criteria-risk-assessment-plants-produced-targeted-mutagenesis-cisgenesis-and-intragenesis>> accessed 3 April 2024; Henk J. Schouten, Frans A. Krens and Evert Jacobsen, 'Cisgenic plants are similar to traditionally bred plants' (2006) 7(8) EMBO Reports 750, 751

¹⁹³ Ibid 750

¹⁹⁴ Executive Summary – Commission Staff Working Document - Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16 [2021] SWD (2021) 92, 2

¹⁹⁵ Ibid 3

¹⁹⁶ Ibid

¹⁹⁷ Frequently Asked Questions: Proposal on New Genomic Techniques (n.190)

¹⁹⁸ Questions and Answers: Study on New Genomic Techniques (n.187)

¹⁹⁹ Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 (n.191)

²⁰⁰ EC study on new genomic techniques (n.188)

The proposed regulation, hereinafter referred to as the NGT Regulation, shall only apply to plants obtained through targeted mutagenesis or cisgenesis (NGT plants), as well as any other product consisting of or produced from NGT plants.²⁰¹ All other life forms and types of genetic modifications are exempted from its scope and shall conform to the GMO Regulation, if necessary, since they *"feature more complex sets of modifications to the genome"*²⁰².

The NGT Regulation also specifies that NGT plants that feature *"herbicide tolerant traits"*²⁰³ shall not be included in the simplified procedures laid down in its provisions since there is a significant risk that they might lead to the development of resistant weeds that may require the use of higher quantities of herbicides to be killed off.²⁰⁴

The NGT Regulation divides NGT plants in two categories, according to which different procedures shall be followed. The first one, or NGT 1 plants, are those that could also *"occur naturally or be produced by conventional breeding techniques"*²⁰⁵, while the latter, or NGT 2 plants, refer to *"all NGT plants that are not category 1"*²⁰⁶. NGT 1 plants are always exempted from the provisions of the GMO Regulation and may circulate the internal market after a verification procedure regarding their status, which is laid down in Art. 5-11.²⁰⁷ NGT 2 plants are still subject to the provisions of the GMO Regulation and Directive 2001/18/EC but their risk assessment and post-market monitoring will be evaluated on a case-by-case level depending on, *inter alia*, the safety risk they pose, *"their history of safe use, familiarity for the environment and the function and structure of the modified/inserted sequence(s)"*²⁰⁸. The specific requirements concerning the authorization of NGT 2 plants are laid down in sections 2-4 of the NGT Regulation and contain multiple references to the GMO Regulation and Directive 2001/18/EC. Treating certain parts of the application portfolio with confidentiality is an option, as well as renewal of the authorization.²⁰⁹ More specifically, after the first renewal, any authorization shall be valid for an unlimited period unless otherwise decided upon risk assessment.²¹⁰

²⁰¹ Proposal for a New Genomics Technique Regulation (n.191) rec 9-10, art 1-2

²⁰² Ibid rec 8, 9, 15

²⁰³ Ibid rec 36

²⁰⁴ Ibid

²⁰⁵ Ibid rec 14

²⁰⁶ Ibid rec 15

²⁰⁷ Ibid rec 15-21

²⁰⁸ Ibid rec 26

²⁰⁹ Ibid art 11

²¹⁰ Ibid rec 30

The NGT Regulation is expected to be adopted through the ordinary legislative procedure and as of March 2024, the proposal is being scrutinized by the Council of the European Union as part of the first reading of the new regulation.²¹¹ The NGT Regulation could help FBOs manufacturing plant-based sources of protein to use genetic modification and benefit from simplified and less time-consuming authorization procedures. For other alternative proteins, more research is required in order for them to eventually be included in the provisions of the NGT Regulation.

2.5 Organic Foods Regulation

The EU Protein Strategy emphasizes the need to promote the production of alternative protein sources to meet the growing needs of the market, ensure food security and reduce reliance on foreign imports.²¹² It was also highlighted that the transition from meat protein to unconventional protein sources should happen in a way that is less burdensome for the environment.²¹³ One way to address the impact of protein production on the environment is through organic farming, an idea which is highly promoted by the EU legal system.²¹⁴ According to the F2F strategy, organic farming should comprise of 25% of the total agricultural sector by 2030.²¹⁵ Therefore, the production of alternative protein sources combined with organic agricultural practices may pave a promising way to solve the protein deficit the world is expected to face in the future.

According to Rec. 1 of Regulation (EU) 2018/848, hereinafter referred to as the Organic Regulation, organic farming is an intertwined food system that, *inter alia*, combines environmentally friendly practices, ensures the preservation of biodiversity and natural resources, promotes high quality standards and practices while providing consumers with the option to consume products made naturally.²¹⁶ FBOs who wish to label their products as organic shall follow the strict requirements of the Organic Regulation, which, *inter alia*, entail specific harvesting, processing and distribution rules, limit the use of plant protection products such as pesticides or herbicides and only permit the use of a limited number of authorized food additives and processing

²¹¹ Procedure 2023/0226/COD' (Eur-Lex) <<https://eur-lex.europa.eu/legal-content/EN/HIS/?uri=CELEX:52023PC0411&qid=1700815673837>> accessed 3 April 2024

²¹² EU protein strategy - Briefing Paper No PE 751.426 (n.10) 3-5

²¹³ Ibid p 5

²¹⁴ Ibid p 6

²¹⁵ A Farm to Fork Strategy (n.10) para 2.1

²¹⁶ Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 [2018] OJ L 150/1

aids.²¹⁷ The labelling requirements are equally strict and limit the use of the term 'bio' only to organic products as defined in the Organic Regulation.²¹⁸ The Organic Regulation strictly prohibits the use of ionizing radiation, animal cloning and artificially induced polyploid animals, GMOs, as well as products produced from or by GMOs.²¹⁹

The Organic Regulation applies to all products mentioned in Annex I of the TFEU which are intended to be marketed as "*live or unprocessed agricultural products*" and "*processed agricultural products for use as food*".²²⁰ The Annex specifies that edible vegetables fall within the scope of the regulation, therefore plant-based products intended to be consumed as an alternative protein source may be produced in accordance with the Organic Regulation. Edible mushrooms and algae may also carry organic labels, provided that they follow the relevant provisions of the Regulation.²²¹ Wild algae may also be harvested as organic products so long as their collection "*does not affect significantly the stability of the natural ecosystem or the maintenance of the species in the collection area*"²²² and "*the growing areas are suitable from a health point of view and are of high ecological status*"²²³. The Organic Regulation is currently lackluster in organic insect farming since there are no specific rules on their production, even though insects are included in the definition of livestock production and may have the potential to be farmed in accordance with organic production specifications.²²⁴

2.6 The Farm-to-Fork Strategy

The current regulatory framework covering the food sector has managed to ensure food safety and high-quality standards all along the supply chain ever since its conception and may serve as a baseline to regulate and support the protein transition.²²⁵ However, the alternative protein market is evolving at a fast pace due technological, societal, environmental and political advancements and may require additional or more

²¹⁷ Ibid Ch. 3, rec. 34, art. 24(2)(a)-(c)

²¹⁸ Ibid art 30(1)

²¹⁹ Ibid rec 23

²²⁰ Regulation (EU) 2018/848 (n. 216) art 2(1)(a)-(b)

²²¹ Directorate-General for Agriculture and Rural Development, 'Frequently asked questions on Organic Rules' (European Commission, 17 July 2023) < https://agriculture.ec.europa.eu/system/files/2023-11/organic-rules-faqs_en.pdf > accessed 3 April 2024, 6; Regulation (EU) 2018/848 (n. 216) annex II part III

²²² Regulation (EU) 2018/848 (n. 216) Annex II part III 2.2(2.2.1) (b)

²²³ Ibid Annex II part III 2.2(2.2.1) (a)

²²⁴ Frequently asked questions on Organic Rules (n.221) p 61; Regulation (EU) 2018/848 (n. 216) art .3(27)

²²⁵ EC, 'Fitness check of General Food Law' (European Commission - Food Safety) < https://food.ec.europa.eu/horizontal-topics/general-food-law/fitness-check-general-food-law_en > accessed 3 April 2024

targeted regulatory or policy action that aligns with the current demands. At the same time, the EC has highlighted the need to transform food systems in order to ensure food security, protect the environment and promote healthy lifestyles.²²⁶ Therefore, it is of great importance to go beyond the current regulatory environment and investigate the relevance and the potential impact of future policy instruments on alternative sources of protein, focusing on the EU Green Deal and the F2F Strategy.²²⁷

The EU Green Deal is an overarching policy strategy presented by the EC in December 2019 as a way to reach environmental targets set by the Paris Agreement and the UN's sustainable development goals.²²⁸ Its main goal is to mitigate the effects of climate change and reach carbon neutrality by 2050, while also ensuring adequate economic and societal growth.²²⁹

The EU Green Deal contains a set of actions and policies that concern multiple sectors, namely energy production, transport, agriculture and environmental conservation.²³⁰ Certain initiatives include the adoption of the EU Climate Law, or Regulation (EU) 2021/119, to facilitate the transition to carbon neutrality and reduce GHG emission by 2030, the presentation of the Biodiversity Strategy for 2030 to protect and restore "*all of the world's ecosystems*"²³¹ through a number of commitments and proposals and the F2F Strategy.²³² Thought-out the EU Green Deal, it is highlighted that the successful implementation of all actions enshrined in it requires "*active public participation and confidence in the transition*"²³³ and is heavily based on cross-sectoral and international co-operation.²³⁴

²²⁶ A Farm-to-Fork Strategy (n.10) Ch. 1

²²⁷ EC, Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - The European Green Deal [2019] COM/2019/640 final; A Farm-to-Fork Strategy (n.10)

²²⁸ The European Green Deal (n.227) Ch. 1

²²⁹ Ibid Ch. 1, 3

²³⁰ EC, 'The European Green Deal' (*European Commission*) <https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en> accessed 3 April 2024

²³¹ EC, Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - EU Biodiversity Strategy for 2030 - Bringing nature back into our lives [2020] COM (2020) 380 final, 3

²³² Biodiversity Strategy for 2030 (n.231) 3; Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law') [2021] OJ 2 243/1, art. 1; A Farm-to-Fork Strategy (n.10)

²³³ The European Green Deal (n.227) Ch. 1

²³⁴ Ibid

The F2F Strategy was published by the EC in March 2020 and was framed as lying at "*the heart of the EU Green Deal*"²³⁵. It proposes a number of legislative and non-legislative initiatives to create 'sustainable' and resilient food systems that ensure healthy lifestyles, climate protection, food security, equality and fairness all along the food supply chain.²³⁶ The F2F strategy is divided into four pillars of actions, namely sustainable food production, sustainable food processing and distribution, sustainable food consumption and food loss and waste prevention, and sets targets which include, *inter alia*, a 50% reduction of the use of pesticides, a 50% reduction in nutrient losses and a 50% reduction in the sales of antimicrobials for livestock by 2030.²³⁷

The various plans and commitments made by the EC in the F2F strategy are deemed to cause a shift from the traditional safety-oriented food system to a sustainability-oriented one.²³⁸ Ever since the publication of the 2000 White Paper on Food Safety, safety is the cornerstone of EU food law and shall be ensured anywhere throughout the supply chain, or "*from farm to table*".²³⁹ The current F2F Strategy does not mention safety in its provisions and mainly calls for the creation of 'sustainable food systems'. However, the term is not more precisely defined or further expanded upon, thus creating space for different and potentially contradicting interpretations of its meaning and its relevance in the achievement of the environmental, economic and social targets set by the EC.²⁴⁰ The only description currently provided is that sustainable development refers to "*meeting the needs of the present whilst ensuring future generations can meet their own needs*"²⁴¹.

As far as meat goes, the F2F Strategy starts off by emphasizing the negative environmental impact of the conventional farming industry. For example, it is mentioned that the animal sector is responsible for almost 70% of the total GHG

²³⁵ A Farm to Fork Strategy (n.6) Ch. 1

²³⁶ Ibid Ch. 2

²³⁷ EC, 'Farm to Fork strategy' (European Commission - Food, Farming, Fisheries) < https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en > accessed 3 December 2023; European commission, 'Questions and Answers: Farm to Fork Strategy - building a healthy and fully sustainable food system' (European Commission - Press Corner) < https://ec.europa.eu/commission/presscorner/detail/en/qanda_20_885 > accessed 3 December 2023

²³⁸ Hanna Schebesta and others, 'Tour de Table: Farm to Fork Law Update' (2022) 17(3) European Food and Feed Law Review 208, 209

²³⁹ White paper on food safety of 12 January 2000 [2000] COM/99/0719, Ch. 2(8)

²⁴⁰ Hanna Schebesta and Jeroen J.L. Candel, 'Game-changing potential of the EU's Farm to Fork Strategy' [2020] 1 Nature Food 586, 586

²⁴¹ EC, 'Sustainable development' (European Commission - Trade) < https://policy.trade.ec.europa.eu/development-and-sustainability/sustainable-development_en > accessed 3 December 2023

emissions produced by agriculture.²⁴² In order to facilitate the transition to more sustainable and carbon-efficient agricultural practices, the EC vows to enable the use of alternative, locally sourced protein as feed material and to offer financial support to farmers.²⁴³ At the same time, the EC recognizes the adverse health effects of excessive meat consumption but without creating an action plan with ways to reduce and substitute meat consumption. The F2F Strategy only goes as far as pointing out that *"moving to a more plant-based diet with less red and processed meat [...] will reduce not only risks of life-threatening diseases, but also the environmental impact of the food system"*.²⁴⁴ The aforementioned goals seem to be contradictory, in the sense that, on one hand consumers are being urged to reduce meat consumption but on the other hand the EC pledges to further support meat production.

In regards to the protein transition, the EC starts off by recognizing the potential of algae and promising that they will provide *"well-targeted support for the algae industry"*²⁴⁵. Indeed, in November 2022, the EC published a Communication document showcasing a set of actions promoting algae production and marketing within the Union.²⁴⁶ The proposed measures aim at surpassing production hurdles, such as high production costs, increasing consumer acceptance of algae-based products and improving their regulatory environment.²⁴⁷ Certain initiatives include the *"development of standard testing, quantification and extraction methods for algae ingredients and contaminants"*²⁴⁸ by 2026, *"the development of new and improved algae processing systems and novel production"*²⁴⁹ and a plea to Member States to *"simplify licensing procedures and governance for algae cultivation"*²⁵⁰.

Furthermore, according to the F2F Strategy, research and innovation is of paramount importance in order to achieve protein sufficiency; hence the financial support that the EC promises to provide to research programs that focus on *"increasing the availability and source of alternative proteins such as plant, microbial, marine and insect-based proteins and meat substitutes"*²⁵¹. In fact, multiple programs have already

²⁴² A Farm-to-Fork Strategy (n.10) 7

²⁴³ Ibid Ch. 2.1

²⁴⁴ Ibid Ch. 2.4

²⁴⁵ Ibid (n.10) Ch. 2.1

²⁴⁶ EC, Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions – Towards a Strong and Sustainable EU Algae Sector [2022] COM (2022) 592 final, 3, 6

²⁴⁷ Ibid 9

²⁴⁸ Ibid 11

²⁴⁹ Ibid 14

²⁵⁰ Ibid 10-11

²⁵¹ A Farm-to-Fork Strategy (n.10) para 2.4

been materialized under the aegis of, *inter alia*, Horizon 2020 and Horizon Europe programs, the European Regional Development Fund and the InvestEU Fund.²⁵² The results of the aforementioned studies may be found in CORDIS, the official portal for all EU funded research programs and their results.²⁵³

Another noteworthy commitment made by the EC, is the proposal for a legislative framework for sustainable food systems. The main objectives will be to create a horizontal and holistic approach to sustainability within the food industry by providing definitions, certification and labelling standards, obligations and requirements of all actors involved.²⁵⁴ The proposal was expected to be tabled by the end of 2023 following an inception impact assessment and a public consultation. However, the proposal has not been presented yet and therefore, it is still not clear what the exact scope of the regulation will be and how, or if at all, alternative proteins will be expanded upon.²⁵⁵

In light of the aforementioned, the European Parliament (EP) adopted in October 2023 a draft report on an EU protein strategy, urging the EC to propose a strategy that will cover all alternative protein sources and will encourage their production and consumption within the Union.²⁵⁶ The report covers a variety of policy actions, ranging from guidance documents to facilitate the authorization of novel foods and financial incentives for farmers engaging in the production of alternative protein sources, to plans to reduce protein imports and increase consumer understanding and acceptance of meat substitutes.²⁵⁷

2.7 Preliminary Conclusions

To conclude, finding ways to substitute meat has proven to be a difficult task that requires cooperation, effort and research. Currently, most alternative protein production technologies seem to be at a primary stage and are occasionally met with skepticism by consumers, political authorities and businesses. At the same time, the

²⁵² Aziz Omar and Martin Hvarregaard Thorsøe, 'Rebalance power and strengthen farmers' position in the EU food system? A CDA of the Farm to Fork Strategy' [2023] Agriculture and Human Values 1, 9

²⁵³ EC, 'Projects & results' (CORDIS - EU research results) < <https://cordis.europa.eu/projects> > accessed 3 December 2023

²⁵⁴ A Farm-to-Fork Strategy (n.10) Ch. 2

²⁵⁵ Ivana Katsarova, 'Legislative framework for sustainable food systems In "A European Green Deal"' (Legislative Train Schedule - European Parliament, 20 October 2023) < <https://www.europarl.europa.eu/legislative-train/theme-a-european-green-deal/file-sustainable-eu-food-system> > accessed 3 April 2024

²⁵⁶ European Parliament resolution of 19 October 2023 European protein strategy [2023] 2023/2015(INI) para 1-2

²⁵⁷ Ibid para 58(i)-(xxiii)

current regulatory landscape is rather complicated. Alternative proteins are required to go through the demands of multiple EU regulations and directives, namely the GFL, the NFR and the GMO Regulation, which leads to time consuming and costly procedures that may be overbearing for food businesses, especially small and medium enterprises (SMEs). In the aftermath of the EU Green Deal, the adoption of multiple legislative and non-legislative measures is currently on the way. The adoption of the NGT Regulation, the proposal for the Sustainable Food Systems Regulation and the implementation of the various commitments made by, *inter alia*, the F2F Strategy, the Algae Initiative and the EU protein strategy from 2020 and onward, is expected to stir the water and greatly impact the protein transition.

Unfortunately, the F2F Strategy does not delve deep enough and does not set tangible targets concerning the protein transition. The EC's approach seems lackluster in regards to lab-grown meat, insect farming and even plant-based protein sources and is mostly limited to their potential as a topic for future research and innovation. In general, different strategies will inevitably lead to different results, which shall be evaluated accordingly, but a common denominator among all proposed measures is the call for simplified authorization procedures, more extensive and organized research efforts and finally, more technical, financial and regulatory support provided by the multiple European and national institutions. It remains to be seen how the EC will eventually handle the protein transition, since they are expected to review their protein policy in the first quarter of 2024.²⁵⁸

²⁵⁸ EU protein strategy - Briefing Paper No PE 751.426 (n.10) 1

Chapter 3: The Labelling of Alternative Proteins in the EU

Food labels are used to convey specific information to consumers regarding the characteristics of a product and are, therefore, a useful tool to help them make informed and rational purchasing choices.²⁵⁹ Truthful and accurate labelling ensures transparency along the food supply chain and reinforces consumer trust.²⁶⁰

Several countries have their own rules in place governing food labelling in order to ensure consumer protection and fair-trade practices.²⁶¹ For instance, food manufacturers operating in the USA are required to follow the labelling requirements set out in the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labelling Act.²⁶² In the EU, clear rules and boundaries vis-à-vis food labelling are, first of all, enshrined in the GFL. According to Art. 16 of the GFL, all information accompanying a food product, be it through labelling, advertising or other presentation forms, shall be provided in such a way that does not mislead the consumers. FBOs are also required to adhere to other, more specific food labelling provisions.²⁶³ Prior to the adoption of Regulation (EU) No 1169/2011 on the provision of food information to consumers, or the FIC Regulation, food labelling obligations were scattered throughout multiple EU Directives that in cases dated back to 1978 and were therefore found to be outdated in a 2008 EC impact assessment report on food labelling issues.²⁶⁴ As a result, the EC submitted later that year a proposal to combine said Directives and create a mandatory and harmonized regulatory framework concerning food information provided to

²⁵⁹Christoph Schulze and others, 'Between farms and forks: Food industry perspectives on the future of EU food labelling' [2023] 217 Ecological Economics 108066, 2

²⁶⁰KM Priya and Alur Sivakumar, 'Analyzing consumer behavior towards food and nutrition labeling: A comprehensive review' [2023] 9 Heliyon e19401, 1

²⁶¹Alan Turner, 'Prepacked food labelling: past, present and future' (1995) 97(5) British Food Journal 23, 23; 'Analyzing consumer behavior towards food and nutrition labeling: A comprehensive review' (n.261) 14

²⁶² U.S. Food & Drugs Administration, Guidance for Industry: Food Labeling Guide (US Food & Drugs Administration 2013) 4

²⁶³ Regulation (EC) No 178/2002 (n.119) art. 16

²⁶⁴ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 [2011] OJ 2 304/18, rec 6; Commission Staff Working Document accompanying the Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers [2008] SEC/2008/0093 final, 6

consumers, in order to simplify legal and administrative procedures and ensure consumer protection through "*clear, comprehensible and legible labelling of foods*"^{265, 266}

3.1 Food Information to Consumers Regulation

The FIC Regulation establishes the general rules and requirements of FBOs in regards to food labelling and applies to all actors involved in the food industry, from production to consumption.²⁶⁷ All food products must be accompanied by "*accurate, clear and easy to understand*"²⁶⁸ information and misleading claims are strictly prohibited.²⁶⁹ The FIC Regulation differentiates between mandatory food information that shall always be displayed on the label and information that may be added on a voluntary basis and only if it does not compromise the display of the former.²⁷⁰ Food labels shall include the mandatory particulars referred to in Art. 9(1)(a)-(l), namely a full list of ingredients, an allergen and nutrition declaration and the name of the food.²⁷¹ At the same time, there are conditions under which certain mandatory information may be omitted from the label and FBOs shall always ensure that they are also complying, if applicable, with the labelling obligations laid down in other, more specific, provisions of Union or Member State law.²⁷² For example, foods containing GMOs in a proportion higher than 0.9% are also required to follow the labelling requirements laid down in the GMO Regulation.²⁷³

