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Sofia Camorani

The rise of alternative proteins: legal challenges

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Faculty of Law
Maastricht University
Postbox 616
6200 MD
Maastricht
The Netherlands

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Alternative proteins could have an important role in the transition towards healthier and more sustainable food systems, contributing to fight increasingly pressing global challenges such as food security and environmental sustainability. In order to harness their potential and equally ensure food safety, the legal framework is of paramount importance. This thesis explores the EU legal framework applicable to alternative proteins, aiming to investigate its adequacy to regulate these foods. It focuses specifically on plant-based alternatives to meat and dairy, cultured meat, edible insects and algae. To do so, it first provides the necessary definitions and examines the reasons for which alternative proteins are relevant in the current EU context. Subsequently, it analyses the EU legal framework which applies to the four types of alternative proteins considered: respectively for plant-based alternatives to meat and dairy, cultured meat, edible insects and algae, this work provides an overview of the applicable EU laws, to understand the structure and functioning of the regime which regulates these foods, and then describes the legal questions that can be raised about it, e.g., the existence of some regulatory gaps, uncertainties and fragmentation. In conclusion, considering the many legal questions that can be identified, it is argued that the EU legal framework could need some changes and clarifications in order to more adequately regulate the current and future developments of alternative proteins.

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Chapter 1: Introduction

The European Green Deal¹ is the package of policy initiatives proposed by the European Commission in 2019 with the goal to move the EU economy and society towards a more sustainable path and the ultimate aim of reaching climate neutrality by 2050.² The action plan foresees intervention in all policy areas; one of the pillars is the Farm to Fork Strategy, which aims at creating a fair, healthy and environmentally-friendly food system.³ Alternative proteins have the potential of being an important factor in this green transition, and in fact it is announced in the Farm to Fork Strategy that a key area of research will be related to increasing the availability and source of alternative proteins.⁴ The strategy also mentions the importance of shifting to a more plant-based diet with less red and processed meat and more fruits and vegetables, as current diets of European consumers are unsustainable both in terms of health and of the environment.⁵ Moreover, to reduce dependency on critical feed materials, the Commission envisages to foster EU-grown plant proteins and alternative feed materials, among which insects and algae.⁶

The regulatory environment is of paramount importance for the EU to harness the potential of alternative proteins, all the while guaranteeing food safety and quality. Firstly, the legal framework needs to pursue, as the general principles of EU food law provide, “a high level of protection of human life and health and the protection of consumers’ interests (...), taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment”.⁷ This includes providing consumers a basis to make an informed choice with regard to the food they eat.⁸ Moreover, the clarity and structure of the regulatory framework affect legal certainty, and hence indirectly food operators, and could also impact the free movement of these products in the internal market.

¹ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, COM (2019) 640 final, Brussels, 11.12.2019.

² “European Green Deal”, European Council and Council of the European Union, accessed August 9, 2023, <https://www.consilium.europa.eu/en/policies/green-deal/>.

³ European Commission, 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, Brussels, 20.5.2020.

⁴ European Commission, “The Farm to Fork Strategy – Publication”, p. 16, available at https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en.

⁵ European Commission, “The Farm to Fork Strategy – Publication”, p. 14.

⁶ European Commission, “The Farm to Fork Strategy – Publication”, p. 10.

⁷ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, *OJ L 31*, 1.2.2002, p. 1-24, as lastly amended by Regulation (EU) 2019/1381, Art. 5, para. 1.

⁸ Regulation (EC) No 178/2002, as lastly amended by Regulation (EU) 2019/1381, Art. 8.

At the current stage, different EU laws are applicable depending on the alternative protein analysed in this thesis (plant-based alternatives, cultured meat, edible insects, algae). Food safety is ensured through the General Food Law Regulation⁹ and the Novel Food Regulation¹⁰ (and possibly the GMO food Regulation¹¹). However, the regulatory context includes many other pieces of legislation that concern aspects of the production and marketing of these products, such as naming and labelling, cultivation, animal welfare and hygiene rules, which generate legal questions. These questions relate to existing legal gaps (e.g., there is a lack of uniform safety rules with regard to heavy metals and toxins in algae food products¹²), laws not intended to regulate these new foods (e.g., EU rules on food hygiene do not have specific rules for foods made of insects¹³), fragmented systems (e.g., labelling rules for plant-based dairy alternatives are different from the ones for plant-based meat alternatives¹⁴), uncertainties (e.g., the nomenclature of cultured meat is not defined¹⁵).

Therefore, this thesis aims to understand whether the current EU regulatory framework is adequate to regulate these new products, in light of the role that they could have in the transition to a more sustainable and healthy food system foreseen by the European Green Deal. This research is important because, if the EU will want to rely on these alternative sources of protein in the near future, there is a pressing need of having a legal framework which is at least clear and comprehensive.

Consequently, the research question for this thesis is: “To what extent is the EU legal framework sufficiently adequate to regulate the current and future developments of alternative proteins?”. This question includes different sub-questions, i.e., to what extent the EU regulatory framework addresses alternative proteins, whether there is legal certainty in all of the aspects that concern the placing on the market of alternative proteins, from food safety to production and labelling, whether fragmentation is present in the legal regime and how this, in case,

⁹ Regulation (EC) No 178/2002, as lastly amended by Regulation (EU) 2019/1381.

¹⁰ 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 (Text with EEA relevance), *OJ L 327*, 11.12.2015, p. 1-22, as lastly amended by Regulation (EU) 2019/1381.

¹¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Text with EEA relevance), *OJ L 268*, 18.10.2003, p. 1-23, as lastly amended by Regulation (EU) 2019/1381.

¹² Anu Lähteenmäki-Uutela *et al.*, “European Union legislation on macroalgae products”, *Aquaculture International* 29 (2021), p. 503, <https://doi.org/10.1007/s10499-020-00633-x>.

¹³ Anu Lähteenmäki-Uutela and Nicole Grmelová, “European Law on Insects in Food and Feed”, *European Food and Feed Law Review* 11, no. 1 (2016), p. 4.

¹⁴ Anu Lähteenmäki-Uutela *et al.*, “Alternative proteins and EU food law”, *Food Control* 130 (2021), pp. 6-7, <https://doi.org/10.1016/j.foodcont.2021.108336>.

¹⁵ Antony Froggatt and Laura Wellesley, “Meat Analogues: Considerations for the EU”, Chatham House, 2019, p. 28.

relates to the internal market, and to what extent the current laws guarantee consumer protection, both in terms of health and provision of information.

The thesis will start with a description of what alternative proteins are and why they are important in the current European context. Subsequently, the following four chapters will provide an overview of the applicable EU laws and the identified legal questions concerning, respectively, each of the four alternative proteins considered in this work. More specifically, the second part of these four chapters has the aim of analysing whether the regulatory regime can be considered problematic in some aspects and will highlight, inter alia, the possible existence of regulatory gaps, uncertainties and legal acts arguably in need of revision, which will lead to the final conclusions.

The research method chosen for this work is a doctrinal legal analysis, for which primary and secondary legal sources were used. However, an inter-disciplinary perspective also shaped this thesis, as sources such as literature and reports covering scientific aspects were relevant for a thorough understanding of the topic.

Chapter 2: Alternative proteins in the European Union

The rise in interest in alternative proteins can be linked to the parallel escalation of global challenges in terms of food demand and food production¹⁶ and to the increase in the past decades of public awareness of health, animal welfare and environmental sustainability,¹⁷ as they can contribute to face these demands. This chapter aims to shed light on what alternative proteins are and the importance they can have. Therefore, firstly, a definition of alternative proteins will be provided, analysing more specifically the four types of protein sources that will be addressed by this thesis. This first part will be followed by an analysis of the reasons that explain the increased attention to alternative proteins and, more specifically, of how the European Union collocates them in its priorities.

2.1. A definition of alternative proteins

Alternative proteins are a branch of bioeconomy that includes different elements.¹⁸ There is no single classification of alternative proteins: a broad categorisation could include whole plant

¹⁶ Simone Belluco, Afton Halloran and Antonia Ricci, "New protein sources and food legislation: the case of edible insects and EU law", *Food Security* 9 (2017), p. 803, <https://doi.org/10.1007/s12571-017-0704-0>.

¹⁷ Clara Frezal, Claude Nenert and Hubertus Gay, "Meat protein alternatives: Opportunities and challenges for food systems' transformation", *OECD Food, Agriculture and Fisheries Papers*, no. 182 (2022), OECD Publishing, Paris, p. 7, <https://doi.org/10.1787/387d30cf-en>.

¹⁸ "Alternative proteins top of the bill for the latest FAO – International Sustainable Bioeconomy Working Group webinar", Sustainable and circular bioeconomy for food systems transformation, Food and Agriculture Organization of the United Nations (FAO), accessed on August 9, 2023, <https://www.fao.org/in-action/sustainable-and-circular-bioeconomy/resources/news/details/en/c/1507553/>.

proteins such as pulses, nuts or grains and traditional products such as tofu or seitan. A narrower classification comprises plant-based products that mimic animal products, microbial proteins, algae, cultured meat and edible insects.¹⁹ Products are being developed not only as alternatives to meat, but also to dairy, eggs and seafood.²⁰ However, this work will focus on the categories of processed plant-based alternatives to meat and dairy, cultured meat, edible insects (in particular for human consumption) and algae.²¹

Plant proteins used in alternative products to meat and dairy can be extracted from conventional plants such as soy, peas, nuts and cereals, from less traditional plants such as chia and rapeseed, or from grass and green leaves.²² Concerning more specifically meat alternative products, the term of plant-based alternatives can include both processed meat alternatives made of plants, such as veggie burgers, and a more recent set of plant-based alternatives that closely mimic meat as to its taste, colour, texture and nutritional characteristics.²³ Comparing to the conventional plant-based alternatives, this new category of products is made of new ingredients or uses innovative processes, with the aim of achieving a high degree of similarity to meat.²⁴ For instance, such artificial meat burgers or sausages, which are still based on plant ingredients such as soy or potato proteins, can “bleed” like meat

¹⁹ Frezal, Nenert and Gay, in “Meat protein alternatives: Opportunities and challenges for food systems’ transformation”, consider as meat alternatives also unprocessed whole food, as nuts and beans, and processed traditional food, including tofu, tempeh and seitan (in figure 3, p. 9). Moreover, they mention microorganisms-based alternatives, including algae, fungi or yeast. However, the report focuses on plant-based alternatives, insect-based alternatives and cultured meat (p. 8).

EIT FOOD, “Protein Diversification”, EIT FOOD White paper, Knowledge & Innovation Center on Food, part of the European Institute of Innovation and Technology (EIT), 2022 describes as examples of alternative proteins those from plants, algae, insects and ingredients produced with cellular agriculture (p. 7).

Lähteenmäki-Uutela *et al.*, in “Alternative proteins and EU food law”, consider in the analysis products of cellular agriculture, including single-cell proteins and cultured meat, plant-based alternative proteins, macroalgae foods and insect foods. The authors also indicate that pulses may be classified as alternative proteins (p. 4, see also p. 1).

The Farm to Fork Strategy mentions as examples of alternative proteins “plant, microbial, marine and insect-based proteins and meat substitutes” (European Commission, “The Farm to Fork Strategy – Publication”, p. 16).

²⁰ Frezal, Nenert and Gay, “Meat protein alternatives”, p. 8.

²¹ This thesis aims at providing an analysis of the EU legal framework and its possible problematic aspects in relation to the regulation of alternative proteins. In light of the many products which can fall under the definition of alternative proteins, it was necessary to narrow down the scope. Algae were considered of interest in this study as the European Commission explicitly stated in the Farm to Fork Strategy that they should become an important source of alternative proteins (see European Commission, “The Farm to Fork Strategy – Publication”, p. 12 and p. 16) and it also recently made a Communication for the algae sector (see note 36, p. 5). Insects for human consumption were included given the recent authorisations as novel foods, which makes them now more than ever a reality. The thesis also briefly touches upon the topic of insects as feed. Cultured meat is more in its infancy; however, including it in the scope of this thesis was, for this reason, considered necessary, in order to analyse the legal framework and understand whether it is ready for the introduction of this product on the EU market. Plant-based alternatives are a more established product category, which can however comprise several products. This work focused on processed plant-based alternatives to meat and dairy in view of the author’s willingness to concentrate on newer developments and of the richness of the literature.

²² EIT FOOD, “Protein Diversification”, p. 7.

²³ Frezal, Nenert and Gay, “Meat protein alternatives”, p. 9.

²⁴ Froggatt and Wellesley, “Meat analogues”, p. 6.

by using beetroot juice.²⁵ In turn, this new class of plant-based meat alternatives is also part of the subcategory of the so-called 'meat analogues', which in fact encompasses those unconventional protein sources that are created to be imitative substitutes of traditional meat products.²⁶ The other product considered a meat analogue is cultured meat, which is produced through tissue engineering based on animal cells.²⁷ Under this process, the selected cells are cultured in vitro to produce tissues (such as muscles), which are then processed into the desired meat product.²⁸

The production and commercialisation of insects differ in the world: while insects are part of the traditional diets in several countries of Asia, Africa and Latin America, it is not the same for North America and Europe.²⁹ However, their acceptance in western countries is slowing growing, also due to the pressing need of finding alternative sources of proteins and to the sustainability of their cultivation.³⁰ Insects can be exploited for human consumption, as a whole or as ingredient in processed products,³¹ or for animal feed. They are considered a particularly nutritious and healthy source of nutrients, among which protein; for instance, the protein content of mealworms is similar to that in fish and meat.³²

The category of algae covers both microalgae and macroalgae (also called seaweed).³³ Macroalgae are simple plant-like organisms that grow in the sea, rivers or lakes.³⁴ They have been used for food, feed and fertilizer for millennia and now they are used also in other sectors, such as for herbal medicines, cosmetics, packaging, biofuel.³⁵ The seaweed industry in Europe is, at the current stage, centred around the harvesting of macroalgae from the wild, rather than cultivation in aquaculture sites;³⁶ however, the European Commission underlined the necessity

²⁵ Astrid Seehafer and Martin Bartels, "Meat 2.0-The Regulatory Environment of Plant-Based and Cultured Meat", *European Food and Feed Law Review* 14, no. 4 (2019), p. 324.

