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Alternative proteins and EU food law

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ABSTRACT

We ask how European food law impacts the transformative potential of alternative proteins, including single-cell proteins, plant-based novel proteins, cultured meat,macroalgae, and insects. The Novel Food Regulation may prove insurmountable for small companies, and it is demanding and time-consuming even for larger companies, dampening the transformative potential of all novel foods and traditional foods from third countries. Several microalgae and macroalgae are non-novel in the EU, which eases their way into the markets. The unclear novel food status of some potential green macroalgae species is a hindrance. All insects are novel, and none has EU-level authorization yet, although some Member States allow insect food. The GM Food Regulation is procedurally and scientifically demanding, and it forces GM labelling. The Regulation dampens the transformative potential of food GM technology. In addition to crops and fruit, GM Food Regulation applies to genetically modified or edited microbes,microalgae, cultured meat, and insects. The naming and labelling rules of plant-based products have caused controversy. From the business perspective, the health claims process is similarly challenging as the novel food process. EU food law must guarantee food safety and consumer rights while applying the principles of nondiscrimination and proportionality.

1. Introduction

According to the UN Food and Agricultural Organization (FAO 2016), "sustainable diets are protective and respectful of biodiversity and ecosystems, culturally acceptable, accessible, economically fair and affordable; nutritionally adequate, safe and healthy; while optimizing natural and human resources." As the livestock sector is highly resource-demanding (Gerber et al., 2013) and the negative environmental, ethical and human health impacts of the meat industry are still increasing (Scollan et al., 2011), alternative proteins are sought for (Post 2012, pp. 297–298). In addition to meat, alternatives are sought for seafood, dairy and egg products.

Sexton et al. (2019) list cultured meat, insects, and plant-based proteins as three important groups of alternative proteins (with algae and pulses included in plants). van der Weele, Feindt, van der Goot, van Mierlo, and van Boekel (2019) studied cultured meat, algae, insects, plant-based meat alternatives, and pulses as five important groups of meat alternatives. Parodi et al. (2018) argue that the potential of cultured meat, algae, and insects as important parts of future diets will depend on nutrient bioavailability and digestibility, food safety, production costs, and consumer acceptance. Parodi et al. do not mention the role of regulation, but van der Weele et al. (2019, p. 509) recognize that meat alternatives are currently embedded in "very different socio-legal regimes". In practice, this means that regulatory unclarities and barriers are relevant for the more innovative types of alternative proteins.

Food system transformations can be studied as sociotechnical system transitions (Anderson & Leach 2019, pp. 131–146). The "Multi-Level Perspective" introduced by Geels (2006) is one of the most popular theories in transition sciences. The theory sees 'niches' of innovation proceeding into the prevalent sociotechnical 'regime' and transforming its science and culture, where this process is affected by the socio-technical 'landscape (Anderson & Leach 2019, pp. 131–146.) The regime is "the highly institutionalized core of an organizational field", and niches represent alternative configurations (Fuenfschilling – Truffer 2014). The Multi-Level Perspective (Geels 2002; Geels - Schot 2007, Geels et al., 2015) posits that the niches should be promoted by the government, i.e. innovation in sustainable and responsible products should be encouraged (Kemper – Ballantine 2017, pp. 382–383). Another important transitions theory, the technological innovation

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systems theory (Bergek, Jacobsson, Carlsson, Lindmark, & Rickne, 2005; Hekkert et al., 2007; Markard -; Truffer 2008; Hekkert et al., 2011; Truffer - Coenen 2012), shares the view of governments as important actors shaping the innovation environment.

In the language of the Multi-Level Perspective, traditional meat, fish, dairy and egg products form the 'regime', alternative proteins are the 'niches', and food law is part of the landscape (McMeekin - Southerton 2012, p. 957). In this review, we explore the implications of current European Union (EU) food law for different alternative proteins and analyse its impacts from a sustainability transition perspective. By food law, we mean government rules on food products. We seek to answer the following research question:

- how does European food law apply to alternative protein products?

Chapter 2 discusses EU food safety law, where the Novel Food Regulation is central for the market access of innovative products. Chapter 3 focuses on EU food marketing law. The names of vegan/vegetarian products have caused legal disputes. The law on names and claims impacts how alternative proteins can be described for consumers. Chapter 4 critically examines the goals and impacts of EU food law and proposes how it could be used to advance the goal of sustainable diets.