Alternative proteins intended for human consumption shall bear specific labels in accordance with the aforementioned.²⁷⁴ Once again, all information displayed on their packaging shall be truthful and straightforward.²⁷⁵ FBOs shall be especially cautious to avoid implying "*by means of the appearance, the description or pictorial representations*"²⁷⁶ that their product contains meat, when in fact it acts as an imitation and meat has been substituted with another ingredient. In such cases, the name of the

²⁶⁵ Ibid rec 9

²⁶⁶ P. Berryman, 1 - The EU food information for consumers regulation. in P Berryman (ed), *Advances in Food and Beverage Labelling* (Woodhead Publishing Series in Food Science, Technology and Nutrition 2015), 3

²⁶⁷ Regulation (EU) No 1169/2011 (n.264) art 1(2)-1(3)

²⁶⁸ Ibid art 7(2)

²⁶⁹ Ibid art 6, 7(1)

²⁷⁰ Ibid Ch. IV, art. 37

²⁷¹ Ibid art 9(1)(a)-(l)

²⁷² Ibid art 16, art 8(5)

²⁷³ Ibid art 13

²⁷⁴ Ibid art. 1(3)

²⁷⁵ Ibid art 7

²⁷⁶ Ibid art 7(1)(d)

substitution must be clearly displayed in close proximity to the name of the product.²⁷⁷ At the same time, it is also essential to not include on the label any other depictions, such as illustrations or words, that have the potential to confuse and mislead the consumers in regards to the true nature of the product. For instance, pictures of, *inter alia*, farm animals or traditional meat cuts shall not be displayed on the packaging of substitutes since this could falsely convey to the consumer the idea that the product contains meat.²⁷⁸ This has been a particularly important constituent of food labelling after a 2015 CJEU decision on the potential of graphic representations on labels to mislead the consumers.²⁷⁹ During the main proceedings of the case, the German consumer association brought Teekanne GmbH & Co. KG, a German company manufacturing tea products, before a regional court on the grounds that one of their product labels was conveying false and misleading information in regards to its ingredients.²⁸⁰ The tea product in question was carrying, *inter alia*, depictions of raspberries and vanilla flowers, while it did not contain any of the aforementioned components or flavorings, as per its list of ingredients.²⁸¹ According to the plaintiff, this confused purchasers, who would naturally expect the fruit tea to contain raspberry and vanilla flavors.²⁸² After a series of appeals on national level, the case was brought before the CJEU for a preliminary ruling, where it was concluded that any type of labelling has the potential to mislead the consumers if it anyhow implies or suggests that an ingredient is present in the final product when in fact it is not and this is only apparent from the list of ingredients.²⁸³

Similarly, FBOs shall be meticulous about the requirements of the FIC Regulation in regards to substances causing allergies or intolerances. This can be particularly important for alternative proteins, mainly insects and mycoproteins, since both have been linked with the occurrence of allergic reactions to certain consumers.²⁸⁴ For example, certain studies have shown that arthropods, which include, *inter alia*, crustaceans, insects and dust mites, can cause an immunological response to humans,

²⁷⁷Commission Notice on questions and answers on the application of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers [2018] 2018/C 196/01, 4

²⁷⁸Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat (n.166) 330

²⁷⁹Case C-195/14 – *Teekanne* [2015] ECLI:EU:C: 2015:361

²⁸⁰ Ibid para 17

²⁸¹ Ibid para 16

²⁸² Ibid para 17

²⁸³ Ibid para 45

²⁸⁴ Self-reported adverse reactions associated with mycoprotein (Quorn-brand) containing foods (n.71) 630; Approval of fourth insect as a Novel Food (n.143); Regulation (EU) No 1169/2011 (n.264) art. 21

mainly due to the presence of the protein tropomyosin.²⁸⁵ Cross-reactive allergies are also common, meaning that individuals with pre-existing allergies to arthropods may also demonstrate symptoms after consuming insects.²⁸⁶ Therefore, in cases where an allergen, as described in Annex II of the FIC Regulation, may be present in the final product, FBOs are required to include it in the list of ingredients in a manner that “*clearly distinguishes it from the rest of the ingredients*”²⁸⁷.

Another component of the FIC Regulation that is of great relevance for alternative proteins, is the name of the food. FBOs shall use clear terminology that enables consumers to understand what their product actually is and whether it serves as a meat substitute or not. Nevertheless, the FIC Regulation does not provide any clear definitions for imitation products. The EC has been granted the right to adopt implementing acts on the “*information related to suitability of a food for vegetarians or vegans*”²⁸⁸ since the conceptualization of the FIC Regulation, but it has yet to happen.²⁸⁹ Even though this type of information falls within the scope of the voluntary food information and therefore it is not directly applicable to alternative proteins, it could provide clarity and legal certainty over their appropriate nomenclature and a more concrete incentive for FBOs to invest in the alternative protein market. Currently, the FIC Regulation briefly describes the different types of names that may be used on labels and food manufacturers are responsible to ascertain which one fits best with their product.²⁹⁰ According to Art. 17(1) of the FIC Regulation, there are three categories of food names: legal, customary and descriptive names.

If a legal name has been provided by Union law, then it shall always be prominently displayed on the packaging.²⁹¹ Products bearing legally defined names under Union law are limited and are required to follow specific rules concerning, *inter alia*, their composition and quality.²⁹² Such products may be defined either in Regulation (EU) 2013/1308 establishing a common organization of the markets in agricultural products

²⁸⁵ Edible Insects in a Food Safety and Nutritional Perspective: A Critical Review (n.86) 303

²⁸⁶ Opportunities and hurdles of edible insects for food and feed (n.88) 303; Approval of fourth insect as a Novel Food (n.143)

²⁸⁷ Regulation (EU) No 1169/2011 (n.264) art. 21(1)(b)

²⁸⁸ Ibid art 36(3)(b)

²⁸⁹ Daniele Pisanello and Luchino Ferraris, 'Ban on Designating Plant Products as Dairy: Between Market Regulation and Over-Protection of the Consumer' (2018) 9(1) European Journal of Risk Regulation 170, 174;

²⁹⁰ Answer given by Mr Andriukaitis on behalf of the Commission to Question E-003755/2017 (27 July 2017)

²⁹¹ Regulation (EU) No 1169/2011 (n.264) art 17(1); Alternative proteins and EU food law (n. 109) 6

²⁹² Alternative proteins and EU food law (n.109) 6

or Regulation (EU) 1151/2012 on quality schemes for agricultural products and foodstuffs, with the purpose of creating minimum marketing standards and protecting traditional specialties or foods originating from a specific geographic location, respectively.²⁹³ Currently, no such standards have been put in place for alternative sources of protein and, therefore, there are currently no legal names for them on EU level.²⁹⁴ However, this only applies to non-novel alternative proteins since novel foods, have specific names assigned to them during the authorization process.²⁹⁵ In the absence of a legal name on Union level, FBOs shall consult with the regulatory framework of the Member State they wish to conduct business in to verify the name of their product.²⁹⁶ The FIC Regulation does not preclude Member States from adopting additional national measures where harmonization is absent, and therefore certain products may have protected names under national legislation.²⁹⁷

When a legal name does not exist, FBOs shall resort to using the customary name of the food, as per Art. 17(1) of the FIC Regulation. Customary names are defined as those that are "*accepted as the name of the food by consumers in the Member State in which that food is sold without that name needing further explanation*"²⁹⁸. Therefore, customary names are defined only on the national level and alternative protein manufacturers shall consult with national laws to ascertain whether a customary name exists for their product.²⁹⁹ Consequently, this means that customary names may not be equally used or even understood by citizens of different Member States but the principle of mutual recognition stands and, therefore, if a product has been lawfully sold in one Member State under a customary name, then its marketing cannot be prohibited in another.³⁰⁰ In cases where a customary name cannot be reasonably conceived by said

²⁹³ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organization of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 [2013] OJ 2 347/671, rec 64; Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [2012] OJ 2 343/1, rec 18, 34

²⁹⁴ Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat (n.166) 328

²⁹⁵ Regulation (EU) 2015/2283 (n. 60) art 10(2)(b)

²⁹⁶ Answer given by Mr Andriukaitis to Question E-003755/2017 (n.290)

²⁹⁷ Regulation (EU) No 1169/2011 (n.264) art 38(2); Karin Verzijden and Jasmin Buijs, 'Meat 3.0 How Cultured Meat is Making its Way to the Market' (2020) 15(2) European Food and Feed Law Review (EFFL) 96, 101

²⁹⁸ Regulation (EU) No 1169/2011 (n.264) art 2(2)(o)

²⁹⁹ Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat (n.166) 328

³⁰⁰ Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat (n.166) 328; Mette Ohm Rørdam, 'EU Law on Food Naming: The Prohibition Against Misleading Names in an Internal Market Context' (PhD thesis, Copenhagen Business School 2013) 16

consumers, then other descriptive information shall be displayed in close proximity to the name of the food to adequately explain the characteristics of the product.³⁰¹

In the absence of a customary name, FBOs may use a descriptive name. This name shall provide a clear and legible description of the food that enables consumers to understand its true nature and differentiates it from similar products.³⁰² It is therefore up to the discretion of the FBO to provide an adequate descriptive name and up to national courts to decide if it is in line with national and Union requirements.³⁰³

In light of the aforementioned, it is important to note that most designations referring to specific meats (e.g. beef, poultry meat, veal) are reserved and shall not be used on substitutes produced from alternative proteins.³⁰⁴ For example, the use of names such as “vegan chicken” or “soy beef” could lead to legal repercussions for the FBO.³⁰⁵ In contrast, terms relating to the shape or composition of meat products (e.g. sausage, burger, steak) are, for the moment, not legally protected.³⁰⁶ In 2019, a member of the EP submitted a proposal for certain amendments of the reformed Common Agricultural Policy (CAP) that would essentially grant exclusive use of all terms traditionally associated with meat to meat products, thus banning substitutes from using them on their labels.³⁰⁷ However, the proposal was officially rejected in 2020.³⁰⁸ Even though this provides FBOs with more flexibility and does not prohibit the use of ‘meat terms’ for substitutes on Union level, the potential of customary and descriptive names to mislead the consumers may be evaluated on a case-by-case level and is

³⁰¹ Regulation (EU) No 1169/2011 (n.264) art 17(2)

³⁰² Ibid art 2(2)(p)

³⁰³ EU Law on Food Naming: The Prohibition Against Misleading Names in an Internal Market Context (n.300) 117

³⁰⁴ Alternative proteins and EU food law (n. 109) 7

³⁰⁵ Ignacio Carreno and Tobias Dolle, 'Tofu Steaks? Developments on the Naming and Marketing of Plant-based Foods in the Aftermath of the TofuTown Judgement' (2018) 9(3) European Journal of Risk Regulation 575, 580

³⁰⁶ Answer given by Mr Andriukaitis to Question E-003755/2017 (n.290)

³⁰⁷ Report on the proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) No 1308/2013 establishing a common organization of the markets in agricultural products, (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs, (EU) No 251/2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatized wine products, (EU) No 228/2013 laying down specific measures for agriculture in the outermost regions of the Union and (EU) No 229/2013 laying down specific measures for agriculture in favor of the smaller Aegean islands [2018] A8-0198/2019, 169

³⁰⁸ Ibid; EP, 'Are veggie burgers, tofu steaks or the use of yogurt pots for plant products going to be banned?' (News - European Parliament, 28 June 2021) < <https://www.europarl.europa.eu/news/en/press-room/2021019BKG89682/eu-farm-policy-reform-as-agreed-by-the-parliament-and-council/7/are-veggie-burgers-tofu-steaks-or-the-use-of-yogurt-pots-going-to-be-banned> > accessed 2 January 2024

heavily based on the regulatory framework of each Member State.³⁰⁹ Consequently, there have been instances where Member States have tried to regulate the use of the aforementioned terms. The approach of certain Member States will be further analyzed in Chapter 5.

Last but not least, the case of cultured meat seems to be even more complicated. As already established, FBOs seeking to gain approval for its marketing shall apply for an authorization under the NFR Regulation, which requires, *inter alia*, a proposal for a legal name for the product.³¹⁰ However, since there is no regulatory framework establishing the rules and boundaries surrounding lab-grown meat, FBOs will face a number of challenges. First of all, it is rather unclear whether cultivated meat may actually be marketed as 'meat' under the context of EU food law even if it is colloquially referred to as such.³¹¹ 'Meat' is a protected term and, as per Regulation (EU) 853/2004, refers to the "*edible parts of animals*"³¹². Even though cultivated meat originates from animal cells, they require further processing before they can be consumed and, therefore, it has been debated whether these starting cells can be considered as an edible part of the animal.³¹³ Furthermore, even if the 'meat argument' is set aside and FBOs choose to avoid its use to ensure legal certainty, choosing a descriptive name for the product may also be a difficult task. FBOs need to strike a balance between a name that provides adequate information concerning the characteristics of the product and is not misleading but is also enticing enough for consumers. Cultured meat is a rather new and unknown product on a global level and therefore wording might play a significant role in its successful introduction to the market. Terms that have gained positive evaluations and could potentially be used, in combination with the relevant 'meat term' are, *inter alia*, 'cultured', 'clean', 'in-vitro' and 'slaughter-free'.³¹⁴

3.2 Nutrition and Health Claims Regulation

Regulation (EC) 1924/2006 sets out the general rules governing nutrition and health claims made on foods. Nutrition claims refer to "*particular beneficial nutritional*

³⁰⁹Tofu Steaks? Developments on the Naming and Marketing of Plant-based Foods in the Aftermath of the TofuTown Judgement (n.305) 3; Neli Sochirca, 'The European Legal Framework on Vegan and Vegetarian Claims' (2018) 13(6) Eur Food & Feed L Rev 514, 519

³¹⁰ Regulation (EU) 2015/2283 (n. 60) art 10(2)(b)

³¹¹ Meat 3.0 How Cultured Meat is Making its Way to the Market (n.297)100

³¹² Regulation (EC) No 853/2004 (n.18) Annex I (1) (1.1)

³¹³ Meat 3.0 How Cultured Meat is Making its Way to the Market (n.297)100

³¹⁴Shujian Ong, Deepak Choudhury and May Win Naing Shujian, 'Cell-based meat: Current ambiguities with nomenclature' (2020) 102(2) Trends in food science & technology 1, 4

*properties*³¹⁵ related to the energy or nutrient content of a food product, while health claims refer to any claim that creates a causal link between a food product and health.³¹⁶ All claims shall not be misleading and fraudulent and shall be scientifically substantiated.³¹⁷

In general, the nutrient profile of alternative proteins is being highlighted to increase their marketability, especially since many of them are being met with skepticism and might require a boost to increase consumer acceptance.³¹⁸ Insects and fungi are being promoted for their protein content, algae are rich in essential fatty acids like linoleic and omega-3 acids and plant-based alternative proteins have a better fiber and cholesterol profile compared to meat.³¹⁹ However, such information shall not be arbitrarily displayed on food labels. Before including any nutrient claim on their packaging, FBOs shall ensure that the claims in question are included in the Union list of authorized claims laid down in the Annex of Regulation (EC) 1924/2006. The Annex meticulously describes the specifications of each nutrient claim and FBOs are not allowed to deviate from them. For example, a product label may display the phrase 'source of protein' only if the energy value provided by the protein is at least 12%.

Health claims, on the other hand, are required to go through a much more rigorous authorization process before being depicted on food labels. FBOs shall apply for an authorization to the national competent authority and their claims may only be allowed after a positive scientific evaluation from EFSA.³²⁰ Data accompanying the application and relating to the scientific substantiation of the health claim may be granted proprietary protection for a 5-year period.³²¹ All authorized claims are bound to strict labelling rules.³²² Naturally, there are restrictions in regards to the type of health claims that may be allowed. For instance, claims referring to the rate of weight loss are prohibited.³²³ In general, health claims may relate to a set of bodily, psychological or

³¹⁵Regulation (EC) No 1924/2006 of the European parliament and of the council of 20 December 2006 on nutrition and health claims made on foods [2006] OJ 2 404/30, art 2(2)(4)

³¹⁶ Ibid art 2(2)(5)

³¹⁷ Ibid art 3 and art 6(1)

³¹⁸Alexandra E Sexton, Tara Garnett and Jamie Lorimer, 'Framing the future of food: The contested promises of alternative proteins' (2019) 2(1) Environment and Planning E: Nature and Space 47, 53

³¹⁹ Alternative proteins and EU food law (n. 109) 7; Framing the future of food: The contested promises of alternative proteins (n.318) 53; Rachel Tso, Amanda Jiaying Lim and Ciarán G Forde, 'A Critical Appraisal of the Evidence Supporting Consumer Motivations for Alternative Proteins' (2021) 10(1) Foods 24, 28

³²⁰ Regulation (EC) No 1924/2006 (n.315) art 15 (1)-(2), rec 23 and

³²¹ Ibid art 21

³²² Ibid art 10(2)

³²³ Ibid art 12(b)

behavioral functions, to the reduction of disease risk or to children's development.³²⁴ Certain examples of authorized health claims are "*protein contributes to a growth in muscle mass*"³²⁵ and "*linoleic acid contributes to the maintenance of normal blood cholesterol levels*"³²⁶, which may be used under specified conditions. If a FBO is able to demonstrate the relationship between a nutrient or a substance present in their product and one of the aforementioned health effects through "*generally accepted scientific evidence*"³²⁷, then the health claim may receive a positive opinion from EFSA and eventually an authorization. Since alternative proteins are dense with substances or nutrients that could potentially have a positive health effect, such as proteins, fibers and vitamins, they are, in theory, eligible for a health claim authorization. However, their health effects are usually evaluated in conjunction with those of conventional meat and therefore there is a lack of robust empirical evidence to substantiate their own short- and long-term impact on human health.³²⁸ For instance, efforts have been made to authorize certain health claims for algae but all applications were rejected due to the absence of sufficient scientific data able to demonstrate a causal link between the claim and its effect on human health.³²⁹

3.3 Green Claims Directive & Sustainability Labelling Framework

As already established in Chapter 1, alternative proteins have been associated with a lower environmental impact compared to meat. Insects and cultured meat require less land and water use, fungi and algae are able to process agricultural waste and plant-based protein production emits less GHG emissions. This positive environmental impact is currently considered as one of the main drivers of the protein transition, even though it has yet to be verified on a large production scale for most of these products.³³⁰

³²⁴ Ibid art 13-14

³²⁵ EC, 'EU Register of authorized health claims – Protein' (European Commission) < <https://ec.europa.eu/food/food-feed-portal/screen/health-claims/eu-register/details/POL-HC-6446> > accessed 15 February 2024

³²⁶ EC, 'EU Register of authorized health claims - Linoleic acid' (European Commission) < <https://ec.europa.eu/food/food-feed-portal/screen/health-claims/eu-register/details/POL-HC-6399> > accessed 15 February 2024

³²⁷ Regulation (EC) No 1924/2006 (n.315) art 13(1)(i)

³²⁸ A Critical Appraisal of the Evidence Supporting Consumer Motivations for Alternative Proteins (n.319) 28; Ashley Green and others, 'The role of alternative proteins and future foods in sustainable and contextually adapted flexitarian diets' [2022] 124 Trends in food science & technology 250, 252

³²⁹ Alternative proteins and EU food law (n. 109) 8

³³⁰ The role of alternative proteins and future foods in sustainable and contextually adapted flexitarian diets (n.328) 252

At the same time, consumers are showing a growing interest in the environmental footprint of their food and are actively trying to make more conscious purchasing choices.³³¹ In order to meet the aforementioned demand, a great number of companies are using sustainability related claims for the promotion of their products and services.³³² However, due to the lack of a specific regulatory framework establishing rules on the use of environmental claims, a concerning number of traders are displaying vague, misleading or unsubstantiated information on their labels.³³³ In an effort to minimize this phenomenon, enable the green transition, increase consumer protection and provide a level of harmonization across the Union, the EC submitted in March 2023 a proposal for a Directive on the substantiation and communication of explicit environmental claims, hereinafter referred to as the Green Claims Directive.³³⁴

According to it, Member States are responsible to, *inter alia*, ensure that traders carry out a proper scientific assessment of their environmental claims, put in place specific rules for the communication of said claims to consumers and conduct regular compliance checks.³³⁵ Member States have the authority to enforce their own assessment and verification procedures, so long as they are in compliance with the requirements set out in the Green Claims Directive.³³⁶ Furthermore, environmental labelling schemes shall go through a third-party verification to ensure their truthful nature and the EC shall create a list including all authorized ones.³³⁷ The Green Claims Directive will apply to "*explicit environmental claims made by traders about products or traders in business-to-consumer commercial practices*"³³⁸, but only in cases where no other, more specific Union laws are put in place and harmonization is absent.³³⁹ For instance, environmental claims relating to organic production fall within the scope of the Organic Regulation and are therefore exempted from the provisions of the Green

³³¹ Towards a sustainable food labelling framework to empower consumers to make sustainable food choices [own-initiative opinion] [2022] NAT/ 857, 3

³³² Proposal for a Directive of the European Parliament and of the Council on substantiation and communication of explicit environmental claims (Green Claims Directive) [2023] COM/2023/166 final, rec 22

³³³ Alternative proteins and EU food law (n. 109) 8; Guillaume Ragonnaud 'Green claims' directive -Protecting consumers from greenwashing' (Briefing Paper No PE 753.958, European Parliamentary Research Service, October 2023), 2

³³⁴ Proposal for a Green Claims Directive (n.332) rec 4-5; Green Claims Directive – Briefing paper No PE 753.958 (n.333) 2

³³⁵ Proposal for a Green Claims Directive (n.332) art 3(1), 5(1), 15(1)

³³⁶ Ibid rec 50

³³⁷ Ibid rec 42 & rec 47

³³⁸ Ibid art 1(1)

³³⁹ Ibid art 1(2)

Claims Directive.³⁴⁰ Similarly, if future legislative action lays down rules on the use and communication of environmental claims by specific actors or sectors, then the Green Claims Directive will no longer apply and those rules shall be enforced.³⁴¹ The Directive has not been adopted yet, but it is expected to come to fruition soon. As of April 2024, the EP has conducted the first reading of the draft and the Council is expected to follow up.³⁴² It remains to be seen what the definitive outcome of the legislative procedure will be and how it will eventually be transposed to national law.

In the absence of a specific regulatory framework surrounding sustainability claims in the food sector, it may be assumed that the provisions of the Green Claims Directive will, initially, also apply to it and, therefore, FBOs wishing to include explicit environmental claims on their product labels might have to abide by its requirements. An interesting point of the Green Claims Directive is that in cases where the positive environmental impact of the product is not yet verifiable but there are strong evidence pointing at that direction, business operators are allowed to publicly share information showcasing and promoting their efforts and results.³⁴³ This could be particularly beneficial for alternative proteins, in order to increase their marketability, while also promoting their potential environmental benefits.