²⁶ Froggatt and Wellesley, "Meat analogues", p. 6.

²⁷ Lähteenmäki-Uutela *et al.*, "Alternative proteins and EU food law", p. 4.

²⁸ Froggatt and Wellesley, "Meat analogues", pp. 7-8.

²⁹ Francesco Montanari, Ana Pinto de Moura and Luís Miguel Cunha, "Introduction", in *Production and Commercialization of Insects as Food and Feed: identification of the main constraints in the European Union* (Springer, Cham, 2021), p. 1.

³⁰ Laura Quintieri *et al.*, "Alternative Protein Sources and Novel Foods: Benefits, Food Applications and Safety Issues", *Nutrients* 15, no. 6 (2023), 1509, <https://doi.org/10.3390/nu15061509>.

³¹ EIT FOOD, "Protein Diversification", p. 9.

³² Arnold van Huis *et al.*, "Executive Summary", in *Edible insects: future prospects for food and feed security*, FAO forestry paper no. 171 (Rome: Food and Agriculture Organization of the United Nations, 2013), p. xiv.

³³ EIT FOOD, "Protein Diversification", p. 8.

³⁴ Lähteenmäki-Uutela *et al.*, "European Union legislation on macroalgae products", p. 487.

³⁵ Lähteenmäki-Uutela *et al.*, "European Union legislation on macroalgae products", p. 488.

³⁶ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Towards a Strong and Sustainable EU Algae Sector, COM (2022) 592 final, Brussels, 15.11.2022, p. 4.

of increasing regenerative algae cultivation and production.³⁷ Algae are considered a healthy and low-calorie food, and in particular some species are characterised by a very high protein content. Additionally, they can be beneficial in so far as the cultivation of seaweed can remove carbon and contribute to decreasing ocean acidification.³⁸

Microalgae also fit under the category of microbial proteins.³⁹ The latter covers alternative proteins produced through cellular agriculture with fermentation, using microorganisms.⁴⁰ The cultivation of microbial cell lines such as those from yeasts, fungi and bacteria is able to produce single-cell proteins, which can then be used to produce familiar animal products.⁴¹ For instance, a famous microbial protein meat-alternative product is Quorn, which is produced from the microprotein of a microfungus.⁴² Microalgae are unicellular, photosynthetic microorganisms, considered as a rich source of proteins, which can make up to 70% of the biomass dry weight for certain species of microalgae.⁴³ One of their main applications is in the food supplement and nutraceutical sector.⁴⁴ In the EU, market demand is growing for *Chlorella*, used as food or food ingredient, and *Spirulina*, used as food supplement.⁴⁵

2.2. Alternative proteins on the EU agenda

In the EU, food consumption patterns are unsustainable both in terms of health and of the environment,⁴⁶ obesity is rising and there is a high prevalence of diet-related diseases, including cancer.⁴⁷ At the same time, around the world we are facing an increasing human population and a reduction of natural resources, along with a growing demand for sustainable and healthy food,⁴⁸ which makes food security a crucial challenge of today.⁴⁹ Moreover, concerns over the sustainability of the agri-food production systems have been raised in the

³⁷ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Towards a Strong and Sustainable EU Algae Sector, p. 9.

³⁸ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Towards a Strong and Sustainable EU Algae Sector, p. 3.

³⁹ Lähteenmäki-Uutela *et al.*, "Alternative proteins and EU food law", p. 2. However, they will be considered under the category of algae in this thesis, as the latter will not cover microbial proteins.

⁴⁰ EIT FOOD, "Protein Diversification", pp. 7-8.

⁴¹ Lähteenmäki-Uutela *et al.*, "Alternative proteins and EU food law", p. 2.

⁴² Lähteenmäki-Uutela *et al.*, "Alternative proteins and EU food law", p. 3.

⁴³ Simona Lucakova, Irena Branyikova and Maria Hayes, "Microalgal Proteins and Bioactives for Food, Feed, and Other Applications", *Applied Sciences* 12, no. 9 (2022), 4402, <https://doi.org/10.3390/app12094402>.

⁴⁴ Anton Kuech, Marcus Breuer and Irina Popescu, "Research for PECH Committee – The future of the EU algae sector", European Parliament, Policy Department for Structural and Cohesion Policies, Brussels, 2023, p. 20.

⁴⁵ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Towards a Strong and Sustainable EU Algae Sector, p. 5.

⁴⁶ European Commission, "The Farm to Fork Strategy – Publication", p. 14.

⁴⁷ European Commission, "The Farm to Fork Strategy – Publication", p. 5.

⁴⁸ Quintieri *et al.*, "Alternative Protein Sources and Novel Foods".

⁴⁹ Belluco, Halloran and Ricci, "New protein sources and food legislation", p. 803.

last few decades, especially in view of the environmental impact of agriculture.⁵⁰ In particular, the livestock sector is highly problematic in terms of environmental footprint, which has increased the belief in the scientific communities that an excessive consumption of meat is no longer sustainable.⁵¹ Equally, this sector is characterised by concerns related to animal welfare and the relation between meat overconsumption and diet-related diseases.⁵²

The transition towards more sustainable, healthier and resilient food systems necessitates a decrease in demand of proteins derived from traditional animal products.⁵³ Insects, cultured meat and many other 'new' foods could be useful to decrease the consumption of certain foods linked with health issues, ensure more sustainable products and production methods and thus contribute to tackle the problems of food security and unsustainability of food production, and at the same time provide important nutrients.⁵⁴ Therefore, alternative proteins could contribute to the challenges of feeding a growing population, lowering the environmental and climate impact of food systems, all the while enhancing their resilience.⁵⁵ It must be noted that an alternative proteins' market expansion is not without obstacles; challenges can relate, inter alia, to their price and to consumer acceptance.⁵⁶ Moreover, the benefits that would derive from a larger use of alternative proteins would depend on the type of alternative protein source and on the type of product it would replace.⁵⁷ Equally, it remains to be seen whether all the promises that derive from their consumption will hold to be true. For instance, research on the nutritional impact of substituting meat with alternative proteins is still not exhaustive.⁵⁸

Nevertheless, alternative proteins are on the radar of the European Union, as it is evident in the Farm to Fork Strategy of the European Green Deal and the Europe's Beating Cancer Plan.⁵⁹ The European Green Deal has the main goal of making Europe climate-neutral by 2050 and delineates a growth strategy to boost the economy, improve people's health, care for nature and leave no one behind; one of its main strategies is the Farm to Fork, which addresses the challenges of sustainable food systems.⁶⁰ The strategy sets different ambitious goals, among which reducing the environmental and climate impact of the EU food system and

⁵⁰ Montanari, Pinto de Moura and Cunha, "Introduction", p. 9.

⁵¹ Froggatt and Wellesley, "Meat analogues", p. 3.

⁵² Froggatt and Wellesley, "Meat analogues", p. 3.

⁵³ EIT FOOD, "Protein Diversification", p. 5.

⁵⁴ Lucia Scaffardi and Giulia Formici, "Introduction: Feeding the Future Sustainably - What Role for Novel Foods and Edible Insects?", in *Novel Foods and Edible Insects in the European Union: an interdisciplinary analysis*, ed. Lucia Scaffardi, Giulia Formici (Springer, Cham, 2022), p. 4.

⁵⁵ EIT FOOD, "Protein Diversification", p. 5.

⁵⁶ Frezal, Nenert and Gay, "Meat protein alternatives", p. 3.

⁵⁷ Frezal, Nenert and Gay, "Meat protein alternatives", p. 4.

⁵⁸ Frezal, Nenert and Gay, "Meat protein alternatives", p. 3.

⁵⁹ European Commission, Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM (2021) 44 final, Brussels, 3.2.2021.

⁶⁰ European Commission, "The Farm to Fork Strategy – Publication", p. 4.

ensuring food security.⁶¹ In this context, increasing the availability and source of alternative proteins is firstly mentioned in the strategy as a key area of research, supported by the EU budget.⁶² Moreover, among the actions to facilitate the placing on the market of sustainable and innovative feed additives, the European Commission (hereinafter referred to as Commission) plans to foster alternative feed materials, including insects and algae.⁶³ With regard to algae, the strategy indicates that the Commission envisages to undertake support actions for the algae industry, as it considers that algae should become a principal source of alternative protein.⁶⁴

Finally, an essential element of the Farm to Fork Strategy is to promote sustainable food consumption and facilitate the shift to healthy and sustainable diets, as current European food habits negatively impact people's health and the environment. In this regard, the strategy also highlights the necessity of shifting to a more plant-based diet with less red and processed meat and more fruits and vegetables.⁶⁵ This element is also covered by the Europe's Beating Cancer Plan, which promotes healthy diets and physical activity as part of the actions for cancer prevention.⁶⁶ The plan was presented by the Commission in February 2021 and contains multiple actions and initiatives that will support, coordinate and complement Member States' effort to fight cancer.⁶⁷

2.3. Conclusions

In conclusion, the concept of alternative proteins includes different sources which are capable of providing this macronutrient; this work will consider plant-based alternatives to meat and dairy, cultured meat, edible insects and algae. Alternative proteins are currently in the spotlight as their use, especially as substitutes of traditional animal sources, could contribute to the resolution of some of the current global challenges, e.g., ensuring food security and environmental sustainability. In the EU, alternative proteins are mentioned in the Farm to Fork Strategy of the European Green Deal as a key area of research; in fact, they could play an important role in the transition towards a sustainable and healthier food system.

However, an important factor to take into account in this scenario is the legal framework, on which the attainment of several objectives is based. First, the legal framework is essential to

⁶¹ European Commission, "The Farm to Fork Strategy – Publication", p. 7.

⁶² European Commission, "The Farm to Fork Strategy – Publication", p. 16.

⁶³ European Commission, "The Farm to Fork Strategy – Publication", p. 10.

⁶⁴ European Commission, "The Farm to Fork Strategy – Publication", p. 12.

⁶⁵ European Commission, "The Farm to Fork Strategy – Publication", p. 14.

⁶⁶ European Commission, Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, p. 10.

⁶⁷ European Commission, Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, p. 2.

guarantee food safety and the protection of consumers' interests, considering, where appropriate, the protection of animal health and welfare, plant health and the environment, as indicated in the general principles of EU food law.⁶⁸ Moreover, it ought to be structured and comprehensive, with a view to ensure legal certainty, necessary especially for food operators. Equally, a possible complexity or fragmentation of the legal framework could negatively affect the expansion of alternative proteins in the EU market or even the free movement of these products. Thus, the following chapters will analyse the legislation of the European Union and the critical aspects it presents with regard to, respectively, the regulation of processed plant-based alternatives to meat and dairy, cultured meat, edible insects and algae.

Chapter 3: The legal framework of plant-based alternatives

3.1. Overview of EU legislation applicable to plant-based alternatives

Plant-based alternatives⁶⁹ are firstly regulated by the General Food law Regulation, the cornerstone of EU food law, which lays down general principles for food and feed as well as procedures for matters that impact food and feed safety and establishes the European Food Safety Authority.⁷⁰ The Regulation provides rules for all the stages of food and feed production, processing and distribution,⁷¹ establishing requirements for, inter alia, food safety, presentation and traceability.⁷² Moreover, plant-based alternatives must respect rules on the hygiene of foodstuffs under Regulation (EC) No 852/2004.⁷³ Other pieces of legislation can be equally applicable to plant-based alternatives;⁷⁴ two relevant laws that concern food safety are the

⁶⁸ Regulation (EC) No 178/2002, as lastly amended by Regulation (EU) 2019/1381, Art. 5, para. 1.

⁶⁹ As considered in this thesis, see section 2.1, pp. 3-4.

⁷⁰ Regulation (EC) No 178/2002, as lastly amended by Regulation (EU) 2019/1381, Art. 1, para. 2.

⁷¹ Regulation (EC) No 178/2002, as lastly amended by Regulation (EU) 2019/1381, Art. 1, para. 3.

⁷² By means of example, Art. 14 provides that food should not be marked if it is unsafe and establishes the conditions for which a food is considered as unsafe. Art. 16 provides that the labelling, advertising and presentation of food and feed shall not mislead consumers. Art. 18 states that the traceability of products shall be established at all stages of production, processing and distribution, and to this end it lays down rules. The Regulation also sets out the relevance of the precautionary principle in EU food law in Art. 7 as well as the rules for the Rapid Alert System, crisis management and emergencies in Chapter IV.

⁷³ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, *OJ L 139*, 30.4.2004, p. 1-54, as lastly amended by Commission Regulation (EU) 2021/382.

As set out in Art. 1, the Regulation applies "to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene", except for the cases set out in para. 2. The definitions of Regulation (EC) No 178/2002 apply (Art. 2, para. 2), therefore also the definition of 'food'. Regulation (EC) No 852/2004 sets out rules for food business operators on the hygiene of foodstuffs (Art. 1) and it provides the general obligation of ensuring that the hygiene requirements laid down in the Regulation are respected at all stages of production, processing and distribution of food (Art. 3). Inter alia, it provides rules for hazard analysis and critical control points (Art. 5) and official controls, registration and approval of establishments (Art. 6).

⁷⁴ This chapter did not include the entirety of the applicable laws, as these depend on the specific product. Other laws that can be relevant are, inter alia, Regulation (EU) 2023/915 on maximum levels for certain contaminants in food (see, for instance, the maximum level of lead for pulses) and Regulation (EC) No 1333/2008 on food additives, when these are present in the plant-based alternative.

Novel Food Regulation⁷⁵ and the GMO Regulation⁷⁶. The first establishes rules for the placing of novel foods on the EU market,⁷⁷ starting from requiring that “only novel foods authorised and included in the Union list may be placed on the market”.⁷⁸ The second establishes procedures for the authorisation, labelling and supervision of genetically modified food and feed.⁷⁹ If a product is considered a novel food as well, it nevertheless has to acquire an authorisation only under the GMO Regulation.⁸⁰ The applicability of the two depends on the specific type of plant-based alternative. In fact, pulses and many other plants that may be classified as alternative proteins⁸¹ are not considered novel foods in the EU, such as soybeans and peas;⁸² however, the final product of an extracted protein treated with novel methods can become a novel food.⁸³ Equally, the Novel Food Regulation is applicable, for instance, to plant-based meat alternatives if they contain novel ingredients.⁸⁴ As an example, mung bean protein is a plant-based food ingredient rich in protein, which has no history of consumption in the EU and has therefore been considered a novel food in the EU,⁸⁵ finally approved for marketing in the EU in 2022.⁸⁶ Regulation (EC) No 1829/2003 applies to GMOs for food use, food that contain or consist of GMOs, food produced from GMOs or that contain ingredients produced from GMOs.⁸⁷ Plant-based alternatives fall under the scope of this Regulation if, for instance, they contain plant ingredients extracted from genetically modified plants, such as products

⁷⁵ Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381.