2. European law on food safety

2.1. Pre-market approval for novel foods

The precautionary principle is laid out in Article 191 (2) of the Treaty on the Functioning of the EU (the Maastricht Treaty). Originally, the principle related to environmental protection, but EU case law has expanded its application to all areas of health and safety (Tosun 2013). In food law, the precautionary principle applies to situations where there are reasonable grounds for concern that an unacceptable level of risk to health exists, and the available supporting information and data are not sufficiently complete to enable a comprehensive risk assessment (Article 7 of the General Food Regulation). In these circumstances, measures may be taken while seeking more complete evidence. The principles of non-discrimination and proportionality must be followed when taking risk management and consumer protection measures. (See Szhajkowska 2010.)

The EU precautionary approach applies to all novel foods including genetically modified foods. Such foods require pre-market approval. The Novel Food Regulation originated in 1997 (EC/258/1997) with the primary objective of regulating genetically modified foods (Ballke 2014). After six years, genetically modified foods were removed from the Novel Food Regulation as the Regulation on Genetically Modified Foods (GM Food Regulation) was given (EC/1823/2003). All non-GM novel foods are currently evaluated under the 'new' Novel Food Regulation that was adopted in 2015 (EU/2015/2283). The Regulation applies to all foods that were not consumed in Europe before 1997, including e.g. all plants and fruit that have been used in third countries but not in Europe (see Hermann 2009). The new Regulation created a simplified notification procedure for traditional foods from third countries, where history of safe use for 25 years is the focus of legal attention. This new procedure is applicable e.g. to some macroalgae and insect species that have long been used for example in Asia. Novel food authorizations, both those based on applications and those based on notifications, are generic: once a novel food has been authorized, anyone can market food products that have the same conditions of use and the same specifications. Authorizations based on proprietary data are an exception with five years of data protection (Article 26 of the Regulation).

According to the General Food Regulation EU/178/2002, pre-market procedures should be based on scientific risk assessment, and they should be transparent. In the European novel food and GM food procedures, food business operators are responsible for proving the safety and nutritional impact of their products. The European Food Safety Authority (EFSA) evaluates the scientific evidence, and the European Commission as the risk manager decides on authorizations. "A high level of protection of human health and of consumers' interests and the effective functioning of the internal market" are stated as the goals of the Novel Food Regulation (preamble 2). Similarly, the GM Food Regulation (EC/1823/2003) states the free movement of goods and the protection of human health as its goals (preambles 1 and 2). Climate change mitigation, environmental protection, circular economy, provision of rural livelihoods, realization of human rights, or transformation towards sustainable diets are not named as targets or even considerations for EU food law, these goals are however recognized in the Farm to Fork Strategy (European Commission 2020).

The EU and the US are often compared as regards their approaches to food safety. Norton discusses how the US does not follow the precautionary principle but instead is "a science-based regulatory country" (Norton 2015, p. 177). With innovative food products, there always tends to be a regulatory lag, even if regulators acknowledge that periods of uncertainty and unpredictability are harmful for innovation and competition. Neuwirth (2014) sees a risk in overregulating novel foods, recalling that food has always been altered, starting from control over fire (Neuwirth 2014, p. 47). Neuwirth sees food technology as a creative economy comparable to ICT where innovation should be promoted instead of being discouraged. van der Weele et al. (2019, p. 509) recognize the European Novel Food Regulation (EU/2015/2283) as a potential barrier to market access with cultured meat, algae, and insects. Proteins extracted from familiar plants may also go under the novel food category. Next, we discuss EU food safety law in the context of different types of alternative proteins.

2.2. Products of cellular agriculture

Rischer et al. (2020) use the term 'cellular agriculture' in a broad sense covering the cultivation of microbes, plant cells, and animal cells. *Fermentation-based* cellular agriculture is routine in industrial biotechnology. Fermentation uses microbes (bacteria, algae or yeasts), usually genetically adapted by adding recombinant DNA, to make organic molecules (Ritala et al., 2017). These molecules can then be used to fabricate familiar animal products. *Tissue engineering* to make cultured meat is more challenging, but still a target of enthusiastic research and innovation. Rischer et al. (2020) see microbes and plant cells as very attractive alternative foods, and animal cells (cultured meat) as a promising technology for the future.