However, as mentioned above, after the adoption of the sustainability labelling framework that the EC has vowed to propose as part of the F2F Strategy, all environmental claims related to the food industry will most likely fall within its scope rather than the Green Claims Directive's. This framework is expected to cover, in combination with other labelling provisions laid down in Union law, "*nutritional, climate, environmental and social aspects of food products*"³⁴⁴, which will not only help consumers make informed choices but will also benefit FBOs who adopt sustainable practices.³⁴⁵ It is currently unknown how the proposal will be structured, what type of rating scale will be used, how sustainability will be evaluated or how this framework will

³⁴⁰ Ibid rec 9

³⁴¹ Ibid rec 13

³⁴² EP, '2023/0085(COD) - Substantiation and communication of explicit environmental claims (Green Claims Directive)' (Legislative Observatory) <[https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2023/0085\(COD\)&l=en](https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2023/0085(COD)&l=en)> accessed 5 April 2024

³⁴³ Proposal for a Green Claims Directive (n.332) rec 29

³⁴⁴ EC, 'Food information to consumers - legislation' (European Commission - Food, Farming, Fisheries) <https://food.ec.europa.eu/safety/labelling-and-nutrition/food-information-consumers-legislation_en> accessed 2 January 2024

³⁴⁵ A Farm-to-Fork Strategy (n.10) 8

relate to the Green Claims Directive but the EC is expected to propose a draft sometime in 2024.³⁴⁶

3.4 Private Certifications

Private standards and certification schemes are a set of rules developed by private entities that set minimum requirements for products, processes and methods, as well as producers.³⁴⁷ They are either used to show compliance with general safety and quality specifications or to promote specific characteristics of a product and signify premium quality and added value.³⁴⁸ FBOs may either follow a "*self-declaration scheme*"³⁴⁹, meaning that no certification takes place and producers base their claims on their own self-testimonies, or an independent third party certification program.³⁵⁰ In general, there is no uniform way to create these schemes but, according to the EU's best practice guidelines for voluntary certification schemes for agricultural products and foodstuffs, they should, *inter alia*, have clearly defined objectives and scope, be based on peer-reviewed scientific evidence and include specific instructions for inspection methods and procedures.³⁵¹ Private standards are, by nature, voluntary and, therefore, it is in the discretion of FBOs to decide if they wish to adhere to their requirements and bear their logos.³⁵²

Over the past years, a number of private certification schemes have emerged and are promoting specific attributes of food products relating to, *inter alia*, religious, environmental and ethical concerns.³⁵³ Even though certain areas may already be covered by EU legislation, private parties are free to create their own schemes and set stricter or more demanding requirements.³⁵⁴ For example, organic foods are already regulated on Union level under Regulation (EU) 2018/848 but there is also a number of private organic logos, such as the German 'Bio-Siegel' or the Ecocert organic certification.³⁵⁵

³⁴⁶ Ibid 22

³⁴⁷ Tetty Havinga *Private Food Safety Standards in the EU* (Nijmegen Sociology of Law Working Papers Series 2017/01, 2017), 5

³⁴⁸ Ibid 7

³⁴⁹ Commission Communication — EU best practice guidelines for voluntary certification schemes for agricultural products and foodstuffs [2010] OJ C 341/5, 3

³⁵⁰ Ibid para 2(2)(5)-(6)

³⁵¹ Ibid para 5(1)1, 5(1)3, 5(2)1 and 6(2)1

³⁵² Ibid 1

³⁵³ Private Food Safety Standards in the EU (n.347) 2

³⁵⁴ Meike Janssen and Ulrich Hamm, 'Governmental and private certification labels for organic food: Consumer attitudes and preferences in Germany' (2014) 49(2) Food Policy 437, 438

³⁵⁵ Ibid 439

In regards to meat substitutes, there is a growing demand for them among vegan and vegetarian consumers and, as a result, FBOs resort to the plethora of private certifications circulating the market in order to showcase that their product conforms with market trends and requirements.³⁵⁶ Besides, these certification schemes are useful for vegan consumers, who are known to value logos and labels declaring the vegan nature of the product, since they can help them identify suitable foods a lot faster and easier.³⁵⁷ Certain well-known private certificates are the European Vegetarian Union's (EVU) V-label and the Vegan society label, which set requirements concerning the presence of animal-derived ingredients, the production units and the tolerance levels for animal traces in the final product.³⁵⁸ Such standards could be used for the marketing of certain alternative proteins that would otherwise be disregarded by consumers due to their novel and innovative nature, in order to increase their popularity and ease their introduction into the market. At the same time, other, more niche certification programs concerning alternative proteins are also slowly emerging. For instance, a number of certifications programs concerning insect farming have been developed, namely the Naturland and Entotrust standards, in order to, *inter alia*, promote ethical farming practices, increase consumer acceptance, set specific standards concerning insect feed, while also ensuring fair treatment of insect farmers and workers.³⁵⁹

Therefore, it appears that a number of private certifications may be applicable to alternative proteins. Many certificates have evolved over the years and the more recent ones seem to also take into consideration not only aspects concerning the overall quality of the product, but also environmental and ethical aspects.³⁶⁰ Consumers seem to show interest not only to the safety of the product, which was one of the initial drivers for the development of quality schemes, but they also seem to value sustainability.³⁶¹ Technology is evolving fast, more alternative proteins are expected to enter the market,

³⁵⁶Bárbara Marques Freire Cardoso, 'The Role of Cruelty-free and Vegan logos on Purchase Intention: Investigating the effects of certification, logo recognizability and pro-environmental attitude' (MSc Thesis, Universidade Católica Portuguesa, 2022), 9-10

³⁵⁷Eleanor Kerslake, Joya A. Kemper and Denise Conroy, 'What's your beef with meat substitutes? Exploring barriers and facilitators for meat substitutes in omnivores, vegetarians, and vegans' (2022) 170(1) *Appetite* 105864, 8

³⁵⁸Marielle Gerke and Meike Janssen, 'Vegan foods: Labelling practice' (2016) 64(3) *Science & Research* 54, 55

³⁵⁹Entotrust, 'The program for insect food quality' (*Entotrust*) <<https://www.entotrust.org/>> accessed 16 February 2024; Naturland, 'Naturland Standards – Organic Insect Breeding' (*Naturland*) <https://www.naturland.de/images/01_naturland/en/Standards/Naturland-Standards_Insect_Breeding.pdf> accessed 16 February 2024

³⁶⁰The Role of Cruelty-free and Vegan logos on Purchase Intention: Investigating the effects of certification, logo recognizability and pro-environmental attitude' (n.356) 1

³⁶¹Private Food Safety Standards in the EU (n.347) 4

consumer perception is rapidly changing and the political environment is expected to shift in the aftermath of the European Green Deal. Consequently, many more private standards may arise in order to meet societal demands, but it still remains to be seen how they will evolve and which direction they will follow.

3.5 Preliminary Conclusions

In conclusion, food labelling has been strictly regulated under EU law in order to ensure consumer protection and transparency along the supply chain. Misleading claims are prohibited and FBOs shall comply with all the relevant labelling provisions of Union and national law. However, labelling alternative proteins has proven to be a rather complicated issue, especially in regards to their marketing names. There is no specific regulatory framework targeting them and there is an ongoing debate concerning the use of 'meat terms'. Terms related to the shape or composition of the product are not prohibited after an EP rejection of the relevant proposal but Member States may be willing to limit their use. First of all, this increases the chances of disrupting transnational trade and causing fractions in the structure of the internal market. Furthermore, it may create an overcomplicated situation where FBOs have to navigate the regulatory framework of each Member State separately and check what type of names are allowed under each jurisdiction. As a result, uncertainty may increase and FBOs may feel discouraged from producing and marketing alternative sources of protein. The EC could provide clarity over the matter if they exercised their right to adopt implementing acts over vegan and vegetarian claims and provide definitions for meat substitutes, specific descriptions of their nature and characteristics and put a definitive end to the 'meat terms' debate by allowing their use. Alternative proteins are also allowed to bear nutrition and health claims so long as they follow the requirements of the NHC Regulation. It remains to be seen how environmental and ethical claims will be regulated under the upcoming proposal for a sustainability food labelling framework. In general, it is important for FBOs to strike a balance between using labels as a marketing tool to create attractive products and increase their sales, while also providing accurate and clear information to consumers and respecting the regulatory requirements of Union and Member State law.

Chapter 4: The Labelling of Dairy Substitutes

In general, the EU legislature has been revolving around food safety and consumer protection which has been achieved, for the most part.³⁶² The alternative protein sector has evolved fairly recently, hence its incomplete integration into the current regulatory environment, as shown by the analysis presented in the previous chapters. Innovative alternative proteins, like insects, are not widely accepted, while others, like cultured meat, remain in a state of limbo since it is still unclear under which regulatory framework they fall.³⁶³ Last but not least, a common concern surrounding all meat substitutes is their labelling, as shown in Chapter 3. Coincidentally, the dairy-substitute industry has dealt with similar challenges and harsher restrictions concerning their labelling, especially after the CJEU's judgment on Case C-422/16 or the *Tofutown* case. Even though the two sectors cannot be directly compared due to their different and unique characteristics, it could prove valuable to investigate their labelling in parallel and understand how one may impact the other. This Chapter will therefore take a deep dive into the chronicles of Case C-422/16, as well as its consequences on the dairy sector and its potential influence on the alternative protein market.

4.1 The Chronicles of *Tofutown*

TofuTown.com GmbH, hereinafter referred to as TofuTown, is a company marketing plant-based alternatives to dairy products under multiple designations, namely 'veggie cheese', 'tofu butter' and 'cream'.³⁶⁴ During the main proceedings of Case C-422/16, a German association dealing with unfair competition practices, the VSW, brought a case against TofuTown before a German regional court on the grounds that such designations were infringing national competition law, as well as certain provisions of Regulation (EU) No 1308/2013 establishing a common organization of the markets in agricultural product, or the COM Regulation.³⁶⁵ TofuTown's main line of defense was, firstly, that these terms were not used in isolation, but in conjunction with other descriptive terms that revealed the true nature of the products, and that, secondly, consumer perception over plant-based products has significantly changed over the past years.³⁶⁶ Initially, the national court referred to a former judgment of the CJEU where it was ruled that the term 'cheese' was protected under Union law and,

³⁶²Fitness check of General Food Law (n.225)

³⁶³ Question for written answer E-004200-18 (n.139)

³⁶⁴Case C-422/16 *TofuTown* [2017] ECLI:EU:C: 2017:458, para 15

³⁶⁵*Ibid* para 16

³⁶⁶*Ibid* para 17

therefore, it could not be used on products where milk had been substituted with vegetable fat.³⁶⁷ However, the regional court deemed that uncertainty still persisted over the dispute in question.³⁶⁸ As a result, a preliminary question was raised before the CJEU, which in essence asked if the COM Regulation precluded the use of the term 'milk' and other designations reserved for milk products, hereinafter referred to as 'milk terms', for the labelling of plant-based substitutes even if other descriptive or explanatory terms were shown in close proximity to them.³⁶⁹ The court stayed consistent with the requirements of the COM Regulation and established case-law and eventually ruled that plant-based products are prohibited from displaying 'milk terms' on their labels, even if they are accompanied by other clarifying terms indicating the true nature of the products, unless these products are included in the exemptions listed in Commission Decision 2010/791/EU.³⁷⁰

The CJEU based their decision on a literal interpretation of the provisions of the COM Regulation, which include, *inter alia*, the definitions for 'milk' and 'milk products'. According to them, milk refers exclusively to the "*normal mammary secretion*"³⁷¹ of animals and milk products refer to "*products derived exclusively from milk*"³⁷², including, *inter alia*, cream, butter and yogurt.³⁷³ Under this context, the CJEU concluded that plant-based dairy substitutes cannot lawfully carry any of the aforementioned terms since they are not an animal product and do not contain milk by default.³⁷⁴ The CJEU then referred to the exemptions listed in Annex I of Commission Decision 2010/791. The list includes a number of product names that can be used in conjunction with 'milk terms' since, according to the COM Regulation, their true nature can be understood due to traditional usage.³⁷⁵ Certain examples are 'coconut milk' and 'peanut butter' but none of the terms mentioned by the referring court where a part of the list.³⁷⁶ The Court finally highlighted that these designations may differ between

³⁶⁷Ibid para 18

³⁶⁸Ibid

³⁶⁹Ibid para 20

³⁷⁰Ibid para 53; 2010/791/EU: Commission Decision of 20 December 2010 listing the products referred to in the second subparagraph of point III (1) of Annex XII to Council Regulation (EC) No 1234/2007 (recast) (notified under document C (2010) 8434) [2010] OJ L 336/55, Annex I

³⁷¹Regulation (EU) No 1308/2013 (n.293) Annex VII, Part III (1)

³⁷²Ibid Annex VII, Part III (2)

³⁷³Ibid Annex VII, Part III (2) (a)

³⁷⁴Case C-422/16 (n.346) para 32

³⁷⁵Regulation (EU) No 1308/2013 (n.293) Annex VII, Part III (5)

³⁷⁶Commission Decision 2010/791/EU (n.370) Annex I

Member States and it cannot be directly deduced that translations in different languages are eligible for an exemption.³⁷⁷

Ultimately, the decision was based on the fact that the EU has a broad discretion to pursue the objectives of the CAP through powers granted by the TFEU.³⁷⁸ In the present case, these objectives relate to “[improving] *the economic conditions for production and marketing of the products concerned and their quality*, [protecting] *consumers and* [maintaining] *the conditions for allowing competition*”.³⁷⁹ Therefore, the EU has the authority to enforce the existing limitations on the use of ‘milk terms’ since they work for the benefit of both producers and consumers.³⁸⁰ By strictly adhering to the provisions of the COM Regulation healthy competition within the industry can be ensured, protection can be granted to dairy products and consumers can clearly understand their composition and quality. According to the Court, if FBOs arbitrarily deviate from the COM Regulation’s requirements, it cannot be guaranteed that consumer confusion will not occur even if additional explanatory terms are displayed on the label.³⁸¹

4.2 The Impact of *Tofutown* on the Dairy Sector

The Court’s decision on Case C-422/16 put a definitive end on the debate surrounding the labelling of dairy substitutes and set, once and for all, that all milk-related designations defined in the provisions of the COM Regulation are strictly reserved for milk and its derivatives, unless deduced otherwise from the Union list of exemptions. In essence, the decision reinforced the exclusive rights granted to the dairy sector through the EU legislature, under the pretext of consumer protection, economic stability and quality assurance.³⁸² The decision reignited conversations surrounding dairy labelling, with its backwash even reaching the other side of the Atlantic Ocean, with the chairman of the US Dairy Farmers Organization stating at the time that “*In the U.S., we should have a close look at the court ruling and the European approach for*

³⁷⁷ Case C-422/16 (n.346) para 36

³⁷⁸ Ibid para 46

³⁷⁹ Ibid para 47

³⁸⁰ Ibid para 48

³⁸¹ Ibid para 47-48

³⁸² Barbara Bolton, 'Dairy's Monopoly on Words: The Historical Context and Implications of the TofuTown Decision' [2017] 12 Eur Food & Feed L Rev (note) 422, 430; Case C-422/16 (n.346) para 43

protecting dairy terms"³⁸³ and had a significant impact on both the consumers and producers.

First of all, the decision set clear boundaries surrounding the nomenclature of dairy substitutes, since the CJEU clearly defined what is permissible and left no leeway for FBOs to apply the naming requirements set out in the EU legislation. At the same time, the CJEU further clarified that the exemptions list provided in Commission Decision 2010/791 is exhaustive and therefore only the exact terms mentioned in it may be used to designate specific non-dairy products.³⁸⁴ On one hand, this created a precisely defined regulatory environment where legal certainty is increased, FBOs can identify which terms are off limits due to protected and exclusive usage and the chances of infringing EU law are reduced. On the other hand, this decision puts on FBOs additional constraints which force them to come up with obscure product names and elaborate marketing ploys in order to describe the nature of their products, when, in fact, it may have been a lot easier to use colloquially understood terms, even if they were not included in the list of exemptions. Something similar was further explored in a Dutch court case concerning the labelling of dairy alternatives manufactured by the company Alpro.³⁸⁵ Alpro is producing soy products imitating, *inter alia*, yogurt and cooking cream under multiple designations, namely 'yoghurt variation' and 'yogurt cultures/ferments'.³⁸⁶ During the main proceedings of the case, a Dutch Dairy Organization (NZO) brought an action against Alpro claiming that they suffered reputational damages due to Alpro's unlawful use of designations exclusively reserved for milk products.³⁸⁷ In light of the judgement on *Tofutown*, the Dutch court ruled that even though it is prohibited to use reserved terms as product names for dairy substitutes, there are alternative ways that these terms may be used. For example, it was not considered unlawful under EU law to use said designations only in explanatory statements indicating the nature and composition of the product (e.g. '(vegetable) yoghurt variation', 'dairy free variation on milk') or the method of use and purpose of

³⁸³Kinga Adamaszewili, 'Why a soy drink cannot be called milk' (EDA Column, 6 July 2017) <https://eda.euromilk.org/fileadmin/user_upload/Public_Documents/Press_Room_PR_and_EDA_in_the_media_IDM_-_Why_a_soy_drink_cannot_be_called_milk_-_July_2017.pdf> accessed 12 January 2024, 2

³⁸⁴ Case C-422/16 (n.346) para 34

³⁸⁵Sarah Arayess and Fleur Jeukens, 'Alpro's Dairy Alternatives: What Is Allowed and What Is Not in the Light of ECJ's TofuTown?' [2018] 13 Eur Food & Feed L Rev 55, 55; Case 200.165.890/01 [2017] ECLI:NL: GHSHE:2017:5731

³⁸⁶ Case 200.165.890/01 (n.385) para 3.7.1, 3.7.2

³⁸⁷ Ibid para 3.12.2

the product (e.g. 'which can be used in the same way as cooking cream').³⁸⁸ This case indicates that, on one hand, FBOs are struggling to adequately describe the nature of their substitute products and convey to consumers accurate information while also avoiding litigation and infringement of the provisions of the COM Regulation. On the other hand, they have apparently managed to creatively navigate the protectionist EU regulatory environment surrounding dairy products and take advantage of its loopholes.

On the contrary, the *Tofutown* decision seems to be a victory for the dairy sector, with the secretary general of the European Dairy Association even exclaiming at the time that "[the day of the decision] *was a good day for dairy*"³⁸⁹. In general, the dairy industry is a great contributor to the European and global economy. For example, it is the biggest exporter of cheese and skimmed milk powder in the world and the total annual milk production amounts to 155 million tons.³⁹⁰ The value of the industry has been historically recognized by European Institutions which led to the adoption of Council Regulation (EEC) No 1898/87 on the protection of designations used in marketing of milk and milk products, which is now repealed by the COM Regulation. The core objectives of both regulations concerning milk remain the same and refer to protecting the interests of dairy producers, promoting the consumption of dairy products and "*establishing conditions of competition between milk products and competing products*"³⁹¹.³⁹² Therefore, maintaining the status-quo is undoubtedly beneficial for dairy producers.

In regards to consumer protection, the CJEU stated on *Tofutown* that the uncontrolled use of 'milk terms' to designate dairy substitutes "*cannot prevent with certainty any likelihood of confusion in the mind of the consumer*"³⁹³. In essence, the CJEU argued that, since it cannot be guaranteed that all consumers will understand the labels in question, the ban is justified. This argument is almost identical to the one that the CJEU presented back in 1999 on a similar case dealing with the labelling of cheese derivatives where milk had been substituted with vegetable fat.³⁹⁴ Even though the CJEU

³⁸⁸ Ibid para 3.7.1, 3.7.12, 3.7.7

³⁸⁹ Deutsche Welle, 'A good day for dairy' after European court judgment' (Deutsche Welle, 14 June 2017) <<https://www.dw.com/en/a-good-day-for-dairy-after-european-court-judgment/a-39250661>> accessed 12 January 2024

³⁹⁰ EC, 'Milk and dairy products' (European Commission - Agriculture and rural development) <https://agriculture.ec.europa.eu/farming/animal-products/milk-and-dairy-products_en> accessed 12 January 2024

³⁹¹ Council Regulation (EEC) No 1898/87 of 2 July 1987 on the protection of designations used in marketing of milk and milk products [1987] OJ 2 182/36, Preamble

³⁹² Regulation (EU) No 1308/2013 (n.293) rec. 24, rec. 65, rec. 190

³⁹³ Case C-422/16 (n.346) para 48

³⁹⁴ C-101/98 – *UDL* [1998] ECLI:EU:C: 1999:615, para 32-33

remained consistent in their subsequent judgement, this particular argument might have made more sense 25 years ago, when substitute products were not so popular within the EU market and were mainly sought-after by a niche group of consumers.³⁹⁵ Currently, it sounds anachronistic since recent studies have shown that, generally, consumers have a better understanding of substitute products and the use of 'milk terms' in conjunction with other explanatory terms can even be helpful to them in order to differentiate substitutes from their original counterparts.³⁹⁶ At the same time, the decision is somewhat uneven in regards to the type of substitute products that, according to the CJEU, are more likely to mislead consumers. The Court highlighted that the list of exemptions is exhaustive and therefore implied that only the terms included in it may be understood by consumers with certainty. According to this train of thought, names like 'coconut milk', which are included in the list, can be recognized by consumers, but 'oat milk' or 'soy milk', which are not on the list, may lead to consumer confusion.³⁹⁷

4.3 The Impact of *Tofutown* on the Meat Sector

During the main proceedings of Case C-422/16, TofuTown argued that producers of dairy substitutes were being subjected to stricter rules in comparison with producers of meat or fish substitutes, since the latter are not obligated to follow similar labelling restrictions.³⁹⁸ According to the company, this was in breach of the principle of non-discrimination, which requires "*comparable situations not to be treated differently and different situations not to be treated alike unless such treatment is objectively justified*".³⁹⁹ On the matter, the CJEU highlighted that, even though all three sectors are part of the common organization of markets for agricultural products, they are all unique, with specific characteristics and needs, and the legislation has been adopted with these differences in mind. Therefore, it was considered justified to not apply the

³⁹⁵Armand V. Cardello and others, 'Plant-based alternatives vs dairy milk: Consumer segments and their sensory, emotional, cognitive and situational use responses to tasted products' [2022] 100 Food Quality and Preference 104599, 2; Oliver Franklin-Wallis, 'White gold: the unstoppable rise of alternative milks' (The Guardian, 29 January 2019) <<https://www.theguardian.com/news/2019/jan/29/white-gold-the-unstoppable-rise-of-alternative-milks-oat-soy-rice-coconut-plant>> accessed 15 January 2024