⁷⁶ Regulation (EC) No 1829/2003, as lastly amended by Regulation (EU) 2019/1381.

⁷⁷ Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 1, para. 1.

⁷⁸ Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 6.

⁷⁹ Regulation (EC) No 1829/2003, as lastly amended by Regulation (EU) 2019/1381, Art. 1.

⁸⁰ Seehafer and Bartels, “Meat 2.0-The Regulatory Environment”, p. 326. Art. 2, para. 2(a) of the Novel Food Regulation provides that the Regulation does not apply to genetically modified foods which are within the scope of Regulation (EC) No 1829/2003.

⁸¹ As specified above, see section 2.1, pp. 3-4.

⁸² In fact, the definition under the Novel Food Regulation provides that ‘novel food’ “means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997” and that falls under at least one of the categories indicated in Art. 3, para. 2(a).

⁸³ Lähteenmäki-Uutela *et al.*, “Alternative proteins and EU food law”, p. 4.

Art. 3, para. 2(a)(vii) provides in fact that “food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances” is to be considered a novel food, as long as it also fulfills the other requirements of Art. 3, para. 2(a).

⁸⁴ Seehafer and Bartels, “Meat 2.0-The Regulatory Environment”, p. 325.

⁸⁵ Lähteenmäki-Uutela *et al.*, “Alternative proteins and EU food law”, p. 4.

⁸⁶ See Commission Implementing Regulation (EU) 2022/673 of 22 April 2022 authorising the placing on the market of mung bean (*Vigna radiata*) protein as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470, *OJ L 122*, 25.4.2022, p. 27-30.

⁸⁷ Regulation (EC) No 1829/2003, as lastly amended by Regulation (EU) 2019/1381, Art. 3, para. 1. Chapter III deals with genetically modified feed. For the definition of “genetically modified organism”, the Regulation refers in Art. 2, para. 5 to the organisms “defined in Article 2(2) of Directive 2001/18/EC, excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC”. With regard to genetically modified food, the Regulation provides for rules relating to, inter alia, the requirements that they must comply with, such as the prohibition of misleading the consumer (Art. 4), the authorisation process (Art. 5-7), supervision (Art. 9), modification, suspension and revocation of authorisations (Art. 10) and labelling (Art. 12-14).

based on soy proteins derived from a genetically engineered soy variety.⁸⁸ A discussed ingredient is leghaemoglobin, a molecule that contains iron which can be used in plant-based products to mimic meat:⁸⁹ leghaemoglobin is itself not a GMO, but it is produced with genetically modified yeast in fermenters.⁹⁰ The discussion therefore regarded whether leghaemoglobin and plant-based products which contain it need to be authorised under Regulation (EC) No 1829/2003.⁹¹ A GMO application was filed in the EU in 2019, but at the moment is still pending.⁹²

The Food Information to Consumers (FIC) Regulation⁹³ lays down the general principles, requirements and responsibilities concerning food information,⁹⁴ which apply to all categories of food products.⁹⁵ The rules on the name of the food are particularly relevant for plant-based alternatives.⁹⁶ In this regard, the Regulation provides that the name of the food must be the legal name,⁹⁷ defined as the name of the food prescribed by EU law or, in case there is no applicable provision, by the national law of the Member State in which the food is sold.⁹⁸ If such a name is absent, the customary name has to be used,⁹⁹ i.e., what is “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”.¹⁰⁰ If the customary name does not exist or is not used, a descriptive name of the food is to be employed,¹⁰¹ which means “a name providing a description of the food, and if necessary of its use, which is sufficiently clear to enable consumers to know its true nature and distinguish it from other products with which it might be

⁸⁸ Seehafer and Bartels, “Meat 2.0-The Regulatory Environment”, p. 327.

⁸⁹ Lähteenmäki-Uutela *et al.*, “Alternative proteins and EU food law”, p. 4.

⁹⁰ Seehafer and Bartels, “Meat 2.0-The Regulatory Environment”, p. 327.

⁹¹ Seehafer and Bartels, “Meat 2.0-The Regulatory Environment”, p. 327. See also Froggatt and Wellesley, “Meat analogues”, pp. 29-30 and Lähteenmäki-Uutela *et al.*, “Alternative proteins and EU food law”, p. 4.

⁹² See Lähteenmäki-Uutela *et al.*, “Alternative proteins and EU food law”, p. 4 and EFSA-Q-2019-00651 at <https://open.efsa.europa.eu/question/EFSA-Q-2019-00651>.

⁹³ 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 Text with EEA relevance, *OJ L 304*, 22.11.2011, p. 18-63, as lastly amended by Regulation (EU) 2015/2283.

⁹⁴ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 1, para. 2.

⁹⁵ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 1, para. 3 states that the Regulation applies “to food business operators at all stages of the food chain, where their activities concern the provision of food information to consumers” and “to all foods intended for the final consumer”.

⁹⁶ Annisa Leialohilani and Alie de Boer, “EU food legislation impacts innovation in the area of plant-based dairy alternatives”, *Trends in Food Science & Technology* 104 (2020), p. 262, <https://doi.org/10.1016/j.tifs.2020.07.021>.

⁹⁷ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 17, para. 1.

⁹⁸ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 2, para. 2(n).

⁹⁹ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 17, para. 1.

¹⁰⁰ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 2, para. 2(o).

¹⁰¹ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 17, para. 1.

confused”.¹⁰² Regulation (EU) No 1308/2013¹⁰³, which establishes a common organisation of the markets in agricultural products (the so-called CMO Regulation), is relevant in this regard, in particular as it lays down protected dairy terms, which therefore cannot be used for plant-based dairy alternatives,¹⁰⁴ but does not provide any similar limitation for vegetarian and vegan meat alternatives.¹⁰⁵ In fact, the CMO Regulation sets out a legal definition of the term ‘milk’, it mandates that the term ‘milk products’ means only products derived from milk and also that names such as ‘butter’ and ‘yogurt’ can only be used for milk products.¹⁰⁶ The only exemption is provided for those products listed in Commission Decision 2010/791/EU¹⁰⁷, which can use the dairy terminology protected by the CMO Regulation¹⁰⁸ as their nature is known because of traditional use or the dairy terminology is clearly used to describe a characteristic quality of the product.¹⁰⁹ For instance, it is possible to use the terms ‘coconut milk’ and ‘cocoa butter’.¹¹⁰ In the *TofuTown* case¹¹¹, the Court of Justice of the European Union (hereinafter referred to as CJEU) confirmed that the term ‘milk’ and the reserved designations for milk products cannot be used for purely plant-based products, even when the product name contains a clarifying or descriptive term which specifies the plant origin of the product at hand, unless it is listed in Commission Decision 2010/791/EU.¹¹²

On the other side, for meat products there are no legal names, with a few exceptions¹¹³ (e.g., the sales descriptions for meat of bovine animals).¹¹⁴ In fact, the CMO Regulation does not define terms as ‘steak’ or ‘burger’ and their use in plant-based products is not explicitly

¹⁰² Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 2, para. 2(p).

¹⁰³ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation 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, *OJ L 347*, 20.12.2013, p. 671-854, as lastly amended by Regulation (EU) 2021/2117.

¹⁰⁴ Leialohilani and de Boer, “Plant-based dairy alternatives”, p. 263.

¹⁰⁵ Seehafer and Bartels, “Meat 2.0-The Regulatory Environment”, p. 328.

¹⁰⁶ Regulation (EU) No 1308/2013, as lastly amended by Regulation (EU) 2021/2117, Annex VII, Part III. This Regulation lays down rules on the labelling for specific agricultural products and it has in general a relationship of *lex specialis* with other rules of food labelling law (Kai P. Purnhagen and Hanna Schebesta, “Food Labelling for Consumers – EU Law, Regulation and Policy Options”, European Parliament, Policy Department for Citizens’ Rights and Constitutional Affairs, Brussels, 2019, p. 27). Art. 78 of the Regulation indicates that the definitions, designations and sale descriptions for the products listed therein are set out in Annex VII.

¹⁰⁷ 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), *OJ L 336*, 21.12.2010, p. 55-59.

¹⁰⁸ Leialohilani and de Boer, “Plant-based dairy alternatives”, p. 263.

¹⁰⁹ Commission Decision 2010/791/EU, Recital 2 and Regulation (EU) No 1308/2013, as lastly amended by Regulation (EU) 2021/2117, Annex VII, Part III, point 5, second paragraph.

¹¹⁰ Commission Decision 2010/791/EU, Annex I.

¹¹¹ Judgment of the Court (Seventh Chamber) of 14 June 2017, *Verband Sozialer Wettbewerb eV v TofuTown.com GmbH*, Case C-422/16, ECLI:EU:C:2017:458.

¹¹² Case C-422/16, para. 52.

¹¹³ Ignacio Carreño and Tobias Dolle, “Tofu Steaks? Developments on the Naming and Marketing of Plant-based Foods in the Aftermath of the *TofuTown* Judgement”, *European Journal of Risk Regulation* 9, no. 3 (2018), p. 576, <https://doi.org/10.1017/err.2018.43>.

¹¹⁴ See Regulation (EU) No 1308/2013, as lastly amended by Regulation (EU) 2021/2117, Annex VII, Part I.

prohibited in any other EU law; therefore they can, in principle, be used for plant-based alternatives, inasmuch as they are not misleading.¹¹⁵ In 2019 the European Parliament's Committee on Agriculture and Rural Development submitted a draft resolution to the European Parliament¹¹⁶ on the Commission's proposal for a regulation to reform the Common Agricultural Policy (CAP).¹¹⁷ One of the amendments proposed that "(n)ames that fall under Article 17 of Regulation (EU) No 1169/2011 that are currently used for meat products and meat preparations shall be reserved exclusively for products containing meat. These designations include, for example: steak, sausage, escalope, burger, hamburger".¹¹⁸ However, the amendment was rejected in a vote of the European Parliament in October 2020.¹¹⁹

¹¹⁵ Froggatt and Wellesley, "Meat analogues", p. 27.

Art. 7, para. 1 of the FIC Regulation in fact provides that "(f)ood information shall not be misleading, particularly: (a) as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production; (b) by attributing to the food effects or properties which it does not possess; (c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients; (d) by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient."

Case law of the CJEU also contributed to clarify when labelling can be misleading. In *Teekanne*, the Court held that "(i)n order to assess the capacity of labelling to mislead, the national court must in essence take account of the presumed expectations, in light of that labelling, which an average consumer who is reasonably well informed, and reasonably observant and circumspect has, as to the origin, provenance, and quality associated with the foodstuff" (Judgment of the Court (Ninth Chamber) of 4 June 2015, *Bundesverband der Verbraucherzentralen und Verbraucherverbände - Verbraucherzentrale Bundesverband e.V. v Teekanne GmbH & Co. KG*, Case C-195/14, ECLI:EU:C:2015:361, para. 36). See also Judgment of the Court (Fourth Chamber) of 10 September 2009, *Alberto Severi v Regione Emilia Romagna*, Case C-446/07, ECLI:EU:C:2009:530, para. 61 and the cited case law.

¹¹⁶ Seehafer and Bartels, "Meat 2.0-The Regulatory Environment", p. 331. See Draft European Parliament Legislative Resolution on the proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) No 1308/2013 establishing a common organisation 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 aromatised 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 favour of the smaller Aegean islands, available at AGRI committee Report https://www.europarl.europa.eu/doceo/document/A-8-2019-0198_EN.html.

¹¹⁷ Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) No 1308/2013 establishing a common organisation 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 aromatised 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 favour of the smaller Aegean islands, COM(2018) 394 final, 2018/0218(COD), Brussels, 1.6.2018.

¹¹⁸ Amendment 165 of Draft European Parliament Legislative Resolution on the proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) No 1308/2013 establishing a common organisation 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 aromatised 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 favour of the smaller Aegean islands.

¹¹⁹ Lähteenmäki-Uutela *et al.*, "Alternative proteins and EU food law", p. 7.

The final act adopted is Regulation (EU) 2021/2117 of the European Parliament and of the Council of 2 December 2021 amending Regulations (EU) No 1308/2013 establishing a common organisation 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 aromatised wine

3.2. Legal questions in the regulation of plant-based alternatives

The different regulation of the naming of plant-based dairy alternatives and plant-based meat ones leads to what can be seen as the main issue with this category of alternative proteins. It has been advanced that the *TofuTown* judgment¹²⁰ brought legal clarity and showed that the CJEU considered necessary to limit potential names for plant-based dairy alternatives in order to avoid that consumers were unable to clearly distinguish products, therefore in view of ensuring consumer protection.¹²¹ At the same time, the different level of consumer protection between sectors has been seen as a barrier in the regulatory framework.¹²² In the *TofuTown* judgment, the CJEU used a literal interpretation of the rules, in light of the need to protect dairy producers as well as consumers' rights.¹²³ Moreover, it underlined that each sector of the common organisation of markets for agriculture products has its own specific features and therefore a comparison of the different rules and procedures "cannot constitute a valid basis for the purpose of proving the complaint of discrimination between dissimilar products which are subject to different rules".¹²⁴ However, the different level of regulation seems to go together also with a different level of consumer protection. In fact, it has been analysed that, as consumer protection depends on the sector concerned and thus consumers are more protected with respect to dairy products than to meat and fish products, consumer protection is asymmetric.¹²⁵ Moreover, the sector categorisation of the CMO Regulation also raises questions related to the objective of ensuring fair competition, as both dairy alternatives and meat alternatives are plant-based and are characterised by the same function of replacing animal products.¹²⁶

Connected to this is the debated topic of defining vegetarian and vegan food.¹²⁷ Currently, information regarding the suitability of products for vegans and vegetarians is given on a voluntary basis¹²⁸ and, as all other types of food information, vegan and vegetarian claims must respect the prohibition of being misleading found in article 7(1)(a) of the FIC

products and (EU) No 228/2013 laying down specific measures for agriculture in the outermost regions of the Union, *OJ L 435*, 6.12.2021, p. 262–314.