2.2.1. Single-cell proteins

Single-cell proteins (SCPs) are produced by the cultivation of microbial cell lines including those from yeasts, fungi, and bacteria. In addition, photosynthetic microalgae and cyanobacteria are a promising alternative protein source: they grow and multiply by harvesting light energy (Grossmann et al., 2020). Regardless of the technical challenges and the regulatory hurdles, the interest towards SCPs is increasing due to the efficient and sustainable biomass production with minimal land use and small input of energy and growth substrates (Ritala et al., 2017; Sillman et al., 2020) Developments in the biomass processing, gene editing methods, and the discovery of novel production organisms is accelerating the research and business in the field.

Microbes can be grown on variety of substrates including side streams and waste from the agri-food industry, making them a sustainable source of protein for human and animal consumption (Matassa et al., 2016; Sharma et al., 2018; Acosta et al., 2019). Moreover, several microbes can utilize unique substrates like CO or methane, providing high efficiency for protein production and a possibility to couple the protein production with industry effluent gases (Ritala et al., 2017; Acosta et al., 2019). Although the use of agri-food side streams and waste as microbial growth substrates sounds appealing, it may cause transfer or accumulation of toxic contaminants like pesticides or heavy

metals into the produced microbial biomass (Acosta et al., 2019). Use of high-grade carbon sources like glucose increasing the production costs but ensures the safety and high quality of the food products.

Microbial biomass typically has a high protein content varying from 30 to 80% of the dry weight and its amino acid composition meets the FAO and WHO requirements concerning the content of essential amino acids for human nutrition (Matassa et al., 2016, Ritala et al., 2017). Genetic modification of the organisms used in the production of single-cell proteins offers appealing solutions for improving the nutritional quality of the SCPs (Xie et al., 2015). Moreover, with genetic modification, the organism's tolerance to various growth substrates can be altered, or the organisms can be modified to utilize different carbon sources (Song et al., 2017). Microbes may be genetically engineered to produce selected animal proteins like casein or whey protein to replace traditional livestock-based food products. These are exemplified by the animal-free ice cream launched in 2019 in the USA by the company Perfect Day, Inc. (www.perfectdayfoods.com). *Genetic modification makes the microbial protein subject to the strict EU GM Food Regulation.*

The Novel Food Regulation focuses on the nutritional and food safety concerns with human foodstuffs, and in microbial proteins the main food safety concerns are the high RNA content, toxic metabolites and contamination of the microbial cultures with other microorganisms (Ritala et al., 2017). The biomass produced by cellular agriculture may be harvested and processed for food as such, or its proteins may be extracted to produce a pure protein isolate. Protein extraction may causes significant changes to the nutritional content of the raw material and the resulting protein isolate may thus be considered a novel food, although the production organisms itself would not fall under Novel Food Regulation (Regulation (EU) 2015/2283, Hilderbrand et al., 2020; Rahman et al., 2021).

Table 1 lists the microorganisms that are accepted for food use in the EU (Table 1). Some of them, like baker's yeast (*Saccharomyces cerevisiae*), have a long history of food use in the EU member countries. One of the most successful microbial protein products is Quorn, which is produced from the mycoprotein of *Fusarium venenatum* microfungus. It came to the market on 1985 in the United Kingdom and to wider distribution in Europe during the 1990's (Wiebe 2004). It is probably the world's largest meat alternative brand. Quorn entered the EU market before the Novel Food Regulation (Wiebe 2004). Four microbial strains have been authorized via the Novel Food Regulation, although their use is restricted to food supplements or they may be used only as small quantities in specified food products (Table 1). Most of the microorganisms that do not fall under the novel food regulation, due to their consumption in EU countries already before the novel food regulation came effective, are cyanobacteria and microalgae, and include three *Chlorella* species, *Arthrospira platensis* and *Spirulina* sp. That may cover various species marketed as spirulina, and one cyanobacterium species, *Aphanizomenon flosaquae* (EU Novel Food Catalogue).