³⁹⁶A. Leialohilani and A. deBoer, 'EU food legislation impacts innovation in the area of plant-based dairy alternatives' [2020] 104 Trends in food science & technology 262, 264

³⁹⁷ Commission Decision 2010/791/EU (n.370) Annex I

³⁹⁸ Case C-422/16 (n.346) para 50

³⁹⁹ Ibid para 49

same measures to regulate these sectors and the claim was deemed as unsubstantiated by the Court.⁴⁰⁰

In essence, the CJEU distanced themselves from the discussion surrounding the labelling of meat substitutes and drew a dividing line between the two sectors. Just because a restriction exists on dairy alternatives, it does not mean that similar restrictions would be directly applicable to meat substitutes. Therefore, it seems as if the decision on *TofuTown* did not have a direct impact on meat imitations and, at first glance, the sector was left unscathed. However, in the aftermath of the decision, proponents of the restrictions apparently used the *Tofutown* case as a starting point to leverage their way into the enforcement of a similar ban on the meat substitute industry. Initially, a snowball effect took place, where multiple conventional meat associations started lobbying in favor of a similar ban on meat designations across the EU, while vegan associations started implying that such decisions are driven by economic motives and are irrelevant to consumer protection.⁴⁰¹ At the same time, the decision sparked conversations among Member States and EU institutions. For instance, France submitted in 2018 a proposal for the adoption of a national law which would ban French producers (see Chapter 5) from using meat-related terms on plant-based substitutes.⁴⁰² Later on, in 2020, certain members of the Parliament drafted a proposal for a ban on meat related terms for labelling substitutes under the reformed CAP (see Chapter 3), while others started referring questions to the EC concerning their intention, or lack thereof, to ban the use of terms traditionally associated with meat on their vegan counterparts.⁴⁰³

Last but not least, national court cases started being adjudicated by taking into consideration the reasoning and final decision of the CJEU on *Tofutown*, with a prominent example being the 2023 judgement of the Finnish Supreme Administrative Court, hereinafter referred to as the KHO, concerning the labelling of plant-based meat

⁴⁰⁰ Ibid para 51

⁴⁰¹ Kate Askew, 'Bring this to Brussels': Meat lobbyists urge EU to follow French ban of 'meaty' terms on plant-based products' (Food Navigator Europe, 4 July 2022) <<https://www.foodnavigator.com/Article/2022/07/04/meat-lobbyists-urge-eu-to-follow-french-ban-of-meaty-terms-on-plant-based-products>> accessed 12 January 2024; Neal Wallace, 'Meat and dairy sectors fight back' (Farmers Weekly, 21 June 2017) <<https://www.farmersweekly.co.nz/news/meat-and-dairy-sectors-fight-back/>> accessed 12 January 2024

⁴⁰² Tofu Steaks? Developments on the Naming and Marketing of Plant-based Foods in the Aftermath of the TofuTown Judgement (n.305) 575

⁴⁰³ Question for written answer E-002681/2022 to the Commission Use of designations intended for meat producers in respect of plant-based vegetarian protein products by Krzysztof Jurgiel (20 July 2022)

alternatives.⁴⁰⁴ Prior to the main proceedings of the case, the food company Pouttu Ltd was producing meat substitutes under multiple designations, namely 'Muu Kasvilihapulla' and 'Muu Burgerpihvi', which can be roughly translated as 'alternative vegetable meatballs' and 'alternative burger patties', respectively.⁴⁰⁵ For the sake of clarity, it is important to highlight that, currently, products branded under the name 'Muu' are marketed by a different company named MeEat Food Tech Ltd.⁴⁰⁶ Since it is not clear when the two companies separated and this is not further clarified in the judgment of the KHO, from this point onward, the producing company of the 'Muu' product range which participated in the legal proceedings will be referred to as 'the Company'. In 2019, the director of the Central Ostrobothnia Environmental Health Service ordered the Company to, *inter alia*, cease using the term 'kasviliha' [vegetable meat] on their products and change the branding of their plant-based meatballs and burger patties, so as to not make any references to meat and not mislead the consumers in regards to the true nature of their products.⁴⁰⁷ After a series of unsuccessful appeals, the case was eventually brought before the KHO and the final ruling was published in February 2023.⁴⁰⁸ The KHO initially made reference to the *Teekanne* case and the average consumer who is "*usually educated and reasonably observant and careful*"⁴⁰⁹ and shall be taken into account to assess whether the aforementioned products were misleading or not.⁴¹⁰ Secondly, the KHO highlighted that even though consumer perception over meat substitutes has massively changed over the years, the term 'kasviliha' cannot be considered as established in the Finnish language in such a way that the average consumer would understand, and therefore it was found to be misleading.⁴¹¹ The KHO continued by stating that the word 'lihapulla' [meatball] is associated in the minds of Finnish consumers with containing meat and that the presence of other descriptive information on the packaging stating that the product is plant-based, is not enough for the average consumer to understand the true nature of the product. Therefore, the packaging of 'Muu Kasvilihapulla' was eventually deemed as misleading.⁴¹² Finally, the KHO highlighted that the term 'burgerpihvi' [burger patty]

⁴⁰⁴ KHO: 2023:16 [2023] ECLI:FI:KHO:2023:16

⁴⁰⁵ Yle news, 'Rebrand your balls, court orders company' (Yle, 13 February 2023) < <https://yle.fi/a/74-20017662> > accessed 16 February 2024

⁴⁰⁶ Ibid

⁴⁰⁷ KHO: 2023:16 (n.404) para 1(1)-1(3)

⁴⁰⁸ Ibid para 5-7

⁴⁰⁹ Ibid para 31

⁴¹⁰ Ibid

⁴¹¹ Ibid para 39

⁴¹² Ibid para 41

is not legally reserved under national or EU legislation and therefore its meaning is not necessarily tied with traditional meat. In conjunction with the other information provided on the label, the KHO ruled that the average consumer was capable of understanding that the product 'Muu Burgerpihvi' did not contain any meat and therefore it was not considered misleading, contrary to the original ruling of the local court.⁴¹³

The influence of the *Tofutown* case on the decision of the KHO is noticeable. The Finnish court followed an almost identical train of thought according to which terms that are either legally protected under national or Union law, such as 'meat', or traditionally associated with conventional meat, such as 'meatballs', shall not be used on the packaging of substitute products since they are tied in the collective mind of consumers with meat and therefore there is a high chance that they will lead to confusion when used for substitute products. At the same time, the KHO seemed to also believe that, in the aforementioned case, the use of explanatory or descriptive terms showcasing the true nature of the product are not helpful enough for consumers to understand the contents of the product. Interestingly enough, the KHO supported the idea that terms that are not legally defined, such as 'burger', are not exclusively linked with meat products and, under the right circumstances, shall not be considered misleading for consumers. As a result, according to the author, the KHO did not set a legal precedent to justify the potential ban of certain 'meat terms', mainly those not referring to specific meats, from vegan and vegetarian labels in the future.

4.4 Preliminary Conclusions

The CJEU, with their judgement on *Tofutown*, followed a rather conservative approach and ruled in favor of limiting the use of 'milk terms'. Even though, it is reasonable that the Court chose to interpret the relevant legal provisions in a literal manner, it could also be argued that their reasoning was short-sided and failed to take into consideration that, indeed, perception over substitute products has changed over the past years and an increasing number of consumers are incorporating them into their diets. It is undeniably important to safeguard traditional products and their characteristics, but this should not happen to the detriment of innovation and progress. At the same time, this decision served as a way to reinforce the dairy monopoly over 'milk terms', thus significantly benefiting the conventional farming industry. By

⁴¹³ Ibid para 42-43

narrowing down the available nomenclature for substitutes, producers might feel limited and will have to go above and beyond in order to name their products, avoid litigation and ensure consumer protection. It is also questionable whether the decision has positively impacted consumers since it could be argued that, in the aftermath of the decision, they stumble upon intricate products labels that do not make any reference to well-known concepts or products. This can be more baffling in regards to the characteristics of a product, as well as its expected use. For instance, it might be easier for consumers to understand how to use a product named 'dairy-free oat milk', since it makes reference to milk and therefore it is clear that it is a substitute product intended to be consumed in a similar manner as milk, while the name 'dairy-free oat beverage' might not induce the same result as easily, thus confusing purchasers in regards to its methods of use and consumption. On the other hand, the decision, undoubtedly led to more legal certainty since it became clear that certain names were off-limits and put an end to the debate over what is permissible and what is not.

Last but not least, the *Tofutown* decision should not be examined in isolation and its impact on other sectors, namely the alternative protein market, should also be evaluated. The world is intertwined and seemingly unrelated events might significantly impact one another. Even though the CJEU did not set any similar restrictions on meat substitutes on *Tofutown* and concluded that each sector shall be treated accordingly, a new political and regulatory movement sprang which called for similar labelling restrictions and even led certain Member States to start drafting national laws imposing bans. For the moment, the EC has repeatedly refused to adopt new labelling specifications for meat substitutes and therefore it may be up to each Member State to decide which route they will follow.

Chapter 5: Case Studies

5.1. France

5.1.1 The Current State of Affairs

After the CJEU's decision on *Tofutown*, conversations were initiated among the French Parliament concerning the nomenclature of meat substitutes, which eventually led in 2018 to the submission of a proposal for an amendment to the French Consumer Code, that would ban the use of 'meat terms' on plant-based sources of protein.⁴¹⁴ The proposed amendment was reminiscent of the *Tofutown* judgement and it was highlighted in its presentation summary that it followed the same logic.⁴¹⁵ Both the Senate and the National Assembly, the two chambers of the French Parliament responsible for adopting national laws, were in favor of the proposed ban but due to minor disagreements between them, the amendment was finally adopted in June 2020.⁴¹⁶ Consequently, Art. 5 of Law n° 2020-699 on the transparency of information on agricultural products and foodstuffs, required that the French Consumer Code would be supplemented by an additional article that would prohibit plant-based food manufacturers from using 'meat terms' for marketing purposes and that all violations of its requirements would lead to sanctions. Explicit details on the enforcement of the measure would be described in a future Decree.⁴¹⁷

Decree N° 2022-947, hereinafter referred to as the Decree, was published in June 2022 and set out specific rules on the use of 'meat terms' on products containing plant-based proteins.⁴¹⁸ The Decree specified that its provisions would only be applicable to French producers and that meat-substitutes imported from the EU, Turkey or any other

⁴¹⁴I. Carreño, 'France Bans "Meaty" Terms for Plant-Based Products: Will the European Union Follow?' (2022) 13(4) European Journal of Risk Regulation 665, 665-666

⁴¹⁵Assemblée Nationale, 'Amendement n°CE2044' (Assemblée Nationale, 19 April 2018) <<https://www.assemblee-nationale.fr/dyn/15/amendements/0627/CION-ECO/CE2044>> accessed 2 March 2024

⁴¹⁶Tofu Steaks? Developments on the Naming and Marketing of Plant-based Foods in the Aftermath of the TofuTown Judgement (n.305) 580; France Bans "Meaty" Terms for Plant-Based Products (n.414) p 666; EU Publications Office, 'About the national database - Légifrance' (N-Lex) <<https://n-lex.europa.eu/n-lex/info/info-fr/index>> accessed 2 March 2024

⁴¹⁷Loi 2020-699 du 10 Juin 2020 relative à la transparence de l'information sur les produits agricoles et alimentaires [Law 2020-699 of 10 June 2020 relating to the transparency of information on agricultural and food products], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O] [Official Gazette of France], June 11, 2020, p. 1, art 5

⁴¹⁸Décret 2022-947 du 29 juin 2022 relatif à l'utilisation de certaines dénominations employées pour désigner des denrées comportant des protéines végétales [Decree 2022-947 of June 29, 2022 relating to the use of certain names used to designate foodstuffs containing vegetable proteins], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O] [Official Gazette of France], June 30, 2022, p. 1

member of the European Economic Area would be exempted from the ban.⁴¹⁹ According to Art. 2, the marketing of plant-based products under any term that either referred to, *inter alia*, animal species, morphology and anatomy, cold cuts and fisheries or that was traditionally associated with the meat industry, would be prohibited.⁴²⁰ However, the Decree specified in Art. 3 that there were certain exemptions. For example, it would be permissible to use the aforementioned 'meat terms' when the final product contained plant-based proteins in a proportion not exceeding the limits set out in its Annex or to designate ingredients that were used as flavoring agents.⁴²¹ Furthermore, 'meat terms' were allowed to be used as a descriptive name on products consisting of a combination of meat and plant-based proteins, with the latter not aiming at substituting the former.⁴²² The only word that seemed to have escaped the stringent requirements of the Decree, since it was not included in its Annex, was 'burger' and therefore, it is assumed that its use on plant-based meat substitutes would be allowed.⁴²³ An infringement of the requirements of the Decree, could lead to financial penalties up to 7.500 EUR.⁴²⁴

In light of the adopted measures, a number of organizations, such as the EVU and the Vegetarian Association of France, brought several legal actions before the Conseil d'État (CE), or the French Supreme Administrative Court, questioning the legality of the proposed measures and requesting the annulment of the Decree.⁴²⁵ The CE tackled and dismissed a number of claims made by the appellants concerning, *inter alia*, the free movement of goods within the internal market and the alleged violations of French law on unfair commercial practices.⁴²⁶ However, the CE had difficulty in assessing how the national measures adopted by the French government fit in with the provisions of the FIC Regulation on the labelling of substitute products.⁴²⁷ For instance, the CE questioned if the use of 'meat terms' on products containing no meat was by nature misleading, and thus already prohibited, as well as harmonized, since the FIC Regulation states that food information shall not be misleading as to "*the nature, identity and*

⁴¹⁹ Decree 2022-947 (n.418) art 1, 5

⁴²⁰ Ibid art 2

⁴²¹ Ibid art 3

⁴²² Ibid art 4

⁴²³ France Bans "Meaty" Terms on Plant-Based Products (n.414) 666

⁴²⁴ Decree 2022-947 (n.418) art 7

⁴²⁵ Conseil d'État [CE] [Supreme Administrative Court], 9ème et 10ème ch. réuns., Jul. 12, 2023, No 465835

⁴²⁶ Ibid para 8-12

⁴²⁷ Ibid para 13-21

characteristics of the product^{428, 429} Furthermore, according to Art. 17(1) of the FIC Regulation, foods shall bear a legal, customary or descriptive name. In the present case, it was stated that plant-based foods do not have a legal name and shall thus be marketed under a customary or descriptive name. At the same time, Part A (4) of Annex VI of the FIC Regulation provides more explicit details in regards to the labelling of substitute products. As a result, the CE questioned if the aforementioned could be interpreted as meaning that the naming of plant-based substitute products was harmonized under Union law and, as a result, the French government did not have the authority to adopt national measures.⁴³⁰ As a result, they halted the legal proceedings and referred to the CJEU for a preliminary ruling in July 2023. In essence, the CE asked two questions. First of all, they asked if the labelling of plant-based meat substitutes was harmonized under Union law, thus precluding Member States from adopting national additional measures, as per Art. 38 of the FIC Regulation. In light of a negative response to the aforementioned question, the EC also asked if the nature of the measures and sanctions presented in the Decree was proportionate to its main objective, meaning consumer protection.⁴³¹ Immediately after the referral to the CJEU, the CE requested the suspension of the enforcement of the Decree until a judgement was provided.⁴³² As of March 2024, the CJEU has not adjudicated on the case yet and therefore it remains to be seen how their decision will impact the decisions and actions of the French government.⁴³³

In the meantime, the French Parliament adopted in February 2024 a renewed version of the Decree which repealed the original one and implemented certain changes, with the main one found in the Annex.⁴³⁴ According to the new Decree, or Decree No. 2024-144, the denominations described in Annex I, such as 'steak' and 'ham', will now be off limits under all circumstances, while the ones included in Annex II, such as

⁴²⁸ Regulation (EU) 1169/2011 (n.264) art 7(1)(a)

⁴²⁹ Conseil d'État No 465835 (n.425) para 17

⁴³⁰ Ibid para 18

⁴³¹ Ibid art 1, 2(1)-2(4)

⁴³² Conseil d'État - juge des référés, 'Conseil d'État, Juge des référés, 27/07/2022, 465844, Inédit au recueil Lebon' (Legifrance, 27 July 2022) <https://www.legifrance.gouv.fr/ceta/id/CETATEXT000046112967?init=true&page=1&query=n%C2%B0+465844&searchField=ALL&tab_selection=all> accessed 2 March 2024

⁴³³ Case C-438/23, *Protéines France and others* [2023] C/2023/744

⁴³⁴ Décret 2024-144 du 26 février 2024 relatif à l'utilisation de certaines dénominations employées pour désigner des denrées comportant des protéines végétales [Decree 2024-144 of February 26, 2024 relating to the use of certain names used to designate foodstuffs containing vegetable proteins], JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE [J.O.] [Official Gazette of France], February 27, 2024, p. 37, art 9

'pastrami' or 'mortadella', may still be used in accordance with the specifications set in the original Decree.⁴³⁵ Decree No. 2024-144 specifies that it will come into force three months after its publication and that FBOs will have one year to implement its requirements.⁴³⁶ Therefore, it may be expected that it will be enforced sometime in mid-2024.

5.1.2 The TRIS Notification Procedure

In general, if a Member State of the EU wishes to adopt national technical regulations on a specific topic where harmonization is absent, then they are allowed to do so through the procedures laid down in Directive (EU) 2015/1535.⁴³⁷ According to it, a technical regulation may provide, *inter alia*, technical rules on services or product specifications concerning their quality, safety or performance.⁴³⁸ The notification procedure and the eventual adoption of the national regulation shall be executed in a transparent manner to ensure the effective functioning of the internal market and the free movement of goods.⁴³⁹ Firstly, Member States shall notify the EC about their intent to adopt a draft technical regulation and provide sufficient explanation concerning the necessity for its adoption.⁴⁴⁰ Immediately after the notification, a 3-month standstill period commences where the Member State is unable to adopt the regulation and other EU members, as well as the EC, are allowed to react to the proposed draft.⁴⁴¹ They may provide comments, which shall be taken into consideration from the Member State in question, or publish a detailed opinion in cases where the proposed measures may impose barriers to the free movement of goods.⁴⁴² If no reaction is invoked or mere comments are being issued, then the Member State may adopt the technical regulation after the standstill period is over.⁴⁴³ If a detailed opinion is published, then the standstill period is being extended and the Member State that has notified the draft shall provide

⁴³⁵ Ibid Annex I-II

⁴³⁶ Ibid art 8

⁴³⁷ Directive (EU) 2015/1535 of the European Parliament and the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification) [2015] OJ 2 241/1, rec 8

⁴³⁸ Ibid art 1(c), 1(f)

⁴³⁹ Ibid rec 2-3

⁴⁴⁰ Ibid art 5(1)

⁴⁴¹ European Commission, 'The notification procedure in brief' (*TRIS - European Commission*) <<https://technical-regulation-information-system.ec.europa.eu/en/about-the-20151535/the-notification-procedure-in-brief1>> accessed 26 February 2024; Directive (EU) 2015/1535 (n.437) art 6(1)

⁴⁴² 'The notification procedure in brief' (n.441)

⁴⁴³ Ibid

relevant clarifications and explain their future actions.⁴⁴⁴ Under certain circumstances, the EC has the right to block the adoption of a technical regulation for a period of 12 to 18 months.⁴⁴⁵ If the Member State makes significant changes to a draft, then they are required to reinitiate the notification procedure.⁴⁴⁶

In regards to the French Decree, France was obligated to follow the TRIS Notification Procedure since the limitations set on the marketing of plant-based products constitute a set of requirements "*applicable to the product as regards the name under which [it may be] sold*"⁴⁴⁷ and therefore fall within the scope of Directive (EU) 2015/1535. As a result, France set in motion the TRIS notification mechanism prior to the adoption of Decree No 2022-947 in October 2021 and received comments from the EC, Portugal, Sweden and the Czech Republic.⁴⁴⁸ At the same time, stakeholders also provided their own remarks. For instance, the European Plant-based Foods Association stated that such a ban would not benefit consumers and would potentially cause more confusion and uncertainty in regards to the expected characteristics of plant-based products.⁴⁴⁹ On the contrary, the Austrian Association of Craft Butchers expressed their support to the French Decree and claimed that it implemented "*a long-standing demand of the meat industry*"⁴⁵⁰. Meanwhile, France decided to re-initiate the TRIS procedure in August 2023 after implementing certain changes to the 2022 Decree (see subchapter 5.1.1) and received comments by the EC, Denmark, Hungary and Sweden, as well as a request for supplementary information submitted by Spain.⁴⁵¹ Similarly, the new Decree gathered mixed comments from meat and plant-based associations, with the first applauding the ban and the latter condemning its requirements.⁴⁵² The standstill period ended in November 2023, which means that from that point onward, the French government was allowed to implement the Decree, which led to its eventual adoption in February 2024.

⁴⁴⁴ Directive (EU) 2015/1535 (n.437) art 6(2)

⁴⁴⁵ Ibid art 6(4)-(5)

⁴⁴⁶ Ibid art 5(1)

⁴⁴⁷ Ibid art 1(1)(c)

⁴⁴⁸ France Bans "Meaty" Terms on Plant-Based Products (n.414) 666

⁴⁴⁹ ENSA statement – French Decree on the use of certain denominations for foodstuffs containing vegetable proteins from ENSA (20 November 2023), 2

⁴⁵⁰ Statement from the Austrian Association of Craft Butchers on the Usage of Designations of Meat Products for Plant-based Products (30 December 2021), 1

⁴⁵¹ French Government, 'Notification Detail - Decree on the use of certain designations used to describe foods containing vegetable proteins' (*TRIS - European Commission*, 23 August 2023) <<https://technical-regulation-information-system.ec.europa.eu/en/notification/24524>>

accessed 2 March 2024

⁴⁵² Ibid

5.1.3 French Case-law

In order to justify the adoption of the Decree, the French government invoked the need to "*interdire certaines pratiques commerciales trompeuses pour le consommateur*"⁴⁵³ [prohibit certain misleading commercial practices for consumers], which would allegedly happen after granting the exclusive rights of 'meat terms' to the meat sector.