¹²⁰ Case C-422/16.

¹²¹ Leialohilani and de Boer, "Plant-based dairy alternatives", p. 264.

¹²² Leialohilani and de Boer, "Plant-based dairy alternatives", p. 264.

¹²³ Daniele Pisanello and Luchino Ferraris, "Ban on Designating Plant Products as Dairy: Between Market Regulation and Over-Protection of the Consumer", *European Journal of Risk Regulation* 9, no. 1 (2018), p. 173, <https://doi.org/10.1017/err.2018.4>. This article provides at pp. 172-173 a more detailed analysis of the reasoning of the CJEU.

¹²⁴ Case C-422/16, para. 51.

¹²⁵ Pisanello and Ferraris, "Ban on Designating Plant Products as Dairy", pp. 173-174.

¹²⁶ Leialohilani and de Boer, "Plant-based dairy alternatives", p. 265. See also Lähteenmäki-Uutela *et al.*, "Alternative proteins and EU food law", p. 7.

¹²⁷ Carreño and Dolle, "Developments on the Naming and Marketing of Plant-based Foods", p. 581.

¹²⁸ Carreño and Dolle, "Developments on the Naming and Marketing of Plant-based Foods", p. 581.

Regulation.¹²⁹ It has been proposed that if there was an EU legal definition of vegan foods, which would thereby certify the absence of animal ingredients, its use together with dairy terms to describe plant-based products could be itself sufficient to avoid any risk of misleading consumers.¹³⁰ This legal definition, however, currently does not exist, as the terms ‘vegan’ and ‘vegetarian’ have not been legally defined at European level¹³¹ and there are no specific rules.¹³² Article 36(3)(b) of the FIC Regulation requires the Commission to adopt an implementing act regarding information related to the suitability of foods for vegetarians and vegans.¹³³ The European Commission was supposed to start the drafting process in 2019;¹³⁴ however, still in 2021, FoodDrinkEurope, EuroCommerce and the European Vegetarian Union (EVU) made a joint statement urging the Commission to start working on the implementing act.¹³⁵ In the meantime, at Member States’ level, Germany first acted on the matter in 2016, when the Conference of Ministers for Consumer Protection of the Federal States came to an agreement regarding the definition of these terms.¹³⁶ Inaction from the EU and consequential initiatives of single EU countries could also ultimately lead to the fragmentation of the internal market and possibly to obstacles to the free movement of food products.¹³⁷

Another possible problematic aspect for the single market is that some countries have started to take unilateral solutions¹³⁸ also on meat-related terms for plant-based alternatives. France passed a decree in June 2022¹³⁹ which prohibited to use names that designate foodstuffs of animal origin for products containing vegetable proteins,¹⁴⁰ therefore banning plant-based products from using denominations linked with meat.¹⁴¹ However, the Conseil d’État

¹²⁹ Neli Sochirca, “The European Legal Framework on Vegan and Vegetarian Claims”, *European Food and Feed Law Review* 13, no. 6 (2018), p. 514.

For a broader analysis of when labelling can be misleading, see *supra* note 115, p. 12.

¹³⁰ Leialohilani and de Boer, “Plant-based dairy alternatives”, p. 266.

¹³¹ Seehafer and Bartels, “Meat 2.0-The Regulatory Environment”, p. 330.

¹³² Sochirca, “The European Legal Framework on Vegan and Vegetarian Claims”, p. 514.

¹³³ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 36, para. (3)(b).

¹³⁴ European Vegetarian Union (EVU), Position paper “Definitions of “vegan” and “vegetarian” in accordance with the EU Food Information Regulation”, July 2019, available at <https://www.euroveg.eu/vegan-and-vegetarian-definitions/>.

¹³⁵ FoodDrinkEurope, EuroCommerce and the European Vegetarian Union (EVU), Joint statement “Seeking a legally-binding definition of the terms “Food suitable for vegans” and “Food suitable for vegetarians” in accordance with Regulation (EU) No. 1169/2011”, 2021, available at <https://www.fooddrinkeurope.eu/resource/joint-statement-vegan-and-vegetarian-definitions/>.

To the author’s knowledge, there is no pending EU initiative in this regard.

¹³⁶ Seehafer and Bartels, “Meat 2.0-The Regulatory Environment”, p. 330.

¹³⁷ Carreño and Dolle, “Developments on the Naming and Marketing of Plant-based Foods”, p. 583.

¹³⁸ Carreño and Dolle, “Developments on the Naming and Marketing of Plant-based Foods”, p. 584.

¹³⁹ Décret n° 2022-947 du 29 juin 2022 relatif à l'utilisation de certaines dénominations employées pour désigner des denrées comportant des protéines végétales.

¹⁴⁰ Ignacio Carreño, “France Bans “Meaty” Terms for Plant-Based Products: Will the European Union Follow?”, *European Journal of Risk Regulation* 13, no. 4 (2022), p. 665, <https://doi.org/10.1017/err.2022.22>.

¹⁴¹ Carreño, “France Bans “Meaty” Terms for Plant-Based Products”, p. 668.

suspended the decree before it entered into force in July 2022.¹⁴² Another example is provided by Italy, where, at the end of 2022, a bill was presented on the naming of food products containing plant-based proteins, very similar to the French one.¹⁴³ Even though the principle of mutual recognition would apply for the products lawfully produced or marketed in another Member State,¹⁴⁴ an eventual rise of individual actions by single Member States could lead to fragmentation and uncertainty for companies.

3.3. Conclusions

With regard to the EU acts applicable to plant-based alternatives, this chapter showed how two highly relevant regulations are the Novel Food Regulation and the GMO Regulation, which can apply depending on the type of alternative protein; equally, the FIC Regulation and the CMO Regulation lay down the rules that lead to the sector-based differentiated treatment in the naming of these products, for which the dairy alternatives sector is subject to more restrictive rules. It can be questioned whether, in light of the different consumer protection that follows and the similarity between the two sectors, an amendment could be made to Regulation (EU) No 1308/2013. Linked to this, it was also underlined how in the EU there is no legal definition of the terms ‘vegan’ and ‘vegetarian’, notwithstanding the presence of Article 36(3)(b) of the FIC Regulation. If present, it could contribute to ensure clarity in the labelling and avoid misinterpretations by consumers. Finally, EU countries have started to take unilateral solutions with the objective of imposing stricter rules to the naming of plant-based meat alternatives, which could eventually create fragmentation.

Chapter 4: The legal framework of cultured meat

4.1. Overview of EU legislation applicable to cultured meat

Cultured meat is not present yet in the EU market, but EU legislation on food safety specifically addresses this product.¹⁴⁵ As cultured meat is a food under the definition of the General Food Law Regulation,¹⁴⁶ the latter will apply.¹⁴⁷ With regard to more specific regulations, the preamble of the Novel Food Regulation explicitly indicates that it regulates also food from the culture of cells or tissues from animals.¹⁴⁸ However, genetic modification could have been used

¹⁴² See Conseil d'État, Juge des référés, 27/07/2022, 465844, Inédit au recueil Lebon, ECLI:FR:CEORD:2022:465844.20220727.

¹⁴³ CARLONI ed altri: "Disposizioni in materia di denominazione dei prodotti alimentari contenenti proteine vegetali", Proposta di legge C. 746, presented on 29 December 2022.

¹⁴⁴ See Proposta di legge C. 746, Art. 6 and Décret n° 2022-947, Art. 5.

¹⁴⁵ FAO & WHO, "Food safety aspects of cell-based food", Rome, 2023, p. 31, <https://doi.org/10.4060/cc4855en>.

¹⁴⁶ See Regulation (EC) No 178/2002, as lastly amended by Regulation (EU) 2019/1381, Art. 2.

¹⁴⁷ For a brief overview of the rules of the Regulation, see *supra* notes 70-72, p. 9.

¹⁴⁸ FAO & WHO, "Food safety aspects of cell-based food", p. 33. See Recital 8 of the preamble.

Moreover, cultured meat falls under the category of Art. 3, para. 2(a)(vi). The Regulation provides that 'novel food' "means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997" and that falls under at least one of the categories indicated in Art. 3, para. 2(a).

to produce improved cell lines.¹⁴⁹ Therefore, depending on the starting cell types employed, either the Novel Food Regulation or GMO legislation will apply,¹⁵⁰ as the former does not apply to genetically modified foods which are under the scope of Regulation (EC) No 1829/2003.¹⁵¹ Moreover, generic rules on food hygiene and safety will apply to cultured meat as well,¹⁵² starting from Regulation (EC) No 852/2004.¹⁵³

With respect to the name, there is no specific EU legal act which defines its legal name.¹⁵⁴ As cultured meat has not been authorised yet in the EU, an agreement on the name the product should use has not been found¹⁵⁵ and it remains uncertain how it may be named and marketed.¹⁵⁶ In any case, in terms of information provided to consumers, cultured meat will be regulated by the FIC Regulation.¹⁵⁷ Moreover, the Novel Food Regulation could be relevant also in this regard as it could impose more requirements for product labelling¹⁵⁸ in order to correctly inform consumers and to indicate, if necessary, the conditions of use of the product.¹⁵⁹ Furthermore, it is relevant to mention that, in July 2023, the Netherlands approved pre-market tastings of cultured meat and seafood, setting out the conditions under which these can happen in a ‘code of practice’.¹⁶⁰

4.2. Legal questions in the regulation of cultured meat

As for plant-based alternatives, a major point of discussion concerning cultured meat is the naming and labelling that the product will have to use. There is currently no legal nor customary name for cultured meat in the EU,¹⁶¹ and the latter is defined with different terms around the

The Regulation is applicable to the placing on the EU market of novel foods (Art. 2, para. 1). It lays down, inter alia, the procedure for determining when a product is to be considered a novel food in Art. 4, the requirements for placing on the market novel foods in Chapter II and the authorisation procedures for a novel food in Chapter III.

¹⁴⁹ FAO & WHO, “Food safety aspects of cell-based food”, p. 34.

¹⁵⁰ Karin Verzijden and Jasmin Buijs, “Meat 3.0 — How Cultured Meat is Making its Way to the Market”, *European Food and Feed Law Review* 15, no. 2 (2020), p. 98.

¹⁵¹ See Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 2, para. 2(a).

¹⁵² FAO & WHO, “Food safety aspects of cell-based food”, p. 34.

As cultured meat has not been approved yet as a novel food, this chapter did not describe all of the laws that will apply to it.

¹⁵³ As set out in Art. 1, the Regulation applies “to all stages of production, processing and distribution of food and to exports, and without prejudice to more specific requirements relating to food hygiene”, except for the cases set out in para. 2. The definitions of Regulation (EC) No 178/2002 apply (Art. 2, para. 2), therefore also the definition of ‘food’. For a brief overview of the rules of Regulation (EC) No 852/2004, see *supra* note 73, p. 9.

¹⁵⁴ Verzijden and Buijs, “How Cultured Meat is Making its Way to the Market”, p. 101. As explained above, the legal name is defined in Art. 17, para. 1 and Art. 2, para. 2(n) of the FIC Regulation.

¹⁵⁵ Froggatt and Wellesley, “Meat analogues”, p. 28.

¹⁵⁶ Froggatt and Wellesley, “Meat analogues”, p. 30.

¹⁵⁷ Froggatt and Wellesley, “Meat analogues”, p. 26.

¹⁵⁸ Froggatt and Wellesley, “Meat analogues”, p. 26.

¹⁵⁹ See Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 9, para. 3.

¹⁶⁰ Flora Southey, “A great achievement for the Dutch government’: First Member State approves pre-market tastings of cultivated meat”, *FoodNavigator*, July 19, 2023, <https://www.foodnavigator.com/Article/2023/07/19/cultivated-meat-tastings-formally-approved-in-the-netherlands>.

¹⁶¹ Froggatt and Wellesley, “Meat analogues”, p. 28.

world, such as ‘cell-based’, ‘cultured’ or ‘cultivated’ meat.¹⁶² A crucial question is whether it will be possible to refer cultured meat products as ‘meat’.¹⁶³ Within the EU, this term is defined in different legal acts, as Regulation (EC) No 853/2004¹⁶⁴ on food hygiene and the FIC Regulation, the latter defining it with regard to the declaration of products containing meat as ingredient.¹⁶⁵ Regulation (EC) No 853/2004 sets out several definitions in connection with the term,¹⁶⁶ e.g., it provides that ‘meat’ means “edible parts” of a series of animals, “including blood”.¹⁶⁷ The FIC Regulation establishes that the category of food which can be designated by the term ‘...meat’ includes “skeletal muscles of mammalian and bird species recognised as fit for human consumption with naturally included or adherent tissue”, when these respect the indicated maximum levels of total fat and connective tissues and the meat is an ingredient of another food.¹⁶⁸ The CMO Regulation does not provide a legal name for meat as such.¹⁶⁹ Therefore, the application of this denomination to cultured meat is unsure.¹⁷⁰ It can be advanced that, according to the current rules, cultured meat does not seem to fit in the definition of Regulation (EC) No 853/2004 and neither in the definition of the FIC Regulation for the declaration of end products which have meat as ingredient. However, if eventually it was to be used, other questions could come up, such as whether food operators should be required to indicate the country of origin of the animal, as it currently must be indicated on traditional meat products.¹⁷¹ Deciding the name that the product will have to use is also important as the terminology of a product can influence, inter alia, consumer perception and acceptance¹⁷² and there could be language barriers and translation issues to take into account,¹⁷³ making terminology an important issue not to be underestimated.¹⁷⁴ Therefore, while the first application for an authorisation will surely bring clarifications, as the applicant will also have to propose the name of the novel food,¹⁷⁵ legal clarity could be brought in

¹⁶² FAO & WHO, “Food safety aspects of cell-based food”, p. 4.

¹⁶³ Verzijden and Buijs, “Meat 3.0 — How Cultured Meat is Making its Way to the Market”, p. 100.

¹⁶⁴ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, *OJ L 139*, 30.4.2004, p. 55-205, as lastly amended by Commission Delegated Regulation (EU) 2023/166.