One potential example of a novel bacteria-produced microbial protein is Solein, a protein-rich powder produced by company Solar Foods. Solein is produced in a fermentation reaction by a soil bacterium that oxidizes hydrogen produced by electrolysis of water and fixes atmospheric carbon dioxide. The product is not yet on the market, and the company is gathering the dossier for novel food authorization and aims for authorization withing the EU in 2021 (https://solarfoods.fi/about-us/#roadmap, site visited in March 2021). Another example of SCPs is PEKILO, a *Paecilomyces variotii* mycoprotein that was first developed already in the 1960's to valorise side streams from paper and pulp industry and produce protein rich feed for fish and poultry (Koivurinta et al., 1980). PEKILO was in commercial production until 1991 and currently, the PEKILO production is owned by a start-up company eniferBio (https://www.eniferbio.fi/). Although PEKILO was first developed for protein rich feed, its properties as food ingredient have also been studied (Koivurinta et al. 1979, 1980).

The use of microbial proteins as animal feed material may pave the way also for microbial proteins for human consumption. The EU catalogue of feed contains multiple materials of microbial origin (Commission Regulation (EU) No 68/2013). Moreover, the feed law also lists the accepted growth substrates for each microbial strain. The used substrate may have a large impact on the nutritional content and possible contaminants in the SCP products, but also determines the sustainability and carbon footprint of the SCPs. From feed safety point of view, the regulation of suitable substrates and production methods for SCPs is apprehensible but increases the regulatory hurdle for novel SCPs and technologies.

Standardised procedures for the identification and analysis methods for the SCPs are crucial to ensure the safety of food and feed products. To address this issue, the EFSA has established a technical committee on algae and algae products with the aim of defining practices and standards for micro- and macroalgae. However, common standards and practices need to be considered for all SCPs. Moreover, in the future, the EU may have to decide whether the SCPs regulation is focused on the final product itself or is there a need to regulate the use of various growth substrates in the production stage. Comparing the prospects on microalgae in the United States and in Europe, Enzing et al. (2014) see

Table 1
Microorganisms accepted as food in the EU. *Consumed in EU countries before 1997.

Scientific name	Common name	Organisms	Legal status	Reference
Aphanizomenon flos-aquae	AFA	Cyanobacterium	Not novel*	EU Novel Food Catalogue
Spirulina sp.	Spirulina	cyanobacterium	Not novel*	EU Novel Food Catalogue
Arthrospira platensis	Spirulina	cyanobacterium	Not novel*	EU Novel Food Catalogue
Chlorella luteoviridis	Chlorella	microalga	Not novel*	EU Novel Food Catalogue
Chlorella pyrenoidosa	Chlorella	microalga	Not novel*	EU Novel Food Catalogue
Chlorella vulgaris	Chlorella	microalga	Not novel*	EU Novel Food Catalogue
Odontella aurita		microalga	Authorized novel food, for use as small quantities in specified food products	(EU) 2017/2470
Tetraselmis chuii		microalga	Authorized novel food, small quantities in specified food products and as food supplements	(EU) 2017/2470
Saccharomyces cerevisiae	Brewer's yeast, budding yeast	microfungus, yeast	Not novel*	
Fusarium venenatum		microfungus	Not novel*	Wiebe (2004)
Yarrowia lipolytica		microfungus, yeast	Authorized novel food, only for use in food supplements	(EU) 2017/2470
Clostridium butyricum		bacterium	Authorized novel food, only for use in food supplements	(EU) 2017/2470

European regulation as a weakness. In particular, the regulations on GMOs are relatively more restrictive in Europe. While the European rules focus on the use of specific technology, the American rules focus on the safety of the final food product. The European Algae Biomass Association urges the governments to accelerate the commercialization of algae through regulation that is "smart and effective" (Health and Beauty Close – Up 2015).