Interestingly enough, this notion was not accepted by national courts in the legal proceedings between the French association of livestock and meat, or INTERBEV, and Nutrition & Santé Group, a French company producing plant-based products.⁴⁵⁴ In February 2017, before the main proceedings of the case, INTERBEV sent a written letter to Nutrition & Santé requesting the immediate desist of all actions related to the use of depictions and terms referring to meat, namely 'steak' and 'sans viande' [meat-free], on their product labels.⁴⁵⁵ After the unsuccessful attempt, INTERBEV sued Nutrition & Santé in April 2018 on the grounds of unfair competition and misleading commercial practices.⁴⁵⁶ In November 2019, the High Court of Rennes, France ruled in favor of Nutrition & Santé and rejected all of INTERBEV's requests, thus leading INTERBEV to file a number of consecutive appeals.⁴⁵⁷ Finally, in April 2022, the Court of Appeals of Rennes upheld the original decision of the High Court and dismissed all claims made by INTERBEV.⁴⁵⁸ To justify their decision, the Appealing Court stated that the depictions used by Nutrition & Santé referring to, *inter alia*, names, shapes, textures and preparation methods, are not exclusively linked with meat products and are also used to describe other foodstuffs, such as fish, fruit or vegetables. Furthermore, the Appealing Court highlighted that those consumers who are purchasing plant-based products manufactured by Nutrition & Santé are actively seeking them, are aware of their nature and composition and are not being misled into thinking that they are identical to meat.⁴⁵⁹ Finally, the Appealing Court stated that since all depictions used by the company are accompanied by explanatory indications showcasing the true composition of the product, consumer deception and confusion cannot be established or supported.⁴⁶⁰ Therefore, they stated that the prohibition to use such designations on

⁴⁵³ Amendement n°CE2044 (n.415)

⁴⁵⁴ Cour d' Appel (CA) [regional court of appeal] Rennes, civ. 1re, Apr. 1 2022, 19/08378

⁴⁵⁵ Ibid para 4

⁴⁵⁶ Ibid para 5-6

⁴⁵⁷ Ibid para 7-8

⁴⁵⁸ Ibid para 72

⁴⁵⁹ Ibid para 35, 36, 38

⁴⁶⁰ Ibid para 37, 39, 55

plant-based products cannot be justified on reasonable grounds.⁴⁶¹ In light of the decision, INTERBEV made another appeal and the case eventually reached the French Supreme Court which ruled in December 2023 that there was no justifiable reason that would lead to the annulment of the decision of the Court of Appeals of Rennes and therefore rejected the appeal.⁴⁶²

In the present case, the Courts of Rennes took in their respective adjudications a route which diverged significantly from the rhetoric of the French government on the labelling of meat substitutes and its relevance for consumer protection. According to the Courts, consumers are aware of their purchasing choices and are not being misled into buying products that do not match up with their expectations. At the same time, the Courts highlighted that the use of meat-related terminology on substitute products cannot be considered as misleading in cases where the label contains enough descriptive and clarifying information that clearly describes the contents of the product.⁴⁶³

5.1.4 The Impact of the Decree

Decree No. 2024-144 and its predecessor was highly controversial and caused great political turmoil. On one hand, supporters of the meat industry applauded the decision of the French government and welcomed the new measures with open arms, with their representatives stating that the Decree "*gives a good example of the way to go to respect and recognize animal products*"⁴⁶⁴. On the other hand, vegetarian and vegan associations, were rather disappointed by the decision and viewed the measures as "*counterproductive and based on misunderstandings*"⁴⁶⁵.

At the heart of everyone's narrative lied consumer protection which was interpreted differently depending on which side of the pendulum one might find themselves in. For instance, the French government, as well as the meat industry, considered that the use of terms like 'steak', 'nugget' or 'sausage' on plant-based substitutes constitutes a misleading practice that prevents consumers from fully

⁴⁶¹ Ibid para 32(1)-(4), 33(1)

⁴⁶² Cour de Cassation (Cass) [Supreme Court for Judicial Matters], Civ. 1re, Dec. 20, 2023, 22-17.285, para 4(1)-(2), 6

⁴⁶³ Cour d' Appel (CA) 19/08378 (n.454) para 38

⁴⁶⁴ UECBV position on the French Tris Notification 2023/0510/FR of its 'Decree on the use of certain designations used to describe foods containing vegetable proteins' (23 November 2023)

⁴⁶⁵ Vegonomist, 'Setback for French Government as Court Supports Plant-Based Meat and Rejects Label Confusion' (Vegonomist, 16 January 2024) <<https://vegconomist.com/politics-law/setback-french-government-court-supports-plant-based-meat-rejects-labels-confusion/>> accessed 2 March 2024

understanding the composition and nutritional value of substitute products.⁴⁶⁶ Consumer protection would, therefore, be ensured through these limiting measures. On the other hand, alternative protein advocates claimed that this terminology has been commonly used for multiple years on plant-based sources of protein, which has helped producers increase the marketability of their products, while also helping consumers make proper purchasing choices that match their expectations.⁴⁶⁷ According to them, consumer protection would, therefore, come from transparency and information that consumers already know how to evaluate and use.⁴⁶⁸

As a matter of fact, there currently is not enough scientific evidence showcasing that consumers are actually being confused when product labels display 'meat terms', with only a very small number of them admitting that they have unintentionally bought a plant-based product thinking that it contained meat.⁴⁶⁹ This point was not only raised by opponents of the Decree but also by French courts, as described in the legal dispute between INTERBEV and Nutrition & Santé Group (see subchapter 5.1.3).⁴⁷⁰ The aforementioned, paired with the fact that France is currently the largest beef producer in the EU, has led skeptics to question the intent of the French government and proclaim that the Decree constitutes a "*protectionist measure benefiting the meat sector*".⁴⁷¹

Another concern raised was how the Decree will impact the environmental and dietary targets set by EU's incentives and policies.⁴⁷² For instance, the F2F Strategy emphasizes the need to reduce meat consumption and opt for alternative sources of protein to create a more balanced diet.⁴⁷³ At the same time, it also stresses the need to promote innovation in the field of alternative proteins so that new products with a lower environmental impact and a favorable nutritional profile emerge in the internal market.⁴⁷⁴ However, by suppressing the marketing of meat substitutes and refusing

⁴⁶⁶ Amendement n°CE2044 (n.415); National Association of Meat Industries from Spain (ANICE) position on the draft French Decree on the use of certain names used to describe foods containing vegetable proteins (21 November 2023), 1

⁴⁶⁷ European Vegetarian Union Response to TRIS 2023/0510/FR: French draft "Decree on the use of certain designations used to describe foods containing vegetable proteins" (19 October 2023), 2

⁴⁶⁸ Ibid 5

⁴⁶⁹ 'France Bans "Meaty" Terms for Plant-Based Products (n.414) 668

⁴⁷⁰ European Vegetarian Union Response to TRIS 2023/0510/FR (n.468) 2-5

⁴⁷¹ France Bans "Meaty" Terms for Plant-Based Products (n.414) 668

⁴⁷² Letter from a number of signatory organizations to the Council of the EU and the European Commission on the French Decree on the use of certain denominations to describe food containing vegetable protein (3 November 2021), 4

⁴⁷³ A Farm-to-Fork Strategy (n.10) 13

⁴⁷⁴ Ibid 15

them access to well-established product names, it has been supported that the French government will hinder innovation and deter food companies from investing in alternative substitute products and operating in French territory.⁴⁷⁵ At the same time, the recently adopted European Climate Law aims at, *inter alia*, reducing GHG emissions by at least 55% by 2030 and since conventional farming is one of the largest contributors to the climate crisis, opponents of the measure supported that it would be beneficial to facilitate the transition to more sustainable practices instead of giving more power to the status-quo.⁴⁷⁶

Last but not least, it was supported that the Decree would hamper the free movement of goods and impose unnecessary barriers to trade.⁴⁷⁷ In general, Art. 34 & 35 of the TFEU state that "*Quantitative restrictions on imports/exports, and all measures having equivalent effect, shall be prohibited between Member States*"⁴⁷⁸. In order to avoid breaching this clause, the French government clarified that only French producers would be affected and that products originating from third countries would not be subject to the requirements of the Decree.⁴⁷⁹ On the matter the Conseil d'Etat started by stating that according to Art. 1 of the Decree, its provisions are only applicable to foods manufactured within "*national territory*". Therefore, the CE deduced that it only concerns French producers and it may not be presumed that it has been created in an effort to restrict imports either from the EU or from third countries. Furthermore, the CE supported that from the available information, it cannot be established that the Decree aims at restricting exports of French products; thus, neither creating an uneven marketing situation between local and international trade, nor providing an unfair advantage to French producers.⁴⁸⁰ As a result, they concluded that the Decree does not constitute a measure having an equivalent effect to quantitative restrictions on imports or exports and, therefore, it is not in violation of the requirements of the TFEU.⁴⁸¹ Similarly, no concerns were raised on the subject by any of the Member States that provided commentary during the TRIS Notification

⁴⁷⁵ Letter to the Council of the EU and the European Commission on the French Decree (n.473) 4

⁴⁷⁶EC, 'European Climate Law' (European Commission - Energy, Climate change, Environment.) <https://climate.ec.europa.eu/eu-action/european-climate-law_en > accessed 2 March 2024; ENSA Statement (n.449) 4

⁴⁷⁷ ENSA Statement (n.449) 4; Letter to the Council of the EU and the European Commission on the French Decree (n.473) 2

⁴⁷⁸ Treaty on the functioning of the European Union (n.17) art 34, 35

⁴⁷⁹ Décret 2024-144 (n.434) art 5

⁴⁸⁰ Conseil d'État No 465835 (n.425) para 11

⁴⁸¹ Ibid

procedure.⁴⁸² In theory, it is true that the phrasing of the Decree does not seem to directly create barriers to trade. However, opponents of the measures seem to believe that, in reality, it will have an indirect negative impact on both imports and exports for a number of reasons. First of all, it was supported that the requirements of the Decree would force French FBOs to change their labels to adhere to the measures, thus increasing manufacturing costs. This would be especially disadvantageous for SMEs that might not have the financial capacity to adapt to the new requirements.⁴⁸³ Furthermore, imported products would have to display the country of origin and create different labels depending on the point of sale, in order to prove that they can be exempted from the provisions of the Decree and avoid financial sanctions.⁴⁸⁴ Once again, this increases costs of production and may pose as a deterring factor for FBOs, who might choose to stop marketing their products in French territory due to the persecutory nature of the Decree.⁴⁸⁵ This may create an overcomplicated situation where the marketing of plant-based substitute products becomes more difficult or scarce overtime, thus only benefiting the conventional meat industry. Last but not least, the Decree might cause disruptions to the harmonization of the internal market. The conception and adoption of multiple national laws governing the labelling of alternative proteins, leads to the continuous fragmentation of the internal market and has the potential to cause confusion to both producers and consumers.⁴⁸⁶ On one hand, FBOs will have to abide by different requirements depending on the country they are operating, without taking advantage of their right to mutual recognition, and consumers might feel unable to properly identify the nature of substitute foods depending on the available information and imposed limitations.⁴⁸⁷

At the moment, it is unknown how the enforcement of the Decree will play out and how it will affect both imports and exports of foods containing vegetable proteins,

⁴⁸² EC, 'Notification Detail - Decree on the use of certain designations used to describe foods containing vegetable proteins - Disclosed messages' (*TRIS - European Commission*, 23 August 2023) <<https://technical-regulation-information-system.ec.europa.eu/en/notification/24524>> accessed 2 March 2024

⁴⁸³ ENSA Statement (n.449) 2-3; Letter to the Council of the EU and the European Commission on the French Decree (n.473) 2; Contribution from the Jeremy Coller Foundation on the Decree on the use of certain designations used to describe foods containing vegetable proteins (31 October 2023), 2

⁴⁸⁴ Letter to the Council of the EU and the European Commission on the French Decree (n.473) 2

⁴⁸⁵ Contribution from the Jeremy Coller Foundation (n.485) 3

⁴⁸⁶ Erik Dahlberg and others, 'Legal obstacles in Member States to Single Market rules (Study Requested by the IMCO Committee No PE 658.189, Policy Department for Economic, Scientific and Quality of Life Policies, November 2020) 39

⁴⁸⁷ Ibid 31

especially with the upcoming decision of the CJEU on the matter. However, the EC has raised concerns on the negative impact that such national measures have on the single market and the food supply chains.⁴⁸⁸ An increasing trend has been observed within the Union with multiple countries adopting measures on domestic labelling requirements and the EC has stressed the need to make these requirements "*motivated and proportional*"⁴⁸⁹.

5.1.5 Preliminary Conclusions

France has recently adopted a new Decree which aims at restricting the available terminology for the marketing of plant-based meat substitutes. Even though its current form is strictly targeting vegetable proteins, it is currently unknown how it may impact other alternative proteins, such as cultivated meat. The Decree itself caused uproar within the community with proponents of the ban applauding the decision to protect the meat industry and grant them exclusive rights to 'meat terms' and opponents condemning the new requirements and raising concerns related to the Decree's political, environmental, economic and societal impact. At the moment, both sides can only speculate and the actual impact of the ban remains to be seen. At the same time, the CJEU's stance on the topic is expected to provide more clarity and give guidance on the next steps. It is unknown if the CJEU will follow a similar route as they did on *Tofutown*, even though they stated in that judgement that the dairy and meat sectors should not be treated equally since they are defined by different needs and characteristics. Besides the EC has clarified that they will not, for now at least, further regulate the labelling of meat substitutes.

5.2. Italy

5.2.1 The Italian Law

In April 2023, the Minister of Agriculture, Food Sovereignty and Forestry and the Minister of Health, presented before the '*Consiglio dei Ministri*' [Council of Ministers] a proposal for a national law that targeted two distinct topics; the manufacturing and marketing of lab-grown meat and the labelling of plant-based meat substitutes.⁴⁹⁰

⁴⁸⁸ Ibid 39

⁴⁸⁹ Ibid 40

⁴⁹⁰ Legge 1 Dicembre 2023, n. 172, G.U. Dec. 1, 2023, n.281; 'LEGGE 1 dicembre 2023, n 172 - LAVORI PREPARATORI ' (Gazzetta Ufficiale della Repubblica Italiana) < <https://www.gazzettaufficiale.it/do/atto/vediLavoriPreparatori?atto.dataPubblicazioneGazzetta=2023-12-01&atto.codiceRedazionale=23G00188> > accessed 10 March 2024.

According to the Minister, the law was not of a persecutory nature and only had the intent to protect the Italian community, culture and tradition.⁴⁹¹ In order to be adopted and enforced, the proposal had to go through the scrutiny of the Italian Parliament, which consists of the '*Senato della Repubblica*' [Senate] and the '*Camera dei Deputati*' [Chamber of Deputies].⁴⁹² In July 2023, the bill was approved by the Senate and in November 2023, it was accepted by the Chamber of Deputies.⁴⁹³ In the final step of the Italian law-making process, the bill had to be promulgated by the '*Presidente della Repubblica*' [President of the Republic] on the '*Gazzetta Ufficiale della Repubblica Italiana*' [Official Journal of the Italian Republic], which occurred in December 2023.⁴⁹⁴ The bill came into force 15 days after its adoption, thus by the end of 2023.⁴⁹⁵

The Italian law begins in Art. 1 by stating that the measures presented in its provisions are designed to ensure "*la tutela della salute umana e degli interessi dei cittadini nonché a preservare il patrimonio agroalimentare*" [the protection of human health and the interests of citizens and to preserve Italy's agrifood heritage].⁴⁹⁶ In regards to cultivated meat, Art. 2 states that FBOs are prohibited from producing, marketing and promoting products containing or produced from cell cultured meat.⁴⁹⁷ In order to justify the ban, the Italian government invoked the precautionary principle and the need to take preventative measures to ensure consumer protection in the absence of solid scientific evidence proving that the consumption of cultivated meat is safe.⁴⁹⁸ The Article also specifies that the ban is not only limited to domestic production, but it is also applicable to imported and exported products.⁴⁹⁹ In Art. 3, the Italian law targets plant-based products and states that it is prohibited to use 'meat terms' for their

⁴⁹¹ Ministero dell'agricoltura, della sovranità alimentare e delle foreste, 'Comunicati stampa - Cibo sintetico Cdm approva divieto produzione e commercializzazione' (Ministero dell'agricoltura, della sovranità alimentare e delle foreste, 28 March 2023) <https://www.politicheagricole.it/cdm_cibi_sintetici> accessed 10 March 2024

⁴⁹² Chamber of Deputies, 'The Passage of a Law Through Parliament' (*Italian Parliament*) <https://en.camera.it/4?scheda_informazioni=15> accessed 10 March 2024

⁴⁹³ LEGGE 1 dicembre 2023, n 172 – LAVORI PREPARATORI (n.493)

⁴⁹⁴ The Passage of a Law Through Parliament (n.495)

⁴⁹⁵ LEGGE 1 dicembre 2023, n. 172' (Gazzetta Ufficiale della Repubblica Italiana) <<https://www.gazzettaufficiale.it/eli/id/2023/12/01/23G00188/sq>> 10 March 2024

⁴⁹⁶ LEGGE 1 Dicembre 2023 n 172 (n.493) art 1

⁴⁹⁷ Ibid art 2

⁴⁹⁸ Ibid; EC, 'Notification Detail - Provisions on the prohibition of the production and marketing of food and feed consisting of, isolated from or produced from cell cultures or tissues derived from vertebrate animals and on the prohibition of the designation as [...] - Impact assessment' (TRIS - European Commission, 1 December 2023) <<https://technical-regulation-information-system.ec.europa.eu/en/notification/25152>> accessed 10 March 2024, 1

⁴⁹⁹ LEGGE 1 Dicembre 2023 n 172 (n.493) art 2

production and marketing "*sul territorio nazionale*" [within national territory].⁵⁰⁰ More specifically, it is stated that all legal, customary or descriptive names referring to, *inter alia*, animal anatomy or morphology and any other denomination traditionally or commercially used by the meat industry shall not be used to designate plant-based substitute products.⁵⁰¹ The draft also presents certain exemptions, according to which the aforementioned denominations may be used on products containing a combination of animal and vegetable proteins, so long as the first ones are the predominant source of protein.⁵⁰² It is also specified that a future decree by the Minister of Agriculture, Food Sovereignty and Forestry will describe the list of the prohibited names.⁵⁰³ The decree is supposed to be adopted 60 days after the adoption of the Italian law.⁵⁰⁴ Infringement of the provisions of the Italian law can lead to financial penalties up to 60.000 EUR depending on, *inter alia*, the magnitude and duration of the violations.⁵⁰⁵

5.2.2 The TRIS Notification Procedure

In July 2023, the Italian government triggered the TRIS mechanism for the first time, to notify the EC about the adoption of the aforementioned law.⁵⁰⁶ Even though the draft gathered a number of comments by multiple stakeholders, all of them were of a negative nature and heavily criticized its content.⁵⁰⁷ No commentary was provided by either the EC or any other Member State.⁵⁰⁸ Italy withdrew the notification in October 2023, right before the end of the standstill period, with the Minister of Agriculture, Food Sovereignty and Forestry stating in a parliamentary session that the withdrawal was only a formality in order to allow the Italian Parliament to amend the draft and adjust its provisions "*in piena autonomia*" [in full autonomy].⁵⁰⁹ In December 2023, Italy re-notified the EC on the draft, accompanied by an impact assessment elaborating on the

⁵⁰⁰ Ibid art 3(1)

⁵⁰¹ Ibid art 3(1)(a)-(d)

⁵⁰² Ibid art 3(3)-3(4)

⁵⁰³ Ibid art 3(5)

⁵⁰⁴ Ibid

⁵⁰⁵ Ibid art 5(1)-5(2)

⁵⁰⁶ EC, 'Notification Detail - Provisions on the prohibition of the production and marketing of food and feed consisting of, isolated from or produced from cell cultures or tissues derived from vertebrate animals and on the prohibition of the designation as [']' (TRIS - European Commission, 27 July 2023) <<https://technical-regulation-information-system.ec.europa.eu/en/notification/24242>> accessed 10 March 2024

⁵⁰⁷ Ibid

⁵⁰⁸ Ibid

⁵⁰⁹ Camera dei deputati, 'Resoconto stenografico dell'Assemblea Seduta n 184 di mercoledì 25 ottobre 2023' (Camera dei deputati - Lavori, 25 October 2023) <<https://www.camera.it/leg19/410?idSeduta=0184&tipo=stenografico#sed0184.stenografico.tit00130.sub00040.int00040>> accessed 10 March 2024, n.3-00758

reasoning behind the ban on cultivated meat.⁵¹⁰ In the impact assessment it was stated that the effects of lab-grown foods on human health have not been extensively studied and, therefore, in the absence of a harmonized EU-wide approach, national measures are required to ensure consumer protection.⁵¹¹ In response to the notification, Lithuania provided a detailed opinion, thus extending the standstill period by an additional trimester.⁵¹² Even though, Lithuania's considerations have not been made public, they are expected to relate to the impact of the Italian law on the free movement of goods within the internal market, as per Art. 5(1) of Directive (EU) 2015/1535. However, the EC exercised their right to halt the notification procedure earlier on the grounds that the Italian government adopted the national measures before the end of the standstill period, an action which is not permitted under Art. 6 of Directive (EU) 2015/1535.⁵¹³ In fact, the Italian government officially adopted the new law the same day as they notified the EC through the TRIS procedure, meaning on December 1st, 2023. However, the violation of the provisions of Directive (EU) 2015/1535 concerning the standstill period, may render the Italian law inapplicable to individuals.⁵¹⁴ This was established in previous case-law, specifically case C-443/98, where the CJEU concluded that national courts may "*refuse to apply a national technical regulation which was adopted during a period of postponement of adoption*"⁵¹⁵.

5.2.3 The Impact of the Italian law

The Italian law tried to tackle two separate concepts concerning the alternative protein market at once: lab-grown meat and plant-based substitute products. Based on the contributions made during the TRIS Notification Procedure, it is safe to conclude that the efforts of the Italian government to regulate these issues caused a significant backlash. Even though the focal point of this Chapter is the labelling of meat substitutes, the provisions related to cultivated meat constitute an integral part of the Italian law and it is important to showcase the traction they gained. In fact, the shockwave caused by the ban on cultured meat overshadowed the restrictions on the labelling of plant-based products.