¹⁶⁵ Ralf Lautenschlaeger and Matthias Upmann, “How meat is defined in the European Union and in Germany”, *Animal Frontiers* 7, no. 4 (2017), pp. 57-59, <https://doi.org/10.2527/af.2017.0446>.

¹⁶⁶ Lautenschlaeger and Upmann, “How meat is defined in the European Union and in Germany”, p. 57.

¹⁶⁷ Regulation (EC) No 853/2004, as lastly amended by Commission Delegated Regulation (EU) 2023/166, Annex I.

¹⁶⁸ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Annex VII, Part B.

¹⁶⁹ Verzijden and Buijs, “Meat 3.0 — How Cultured Meat is Making its Way to the Market”, p. 100.

¹⁷⁰ Verzijden and Buijs, “Meat 3.0 — How Cultured Meat is Making its Way to the Market”, p. 100 and Froggatt and Wellesley, “Meat analogues”, p. 28.

¹⁷¹ Froggatt and Wellesley, “Meat analogues”, p. 28.

¹⁷² FAO & WHO, “Food safety aspects of cell-based food”, p. 9.

¹⁷³ FAO & WHO, “Food safety aspects of cell-based food”, p. 10.

¹⁷⁴ FAO & WHO, “Food safety aspects of cell-based food”, p. 118.

¹⁷⁵ See Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 10, para. 2(b).

advance. On this point, setting a clear and consistent terminology from the early stages could also be relevant to reduce potential miscommunications on the topic in the future.¹⁷⁶

Moreover, an important point regards whether the label and name of cultured meat will have to indicate clearly the production process.¹⁷⁷ In this regard, the requirement that food information should not be misleading provided by the FIC Regulation is relevant for cultured meat in particular in respect of the characteristics of the product and its method of production.¹⁷⁸ It has been advanced that, in order to respect it, operators will probably have to make sure that consumers are informed by way of the label that the meat was grown in a laboratory, and this could be asked for in a specification set out by the authorisation of the Commission once cultured meat will be approved as a novel food in the EU.¹⁷⁹ In fact, the Commission implementing regulations for the authorisation of a novel food on the market include the specification of the novel food¹⁸⁰ and can impose, where appropriate, further requirements in terms of post-market monitoring requirements,¹⁸¹ the conditions under which the product may be used, including “the exceeding of maximum intake levels and risks in case of excessive consumption”,¹⁸² as well as additional specific labelling requirements to inform consumers “of any specific characteristic or food property” which makes the food “no longer equivalent to an existing food or of implications for the health of specific groups of the population”,¹⁸³ therefore including information on allergenicity.¹⁸⁴

Lastly, it is worth mentioning the initiative recently taken by one Member State, Italy, regarding cultured meat, which poses questions related to the integrity of the internal market. Recently the government approved a bill, at the time of writing in consideration at Parliament level,¹⁸⁵ which aims to ensure human health and the interests of citizens and to safeguard the agri-food heritage,¹⁸⁶ in consideration of the precautionary principle (enshrined in Article 7 of the General

¹⁷⁶ FAO & WHO, “Food safety aspects of cell-based food”, p. 17.

¹⁷⁷ Froggatt and Wellesley, “Meat analogues”, p. 28.

¹⁷⁸ Verzijden and Buijs, “Meat 3.0 — How Cultured Meat is Making its Way to the Market”, p. 100. For a broader analysis of when labelling can be misleading, see *supra* note 115, p. 12.

¹⁷⁹ Froggatt and Wellesley, “Meat analogues”, p. 28.

¹⁸⁰ Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 9, para. 3.

¹⁸¹ Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 9, para. 3(c).

¹⁸² Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 9, para. 3(a).

¹⁸³ Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 9, para. 3(b).

¹⁸⁴ By way of example, see Commission Implementing Regulation (EU) 2023/58 of 5 January 2023 authorising the placing on the market of the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) as a novel food and amending Implementing Regulation (EU) 2017/2470 (Text with EEA relevance), *OJ L* 5, 6.1.2023, p. 10-15, Annex.

¹⁸⁵ The draft law has been notified to the Commission (see Notification 2023/0469/IT, available at “Notification Detail”, European Commission, accessed August 19, 2023, <https://technical-regulation-information-system.ec.europa.eu/en/notification/24242>).

¹⁸⁶ “Disposizioni in materia di divieto di produzione e di immissione sul mercato di alimenti e mangimi costituiti, isolati o prodotti a partire da colture cellulari o di tessuti derivanti da animali vertebrati nonché di divieto della denominazione di carne per prodotti trasformati contenenti proteine vegetali”, Disegno di legge C. 1324, transmitted

Food Law Regulation), by prohibiting the production and commercialisation of cultured food and feed.¹⁸⁷ This bill comes in a framework in which, once a novel food is authorised, it can be marketed freely in the internal market. The only case in which Member States can ban a novel food is if they believe it can constitute a serious risk to human health, animal health or the environment, and in this situation they can suspend or provisionally restrict the marketing of such product, according to the safeguard provisions of the General Food Law Regulation,¹⁸⁸ i.e., Articles 53 and 54 of Regulation (EC) No 178/2002. However, they should inform the Commission, which will examine these protective measures¹⁸⁹ and possibly implement emergency measures.¹⁹⁰ In any case, at the present state, cultured meat is not marketed in the EU as it has not been approved as a novel food. Moreover, once the Commission will provide the first authorisation, it will mean that cultured meat will have been considered safe for human health. Therefore, it is difficult to see how the Member State can rely on the precautionary principle and it could be questioned whether this bill can be considered in compliance with EU law and notably internal market rules when it would prohibit to sell, import and even produce to export¹⁹¹ cultured meat. As this is still a draft, it remains to be seen how this matter will evolve and, most importantly, what will be the opinion of the Commission.

4.3. Conclusions

With regard to EU laws applicable to cultured meat, it was analysed in this chapter that it is certain that the Novel Food Regulation, possibly substituted by the GMO legislation, will apply, as well as the FIC Regulation and Regulation (EC) No 852/2004 on food hygiene. The main questions that can be advanced about the EU legal framework concern the naming, as there is currently uncertainty regarding the way the product will need to be named, and the labelling. In this regard, it will be necessary for the EU to provide clarifications, especially considering that it is expected that an application will be submitted to the European Food Safety Authority (EFSA) soon, as there are many start-ups working in this sector at EU level.¹⁹² Furthermore, the intervention of a Member State had to be highlighted, as the latter proposed to ban cultured meat before it is even approved as a novel food.

to the Chamber of Deputies on 20 July 2023 after approval by the Senate of the Republic (originally presented on 7 April 2023 as S. 651), Art. 1.

¹⁸⁷ Disegno di legge C. 1324, Art. 2.

¹⁸⁸ "Questions and Answers: New Regulation on Novel Food", Press corner, European Commission, accessed August 17, 2023, https://ec.europa.eu/commission/presscorner/detail/en/MEMO_15_5875.

¹⁸⁹ Regulation (EC) No 178/2002, as lastly amended by Regulation (EU) 2019/1381, Art. 54.

¹⁹⁰ Regulation (EC) No 178/2002, as lastly amended by Regulation (EU) 2019/1381, Art. 53.

¹⁹¹ Disegno di legge C. 1324, Art. 2.

¹⁹² Natasha Foote, "Cultivated meat companies gear up for first EU approval applications", *Euractiv*, April 14, 2022, <https://www.euractiv.com/section/agriculture-food/news/cultivated-meat-companies-gear-up-for-first-eu-approval-applications/>.

Chapter 5: The legal framework of edible insects

5.1. Overview of EU legislation applicable to edible insects

The EU legal framework for edible insects is characterised by many non-specific legislative requirements.¹⁹³ Firstly, whole insects were not mentioned explicitly in the old Regulation (EC) No 258/97¹⁹⁴ on novel foods,¹⁹⁵ a regulatory uncertainty which led to different legal interpretations and policy approaches by EU countries:¹⁹⁶ some Member States considered whole insects intended for human consumption as not novel (and consequently that they did not need to comply with Regulation (EC) No 258/97), while others had a more restrictive approach and considered that they were to be regulated as novel foods.¹⁹⁷ On the contrary, in the subsequent Regulation (EU) 2015/2283 insects are considered to be included in the definition of Article 3, which refers to “food consisting of, isolated from or produced from animals or their parts, except for animals obtained by traditional breeding practices which have been used for food production within the Union before 15 May 1997 and the food from those animals has a history of safe food use within the Union”,¹⁹⁸ and Recital 8 explicitly mentions whole insects, as it states that the categories of food which are to be considered novel foods “should cover whole insects and their parts”^{199,200} Therefore, the Novel Food Regulation applies to whole insects, parts of insects, insect flour and insect extracts.²⁰¹ It is relevant to mention the *Entoma* case²⁰², in which the CJEU confirmed that whole insects were not within the scope of the old Regulation (EC) No 258/97.²⁰³

¹⁹³ Lidia Delgado *et al.*, “Sustainable Food Systems: EU Regulatory Framework and Contribution of Insects to the Farm-To-Fork Strategy”, *Food Reviews International* (2022), p. 2, <https://doi.org/10.1080/87559129.2022.2130354>. This chapter did not cover the entirety of the applicable laws, but see IPIFF, Guide on Good Hygiene Practice for European Union (EU) producers of insects as food and feed, last updated version of November 2022, pp. 9-10, available at <https://ipiff.org/good-hygiene-practices/>, for a complete list of all the EU laws IPIFF indicates insect producers to check in order to comply with food and feed safety objectives.

¹⁹⁴ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, *OJ L* 43, 14.2.1997, p. 1-6.

¹⁹⁵ Delgado *et al.*, “EU Regulatory Framework and Contribution of Insects to the Farm-To-Fork Strategy”, p. 5.

¹⁹⁶ Francesco Montanari, Ana Pinto de Moura and Luís Miguel Cunha, “The EU Regulatory Framework for Insects as Food and Feed and Its Current Constraints”, in *Production and Commercialization of Insects as Food and Feed: identification of the main constraints in the European Union* (Springer, Cham, 2021), p. 44.

¹⁹⁷ Montanari, Pinto de Moura and Cunha, “The EU Regulatory Framework for Insects as Food and Feed and Its Current Constraints”, pp. 46-48.

¹⁹⁸ Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 3, para. 2(a)(v).

¹⁹⁹ Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Recital 8.

²⁰⁰ Giulia Formici, “Legislative and Judicial Challenges on Insects for Human Consumption: From Member States to the EU, Passing Through the Court of Justice of the EU”, in *Novel Foods and Edible Insects in the European Union: an interdisciplinary analysis*, ed. Lucia Scaffardi, Giulia Formici (Springer, Cham, 2022), pp. 107-108.

²⁰¹ Lähteenmäki-Uutela *et al.*, “Alternative proteins and EU food law”, p. 5.

²⁰² Judgment of the Court (Third Chamber) of 1 October 2020, *Entoma SAS v Ministre de l'Économie et des Finances and Ministre de l'Agriculture et de l'Alimentation*, Case C-526/19, ECLI:EU:C:2020:769.

²⁰³ Case C-526/19, para. 45.

Insect producers must respect, inter alia, the General Food Law Regulation and the hygiene regulations,²⁰⁴ i.e., Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004. Equally, they also have to abide to EU environmental laws, in particular Regulation (EU) No 1143/2014²⁰⁵ on the prevention and management of the introduction and spread of invasive alien species.²⁰⁶ A package of five regulations determining the import conditions for animals and goods for human consumption is relevant for the import of insects as food from third countries.²⁰⁷ On the contrary, Directive 98/58/EC concerning the protection of animals kept for farming purposes²⁰⁸, Regulation (EC) No 1/2005 on the protection of animals during transport and related operations²⁰⁹ and Regulation (EC) No 1099/2009 on the protection of animals at the time of killing²¹⁰ do not apply to insects as they are not applicable to invertebrates.²¹¹

For what concerns labelling, the FIC Regulation imposes general labelling requirements to authorised insects.²¹² Importantly, Annex II of the Regulation contains a list of substances or

²⁰⁴ Formici, “Legislative and Judicial Challenges on Insects for Human Consumption”, p. 117. For a brief overview of the rules of Regulation (EC) No 178/2002, see *supra* notes 70-72, p. 9. For a brief overview of the rules of Regulation (EC) No 852/2004, see *supra* note 73, p. 9. Regulation (EC) No 853/2004 provides rules for food business operators on the hygiene of food from animal origin, supplementing Regulation (EC) No 852/2004 (Art. 1, para. 1).

Producers of insects for feed purposes must also comply with Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (Text with EEA relevance), *OJ L 35*, 8.2.2005, p. 1–22.

For an overview of the different rules of these regulations which are applicable to insect producers depending on the stage of production, see IPIFF, Guide on Good Hygiene Practice for European Union (EU) producers of insects as food and feed, pp. 12-16.

²⁰⁵ Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species, *OJ L 317*, 4.11.2014, p. 35–55, as lastly amended by Regulation (EU) 2016/2031.

²⁰⁶ Delgado *et al.*, “EU Regulatory Framework and Contribution of Insects to the Farm-To-Fork Strategy”, p. 2.

The Regulation lays down rules “to prevent, minimise and mitigate the adverse impact on biodiversity of the introduction and spread” in the EU of invasive alien species (Art. 1). If an insect species is listed in Commission Implementing Regulation (EU) 2016/1141, which is the list of invasive alien species of Union concern, it cannot be intentionally, among other prohibitions, brought into the EU territory or placed on the market (Art. 7, para. 1).

²⁰⁷ Delgado *et al.*, “EU Regulatory Framework and Contribution of Insects to the Farm-To-Fork Strategy”, p. 6. The package comprises the Official Controls Regulation (EU) 2017/625, Commission Delegated Regulation (EU) 2022/2292, Commission Implementing Regulation (EU) 2020/2235, Commission Implementing Regulation (EU) 2021/405 and Commission Implementing Regulation (EU) 2021/632. An overview of these laws is provided at Delgado *et al.*, “EU Regulatory Framework and Contribution of Insects to the Farm-To-Fork Strategy”, pp. 6-7.

²⁰⁸ Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes, *OJ L 221*, 8.8.1998, p. 23-27, as lastly amended by Regulation (EU) 2017/625.

²⁰⁹ Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97, *OJ L 3*, 5.1.2005, p. 1-44, as lastly amended by Regulation (EU) 2017/625.

²¹⁰ Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (Text with EEA relevance), *OJ L 303*, 18.11.2009, p. 1-30, as lastly amended by Commission Implementing Regulation (EU) 2018/723.

²¹¹ Lähteenmäki-Uutela and Grmelová, “European Law on Insects in Food and Feed”, p. 6.

See Directive 98/58/EC, as lastly amended by Regulation (EU) 2017/625, Art. 1, para. 2, Regulation (EC) No 1/2005, as lastly amended by Regulation (EU) 2017/625, Art. 1, para. 1, Regulation (EC) No 1099/2009, as lastly amended by Regulation (EU) 2018/723, Art. 1 and Art. 2(c).

²¹² Delgado *et al.*, “EU Regulatory Framework and Contribution of Insects to the Farm-To-Fork Strategy”, p. 6.

products causing allergies or intolerances whose indication is mandatory.²¹³ However, insects are not included.²¹⁴ Nevertheless, Article 4 of the FIC Regulation provides that information on “compositional attributes that may be harmful to the health of certain groups of consumers” is mandatory,²¹⁵ and this requirement is reflected in the additional labelling requirements that can be found in the Commission implementing regulations for the authorisation of insects as novel foods.²¹⁶ For instance, in January 2023 the Commission authorised the placing on the market of a fourth insect (the lesser mealworm) as a novel food, and the authorisation provides for specific labelling requirements concerning allergenicity:²¹⁷ it specifies that the label of the products containing the insect “shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans, and products thereof, and to dust mites”, which must be put close to the list of ingredients.²¹⁸ Finally, producers who would want to use nutritional or health claims to highlight certain nutritional or health benefits that insects may bring would need to comply with Regulation (EC) No 1924/2006^{219, 220}

In respect of feed for insects, several pieces of EU law are applicable.²²¹ Firstly, insects intended for food and feed production are included in the category of ‘farmed animals’, as defined in Article 3(6)(a) of Regulation (EC) No 1069/2009^{222, 223}. Consequently, they are subject to the same feed rules as any farmed animal.²²⁴ Applicable EU restrictions on substrates of animal origin as feed for insects are found in Regulation (EC) No 767/2009²²⁵,

²¹³ See Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 9, para. 1(c). Art. 21 further sets out the requirements that the particulars of Art. 9, para. 1(c) must meet, notably that they should be indicated in the list of ingredients and that the name of the substance or product of Annex II must be emphasized with a typeset that makes it clearly distinguishable from the rest of the ingredients.

²¹⁴ Delgado *et al.*, “EU Regulatory Framework and Contribution of Insects to the Farm-To-Fork Strategy”, p. 6.

²¹⁵ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 4.

²¹⁶ Delgado *et al.*, “EU Regulatory Framework and Contribution of Insects to the Farm-To-Fork Strategy”, p. 6.

²¹⁷ “Approval of fourth insect as a Novel Food – Questions and answers”, Food Safety, European Commission, accessed August 12, 2023, https://food.ec.europa.eu/safety/novel-food/authorisations/approval-insect-novel-food_en.

²¹⁸ Commission Implementing Regulation (EU) 2023/58 of 5 January 2023 authorising the placing on the market of the frozen, paste, dried and powder forms of *Alphitobius diaperinus* larvae (lesser mealworm) as a novel food and amending Implementing Regulation (EU) 2017/2470 (Text with EEA relevance), *OJ L 5*, 6.1.2023, p. 10-15, Annex.

²¹⁹ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, *OJ L 404*, 30.12.2006, p. 9-25, as lastly amended by Commission Regulation (EU) No 1047/2012.

²²⁰ Lähteenmäki-Uutela and Grmelová, “European Law on Insects in Food and Feed”, pp. 6-7.

²²¹ For a complete overview of applicable laws of feed for insects and insects as feed, see Delgado *et al.*, “EU Regulatory Framework and Contribution of Insects to the Farm-To-Fork Strategy”, pp. 2-5.

²²² Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation), *OJ L 300*, 14.11.2009, p. 1-33, as lastly amended by Regulation (EU) 2019/1009.

²²³ Montanari, Pinto de Moura and Cunha, “The EU Regulatory Framework for Insects as Food and Feed and Its Current Constraints”, p. 77.

²²⁴ Lähteenmäki-Uutela and Grmelová, “European Law on Insects in Food and Feed”, p. 3.

²²⁵ Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC,

Regulation (EC) No 999/2001²²⁶ (the so-called TSE Regulation), Regulation (EC) No 1069/2009 and the implementing Regulation (EU) No 142/2011^{227, 228}. As a result, for example, catering waste, manure and unprocessed former foodstuffs which contain meat or fish cannot be used for the feeding of insects.²²⁹ Concerning insects used as feed, the TSE Regulation prohibited to use processed animal proteins (PAPs) derived from farmed animals as feed materials for certain categories of animals,²³⁰ such a restrictive approach being linked to the history of bovine spongiform encephalopathy (BSE).²³¹ However, this restriction was relaxed as the TSE Regulation was amended by Regulation (EU) 2017/893²³², which allowed to use insect-based meal in aquafeed from certain species of insects; moreover, Regulation (EU) 2021/1372²³³ permitted the use of insect PAPs in formulated pig and poultry feeds.²³⁴

5.2. Legal questions in the regulation of edible insects

A first problematic aspect regarding insects as food in the EU has been identified in the fragmentation of the single market related to the uncertainty on the regulation of whole insects with the old novel food regime, which has continued, to some extent, to have effects for the transitional measure provided by Regulation (EU) 2015/2283.²³⁵ As explained above, the uncertainty regarding the status of whole insects under the old Regulation (EC) No 258/97 led to different approaches by Member States. This is relevant considering that Regulation (EU)

83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (Text with EEA relevance), *OJ L 229*, 1.9.2009, p. 1–28, as lastly amended by Commission Regulation (EU) 2018/1903.

²²⁶ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, *OJ L 147*, 31.5.2001, p. 1–40, as lastly amended by Commission Regulation (EU) 2022/2246.

²²⁷ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive Text with EEA relevance, *OJ L 54*, 26.2.2011, p. 1–254, as lastly amended by Commission Regulation (EU) 2022/488.

²²⁸ For an overview of the applicable rules of these regulations see IPIFF, Guide on Good Hygiene Practice for European Union (EU) producers of insects as food and feed, pp. 17–21.

²²⁹ IPIFF, “Position paper on the use of insect proteins as animal feed”, Brussels, 26 July 2017, available at <https://ipiff.org/position-papers/>.

²³⁰ Formici, “Legislative and Judicial Challenges on Insects for Human Consumption”, p. 116.

²³¹ Anu Lähteenmäki-Uutela *et al.*, “The impact of the insect regulatory systems on the insect marketing system”, *Journal of Insects as Food and Feed* 4, no. 3 (2018), p. 189.

²³² Commission Regulation (EU) 2017/893 of 24 May 2017 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein (Text with EEA relevance), *OJ L 138*, 25.5.2017, p. 92–116.

²³³ Commission Regulation (EU) 2021/1372 of 17 August 2021 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the prohibition to feed non-ruminant farmed animals, other than fur animals, with protein derived from animals (Text with EEA relevance), *OJ L 295*, 18.8.2021, p. 1–17.

²³⁴ Quintieri *et al.*, “Alternative Protein Sources and Novel Foods”.

PAPs from farmed insects for the feeding of farmed fish, poultry and pig can only be obtained from eight species, i.e.: Black Soldier Fly, Common Housefly, Yellow Mealworm, Lesser Mealworm, House Cricket, Banded Cricket, Field Cricket, Silkworm (see Regulation (EU) No 142/2011, as lastly amended by Regulation (EU) 2022/488, Annex X, Chapter II, Section 1).

²³⁵ Francesco Montanari, Ana Pinto de Moura and Luís Miguel Cunha, “Conclusions”, in *Production and Commercialization of Insects as Food and Feed: identification of the main constraints in the European Union* (Springer, Cham, 2021), p. 79.

2015/2283 includes a transitional measure, under which foods that did not fall under the scope of the old Regulation, “which are lawfully placed on the market by 1 January 2018 and which fall within the scope of this Regulation”²³⁶ (which could be whole insects), may continue to be marketed until a decision is taken at EU level and provided that a novel food application was submitted by 1 January 2019.²³⁷ In the *Entoma* case²³⁸, the CJEU concluded that whole insects were not included in the scope of Regulation (EC) No 258/97, putting an end to the uncertainty regarding its scope of application. However, this decision raised doubts regarding the situations in which the transitional measure would have applied and in particular whether its advantageous effects should have been extended to all Member States,²³⁹ including those who had, under the old regime, considered whole insects as novel foods. The answer is not that simple: companies could be allowed to benefit from the transitional measure even in those Member States whose national authorities have denied its implementation or applied it restrictively.²⁴⁰ However, this depends on the situation, e.g., whether the company had decided not to market an insect product before 1 January 2018 because of the restrictive approach of the Member State, or whether the decision is definitive or not.²⁴¹ Consequently, notwithstanding the clarification of the CJEU, the old approach of Member States on the consideration of whole insects and the consequent fragmented situation appear to still have an influence on the implementation of the transitional measure, and this could remain so until the end of the authorisation procedures²⁴² (and therefore of the application of the transitional measure).

Moreover, a critical regulatory gap is the lack of specific hygiene rules under Regulation (EC) No 853/2004.²⁴³ Specific hygiene requirements are currently defined for a number of food of animal origin, but these do not include insects.²⁴⁴ However, tailored hygiene requirements designed to address the specificities and risks of the sector would be important to promote a

²³⁶ Regulation (EU) 2015/2283, as lastly amended by Regulation (EU) 2019/1381, Art. 35, para. 2.

²³⁷ Montanari, Pinto de Moura and Cunha, “The EU Regulatory Framework for Insects as Food and Feed and Its Current Constraints”, p. 54, referring to Regulation (EU) 2017/2468 and Regulation (EU) 2017/2469.

²³⁸ Case C-526/19.

²³⁹ Formici, “Legislative and Judicial Challenges on Insects for Human Consumption”, p. 111.

²⁴⁰ For a detailed view of the approaches on the novel status of ‘whole insects and their preparations’ of most of the Member States and the application of the transitional measure (updated June 2021) see IPIFF, “Briefing paper on the provisions relevant to the commercialisation of insect-based products intended for human consumption in the EU”, Brussels, 2021, pp. 40-45, available at <https://ipiff.org/position-papers/>.

²⁴¹ For a more detailed explanation, see IPIFF, “Briefing paper on the provisions relevant to the commercialisation of insect-based products intended for human consumption in the EU”, pp. 36-37.

²⁴² Formici, “Legislative and Judicial Challenges on Insects for Human Consumption”, p. 112.

²⁴³ Montanari, Pinto de Moura and Cunha, “Conclusions”, p. 80. See also Lähteenmäki-Uutela and Grmelová, “European Law on Insects in Food and Feed”, p. 4 and Formici, “Legislative and Judicial Challenges on Insects for Human Consumption”, p. 117.

²⁴⁴ Montanari, Pinto de Moura and Cunha, “The EU Regulatory Framework for Insects as Food and Feed and Its Current Constraints”, p. 72. See Regulation (EC) No 853/2004, as lastly amended by Commission Delegated Regulation (EU) 2023/166, Annex III.

comprehensive legal framework,²⁴⁵ as well as help operators working with insects to use proper good hygiene manufacturing practices and therefore also ensure a high level of public health protection in the EU.²⁴⁶ A draft regulation amending Regulation (EC) No 853/2004 was considered in 2019,²⁴⁷ however the initiative was abandoned.²⁴⁸ The International Platform of Insects for Food and Feed (IPIFF) developed a Guide on Good Hygiene Practice for EU producers of insects as food and feed,²⁴⁹ which has also been seen as a sign that the legal framework needs at least to be seen under a new perspective in order to be correctly applied to the insect sector.²⁵⁰ In addition, both microbiological criteria and maximum levels of contaminants have been set for now in the Commission authorisations;²⁵¹ however, in the long run, an amendment of the respective regulations could be considered in order to cover all future authorised insects.²⁵²

On another note, as mentioned above, the EU legislation on animal welfare²⁵³ excludes insects from the scope of application. In this regard, even if IPIFF tried to promote the debate,²⁵⁴ setting animal welfare rules for insects is a topic that requires different considerations²⁵⁵ and for now it does not seem to be on the agenda. In fact, under the Farm to Fork Strategy, the Commission indicated that it would review the animal welfare legislation and the proposal should come

²⁴⁵ Formici, “Legislative and Judicial Challenges on Insects for Human Consumption”, p. 117.

²⁴⁶ Montanari, Pinto de Moura and Cunha, “The EU Regulatory Framework for Insects as Food and Feed and Its Current Constraints”, p. 72.

²⁴⁷ Commission Regulation (EU) .../... of XXX amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards specific hygiene requirements for insects intended for human consumption, Ref. Ares(2019)382900, 23/01/2019, available at https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2079-Specific-hygiene-rules-for-insects-intended-for-human-consumption_en.

²⁴⁸ “Specific hygiene rules for insects intended for human consumption”, Published initiatives, European Commission, accessed August 12, 2023, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2079-Specific-hygiene-rules-for-insects-intended-for-human-consumption_en.

²⁴⁹ IPIFF, Guide on Good Hygiene Practice for European Union (EU) producers of insects as food and feed, last updated version of November 2022, available at <https://ipiff.org/good-hygiene-practices/>.

²⁵⁰ Montanari, Pinto de Moura and Cunha, “The EU Regulatory Framework for Insects as Food and Feed and Its Current Constraints”, p. 71.

²⁵¹ By means of example, see Commission Implementing Regulation (EU) 2022/169 of 8 February 2022 authorising the placing on the market of frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470 (Text with EEA relevance), C/2022/658, OJ L 28, 9.2.2022, p. 10–16.

²⁵² Montanari, Pinto de Moura and Cunha, “The EU Regulatory Framework for Insects as Food and Feed and Its Current Constraints”, p. 72. See also Lähteenmäki-Uutela and Grmelová, “European Law on Insects in Food and Feed”, p. 4.