⁵¹⁰Notification Detail of 1 December 2023 (n.501)

⁵¹¹ Impact assessment (n.501) 1-2

⁵¹² Directive (EU) 2015/1535 (n.437) art 6(2)

⁵¹³ EC, 'Communication from the Commission on Notification: 2023/675/IT', TRIS/(2023) 0244

⁵¹⁴European Commission, 'Frequently Asked Questions (FAQ)' (TRIS - European Commission) <<https://technical-regulation-information-system.ec.europa.eu/en/faq>> accessed 10 March 2024

⁵¹⁵ C-443/98 *Unilever* [2000] ECLI:EU:C:2000:496, para 52

In regards to the use of 'meat terms', opponents of the ban claimed that the Italian draft is highly reminiscent of the French Decree, a situation which could create an array of issues, ranging from difficulties in adapting food labels to meet the requirements of each Member State, to significant distortions in international trade.⁵¹⁶ In fact, a quick comparison between the two laws proves that the measures created by the French legislators most likely served as an inspiration for the Italian government. For instance, Art. 3 of the Italian law follows the same structure and presents almost identical requirements for the marketing of plant-based substitutes produced domestically as Arts. 2-5 of the French Decree. In both cases, an additional decree would provide a list of the prohibited 'meat terms', but it is currently unknown how extensive Italy's list will be or how it will compare to the French one, since the Italian Minister of Agriculture and Food Sovereignty has yet to publish any relevant documents.⁵¹⁷ Similarly, an infringement of the provisions of both laws will lead to financial penalties.⁵¹⁸ However, Italy seems to have adopted a significantly stricter approach to sanctions, which, depending on the nature and severity of the violation, could be almost 10 times higher compared to France's penalties.

At the same time, multiple organizations showed their opposition to the labelling measures by stating that there is not enough evidence showing that consumers are being misled by the use of 'meat terms' on plant-based products and that, in reality, they are a helpful tool to convey to consumers specific information about the expected quality and attributes of the product, as well as its preparation method.⁵¹⁹ Furthermore, issues concerning the impact of the Italian law on the free movement of goods were raised. It was hypothesized that producers would be burdened with additional costs to modify their labelling and that both domestic producers and importers would be prone to legal repercussions due to the nature of the Italian law.⁵²⁰ Finally, the need to promote the production and consumption of plant-based products and not overcomplicate their marketing was also highlighted, in order to meet the

⁵¹⁶ European Vegetarian Union Response to TRIS notification 2023/0675/IT (1 January 2024), 1

⁵¹⁷ Ministero dell'agricoltura, della sovranità alimentare e delle foreste, 'Etichettatura alimentare' (Ministero dell'agricoltura, della sovranità alimentare e delle foreste - Politiche Nazionali) <<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/7681>> accessed 10 March 2024

⁵¹⁸ LEGGE 1 Dicembre 2023 n 172 (n.493) art 5; Décret 2024-144 (n.434) art 7

⁵¹⁹ Eurogroup for Animals' response to TRIS Notification 2023/0675/IT (20 January 2024), 3; European Vegetarian Union Response to 2023/0675/IT (n.519) 2

⁵²⁰ Letter from the European Alliance for Plant-based Foods (EAPF) to the Council of the EU and to the European Commission on the Italian law (15 December 2023), 2

environmental and dietary targets set in international policies and incentives.⁵²¹ Similar arguments were used against the French Decree, showing that the adoption of such restrictive measures and the extensive fragmentation of the EU food labelling framework might cause more hurdles overtime, rather than ensure adequate consumer protection. This was also highlighted in a 2020 evaluation of the state of the internal market conducted by the EU Policy Department for Economic, Scientific and Quality of Life Policies, which showed that the continuous adoption of different national food labelling laws *"has a negative effect on the EU food supply chain and constitutes a barrier to the Single Market"*⁵²².

Last but not least, it is important to highlight that, according to Italian media sources, in February 2024, the Italian Minister of Agriculture, Food Sovereignty and Forestry stated that certain companies had risen their concerns in regards to the impact of the Italian law on their future operations. As a result, the Minister disclosed that discussions with representatives of the alternative protein industry have been opened, in order to come up with a shared plan on the ban and meet the demands of the industry, while also ensuring that consumers are not being misled.⁵²³

As far as cultivated meat goes, the reactions to the ban were mixed. On one hand, Coldiretti, the main farmer's organization in Italy, orchestrated a petition requesting the ban of the production, marketing and distribution of lab grown meat, several months before the introduction of the Italian law.⁵²⁴ In their announcement, Coldiretti claimed that *"Le bugie sul cibo in provetta confermano che c'è una precisa strategia delle multinazionali che con abili operazioni di marketing puntano a modificare stili alimentari naturali fondati sulla qualità e la tradizione"* [the introduction of cultured meat in the market is a strategic move aiming at modifying natural eating styles based on quality and tradition].⁵²⁵ The petition gained a massive response and gathered half a million signatures from a number of farmer's organizations, citizens and even political figures, including the President and the Minister of Agriculture, Food Sovereignty and Forestry, thus showing that there is a significant part of the Italian population that is skeptical

⁵²¹ Ibid 3

⁵²² Legal obstacles in Member States to Single Market rules (n.488) 39

⁵²³ Novanews, 'Lollobrigida: "Sulla carne a base vegetale serve un accordo di filiera"' (Novanews, 22 February 2024) <<https://www.agenzianova.com/news/lollobrigida-sulla-carne-a-base-vegetale-serve-un-accordo-di-filiera/>> accessed 10 March 2024

⁵²⁴ Coldiretti, 'Una firma contro il cibo sintetico: scatta la mobilitazione Coldiretti' (Coldiretti, 10 November 2022) <<https://www.coldiretti.it/economia/una-firma-contro-il-cibo-sintetico-scatta-la-mobilitazione-coldiretti>> accessed 10 March 2024

⁵²⁵ Ibid

towards lab-grown meat and is not willing, at least at the moment, to incorporate such new technologies in their day-to-day lives.⁵²⁶

On the other hand, opponents of the law presented several arguments against the ban, namely regulatory, environmental and technological. First of all, it was supported that the measure constitutes a violation of the Novel Foods Regulation, while also disregarding the exclusive competence of the EC to authorize novel foods within the EU.⁵²⁷ As already established, cultured meat will most likely fall within the scope of the NFR and, therefore, its marketing within the Union will only be authorized after going through EFSA's rigorous safety assessment; thus ensuring its safety for human consumption.⁵²⁸ Therefore, the argument of the Italian government that the ban was justified due to safety concerns was considered to be invalid.⁵²⁹ Moreover, it was highlighted that the EU has already established a framework covering the introduction of cultured meat in the market through the NFR, thus harmonizing its regulation and precluding Member States from adopting national measures to either allow or prohibit its production and consumption.⁵³⁰

Furthermore, it was supported that the Italian government chose to misinterpret the meaning of the precautionary principle, thus wrongfully invoking it to justify their measures.⁵³¹ According to Art. 7 of the GFL, Member States may take temporary measures to ensure consumer protection in cases where more scientific data is required to conduct a definitive risk assessment and "*the possibility of harmful effects on health is identified*".⁵³² In the present case, the Italian government reversed the meaning of the requirement and stated in their impact analysis that there currently is not enough evidence to conclude that the consumption of cultivated meat is safe, without showing any evidence that it might be harmful.⁵³³

Moreover, it was supported that the measure would create significant distortions to the free movement of goods, since it not only prohibits the marketing of lab-grown domestically, but also bans imports and exports.⁵³⁴ In general, such a measure may be

⁵²⁶ Coldiretti, 'CdM: bene il ddl contro il cibo sintetico, 1/2 mln di firme' (Coldiretti, 28 March 2023) <<https://www.coldiretti.it/consumi/cdm-bene-il-ddl-contro-il-cibo-sintetico-1-2-mln-di-firme>> accessed 10 March 2024

⁵²⁷ Comments on Italian Law on Cultured Meat from the Associazione Luca Coscioni APS (10 January 2024) para 1

⁵²⁸ Regulation (EU) 2015/2283 (n. 60) art 3(2)(a)(vi), 10-11

⁵²⁹ European Vegetarian Union Response to 2023/0675/IT (n.519) 2

⁵³⁰ Eurogroup for Animals' response to Notification 2023/0675/IT (n.522) 2

⁵³¹ Comment from the Associazione Luca Coscioni (n.530) para 4

⁵³² Regulation (EC) No 178/2002 (n.119) art 7(1)

⁵³³ Comment from the Associazione Luca Coscioni (n.530) para 4; Impact assessment (n.501) 2

⁵³⁴ LEGGE 1 Dicembre 2023 n 172 (n.493) art 2(1)

allowed under Art. 36 of the TFEU, which states that Member States may impose prohibitions or restrictions on imports and exports in order to ensure the "*protection of health and life of humans*".⁵³⁵ However, these measures shall not constitute an "*arbitrary discrimination or a disguised restriction*".⁵³⁶ Even though the Italian government stated that their main objective was to protect consumers from the imminent dangers of synthetic foods, opponents of the ban stated that they did not provide solid reasoning proving the need to impose such measures and therefore are in breach of Arts. 34 and 35 of the TFEU.⁵³⁷

Finally, it was supported that the measures will create significant burdens on the future development of lab grown-meat, since it is a technology that is currently at its early developmental stages and, therefore, it is necessary to reward innovative practices, rather than demonize and ostracize them.⁵³⁸ This was also highlighted in a parliamentary session during the assessment of the Italian draft, with opposing parties stating that "*La verità [...], è che con le sue scelte sta bloccando l'innovazione, [...] e soprattutto lo sviluppo e la ricerca scientifica e tecnica tutelata*" [the measures were blocking innovation, [...], and above all scientific and technical development and research].⁵³⁹

Even though political opposition was present during the adoption procedure, the draft eventually got adopted and in theory is now enforceable. However, following the EC's decision to abruptly end the TRIS procedure, it remains to be seen how, or even if, it will be implemented and whether national courts will declare it invalid. At the same time, uncertainty surrounds the labelling of meat substitutes following the statements of the Minister of Agriculture, Food Sovereignty and Forestry and his potential intent to amend the relevant provisions.

5.2.4 Preliminary Conclusions

Italy recently adopted a national law covering the marketing of lab grown meat and the labelling of plant-based substitute products. In regards to plant based products, Italy followed the steps of the French government and imposed similar, if not almost identical, measures that aim at banning the use of 'meat terms' on substitute products.

⁵³⁵ Treaty on the Functioning of the EU (n.17) art 36

⁵³⁶ Ibid

⁵³⁷ Comment from the Associazione Luca Coscioni (n.530) para 2

⁵³⁸ Comment from the Associazione Luca Coscioni (n.530) para 5

⁵³⁹ Resoconto stenografico dell'Assemblea Seduta n 184 di mercoledì 25 ottobre 2023 (n.512) n. 3-00757

The shared similarities between the two laws, show that the French Decree was highly influential and led other countries to impose restrictions that provide a strategic advantage to the meat industry and severely limit the alternative protein market. Even though both governments invoked consumer protection to justify the ban, the current scientific knowledge has yet to definitively prove that the use of meat terms leads to consumer confusion. On the contrary, it has even been supported that consumers prefer substitute products marketed under meaty denominations because they create a sense of familiarity and help consumers better identify the nature of the product.⁵⁴⁰ Moreover, the true intentions behind these measures have been questioned, since Italy and France are two of the largest meat producers within the EU and they have been accused of purposefully benefitting the meat sector.⁵⁴¹ Besides, the intent to protect and promote products that play a role in the socio-economic development of the community was also emphasized in the Italian law.⁵⁴²

At the same time, the legitimacy of the Italian law has yet to be verified in the absence of the CJEU's decision concerning the possibility to adopt national measures on the labelling of meat substitutes (see subchapter 5.1.1). In light of a positive response from the CJEU, the road to more fragmentation of food labelling requirements will be paved. Each Member State will be allowed to create their own obligations and requirements, a situation which may be difficult to navigate for both FBOs and consumers. For instance, FBOs will be required to adjust their product labels to conform to the requirements of each country and prove their country of origin in order to justify the terms they are displaying on their labels. As a result, FBOs will, on one hand, be more prone to legal insecurity and, on the other hand, face increasing packaging and marketing costs. At the same time, this situation creates a hostile marketing environment where local producers will be facing labelling restrictions, while imported products will be allowed to use 'meat terms'. If the argument of vegan associations that 'meat terms' are actually useful for consumers is actually valid, this will create an uneven playing field where domestic products will be forced to bear new and unfamiliar terminology, thus potentially deterring consumers who are trying to find products imitating specific tastes, textures and preparation methods.

⁵⁴⁰ Danae Marshall, Faiza Bano and Kasia Banas, 'A meaty issue: The effect of meat-related label terminology on the willingness to eat vegetarian foods' (2022) 96(104413) Food Quality and Preference, 9

⁵⁴¹ Eurostat, 'Agricultural production - livestock and meat' (Eurostat-Statistics Explained, September 2023) <https://ec.europa.eu/eurostat/statistics-explained/index.php?oldid=427096#Meat_production> accessed 28 March 2024

⁵⁴² LEGGE 1 Dicembre 2023 n 172 (n.493) art 1, 3(1)

Moreover, this situation could create legal loopholes where international FBOs might transfer production to countries not imposing the ban and start importing these products to countries enforcing the ban, in order to avoid adhering to the restricting labelling requirements. However, this will not be possible for SMEs who will not have the financial capacity to navigate the regulatory environment. However, the final form of the law and how it will actually affect the Italian and international community is unknown and the way the ban will be enforced is allegedly still under consideration.

In regards to lab-grown meat, Italy has been the first country within the Union to impose such a ban. Even though it is true that the effects of cultured meat on human health and its environmental and ethical impact are not fully explored yet, it sounds counterproductive to limit the development and evolution of a potentially fruitful sector and one of the viable options to reduce GHG emissions and meat consumption. At the same time, it is not clear whether it is even allowed to create such a measure domestically since cultivated meat will most likely fall within the scope of the NFR. Besides, for the moment, there are no applications requesting an authorization for marketing lab grown meat within the EU. As a result, this measure does not combat a real and embodied issue but is rather tilting at windmills and is limiting the country's innovative potential. At the same time, it is rather arbitrary and unreasonable to invoke the precautionary principle in order to, *inter alia*, protect a nation's cultural and livestock heritage.

In general, besides the content of the law, the Italian government chose to disregard the requirements of the TRIS notification procedure and disobeyed the standstill period requirement. Even though the motivation behind this move is unknown, it may be assumed that the Italian government wanted to speed up the procedure and enforce the national measures quickly. However, the move backfired and led to the closure of the procedure by the EC, which can have negative consequences concerning the enforceability of the law. It would be interesting to know the opinion of the EC on a substantial level, but their comments were limited to procedural considerations.

5.3. Germany & the Netherlands

5.3.1 The German Guidelines

After the adoption of the FIC Regulation in 2011, the EVU started using their political influence in order to achieve the adoption of legally binding definitions for

'vegan' and 'vegetarian' products.⁵⁴³ Since Germany is a country renowned for their positive attitude towards vegetarianism, the German branch of EVU, or ProVeg, created a working group together with the '*Lebensmittelverband Deutschland*' [the German Federation for Food] and representatives from the 16 German Federal States in order to submit a proposal for these definitions.⁵⁴⁴ Consequently, in April 2016, the Consumer Protection Ministers from all Federal States agreed on the proposal and announced the implementation of the aforementioned definitions.⁵⁴⁵ Even though the Ministers did not have the authority to adopt national food labelling laws, since lawmaking falls within the competence of the Federal Government and the '*Bundestag*' [German Parliament], their definitions are considered *defacto* binding.⁵⁴⁶ This means that even though the definitions were not legally adopted, they have a binding effect since it was stated by the Ministers that the food control authorities should use them to assess and verify the nature of substitute products.⁵⁴⁷

According to EVU's criteria, the definitions were "*sufficiently narrow, pragmatic and realistic*"⁵⁴⁸ and "*fully implemented the expectations of interested consumers*"⁵⁴⁹. Similarly, the German ministers highlighted that the definitions and their conditions of use were created in order to satisfy the growing needs of the market for vegan and vegetarian products and ensure that consumers have access to clear and truthful information.⁵⁵⁰ In light of the aforementioned, it was established that 'vegan' foods shall be free from any product of animal origin, namely any type of ingredient, processing aid or non-food additive, during all stages of production and processing.⁵⁵¹ Similarly, 'vegetarian' foods shall meet the aforementioned requirements, with the exception that

⁵⁴³Till Strecker, 'Developments in European Food Law: What Is Vegetarian?' (2016) 11(1) European Food and Feed Law Review 21, 23

⁵⁴⁴Felix Domke, 'Vegetarian and Vegan Products - Labelling and Definitions' (2018) 13(2) European Food and Feed Law Review 102, 104

⁵⁴⁵VSMK, 'Definitionen sowie Gründe und Ziele der Definitionen "vegan" und "vegetarisch" – Stand 05/2016' (*Verbraucherschutzministerkonferenz*, 22 April 2016) <<https://www.verbraucherschutzministerkonferenz.de/VSMK-Dokumente.html>> accessed 16 March 2024

⁵⁴⁶ Federal Ministry of the Interior and Community, 'Legislation' (*Federal Ministry of the Interior and Community*) <<https://www.bmi.bund.de/EN/topics/constitution/legislation/legislation-node.html>> accessed 16 March 2024; Vegetarian and Vegan Products - Labelling and Definitions (n.547) 104;

⁵⁴⁷ Definitionen sowie Gründe und Ziele der Definitionen "vegan" und "vegetarisch" (n.548)

⁵⁴⁸ EVU Position Paper - Definitions of "vegan" and "vegetarian" in accordance with the EU Food Information Regulation (July 2019), 3

⁵⁴⁹ Ibid 2

⁵⁵⁰ VSMK Gründe und Ziele der Definitionen für die Begriffe "vegan" und "vegetarisch" (VSMK's Reasons and goals of the definitions for the terms "vegan" and "vegetarian") (12 April 2016) 1

⁵⁵¹ VSMK - Definitionen vegan-vegetarisch (Definitions of "vegan" and "vegetarian") (22 April 2016), art 1

certain ingredients of animal origin may be used, namely milk, colostrum, eggs, honey, beeswax, propolis, wool fat and its derivatives.⁵⁵² In Art. 3 of the proposal, it was stated that unintentional contamination of vegetarian or vegan foods with products of animal origin that could not be avoided through the implementation of good manufacturing practices is permitted, since it was supported that zero tolerance would create unnecessary constraints for FBOs. Finally, in Art. 4 it was highlighted that the aforementioned definitions not only referred to the use and display of the specific words 'vegetarian' and 'vegan', but also for any other derivate.

In December 2018, the German Food Book Commission elaborated on the definitions and published set of guidelines for vegan and vegetarian foods acting as substitutes of products of animal origin.⁵⁵³ The manufacturing and commercial practices presented in the guidebook are not legally binding but rather serve as an expert's opinion and a tool that FBOs may use to ensure that their products meet consumer expectations and are adequately labelled.⁵⁵⁴ According to Art. 2 of the guidelines, the designation of these products is dependent on two factors; the sensory similarity to the food they are imitating and whether the 'meat term' they wish to use is classified as customary or non-customary.⁵⁵⁵ For instance, names referring to specific cuts of meat, animal species or organs are not considered customary and they may be used only when there is a "*weitgehende sensorische Ähnlichkeit*"⁵⁵⁶ [an extensive sensory similarity] to the food of animal origin. Such terms are 'steak', 'kidney' or 'fillet'. Furthermore, names referring to pieces of meat, shapes or minced meat, such as 'meat balls', 'schnitzel' or 'sausage', are considered customary and they may be used on substitute products that share a "*hinreichende sensorische Ähnlichkeit*" [sufficient sensory similarity] with the original product.⁵⁵⁷ However, names referring to specific types of sausages are not customary and they may only be used as additional explanatory or descriptive information, e.g. 'vegan sausage salami-style'.⁵⁵⁸ The guidelines also clarify that names protected under a geographical indication, names

⁵⁵² Ibid art 2

⁵⁵³ Leitsätze für vegane und vegetarische Lebensmittel mit Ähnlichkeit zu Lebensmitteln tierischen Ursprungs (Guidelines for vegan and vegetarian foods that are similar to foods of animal origin) [2018] BAnz AT 20.12.2018 B1, GMBI 2018 S. 1174, para 1; Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat (n.166) 329

⁵⁵⁴ Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat' (n.166) 328

⁵⁵⁵ Guidelines for vegan and vegetarian foods that are similar to foods of animal origin (n.556) para 2

⁵⁵⁶ Ibid para 2.1

⁵⁵⁷ Ibid para 2.1

⁵⁵⁸ Ibid para 2.1

referring to traditional specialties and other legally protected names shall not be used on substitute products no matter the level of sensory similarity.⁵⁵⁹ As far as presentation goes, the terms 'vegan' and 'vegetarian' shall be prominently displayed on the label and accompanied by the substitution ingredient, e.g. tofu-based vegan meatballs.⁵⁶⁰

5.3.2 The Dutch Guidelines

In late 2019, the Minister of Health, Welfare & Sport (VWS) stated their intent to legally permit the use of the term '*vegetarisch gehak*' [vegetarian minced meat] on substitute products. In order to accomplish this, they submitted a proposal for defining the words 'vegan' and 'vegetarian'. The suggested descriptions were identical to the ones provided by EVU and the German Federal States.⁵⁶¹ After these definitions were discussed and approved during a Food Labeling Expert Consultation conducted by the VWS, the Ministry initiated further policy actions to establish rules concerning the labelling of meat substitutes.⁵⁶² These rules were presented in the form of guidelines and are currently published in the Food Labelling Handbook, which is issued by the Dutch Food and Consumer Product Safety Authority (NVWA). The guidelines serve as a useful tool for FBOs to navigate the EU and national regulatory framework concerning food labelling and ensure that they are adhering to its requirements.⁵⁶³

According to the guidelines, names that are considered customary may be used to designate substitute products as long as it is clearly stated that they do not contain ingredients of animal origin. Therefore, it is allowed to market products under denominations such as 'vegan schnitzel', 'vegetarian sausage' or 'vegan burger'. Similarly, terms referring to animal species are also permitted under the same conditions of use. However, the guidelines specify that they should only be displayed in conjunction with the words 'vegan' and 'vegetarian' and never as standalone denominations. Therefore, terms such as 'vegan chicken pieces' or 'vegan tuna' are

⁵⁵⁹ Ibid para 1.4

⁵⁶⁰ Ibid

⁵⁶¹ Ministerie van Volksgezondheid Welzijn en Sport, 'Bijlage 1- Voorstel definities vegetarisch en veganistisch' (Regulier Overleg Warenwet, 8 July 2021) <<https://www.row-minvws.nl/row-nl/etikettering-levensmiddelen-del/vergaderstukken-del/8-juli-2021>> accessed 16 March 2024

⁵⁶² Nederlandse Voedsel- en Warenautoriteit in samenwerking met Lugt Food Law (Marieke Lugt), *Handboek Etikettering van levensmiddelen* (8th edn, NVWA, 2022), 93

⁵⁶³ NVWA, 'Handboek Etikettering van levensmiddelen' (NVWA: Home, 27 June 2022) <<https://www.nvwa.nl/onderwerpen/etikettering-van-levensmiddelen/documenten/consument/eten-drinken-roken/etikettering/publicaties/handboek-etikettering-van-levensmiddelen>> accessed 16 March 2024

allowed. Finally, the guidelines highlight that legally protected denominations shall not be used, even in combination with explanatory or descriptive terms proving the nature of the food.⁵⁶⁴

5.3.3 Comparison & Impact of the Guidelines

Both Germany and the Netherlands adopted the aforementioned guidelines in order to create a reliable path that FBOs may use to manufacture and market vegan and vegetarian products of high quality and consistency. According to the German guidelines, the increasing demand for substitute products had led FBOs to enforce their own rules in the absence of legally defined requirements and conditions of use for meat-related names. As a result, it was impossible to guarantee a high level of information and ensure consumer protection.⁵⁶⁵ The guidelines would, therefore, enable consumers to identify the nature and expected characteristics of substitute products through the use of already established and well-understood terminology.

The guidelines from both countries share multiple similarities. First of all, none of them are *de jure* binding meaning that they have not been legally adopted and FBOs are not required to adhere to their provisions. In fact, some companies have already denounced the content of the guidelines and have paved their own way for the marketing of their products.⁵⁶⁶ Moreover, none of the two countries specify whether their guidelines are applicable to domestic producers alone, or if imported products may also adhere to their provisions. In general, the reason for the adoption of mere guidelines by both countries, rather than national laws, may only be speculated and could be attributed to the fact that, according to the FIC Regulation, the EC shall adopt implementing acts concerning the suitability of foods for vegans and vegetarians.⁵⁶⁷ Even though the EC has yet to take action on this and as a result there are still no definitions for these terms, it is unknown what a future implementing act will entail and what type of manufacturing, labelling and overall marketing requirements will enforce, thus invalidating all relevant national measures and precluding future regulatory action by Member States.

Furthermore, both countries recognized the same definitions for the terms 'vegan' and 'vegetarian', thus establishing an identical understanding of the terms on a

⁵⁶⁴ Handboek Etikettering van levensmiddelen (n.565) 93

⁵⁶⁵ VSMK Gründe und Ziele der Definitionen für die Begriffe "vegan" und "vegetarisch" (n.553) 1

⁵⁶⁶ Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat (n.166) 329

⁵⁶⁷ Regulation (EU) 1169/2011 (n.264) art 36(3)(b)

transnational level. The recognition of clear and concise definitions can provide an outline for the proper manufacturing and marketing of substitute products, as well as enable the correct identification of these products by consumers. Of course, the non-binding nature of the guidelines allows FBOs to deviate but it could be a safe option in order to lower their chances of infringing national and EU law and facing legal actions. At the same time, both countries seem to base the possibility to use meat terms on the customary usage of a product name. However, the reasoning behind the classification of each name is unknown with scholars stating, for example, that for certain names customary usage has not necessarily been established within the German community and the guidelines arbitrarily place them within this spectrum.⁵⁶⁸ Both countries also establish that legally protected names shall not be used under any circumstances.

The main difference between the two set of guidelines is the requirement for a sensory similarity between the product of animal origin and its substitute in order to use 'meat terms'. No such condition may be found on the Dutch guidelines, while the German ones specify that an 'extensive' or a 'sufficient' sensory similarity in terms of appearance, texture and mouthfeel shall be established. However, no further clarification is provided and, therefore, whether the desired level of similarity has been achieved by FBOs may only be established on a case-by-case level in light of legal proceedings.⁵⁶⁹

In general, both countries have adopted a more liberal approach to the use of meat terms on alternative proteins, where FBOs are endorsed to add them on their packaging so long as they are not trying to capitalize on terms that are legally protected under Union or national law and they clearly state that the product is either a vegan or a vegetarian alternative. Vegetarian and vegan products are no longer part of a niche market and the number of consumers who are actively seeking them is on the rise.⁵⁷⁰ Both Germany and the Netherlands are open towards the vegan movement and many locals are showing interest in reducing their meat consumption and incorporate alternative sources of protein into their routines.⁵⁷¹ For example, in Germany the

⁵⁶⁸ Meat 2.0 - The Regulatory Environment of Plant-Based and Cultured Meat (n.166) 329

⁵⁶⁹ Tofu Steaks? Developments on the Naming and Marketing of Plant-based Foods in the Aftermath of the TofuTown Judgement' (n.305) 59

⁵⁷⁰ Gelareh Salehi and others, 'Forty-five years of research on vegetarianism and veganism: A systematic and comprehensive literature review of quantitative studies' [2023] 9(5) Heliyon e16091, 2

⁵⁷¹ Tim O'Riordan and Susanne Stoll-Kleemann, 'The Challenges of Changing Dietary Behavior Toward More Sustainable Consumption' (2015) 57(5) Environment: Science and Policy for Sustainable Development 4, 7; Hans Dagevos and Wim Verbeke, 'Meat consumption and flexitarianism in the Low Countries' [2022] 192 Meat Science 108894, 6

production value of meat substitute products was raised by 37% from 2019 to 2020, showing that a growing number of consumers is adding them to their shopping basket.⁵⁷² Maybe this trend could explain the stance of the German and Dutch governments and their intent to allow the use of 'meat terms', even in the form of guidelines.

In regards to consumer confusion, opponents of the German guidelines stated at the time of their publication that the suggested terminology is "*completely misleading and unsettles consumers*"⁵⁷³. However, no substantial evidence has been provided in order to support such claims, with studies pointing to the fact that only a very small number of consumers do not know how to evaluate labels. For example, a study conducted in 2017 by the Federation of German Consumer Organizations showed that only 4% of German consumers have ever unintentionally purchased vegan and vegetarian products thinking that they contained products of animal origin.⁵⁷⁴

Last but not least, it is important to highlight that, similarly to the national laws adopted by France or Italy, these guidelines also contribute to the increasing fragmentation of the EU labelling framework. Again, the establishment of different rules and requirements for each Member States has the potential to cause an array of barriers to the free movement of goods within the Union and hinder FBOs willingness to invest in alternative sources of protein. At the same time, consumer trust and, subsequently, acceptance cannot be built, since there is no consistency or sense of familiarity in regards to these products.

⁵⁷² Gesa Stremmel and others, 'Vegan labeling for what is already vegan: Product perceptions and consumption intentions' (2022) 75(1) *Appetite* 106048, 1

⁵⁷³ The Guardian, 'Telling porkies: German MP attacks vegetarian products with meaty names' (*The Guardian*) <<https://www.theguardian.com/world/2016/dec/29/telling-porkies-german-mp-attacks-vegetarian-products-with-meaty-names>> accessed 16 March 2024

⁵⁷⁴ Vegetarian and Vegan Products - Labelling and Definitions (n.547) 105

Chapter 6: 'Meat terms' & Consumer Confusion

In the previous Chapters, the EU regulatory framework concerning the marketing and labelling of alternative sources of protein, as well as the individual stance of certain Member States, were explored. Depending on, *inter alia*, the cultural background, the societal demands and the political aspirations of each country, different regulatory and policy instruments have been presented in order to guide the industry into the intricacies of the labelling of meat substitutes. Some of these tools enable the use of 'meat terms' to describe these products, while others are following a more conservative approach and enforce limitations on their use. One of the more common justifications for such bans is the need to ensure consumer protection and deter FBOs from engaging in misleading commercial practices. However, this raises questions concerning the actual correlation between the use of 'meat terms' on alternative proteins and consumer confusion. In order to evaluate the goals envisioned by such regulatory bans and the means to achieve them, it is important to investigate the aforementioned relationship. Therefore, this chapter aims at evaluating whether the use of 'meat terms' on alternative proteins has the potential to mislead the consumers from a social, economic, legal, ethical and environmental point of view.

6.1 Social & Economic Considerations

In order to evaluate the misleading effect of 'meat terms', it is necessary to take a look into the results of studies evaluating consumer understanding and acceptance of substitute products. In general, it has been shown that consumer perception can be influenced by a number of factors intrinsic to the product, namely its sensory characteristics, its perceived benefits and risks, such as its nutritional value, healthiness and safety, its price point and its similarity to other, more familiar products.⁵⁷⁵ Furthermore, it can also be affected by properties granted to the product externally through, for example, advertising, packaging and labelling.⁵⁷⁶ In fact, it is believed that

⁵⁷⁵Annet C Hoek and others, 'Identification of new food alternatives: How do consumers categorize meat and meat substitutes?' [2011] 22 Food Quality and Preference 371, 371; Michael Siegrist, 'Factors influencing public acceptance of innovative food technologies and products' (2008) 19(11) Trends in Food science & Technology 603, 603-604

⁵⁷⁶T. Ye, A. Mattila and S. Dai 'The impact of product name on consumer responses to meat alternatives' (2023) 35(3) International Journal of Contemporary Hospitality Management 1051, 1052; Cathlijn Croll 'Vegetarian or Meatless, does it matter? To what extent do word choice and motivation type on the packaging of meat substitutes influence the buying behavior of the consumer' (MSc Thesis, University of Twente, Enschede, The Netherlands, 2021), 6; E.J. Van Loo, V. Caputo and J.L. Lusk, 'Consumer preferences for farm-raised meat, lab-grown meat, and plantbased meat alternatives: Does information or brand matter?' [2020] 95 Food Policy 10193, 13

almost 90% of consumers are making their purchases purely based on the visual stimuli triggered by the packaging.⁵⁷⁷

One of the most important constituents of a product's label is its name, which can convey crucial information to consumers in regards to the nature and composition of a product and has the power to curate a specific image for it, thus altering consumer's expectations and requirements.⁵⁷⁸ For example, a 2016 study evaluating the relationship between the words used to describe meat and the evoked feelings towards animals as a result of said words, showed that using words like 'cow' or 'pig' on restaurant menus, instead of 'beef' and 'pork' respectively, increased feelings of disgust and reduced willingness to consume meat.⁵⁷⁹ This is a testament to the effect of names on consumer perception, as well as the importance of accurate labelling that consumers may consult to make proper purchasing decisions in accordance with their needs and preferences.⁵⁸⁰

However, even though the general effects of brand names, logos, labelling and advertising on consumer acceptance have been studied extensively, there currently is limited academic research evaluating the relationship between the use of 'meat terms' on substitute products and consumer perception.⁵⁸¹ Therefore, it could be argued that some of the existing opinions on the subject are not based on scientifically backed evidence but rather on preconceived notions or prejudices towards meat consumption and vegetarianism. For instance, it appears that meat eaters are negatively predisposed against vegetarians and vegans, which could explain the great number of people who appear to be in favor of banning the use of 'meat terms' on substitute products.⁵⁸² More specifically, a 2020 study evaluating consumer preferences of US citizens over conventional beef patties, lab-grown patties and plant-based patties indicated that over 70% of the participants were in favor of a stricter regulatory environment where the word 'beef' would be reserved exclusively for conventional meat.⁵⁸³

⁵⁷⁷ Jesper Clement, 'Visual influence on in-store buying decisions: an eye-track experiment on the visual influence of packaging design' (2007) 23(9) *Journal of Marketing Management* 917, 917

⁵⁷⁸ Ibid

⁵⁷⁹ J.R. Kunst and S.M. Hohle, 'Meat eaters by dissociation: How we present, prepare and talk about meat increases willingness to eat meat by reducing empathy and disgust' [2016] 105 *Appetite* 758, 771

⁵⁸⁰ Christopher J. Bryant and Julie C. Barnett, 'What's in a name? Consumer perceptions of in vitro meat under different names' [2019] 137 *Appetite* 104, 105

⁵⁸¹ Vegetarian or Meatless, does it matter? (n.579) 6

⁵⁸² Ibid 13

⁵⁸³ Consumer preferences for farm-raised meat, lab-grown meat, and plantbased meat alternatives: Does information or brand matter? (n.579) 10

Moreover, the concept of anchoring seems to be playing an important role in consumer judgement.⁵⁸⁴ Anchoring refers to the psychological effect where people form an opinion for unknown concepts based on familiar ideas.⁵⁸⁵ In the present case, this means that consumers seek a point of reference to gain a better understanding of what alternative sources of protein are and form realistic expectations in regards to their composition and characteristics.⁵⁸⁶ This means that it may be easier for consumers to comprehend what a 'plant-based meatball' is, rather than a 'plant-based protein ball', or what 'lab grown steak' is, rather than 'lab grown muscle tissue'. This type of anchoring may help consumers be more open towards trying new sources of protein, since it can create a sense of familiarity, which is extremely important when forming eating habits.⁵⁸⁷ Therefore, by excluding the use of familiar terms on alternative proteins people may lose the ability to create these connections and thus potentially causing more confusion in regards to the nature of the product.

Last but not least, it is interesting to mention one particular study evaluating the effects of restricting the use of 'meat terms' on consumer choice since it provided some noteworthy results.⁵⁸⁸ This study was conducted in the USA as a result of the ongoing political and legislative debate regarding the use of 'meat terms' on substitute products. Similarly to the EU, a number of US States have proposed and enforced regulatory bans, thus limiting the available terminology for alternative proteins.⁵⁸⁹ In this study, respondents were divided into two groups and were asked the same questions regarding the nature and characteristics of meat substitutes and their labels. In the first group there were no restrictions in the available terminology, while, in the second group, a ban was enforced.⁵⁹⁰ The results showed that consumers from both groups could not correctly identify the content of meat substitutes, with almost 30% of them believing that they contained meat.⁵⁹¹ This shows that the ban did not have a significant effect on consumer confusion and its enforcement would most likely not have the power to

⁵⁸⁴ Adrian Furnham and Hua Chu Boo, 'A literature review of the anchoring effect' (2011) 40(1) *The Journal of Socio-Economics* 35, 35

⁵⁸⁵ Afrodita Marcu and others, 'Analogies, metaphors, and wondering about the future: Lay sense-making around synthetic meat' (2015) 24(5) *Public Understanding of Science* 547, 547

⁵⁸⁶ What's in a name? Consumer perceptions of in vitro meat under different names (n.583) 110

⁵⁸⁷ Madeleine Lanz and others, 'Consumer acceptance of cultured, plant-based, 3D-printed meat and fish alternatives' [2024] 9 *Future Foods* 100297, 6

⁵⁸⁸ Benjamin Demuth and others, 'Choice effects associated with banning the word "meat" on alternative protein labels' (2022) 45(1) *Applied Economic Perspectives and Policy* 128

⁵⁸⁹ *Ibid* 129

⁵⁹⁰ *Ibid* 130

⁵⁹¹ *Ibid* 140

protect consumers from misleading or inaccurate claims.⁵⁹² On the contrary, these results uncover a systemic failure to properly educate consumers on issues concerning food and its labelling, as well as the importance of healthy dietary and purchasing choices.

From an economic perspective, prepackaged foods can be considered as experience goods, meaning that consumers can evaluate their quality after purchasing them.⁵⁹³ For such products, advertising can play a significant role in order to convey to consumers as much information as possible through their labels in order to attract them and influence their decision making.⁵⁹⁴ At the same time, it has been shown that consumers do not spend much time inspecting labels, while warning signs or long descriptive statements either go unnoticed or discourage consumers.⁵⁹⁵ Under these circumstances, businesses might be incentivized to provide misleading or inaccurate information or intentionally highlight specific aspects on their labels, while concealing others, in an effort to maximize their profits and increase their sales.⁵⁹⁶ For example, by displaying 'meat terms' at a prominent place on the label of substitute products, while purposefully undermining the fact that they do not contain meat could mislead consumers into mistakenly purchasing these products.

However, engagement in such practices also comes with several risks. If the risks outweigh the potential benefits, then FBOs will most likely not try to manipulate consumers into buying their products. Those risks might appear in the form of legal proceedings, financial or reputational damages. Firstly, Directive 2005/29/EC concerning unfair business-to-consumer commercial practices stipulates that all actions that are "*likely to materially distort the economic behavior [...] of the average consumer*"⁵⁹⁷ are prohibited. Therefore, commercial practices that provide false or misleading information, even if "*the information is factually correct*"⁵⁹⁸, concerning,

⁵⁹² Ibid

⁵⁹³ Elise Golan and others, 'Economics of Food Labeling' (2001) 24(2) Journal of Consumer Policy 117, 127-128

⁵⁹⁴ Ibid 119

⁵⁹⁵ Ibid 139

⁵⁹⁶ Ellen R. Jordan and Paul H. Rubin, 'An Economic Analysis of the Law of False Advertising' (1979) 8(3) Journal of Legal Studies 527, 529

⁵⁹⁷ Directive 2005/29/EC of the European Parliament And Of The Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council [2005] OJ 2 249/22, art 5(2)(b)

⁵⁹⁸ Ibid art 6(1)

inter alia, the nature and characteristics of a product are prohibited.⁵⁹⁹ Trying to omit certain information or providing them in an ambiguous and deceitful manner is also prohibited.⁶⁰⁰ For instance, a FBO might choose to highlight the term 'sausage' on their label, while concealing in the back of the packaging or adding in a small, unnoticeable font that the product is a meat free substitute. Even though the information presented is not necessarily false, it might be difficult for consumers to identify the true nature of the product and can thus be considered a misleading practice. All violations might lead to legal repercussions which will undoubtedly also have a negative financial impact on the FBO.⁶⁰¹ Secondly, after engaging in such practices, it is highly likely that FBOs will suffer reputational damages as well.⁶⁰² Deceived or unsatisfied consumers are less likely to repurchase the same products and, thus, the potential short-term benefits of misguiding them into buying a product that they otherwise would not, may not be greater than the long-term impact of engaging in misleading practices.⁶⁰³

6.2 Legal Considerations

Regulatory limitations on the use of terminology traditionally reserved by the meat industry to describe alternative proteins are usually based on the idea that consumers will be misled in regards to the true nature of the alternative product.⁶⁰⁴ In fact, this notion does carry some merit in the sense that there is always going to be a number of people who are unable to correctly identify the elements of a label, something which is especially relevant for those belonging in vulnerable groups of the population such as the elderly or people with functional illiteracy.⁶⁰⁵ A somewhat similar reasoning was presumably presented by the CJEU on *Tofutown* (see Chapter 4), which based their decision on the "*likelihood of confusion*"⁶⁰⁶ that would be created and the potential inability of consumers to identify the nature of a product with *certainty* if there was no legal protection for 'milk terms'.⁶⁰⁷ This argument could be extended by proponents of the ban to justify similar restrictions on the meat sector but it is debatable whether it

⁵⁹⁹ Ibid art 6(1)(a)-(g)

⁶⁰⁰ Ibid art 7(1)-(2)

⁶⁰¹ Ibid art 11(1)

⁶⁰² An Economic Analysis of the Law of False Advertising (n.599) 531

⁶⁰³ Ibid 530

⁶⁰⁴ Cell-based meat: Current ambiguities with nomenclature (n.314) 4

⁶⁰⁵ Hope Johnson, Christine Parker and Brodie Evans, "'Don't mince words': analysis of problematizations in Australian alternative protein regulatory debates" [2023] 40 Agriculture and Human Values 1581, 1590

⁶⁰⁶ Case C-422/16 (n.346) para 44

⁶⁰⁷ Ibid

is strong enough to solidify their position. First of all, it is not necessarily aligned with previously settled case-law.⁶⁰⁸ According to the CJEU, in cases where it has to be decided whether food information provided to consumers are misleading or not, the Courts ought to take into consideration the expectations of the so-called average consumer, which has been defined as the "*reasonably well-informed and reasonably observant and circumspect*"⁶⁰⁹ consumer. The EC has similarly stated that a commercial practice may be considered as misleading if the information provided to consumers under the FIC Regulation "*can be considered likely to cause the average consumer to take a transactional decision he or she would not have taken otherwise*".⁶¹⁰ For the moment, there is no reason to believe that the average consumer cannot comprehend the meaning of a label including a 'meat term' to describe an alternative source of protein. For instance, the UK's Energy and Environment Sub-Committee has stated that less than 4% of consumers have ever unintentionally bought vegetarian products, while, the US Cattlemen's Beef Association has stated that 7% of US consumers believe that plant-based beef contains meat.⁶¹¹ Furthermore, the Australian Competition and Consumer Commission has stated that, from January 2020 to June 2021, the complaints received concerning the labelling of meat substitute products, amounted to 0.003% of the total complaints.⁶¹²

At the same time, national courts have ruled against the idea that 'meat terms' are by nature misleading way before the debate concerning the labelling of alternative proteins became so prevalent. For example, the '*Verwaltungsgericht Gelsenkirchen*', or the Gelsenkirchen Administrative Court, located in the state of North Rhine-Westphalia, Germany, was asked to evaluate the alleged misleading effect of the use of certain 'meat terms' on substitute products in 2012.⁶¹³ In case n° 19 L 145/12, the German Court was asked to assess whether a number of claims presented on food labels, most

⁶⁰⁸Ban on Designating Plant Products as Dairy: Between Market Regulation and Over-Protection of the Consumer (n.289) 173

⁶⁰⁹ Case C-210-96 - *Gut Springenheide and Tusky v Oberkreisdirektor des Kreises Steinfurt* [1998] ECLI:EU:C: 1998:369, para 31

⁶¹⁰Commission Notice on the application of EU food and consumer protection law to issues of Dual Quality of products — The specific case of food [2017] 2017/C 327/01, 3

⁶¹¹ UK Parliament, 'Lords find no evidence "vegetarian burgers" are misleading for consumers' (UK Parliament) <<https://www.parliament.uk/business/lords/media-centre/house-of-lords-media-notices/2019/july-2019/lords-find-no-evidence-vegetarian-burgers-are-misleading-for-consumers/>> Accessed 9 February 2024; Consumer preferences for farm-raised meat, lab-grown meat, and plant-based meat alternatives: Does information or brand matter? (n.579) 11

⁶¹² "Don't mince words": analysis of problematizations in Australian alternative protein regulatory debates' (n.608) 1590

⁶¹³ VG Gelsenkirchen, 19 L 145/12, 2012, 10611

importantly the term '*W. Schnitzel fleischfrei*' [meat-free Schnitzel], was misleading and, thus, unlawful to use under national food labelling requirements.⁶¹⁴ In their judgement, the German Court initially mentioned that this type of product is neither legally defined nor has been traditionally marketed under a customary name. Therefore, the product shall be marketed under a name that adequately described its ingredients and specific characteristics.⁶¹⁵ According to the Court, this requirement was fulfilled by the company, since they displayed on the packaging the phrase '*Panierter Bratling aus Milch*' [breaded patty from milk], which clearly indicated the nature of the product. Moreover, this information was presented in German and in a clear and legible manner, while also taking up a prominent space on the label. The Court also highlighted that the terms '*Schnitzel*' and '*fleischfrei*' [meat-free] were in close proximity to each other, thus enabling consumers to understand that the product did not contain any meat.⁶¹⁶ In light of the aforementioned, the German Court deemed that the information provided by the brand and the packaging of the product were not misleading.⁶¹⁷ The Court finally highlighted that, in such cases, the name of the food shall not be examined in isolation, but the overall presentation of the food should be taken into consideration, which serves as a good starting point from where the evaluation of a label should take off.⁶¹⁸ Undeniably, the mere use of words like 'steak' or 'nugget' will give off the impression of a product containing meat. However, if FBOs ensure that they provide clarifying information in a comprehensible and easily detectable manner, the likelihood of confusion may significantly drop.