²⁵³ i.e., Directive 98/58/EC, Regulation (EC) No 1/2005 and Regulation (EC) No 1099/2009.

²⁵⁴ Formici, “Legislative and Judicial Challenges on Insects for Human Consumption”, p. 118, in reference to IPIFF reflection paper “Animal Welfare in Insect Production”.

²⁵⁵ For a more detailed analysis, see Montanari, Pinto de Moura and Cunha, “The EU Regulatory Framework for Insects as Food and Feed and Its Current Constraints”, p. 75.

before the end of 2023;²⁵⁶ however, it will not regulate invertebrate animals,²⁵⁷ therefore insects will not be included.

Another limitation of the legal framework concerns the current prohibitions on feed for insects: in light of the possible ecological benefits that could derive from using waste and manure as substrates for insect farming,²⁵⁸ as well as other materials currently prohibited, it has been argued that these rules highly impact the sustainability of insect farming²⁵⁹ and could be revised to promote a circular economy.²⁶⁰ Furthermore, it is relevant to note that the process for developing EU rules regarding the organic farming of insects has been delayed²⁶¹ and at present there are no specific rules for organic insect production other than bees.²⁶² New rules for the organic production of insects used in feed and food are the subject of an EU initiative which could culminate in a delegated regulation. However, even if the Commission's adoption was planned for the third quarter of 2022, the initiative is still pending.²⁶³

Lastly, a final consideration regards recent initiatives of some Member States. In March 2023, the Italian government announced that four decrees were signed regarding specific indications to be inserted in the label of food products prepared using one of the four insects authorised as novel foods so far.²⁶⁴ However, before they can be adopted, they need to be notified to the European Commission (which currently does not appear to have been done).²⁶⁵ If approved, they would require such products, according to the statements of the competent Minister reported by the press, to have a label indicating the origin, the risks of consuming them and

²⁵⁶ "Revision of the animal welfare legislation", European Commission, accessed August 14, 2023, https://food.ec.europa.eu/animals/animal-welfare/evaluations-and-impact-assessment/revision-animal-welfare-legislation_en.

²⁵⁷ European Commission, "Inception Impact Assessment – Revision of the EU legislation on animal welfare", p. 1, available at https://food.ec.europa.eu/animals/animal-welfare/evaluations-and-impact-assessment/revision-animal-welfare-legislation_en.

²⁵⁸ Belluco, Halloran and Ricci, "New protein sources and food legislation", p. 810. See also Delgado *et al.*, "EU Regulatory Framework and Contribution of Insects to the Farm-To-Fork Strategy", p. 13.

²⁵⁹ Formici, "Legislative and Judicial Challenges on Insects for Human Consumption", p. 117.

²⁶⁰ Lähteenmäki-Uutela and Grmelová, "European Law on Insects in Food and Feed", p. 3.

²⁶¹ Lähteenmäki-Uutela *et al.*, "Alternative proteins and EU food law", p. 8.

²⁶² European Commission, "Organic rules – frequently asked questions", updated on 17 July 2023, p. 61, available at https://agriculture.ec.europa.eu/farming/organic-farming/organics-glance_en.

²⁶³ "Organic insects - detailed production methods (new rules)", Published initiative, European Commission, accessed August 14, 2023, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13373-Organic-insects-detailed-production-methods-new-rules_en.

²⁶⁴ "Masaf, al via con Mimit e Salute a decreti per chiara etichettatura dei prodotti a base di insetti", Comunicati stampa, *Ministero dell'agricoltura, della sovranità alimentare e delle foreste*, March 23, 2023, https://www.politicheagricole.it/decreti_etichettatura_insetti.

The text of the decrees is not publicly available.

²⁶⁵ See Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 45 and Art. 39, and Directive (EU) 2015/1535 of the European Parliament and of 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) (Text with EEA relevance), *OJ L 241*, 17.9.2015, p. 1–15.

At the time of writing (August 2023), the TRIS database (<https://technical-regulation-information-system.ec.europa.eu/en/search>) does not show any notification from Italy with regard to these four decrees.

the quantity of insect flours that is present; equally, they would require the placing of these foods on special shelves in the shops.²⁶⁶ Similarly, Hungary and Romania have notified to the Commission draft technical regulations. The notification of Romania regards a draft order that would require food operators to, inter alia, present foodstuffs which are or contain insect species in separate stands.²⁶⁷ The notification of Hungary regards a draft decree which would also require to accompany the name of foodstuffs containing insect protein with the indication “Attention! Food contains insect protein” and to place these products separately on the shelves for consumers.²⁶⁸ The legitimacy of these draft decrees with European law, among which Article 39 of the FIC Regulation,²⁶⁹ will need to be checked by the Commission.

5.3. Conclusions

This chapter analysed how the EU legal framework for edible insects is formed by various legal acts. Regulation (EU) 2015/2283 brought some clarity concerning the characterisation of insects as novel foods. Several other laws are applicable, inter alia on food hygiene, imports, labelling, feeds materials, and it is important to note that the Commission implementing regulations for the authorisation of insects as novel foods add considerable requirements, such as specific labelling indications on allergenicity.

The second part of the chapter analysed what can be considered as problematic aspects of this legal framework. The first issue regards the existence of a level of fragmentation in the market, initially caused by the old legal regime and which partially remained because of the transitional measure of the new Novel Food Regulation. Moreover, the legal framework is characterised by different pieces of legislation that do not include specific rules for insects, which could therefore be adapted. In particular, the development of specific hygiene requirements has been advocated. Equally, existing debates relate to other EU acts that exclude insects completely from their scope of application and to the restrictions on permitted substrates for the feeding of insects. Finally, the initiatives of three Member States were

²⁶⁶ Redazione ANSA, “Stretta sulla vendita delle farine d’insetti, l’Italia vara 4 decreti”, ANSA, March 23, 2023, https://www.ansa.it/canale_terraegusto/notizie/in_breve/2023/03/23/stretta-sulla-vendita-delle-farine-di-insetti-litalia-vara-4-decreti_60926096-f9dd-4dd3-bd95-92e65a492882.html.

²⁶⁷ See Notification 2023/0111/RO, available at “Notification Detail”, European Commission, accessed August 15, 2023, <https://technical-regulation-information-system.ec.europa.eu/en/notification/23293>.

²⁶⁸ See Notification 2023/0109/HU, available at “Notification Detail”, European Commission, accessed August 15, 2023, <https://technical-regulation-information-system.ec.europa.eu/en/notification/23699>.

²⁶⁹ Regulation (EU) No 1169/2011, as lastly amended by Regulation (EU) 2015/2283, Art. 39, para. 1 provides that, in addition to the mandatory particulars indicated in the Regulation, Member States may adopt measures requiring additional ones for specific foods. However, they must be justified by at least one of the indicated grounds, i.e.:

“(a) the protection of public health;

(b) the protection of consumers;

(c) the prevention of fraud;

(d) the protection of industrial and commercial property rights, indications of provenance, registered designations of origin and the prevention of unfair competition”.

mentioned as they aim to apply stricter conditions to the labelling and selling of insect products and whose compliance with EU law has to be checked by the European Commission.

Chapter 6: The legal framework of algae

6.1. Overview of EU legislation applicable to algae

In the European Union there is not a single policy concerning algae, but several ones that regulate the topic in different aspects.²⁷⁰ First of all, the Habitats Directive²⁷¹, the Marine Strategy Framework Directive²⁷² and the Water Framework Directive²⁷³ are important EU laws applicable to algae.²⁷⁴ With regard to their production, algae can be farmed with aquaculture or harvested from the wild, and both methods are covered by the Commission's Common Fisheries Policy.²⁷⁵ The EU legislation on cultivation and collection of algae includes the Maritime Spatial Planning Directive²⁷⁶, the Alien Species Regulation²⁷⁷, the Environmental

²⁷⁰ Felix Leinemann and Valentina Mabilia, "European Union Legislation and Policies Relevant for Algae", in *Grand Challenges in Algae Biotechnology*, Grand Challenges in Biology and Biotechnology, ed. Armin Hallmann, Pablo H. Rampelotto (Springer, Cham, 2019), p. 578, https://doi.org/10.1007/978-3-030-25233-5_16.

²⁷¹ Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, *OJ L 206*, 22.7.1992, p. 7-50, as lastly amended by Council Directive 2013/17/EU.

²⁷² Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (Text with EEA relevance), *OJ L 164*, 25.6.2008, p. 19-40, as lastly amended by Commission Directive (EU) 2017/845.

²⁷³ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, *OJ L 327*, 22.12.2000, p. 1-73, as lastly amended by Commission Directive 2014/101/EU.

²⁷⁴ Leinemann and Mabilia, "European Union Legislation and Policies Relevant for Algae", p. 578.

A summary explanation of these acts is provided at European Commission, Directorate-General for Environment, "Guidance on aquaculture and Natura 2000 – Sustainable aquaculture activities in the context of the Natura 2000 Network", Publications Office, 2019, pp. 78-80, <https://data.europa.eu/doi/10.2779/34131>.

²⁷⁵ Leinemann and Mabilia, "European Union Legislation and Policies Relevant for Algae", p. 579.

²⁷⁶ Directive 2014/89/EU of the European Parliament and of the Council of 23 July 2014 establishing a framework for maritime spatial planning, *OJ L 257*, 28.8.2014, p. 135-145.

The Directive applies when algae production takes place in marine waters, as its scope of application is limited to marine waters of the Member States (Art. 2). This act lays down a framework for maritime spatial planning (Art. 1), which is to be established and implemented by each Member State (Art. 4). In this regard, the Commission also indicated in the Communication 'Towards a Strong and Sustainable EU Algae Sector' that it will encourage Member States to include algae cultivation in their maritime spatial plans (European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Towards a Strong and Sustainable EU Algae Sector, p. 10). In fact, as shown by Kuech, Breuer and Popescu, "Research for PECH Committee – The future of the EU algae sector", p. 34, seaweeds are not always included in the maritime spatial plans of Member States.

²⁷⁷ Council Regulation (EC) No 708/2007 of 11 June 2007 concerning use of alien and locally absent species in aquaculture, *OJ L 168*, 28.6.2007, p. 1-17, as lastly amended by Commission Delegated Regulation (EU) 2022/516. Art. 1 states that the subject matter of the Regulation is to establish a framework for aquaculture practices with regard to alien and locally absent species "to assess and minimise the possible impact of these (...) on aquatic habitats" and therefore also "contribute to the sustainable development of the sector". An important rule is found in Art. 6, under which aquaculture operators who wish to introduce an alien species or translocate a locally absent species must apply for a permit from the receiving Member State.

Impact Assessment Directive²⁷⁸ and the Regulation on Organic Production and Labelling²⁷⁹.²⁸⁰ Importantly, while cultivation rules are based on EU laws, the licensing procedures are national or regional.²⁸¹ Moreover, the European Committee for Standardization (CEN) created a technical committee for algae and algae-based products (CEN/TC 454) in 2017,²⁸² which, under a standardisation request,²⁸³ standardises specifications, classification, terminology and determination methods for algae and algae-based products.²⁸⁴

Once produced, when algae are used as food,²⁸⁵ the regulatory framework is complex.²⁸⁶ The General Food Law Regulation applies, along with Regulation (EC) No 852/2004 on food hygiene and legislation on traceability and safe food packaging.²⁸⁷ As many macroalgae have long been used to produce thickening and gelling agents used as additives, Regulation (EC) No 1333/2008 on food additives²⁸⁸ is applicable in this case,²⁸⁹ while Directive 2002/46/EC²⁹⁰

²⁷⁸ Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (codification) Text with EEA relevance, *OJ L* 26, 28.1.2012, p. 1-21, as lastly amended by Directive 2014/52/EU.

The Directive is relevant as it could impose an environmental impact assessment in order to create new algae farms (Leinemann and Mabilia, “European Union Legislation and Policies Relevant for Algae”, p. 580). The Directive in fact imposes to Member States to adopt all necessary measures “to ensure that, before development consent is given, projects likely to have significant effects on the environment by virtue, inter alia, of their nature, size or location are made subject to a requirement for development consent and an assessment with regard to their effects on the environment” (Art. 2).

²⁷⁹ 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, *OJ L* 150, 14.6.2018, p. 1-92, as lastly amended by Commission Delegated Regulation (EU) 2023/207.

In particular, detailed production rules for algae are set in Part III of Annex II of the Regulation, in addition to the general production rules of Art. 9, 10, 11 and 15.

²⁸⁰ Leinemann and Mabilia, “European Union Legislation and Policies Relevant for Algae”, p. 579.

²⁸¹ Lähteenmäki-Uutela *et al.*, “European Union legislation on macroalgae products”, p. 502.

For an overview of the variation in licensing procedures for seaweed cultivation in EU Member States, see Kuech, Breuer and Popescu, “Research for PECH Committee – The future of the EU algae sector”, p. 32 and p. 34.

²⁸² Lähteenmäki-Uutela *et al.*, “European Union legislation on macroalgae products”, p. 494.

²⁸³ See CEN and CENELEC Work Programme 2023, p. 54. The work is financed by the European Commission and the European Free Trade Association (EFTA) (“Food and Agriculture”, CEN sectors, CEN-CENELEC, accessed August 16, 2023, <https://www.cencenelec.eu/areas-of-work/cen-sectors/food-and-agriculture/agricultural-farming-fishing-forestry-and-related-products/>).

²⁸⁴ “Food and Agriculture”, CEN sectors, CEN-CENELEC, accessed August 16, 2023, <https://www.cencenelec.eu/areas-of-work/cen-sectors/food-and-agriculture/agricultural-farming-fishing-forestry-and-related-products/>.

²⁸⁵ Regulation (EC) No 178/2002, as lastly amended by Regulation (EU) 2019/1381, defines ‘food’ in Art. 2 as “any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans”.

²⁸⁶ Leinemann and Mabilia, “European Union Legislation and Policies Relevant for Algae”, p. 581. At p. 582, Leinemann and Mabilia provide an overview of the pieces of EU legislation applicable to algae as food and feed and the relations between them.

²⁸⁷ See Leinemann and Mabilia, “European Union Legislation and Policies Relevant for Algae”, pp. 581-583.

²⁸⁸ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (Text with EEA relevance), *OJ L* 354, 31.12.2008, p. 16-33, as lastly amended by Commission Regulation (EU) 2023/1329.