6.3. Ethical & Environmental Considerations

In general, ethics is a philosophical concept questioning the moral standing of human conduct. In other words, ethics aims at differentiating between the concepts of 'right' and 'wrong' and determining how people should act based on a set of moral values.⁶¹⁹ In regards to food labelling, ethics could relate to the provision of accurate, clear and trustworthy information to consumers, respecting their autonomy in decision making and enabling them to consume foods that are aligned with their dietary needs

⁶¹⁴ Ibid para 10

⁶¹⁵ Ibid para 18

⁶¹⁶ Ibid para 24-26, 34

⁶¹⁷ Ibid para 27,29

⁶¹⁸ Ibid para 32

⁶¹⁹ Nina Veflen and Diána Bánáti, Chapter 54 - Ethics in Food Safety Management. in Veslemøy Andersen, Huub Lelieveld and Vasmirine Motarjemi (ed), Safety Management - A Practical Guide for the Food Industry (Academic Press 2023), 1082

and moral values.⁶²⁰ Therefore, besides being legally obligated to not mislead the consumer, FBOs are also under a moral responsibility to ensure transparency through their labels.

In regards to alternative proteins, this moral obligation can relate to two things; the use of terms like 'vegan' and 'vegetarian' and the use of 'meat terms'. First of all, in the absence of legal definitions for these terms on EU and national level, FBOs can follow a third-party certification scheme concerning these products, which entail specific manufacturing and labelling requirements. In this way, they can ensure the quality and characteristics of their products through recognizable logos and labels that consumers value and trust. However, FBOs should not try to conceal specific aspects of their products that could otherwise deter consumers from purchasing them. For example, certain vegan labels allow the accidental contamination of substitute products with components of animal origin. In such an event, FBOs are under a moral obligation to disclose the names of said contaminants so as to not provide misleading information concerning the actual components of the product. A great number of consumers are not willing to accept any level of contamination on vegan and vegetarian products and by not disclosing all relevant information, FBOs are stripping consumers of their right to make informed choices. As far as 'meat terms' go, their intentional misuse may indeed lead to confusion and manipulate consumers into purchasing an item that they would not otherwise. For example, if a FBO is marketing their substitute product under a 'meaty' denomination like 'sausage' while concealing that it does not contain meat in an effort to attract more consumers, then their product will most likely also be considered as misleading from an ethical point of view.

In general, FBOs are morally responsible to use product names with prudence and care in order to strike a balance between respecting their legal obligations, ensuring consumers' right to information and branding their products. Labelling is a great tool to convey information to consumers and enable them to purchase products that are aligned with their views and values but it should not be used in a predatory or misleading manner, even if the legal framework has not sufficiently covered the subject in question. FBOs should enforce ethical decision-making practices that align with their target audience's values and consumption patterns and evaluate accordingly the trade-off between risks and benefits.⁶²¹ Building a trusting relationship between the company

⁶²⁰ Christian Coff and others, *Ethical Traceability and Communicating Food* (Springer 2008), 238; Nordic Council of Ministers, *Ethical Labelling of Food* (ANP 2004:741, Nordic Environmental Labelling, 2004), 37-38

⁶²¹ Chapter 54 - Ethics in Food Safety Management (n.622) 1086

and consumers is of paramount importance in order to establish new products into the market.

From an environmental perspective, consumers are showing an increasing interest in the environmental impact of the food supply chain; hence the emergence of a great number of sustainability related claims.⁶²² The negative environmental impact of the livestock industry has been documented as a particularly important driver of the protein transition, with many consumers trying to reduce their meat consumption and turning to alternative or substitute products to meet their dietary needs.⁶²³ The intent to shift to other sources of protein with a better environmental profile, has caused an increase in sustainability related food labels which aim at increasing transparency, decreasing information asymmetry between consumers and manufacturers and promoting a specific aspect of a product, in the present case its lower environmental footprint, in order to attract more consumers.⁶²⁴ However, it has been shown that consumers are not always capable of interpreting correctly the elements of such labels and have the tendency to overestimate the positive effects of products containing such claims, creating a halo-effect around certain categories of foods.⁶²⁵ For instance, the use of the 'organic logo' has been shown to lead consumers to believe that the product is healthier and has a better sensory profile, while the use of eco-labels can increase consumers' willingness-to-pay a premium price for a product.⁶²⁶ In the absence of a uniform or well-established regulatory framework covering sustainability claims, this paves the way to the intentional or unintentional spread of misinformation that can deceive consumers in regards to the actual environmental impact of their food.⁶²⁷

In the context of alternative proteins and the use of 'meat terms' this phenomenon could translate to the misleading presentation of 'comparative environmental claims', with FBOs intentionally claiming that their substitute product has a lower or a better impact in comparison to the original product of animal origin, without being able to properly substantiate such a claim and thus not only confusing consumers but also

⁶²²Daniele Asioli and others, 'Sustainability-Related Food Labels' [2020] 12 Annual Review of Resource Economics 171, 172

⁶²³ Joop deBoer, and Harry Aiking, 'EU consumer awareness of food safety and healthy diets: Are there synergies to benefit a sustainable protein transition?' [2023] 111 Food Quality and Preference 104981, 6

⁶²⁴Sustainability-Related Food Labels (n.625) 172

⁶²⁵Ibid 176; Laura Daniuseviciute-Brazaite, 'Education for Sustainable Development: Sustainability-Related Food Labels' [2021] 13 Sustainability 8117, 1

⁶²⁶ Sustainability-Related Food Labels (n.625)176, 179

⁶²⁷ Ibid 176

putting the traditional farming industry at a disadvantaged position.⁶²⁸ For example, a FBO should not somehow imply that a 'vegan sausage' has a lower environmental impact compared to its original counterpart only because the product is of plant-based origin. According to the Green Claims Directive, comparative claims need to be properly substantiated through the use of comparable data between the two products in question covering the same aspects and stages along the supply chain, while taking into account all the relevant information in order to present the claim.⁶²⁹

6.4. Preliminary Conclusions

To conclude, in order to assess the impact of 'meat terms' on consumer perception, it is important to understand that it is a multifaceted issue that shall be evaluated through different lenses, in order to grasp its essence as a whole. Some of the aspects that have been examined in this chapter refer to ethical, environmental, social, economic and legal considerations.

Social studies have shown that consumer perception of alternative sources of protein can be affected by multiple factors ranging from their intrinsic properties to extrinsic characteristics. For the moment, the available academic literature is lacking and, therefore, it is not easy to draw concrete conclusions concerning the misleading effect of the use of 'meat terms' on substitute products. Even though the current assumption is that the use of 'meat terms' is even sought out by consumers in order for them to better identify substitute products, more targeted research is evidently required in order to better understand consumer trends occurring in specific populations, under specific circumstances.

From an economic perspective, it is apparent that FBOs can be incentivized to deceive consumers in an effort to increase their sales and profits. However, in the current regulatory environment surrounding food labels, it sounds counterproductive to try and manipulate the system into misleading consumers in order to have financial gains, especially as a SME, due to legal, financial and reputational losses.

From a legal perspective, even though proponents of limiting the available nomenclature are eager to impose regulatory bans and restrictions in the name of consumer protection, there is currently no strongly backed evidence showing that further regulatory action limiting the use of 'meat terms' on substitute products is needed. This idea was also reinforced by national courts more than a decade ago, which

⁶²⁸ Proposal for a Green Claims Directive (n.332) rec 27

⁶²⁹ Ibid art 4(1)

raises questions in regards to the actual motives behind the intent to ban the use of 'meat terms'.

From an ethical perspective, FBOs are, on one hand, required to do their due-diligence and enable consumers to make informed and rational choices that align with their views and moral values. Even though FBOs might not always show interest in doing so, the current EU regulatory framework is quite stringent; thus, potentially deterring FBOs from engaging in unethical practices in regards to food labelling.

From an environmental perspective, the lack of a fully formed regulatory framework covering the use of environmental claims on food labels has led to an increase in the number of unsubstantiated and misleading claims, with consumers being unable to properly identify the nature and meaning of said claims. The Green Claims Directive, as well as the Sustainability Labelling Framework, might provide more clarity in this regard and stop the proliferation of such fraudulent practices.

Discussion

This thesis examined the regulatory environment that surrounds alternative proteins in the EU and aimed at evaluating whether it has the capacity, at its current form, to address their labelling. To assess this situation, the thesis tackled a series of subquestions that captured the greater technological, societal, regulatory and political landscape covering the protein transition. The main key findings of each chapter, as well as their relevance to the main research question, are expanded below.

Chapter 1: What are alternative proteins and how are they categorized?

Alternative proteins cover a wide range of products, from plant-based foods and fungi to insects and lab grown meat. The main issue with many of these products is that they are at an embryonic developmental stage and, therefore, their potential from a(n), *inter alia*, technological, nutritional, environmental and ethical perspective, has only been evaluated on a small-scale. As a result, it is not easy to predict how well they will fare within the EU market or how effective they will be in enabling the protein transition.

Furthermore, alternative proteins are currently associated with high manufacturing costs, suboptimal production methods, low resemblance to meat and low consumer acceptance. In order to get a better understanding on how to address this complex situation and come up with effective solutions, it is necessary to engage in more intensive research. It is also important that FBOs are enabled to invest in innovative technologies through targeted incentives and policies, something which has already been envisioned in the F2F Strategy and the EU Green Deal.

Last but not least, it is necessary to properly address consumer perception and understanding over these products. The thesis showed that consumers are generally reluctant to try new foods, especially when they are associated with unknown technologies. This negative perception may be tackled through a number of actions, namely educating consumers on the safety and nutritional value of such products, investing in truthful and accurate certification programs that enable consumers to buy products that match their expectations and values and increasing their trust in the food supply chain through transparent traceability systems and fair commercial practices.⁶³⁰

⁶³⁰Shahida Anusha Siddiqui, 'Avoiding Food Neophobia and Increasing Consumer Acceptance of New Food Trends—A Decade of Research' (2022) 14(16) Sustainability 10391, 18

Chapters 2 & 3: How can alternative proteins be marketed and labelled in the EU?

In order to properly assess the regulatory environment surrounding the marketing and labelling of alternative proteins, it is important to investigate safety and sustainability elements separately, since they are not equally covered and relate to different areas of consumer protection.

In general, there are no regulations targeting alternative proteins exclusively. However, the results of the thesis have shown that the current EU regulatory framework is quite extensive and detailed, thus covering most aspects related to the marketing and labelling of safe food and by extension safe meat substitutes. The GFL, the FIC Regulation, as well as other more specific Union provisions, have managed, for the most part, to achieve their main objective, namely consumer protection, without major implications.⁶³¹ Furthermore, the stringent authorization procedures, the rigorous safety assessments and the explicit marketing and labelling requirements have managed to ensure that most foods circulating the EU market are safe and adequately labelled. However, this highly technical nature of the EU regulatory framework has been labelled as extremely time consuming and financially burdensome by multiple stakeholders.⁶³² Therefore, it may be suggested that simplification of current procedures and adequate guidance of both FBOs and consumers should be prioritized over the adoption of more regulations specifically covering a niche part of the market.⁶³³

With that being said, it is important to highlight that one particular aspect related to the labelling of alternative proteins seems to be more problematic and might require political intervention and action. This issue refers to the name under which alternative proteins may be legally sold and the potential to use terms traditionally associated with the meat industry. So far, the EC has not provided any concrete guidance in that area and FBOs have occasionally found themselves unable to make proper labelling decisions, as shown by some of the established case law presented in this thesis. On one hand, it would probably be unreasonable and counterproductive to lobby in favor of a completely new labelling framework covering only these products, since no justifiable reason warranting the adoption of such regulations has been identified, the

⁶³¹ Fitness check of General Food Law (n.225); Commission Staff Working Document - The Refit Evaluation of The General Food Law (Regulation (EC) No 178/2002) [2018] SWD (2018) 38 final, 85, 114

⁶³² Fitness check of General Food Law (n.225)

⁶³³ Commission Staff Working Document - The Refit Evaluation of The General Food Law (n.633) 105-106

law-making procedure would be too time consuming and FBOs would be burdened to follow additional requirements; thus, further perplexing the regulatory environment. On the other hand, it has become clear that clarifications are needed that may hopefully come from the CJEU and their upcoming judgement on the labelling of meat substitutes, as described in Chapter 5. At the same time, another viable solution to tackle this issue could be the adoption of an implementing act concerning vegan and vegetarian products, something which the EC has been expected to deliver since the conception of the FIC Regulation. As a result, adequate definitions for meat and dairy substitute products could be put in place, FBOs could have solid guidance and clear obligations all along the manufacturing and marketing process, consumers could feel more confident in their purchasing decisions and the debate surrounding the use of 'meat terms' and their alleged misleading effect could be put to rest.

Moreover, it is important to note that it is debated whether the aforementioned regulatory framework can adequately address the marketing and labelling of lab-grown meat. Even though there is currently no reason to suspect that the Novel Foods Regulation is unable to process its authorization, something which has also been supported by the EC, participants of the January 2024 Agriculture and Fisheries Council raised their concerns in regards to the legal status of lab-grown meat and asked the EC to conduct a thorough impact assessment in order to address the situation.⁶³⁴ It is currently unknown how the EC will respond to the considerations of EU institutions and Member States and how, or even if, the first authorization will take place. More nuanced, targeted and open-minded research is necessary to evaluate, *inter alia*, the societal, technological, environmental and health impact of cultivated meat in order to properly process its integration into the EU regulatory framework.

In regards to sustainability, the current regulatory framework seems lackluster when it comes to addressing environmentally and ethically related concerns. This was also highlighted by the EC during a fitness check of the GFL.⁶³⁵ The environmental and ethical impact of the food supply chain is a newly founded issue that has recently started to take up space in political conversations. As a result, this has been uncharted territory and is creating space for arbitrary actions and the proliferation of misleading commercial practices. The EC is taking steps in addressing these concerns but it remains to be seen how they will be practically resolved through, *inter alia*, the Green Claims Directive, the

⁶³⁴ E-001778/2023 Answer given by Executive Vice-President Vestager on behalf of the European Commission (2 August 2023)

⁶³⁵ Fitness check of General Food Law (n.225)

Sustainable Food Systems Regulation and the Sustainability Labelling Framework and what kind of impact they will have on the alternative protein sector.

Chapter 4: How has the EU dealt with similar situations and what impact does that have on the alternative protein market?

This chapter showed that the labelling of dairy substitutes has been equally complicated. Even though the dairy sector is strictly defined and regulated, the labelling of dairy substitutes required an intervention from the CJEU. In *Tofutown*, the CJEU chose to follow a conservative route and impose limitations on dairy alternatives. Even though it was stated that the meat sector is not comparable to the dairy sector, their decision had a significant impact on the former, which translated into legal uncertainty, as well as the subsequent adoption of national laws restricting their labelling. This shows that the political and regulatory environment between sectors is highly intertwined and each action can have significant consequences on sectors that, at first glance, are seemingly unrelated. Therefore, caution and due care is needed when addressing such polarizing situations. At the moment, it remains to be seen whether the CJEU will follow the same reasoning on their upcoming judgement concerning the labelling of meat substitutes and the use of 'meat terms' on alternative proteins.

Chapter 5: How are Member State laws approaching the labelling of alternative proteins?

The case studies showed that Member States can have very opposing views in regards to the labelling of alternative proteins. On one hand, the more conservative approaches generally invoked the need to ensure consumer protection but did not necessarily provide any concrete evidence showcasing the need to impose such bans and limitations. This situation raises questions concerning the actual motivations behind such measures and potentially uncovers the wish to retain the status-quo for the benefit of certain actors. At the same time, issues regarding the enforceability of such measures are prominent and more light will be shed after the judgement of the CJEU on the matter. On the other hand, the more liberal approaches reserved themselves and only went as far as providing guidance documents enabling the use of 'meat terms'; thus, having a voluntary nature and allowing FBOs to diverge from their provisions. These differences in the approaches of different Member States uncovered the negative impact of the constant fragmentation of the EU labelling framework that potentially overshadows the benefits of adopting national measures on the matter and shows that

unifying actions and harmonization could work for the benefit of both consumers and FBOs.

Chapter 6: Does the use of meat related terms on the labelling of alternative proteins have the potential to mislead the consumers?

This Chapter showed that misleading practices can occur in different manners and from different perspectives. However, a well-structured and robust regulatory framework can mitigate unfair commercial practices and consumer deception. In general, it seems that there is not enough evidence to support the argument that consumers do not have the capacity to understand labels bearing 'meat terms' and that they are being misled. The evidence from the literature is scarce and more research is required in order to assess and evaluate the correlation between consumer deception and the terminology used on food labels. Therefore, it is assumed that, at the moment, no strong reason warranting the need for additional regulatory restrictions and limitations is present. However, this might not be the case concerning ethical and environmental claims. In the thesis it was shown that consumers do not always have the ability to assess claims relating to the environmental and ethical impact of the food supply chain and FBOs tend to present misleading claims, either intentionally or unintentionally. This could be attributed to the lack of a harmonized regulatory framework covering this aspect and the limited knowledge that people have on the concept of sustainability. The adoption of the Green Claims Directive and the Sustainability Labelling Framework is expected to provide more clarity.

Conclusions & Recommendations

To sum up, the alternative protein sector seems to be rapidly expanding, thus also creating growing needs within the EU market. This thesis analyzed the current EU regulatory framework covering these products and evaluated whether it is fit-for-purpose in order to address their labelling. Tying it back to the main research question, it is supported that the EU regulatory framework has the capacity to adequately address *certain* aspects concerning the labelling of alternative proteins, while others might benefit from future regulatory and policy action. Most aspects related to food safety seem to be adequately covered and, therefore, a more targeted framework would most likely be considered counterproductive. However, aspects related to the name used to market such products, as well as environmental and ethical claims have proven to be more difficult to manage under the current regulatory regime.

In order to adequately address the aforementioned and provide effective solutions, there is a number of actions that both FBOs and policymakers could take. On a European level, the EC could adopt definitions and specifications concerning the manufacturing and marketing of vegetarian and vegan products in order to provide additional clarity in regards to the labelling of meat substitutes. Moreover, the upcoming sustainability labelling framework is expected to promote consumer protection and ensure that ethical and environmental claims made on food, and consequently alternative proteins, are properly regulated. Furthermore, the EU could take other, non-regulatory actions, in order to enable the protein transition. For instance, practical incentives could be offered to producers and FBOs, in order to increase and facilitate their operations in the alternative protein sector. For instance, the EU institutions could offer financial support to alternative protein farmers and FBOs, reduce taxes on producers employing environmentally friendly and ethical practices, simplify the current authorization procedures and reduce administrative and financial burdens that are tied to the relevant pre-market authorizations. At the same time, the EU could empower EFSA to engage in further scientific and safety assessments of alternative proteins, as well as invest in research and innovation programs, such as the EU Horizon, in order to address the technological, environmental and ethical impact of alternative proteins and evaluate consumer understanding and acceptance. Last but not least, the upcoming decision of the CJEU is also expected to provide more clarity on the use of meat terms on substitute products and the potential of Member States to adopt national labelling laws.

On a national level, Member States could engage in international discussions in order to address the alternative protein sector, increase cooperative action, bridge

cultural and societal differences in meat consumption patterns, reward innovation and promote harmonization. The adoption of national laws that are restricting trade, hindering the free movement of goods and put a whole sector at a disadvantage should be avoided. Furthermore, Member States should ensure, through proper official controls and proportionally strict sanctions, that misleading practices are avoided and consumer protection is ensured. Finally, they could, in collaboration with consumer organizations, fund educational programs which would, on one hand, help consumers identify the key characteristics of substitute products and understand their potential nutritional and environmental benefits and, on the other hand, recognize and reject unsubstantiated and potentially misleading claims.

On a business level, FBOs shall firstly ensure that they abstain from misleading and fraudulent practices and adhere by all relevant regulatory demands, in order to cultivate consumer trust and grow a steady customer base. Secondly, they shall be mindful of the terms used on their labels and the way they are describing the nature and properties of their products, in order to ensure that the information presented is easily comprehensible, legible and truthful. The inclusion of other explanatory information in regards to, *inter alia*, cooking and preparation methods, the nutritional value and composition of their products and their intended use can also contribute to consumer protection. Thirdly, FBOs could organize marketing and advertising campaigns, for example through the use of QR codes on their labels providing additional information, in order to promote alternative proteins and increase consumer understanding and acceptance. Last but not least, producers could organize themselves and start lobbying in favor of a more liberal regulatory environment that enables the protein transition and does not set redundant labelling restrictions.

In conclusion, the implementation of a new food system that is shifting away from traditional production and consumption patterns is a challenging task that can only be successful through collaborative action between all relevant stakeholders, open communication, transparency and an overall open-minded approach.

Limitations

First of all, the regulatory analysis conducted is not exhaustive, meaning that very specific aspects of the EU and national legislative framework covering the marketing and labeling of alternative proteins were examined. The conclusions drawn in this thesis are limited to these regulatory and policy instruments.

Furthermore, the case studies evaluated only 4 Member States of the EU; thus, reflecting only on their respective regulatory and policy actions. They have provided an insight on the actions of specific actors involved in the alternative protein sector. Based on these results, it is not possible to make generalizations and draw conclusions for the EU as a whole concerning the political and societal environment surrounding alternative proteins.

Last but not least, the thesis is tackling an ongoing situation and therefore it is not possible to have the full picture and draw concrete conclusions. A significant portion of the current policy initiatives that surround alternative proteins have yet to be adopted. Future research is going to shed more light on the actual potential and impact of alternative proteins.

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