²⁸⁹ Lähteenmäki-Uutela *et al.*, “European Union legislation on macroalgae products”, p. 493.

²⁹⁰ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (Text with EEA relevance), *OJ L* 183, 12.7.2002, p. 51-57, as lastly amended by Commission Regulation (EU) 2021/418.

applies when algae are used as food supplements.²⁹¹ Moreover, Regulation (EC) No 1829/2003 on GMOs can apply.²⁹² With regard to EU rules on contaminants in foods, maximum levels have currently not been set for arsenic, cadmium, lead and mercury in seaweed,²⁹³ as the list of Regulation (EU) 2023/915²⁹⁴ does not include seaweed. The only exceptions are the maximum level that has been set for cadmium for food supplements that consist mainly or entirely of seaweed or products derived from it and a maximum residue level of mercury for algae.²⁹⁵

Regulation (EU) No 1169/2011 applies for all matters regarding information provided to consumers.²⁹⁶ Moreover, with respect to macroalgae, special requirements for labelling and marketing are established in Regulation (EU) No 1379/2013²⁹⁷ on the common organisation of the markets in fishery and aquaculture.²⁹⁸ The latter imposes additional mandatory information, including to indicate on the label the production method and the area where the product was caught or farmed.²⁹⁹ Nutritional and health claims could potentially be used as well, regulated by Regulation (EC) No 1924/2006.³⁰⁰ Furthermore, those producers who want to obtain the organic label have to comply with the above-mentioned Regulation (EU) 2018/848.³⁰¹

²⁹¹ Madalena Caria Mendes *et al.*, "Algae as Food in Europe: An Overview of Species Diversity and Their Application", *Foods* 11, no. 13 (2022), 1871, <https://doi.org/10.3390/foods11131871>.

²⁹² Leinemann and Mabilia, "European Union Legislation and Policies Relevant for Algae", p. 583.

For a brief overview of the scope of application and the applicable rules of the Regulation, see *supra* note 87, p. 10.

²⁹³ European Food Safety Authority (EFSA), Bruno Dujardin, Rita Ferreira de Sousa, Jose Ángel Gómez Ruiz, "Scientific Report on the dietary exposure to heavy metals and iodine intake via consumption of seaweeds and halophytes in the European population", *EFSA Journal* 21, no. 1 (2023):7798, p. 8, <https://doi.org/10.2903/j.efsa.2023.7798>. This article refers to the situation as it was before the adoption of Regulation (EU) 2023/915, which repealed Regulation (EC) No 1881/2006. However, the situation has remained unchanged.

²⁹⁴ Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (Text with EEA relevance), *OJ L* 119, 5.5.2023, p. 103–157.

²⁹⁵ EFSA, Dujardin, Ferreira de Sousa and Gómez Ruiz, "Scientific Report on the dietary exposure to heavy metals and iodine intake", p. 8. See Annex I of Regulation (EU) 2023/915 and Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC Text with EEA relevance, *OJ L* 70, 16.3.2005, p. 1–16, as lastly amended by Commission Regulation (EU) 2023/679.

²⁹⁶ Leinemann and Mabilia, "European Union Legislation and Policies Relevant for Algae", p. 583.

²⁹⁷ Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000, *OJ L* 354, 28.12.2013, p. 1-21, as lastly amended by Regulation (EU) 2020/560.

²⁹⁸ Lähteenmäki-Uutela *et al.*, "European Union legislation on macroalgae products", p. 494.

As indicated in Art. 2, Regulation (EU) No 1379/2013 applies to the products listed in Annex I, and the latter includes 'seaweeds and other algae'.

²⁹⁹ Regulation (EU) No 1379/2013, as lastly amended by Regulation (EU) 2020/560, Art. 35.

³⁰⁰ Lähteenmäki-Uutela *et al.*, "European Union legislation on macroalgae products", p. 494.

³⁰¹ Leinemann and Mabilia, "European Union Legislation and Policies Relevant for Algae", p. 580. See *supra* note 279, p. 29.

Finally, in the EU algae are considered novel foods,³⁰² therefore the Novel Food Regulation can apply. However, many species are considered as ‘not novel’, as it is visible from the Novel Food Catalogue,³⁰³ and thus their access to the market is not subject to Regulation (EU) 2015/2283, because they were consumed to a significant degree in at least one Member State before 15 May 1997.³⁰⁴ Considered and authorised as novel foods are instead two microalgae and different components extracted from and produced by certain microalgae³⁰⁵ and seaweeds, such as algal oil from the microalgae *Ulkenia sp.* and fucoidan extract from the seaweed *Fucus Vesiculosus*.³⁰⁶

6.2. Legal questions in the regulation of algae

A first problematic aspect of the EU legal framework applicable to algae is the lack of uniform safety rules with regard to heavy metals and toxins in algae food products.³⁰⁷ In 2018, the Commission requested Member States to monitor the levels of arsenic, cadmium, iodine, lead and mercury for the most common edible species of seaweeds in the period of 2018 to 2020,³⁰⁸ with Recommendation (EU) 2018/464.³⁰⁹ Here the Commission highlighted that available data showed how seaweeds contain important concentrations of these substances,³¹⁰ and that at the same time they are increasingly becoming a considerable contribution to the diet of certain European consumers, hence the need to assess whether the establishment of new maximum levels was necessary.³¹¹ In 2022, EFSA was also requested to assess the relevance of seaweed and halophyte consumption with respect to the dietary exposure to these heavy metals and the intake of iodine in the European population, and the relevance was confirmed by the results.³¹² However, the recently adopted Regulation (EU) 2023/915 on maximum levels

³⁰² EFSA, Dujardin, Ferreira de Sousa and Gómez Ruiz, “Scientific Report on the dietary exposure to heavy metals and iodine intake”, p. 7.

³⁰³ The Novel Food Catalogue is a non-exhaustive list of foods subject to Regulation (EU) 2015/2283, based on information given by EU countries. It serves as an orientation on whether a product will require an authorisation under such Regulation (“Novel Food Catalogue”, Food Safety, European Commission, accessed August 16, 2023, https://food.ec.europa.eu/safety/novel-food/novel-food-catalogue_en).

³⁰⁴ EFSA, Dujardin, Ferreira de Sousa and Gómez Ruiz, “Scientific Report on the dietary exposure to heavy metals and iodine intake”, p. 7.

³⁰⁵ EFSA, Dujardin, Ferreira de Sousa and Gómez Ruiz, “Scientific Report on the dietary exposure to heavy metals and iodine intake”, p. 7.

³⁰⁶ See Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (Text with EEA relevance), *OJ L 351*, 30.12.2017, p. 72–201, as lastly amended by Commission Implementing Regulation (EU) 2023/972.

³⁰⁷ Lähteenmäki-Uutela *et al.*, “European Union legislation on macroalgae products”, p. 503.

³⁰⁸ National Food Institute *et al.*, “Analysis and Risk Assessment of Seaweed”, *EFSA Journal* 17, no. S2 (2019):e170915, p. 4, <https://doi.org/10.2903/j.efsa.2019.e170915>.

³⁰⁹ Commission Recommendation (EU) 2018/464 of 19 March 2018 on the monitoring of metals and iodine in seaweed, halophytes and products based on seaweed (Text with EEA relevance), C/2018/1560, *OJ L 78*, 21.3.2018, p. 16–18.

³¹⁰ Commission Recommendation (EU) 2018/464, Recital 4.

³¹¹ Commission Recommendation (EU) 2018/464, Recital 5.

³¹² EFSA, Dujardin, Ferreira de Sousa and Gómez Ruiz, “Scientific Report on the dietary exposure to heavy metals and iodine intake”, p. 41. See the article in its entirety for a more detailed explanation of the results.

for certain contaminants in food, which repealed the old Regulation (EC) No 1881/2006³¹³, has not altered the situation regarding maximum levels for seaweeds: as explained above, there is still no regulation at EU level on the maximum level of cadmium, mercury, arsenic and lead in seaweeds.³¹⁴ Nevertheless, the Commission indicated in the Communication 'Towards a Strong and Sustainable EU Algae Sector', that it will, subject to EFSA's advice, "start discussions on the establishment of maximum levels of contaminants and iodine in algae and/or the adoption of a new monitoring Recommendation" for those species for which there is still insufficient data, with a view to establish maximum levels.³¹⁵

Moreover, in the same Communication, the Commission also highlighted that the governance framework and legislation need to be improved in order to fully harness the opportunities of the EU algae sector.³¹⁶ In fact, several EU and national laws are applicable to seaweed aquaculture,³¹⁷ as analysed above, and there is significant fragmentation in areas where there is no EU harmonisation and therefore different national laws apply, such as in licensing, access to marine space and species to farm.³¹⁸ Consequently, it was stressed that a more coherent approach could strengthen the algae sector.³¹⁹

6.3. Conclusions

This chapter firstly analysed the EU legislation applicable to algae, and it highlighted that they are regulated by a variety of legal acts. In particular, the EU regulatory framework for algae as food products includes rules on food additives and food supplements, hygiene requirements, labelling (including the use of organic labels). The Novel Food Regulation can apply, but many species are placed on the market as 'not novel'. In this regard, the main issue can be identified

³¹³ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (Text with EEA relevance), *OJ L 364*, 20.12.2006, p. 5-24.

³¹⁴ See Regulation (EU) 2023/915, Annex I.

³¹⁵ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Towards a Strong and Sustainable EU Algae Sector, p. 14.

Moreover, the Commission also indicated in this Communication that, by the end of 2026, it will "develop standard testing, quantification and extraction methods for algae ingredients and contaminants" together with CEN (p. 10).

³¹⁶ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Towards a Strong and Sustainable EU Algae Sector, p. 9.

³¹⁷ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Towards a Strong and Sustainable EU Algae Sector, p. 8.

³¹⁸ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Towards a Strong and Sustainable EU Algae Sector, p. 10.

³¹⁹ European Commission, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Towards a Strong and Sustainable EU Algae Sector, p. 8.

in the fact that there is a regulatory gap in the lack of uniform safety rules and general fragmentation in the legislation, for which a more coherent approach is needed.

In light of what analysed so far, the final section of the paper will draw the final conclusions in order to answer to the initial research question.

Chapter 7: Conclusion

This thesis aimed to understand to what extent the EU legal framework is sufficiently adequate to regulate the current and future developments of alternative proteins. In fact, these are evolving fast, and while some are still in the research phase, many are already on the market.

It was highlighted how the concept of alternative proteins is broad and can include different sources of this macronutrient. This work focused on four categories, i.e., plant-based alternatives to meat and dairy, cultured meat, edible insects and algae. The first chapter provided the necessary definitions and analysed the reasons that explain the rise in interest in alternative proteins, and it underlined how the latter could be useful in view of current global challenges, e.g., guaranteeing food security and environmental sustainability. Accordingly, they can be found on the EU agenda, as they are included in the Farm to Fork Strategy of the European Green Deal, notably as a key area of research. In order to ensure food safety and at the same time harness their full potential, the legal framework is extremely relevant. Therefore, the following chapters first provided an overview of applicable EU laws, in order to understand the complex structure and functioning of the legal framework, and subsequently highlighted what can be considered as problematic aspects in the legislation, respectively for plant-based alternatives, cultured meat, edible insects and algae.

The second chapter underlined that there exists a difference of treatment for plant-based meat alternatives and plant-based dairy alternatives in terms of naming, with the regulation of the latter being more restrictive; however, it can be questioned whether, considering the unequal consumer protection and the similarity between the two sectors, the legislation could be updated. The possible use of the terms 'vegan' and 'vegetarian' has been advanced as another solution, but there is currently no homogenous EU legal definition. For cultured meat, which is not present yet on the EU market, the discussion mainly revolves around the naming and the labelling. In this scenario, the specific authorisations that currently play an important role for the regulation of approved insects will probably do the same for cultured meat. However, it can be questioned whether it would be desirable to have some prior interventions in the legal framework or clarifications, for instance regarding the terminology, which is an issue of current legal uncertainty. The fourth chapter on insects underlined different concerns. These relate, inter alia, to the persistence of legal acts not envisaged for the regulation of insects and of a partial fragmentation of the market due to the old regime and the transitional measure of the Novel Food Regulation. Moreover, the Commission authorisations for the placing of insects on the market are used for the imposition of further requirements, however these are applicable only to the concerned species; therefore, in the future they could be translated, if relevant for all insects, to the general regulations. Insects are also excluded from the animal welfare

legislation and there are no specific rules for organic insect production, even if for the latter there is a pending initiative at EU level. Moreover, existing discussions concern as well feed materials that can be used for insects. The last chapter on algae firstly examined the lack of harmonised rules on heavy metals and toxins, which is of particular importance also for what concerns the protection of health; in this regard, the Commission is in fact envisaging to act in the near future. Equally, it was underlined at EU level that a more coherent approach is needed in the sector's governance framework and regulation. Finally, this thesis described different unilateral interventions by Member States that deserve careful attention.

In conclusion, it can be asserted that, considering the several legal questions that can be raised, the EU legal framework could use some reforms. While some actions are on the agenda, such as improving the governance framework of the algae sector under the recent Communication COM (2022) 592 final, others are absent, for example, there seem to be no plans to implement Article 36(3)(b) of the FIC Regulation or to set animal welfare rules for insects. Apparently, the legislator does not see the need of intervening in this moment. However, the recent initiatives of some Member States on the naming of plant-based food, the knowledge that sooner or later an application to EFSA for cultured meat will arrive, the growing number of authorisations for insects as novel foods and the clear action points of the Communication concerning the algae sector are examples that press for some changes or clarifications. What is key is not only the protection of consumers, both in terms of food safety and provision of information, but also legal clarity for food operators, the respect of the free movement in the internal market as well as ensuring that these alternative proteins can effectively contribute to pressing global challenges. Moreover, the unilateral interventions of some Member States, from aiming to impose further labelling requirements on products containing insects to proposing the prohibition of producing and marketing cultured meat before it is authorised, could also be interpreted as a sign that a strong EU legal framework, capable of ensuring uniformity and stability, is even more essential. Therefore, it could be concluded that the EU legal regime, although certainly advanced and capable of guaranteeing the attainment of its objectives, could need some further intervention in order to more adequately regulate the current and future developments of alternative proteins.

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