2.2.2. Cultured meat: tissue engineering based on animal cells

In addition to microbes and plant cells, animal cell cultures can be used to produce protein rich biomass, more complex biochemicals or tissues. For producing cultured meat or seafood, cells are taken from a live animal, put into a bioreactor and fed a growth medium which enables them to grow and divide. The cells are turned into muscle and fat cells through a process called 'differentiation'. Cultured meat is produced out of these differentiated cells through tissue engineering (Tuomisto et al., 2011; Stephens et al., 2018). In comparison to meat production, the cultured meat process has potential to lower the environmental impacts while also providing safer and healthier foods without the risk of zoonosis and without antibiotic residues or growth hormones. In December 2020, the Singapore Food Agency authorized the lab-grown chicken by US start-up Eat Just. This was the first cultured meat authorization in the world (Lucas 2020). Other cultured meat companies include for example Mosa Meat, Memphis Meats, JUST Meat, and Aleph Farms. Hoxton Farms cultivates animal fat to be added to plant-based products, and Gourmey prepares foie gras from duck egg cells. The first target market of Gourmey is the United States, as "the FDA and the USDA are making great progress in paving the way for cultured meat access to market". Gourmey also mentions Singapore as a country that welcomes cultured meat and sees the European Novel Food Regulation as offering a clear procedure (FoodNavigator.com May 14, 2020.). Companies around the cultured meat production process include CellulARevolution with their 'continuous bioreactors' and CellRx that focuses on the signalling proteins that guide cell growth and differentiation in the reactors.

In Europe, all types of cultured animal tissue are considered novel foods due to the novel production process. If the cell-lines used in the bioreactor are genetically modified, the GMO food regulation applies (Stephens et al., 2018). Petetin (2014) says the EU Novel Food Regulation needs to be developed as in how it relates to cultured meat. Norton (2015) also argues that with cultured meat, the precautionary approach as implemented by the EU may lead to hard demands that producers just cannot meet (Norton 2015, p. 178). Lee (2018), on the other hand, sees that regulating cultured meat as a natural science issue only can be non-democratic, non-transparent, and exclusionary (Lee 2018, 30). Regulators may hide behind science and further only one set of value judgments, the technocratic one. Lee sees the approval of cultured meat as a value judgment that confirms meat as desired and meat-eating as inevitable.

2.3. Plant-based alternative proteins

Pulses and many other protein-rich plants that may be categorized as alternative proteins are not novel foods in the EU. This applies e.g. to soybean, chickpeas, lentils, peas, and fava beans. From the list of van der Weele et al. (2019), pulses are the meat alternatives with clearly the easiest access to the EU markets. Extracting a protein and treating it with novel methods may alter the nutritional impact and make the final product a novel food. Plant proteins are now used in several products that mimic meat, seafood, and dairy products. Beyond Meat and Impossible Foods are examples of plant-based meat companies. Companies such as Good Catch, Ocean Hugger and Loryma are developing plant-based seafood, and for example Oatly and Valio have their plant-based dairy alternatives.

One interesting technological innovation in the plant-based business is leghaemoglobin (Seehafer & Bartels 2019; Petetin 2014). Leghaemoglobin is found in the nitrogen-fixing root nodules of leguminous plants. It is produced in response to the roots being colonized by nitrogen-fixing bacteria, rhizobia, as part of the symbiosis between the plant and the bacterium. Leghaemoglobin is an iron-containing molecule similar to hemoglobin derived from meat, and it can be used in plant-based products to mimic the color, taste, and texture of meat. In the US, the company Impossible Foods got FDA approval to use soy leghaemoglobin in foods in 2019. Impossible Foods ultimately sees Asia as its core market. Impossible Foods is also targeting the EU. The company uses genetically modified yeast in the production process of soy leghaemoglobin, which may mean difficulties in Europe. Impossible Foods filed the application for the authorization of the end-product in the Netherlands in September 2019. It is still unclear whether using genetically modified ingredients in the production process will make the end product fall under the EU GMO regulation, if the product itself is not a GMO (Seehafer & Bartels 2019). According to Stephens et al. (2018), it is likely that the production method will have an impact on the regulatory pathway in the EU.

Another example of a plant-based novel protein-rich food ingredient is mung bean protein produced by the US start-up JUST. The protein extraction technology is patented at least in the United States. The isolate has mainly been used as a scrambled egg alternative, but the intention of the company is to use it in a variety of products ranging from crackers and snacks to beverages. In order to access the EU markets, the company filed an application for consultation to determine the status of a novel food, pursuant to Article 4 (2) of the Novel Food Regulation. The application was submitted at the Food Standard Agency of the UK. The isolate differs from mung bean flour that has previously been used in the EU: the new product has 95% protein as the fat and carbohydrate fractions have been removed. Because the protein isolate has no history of consumption in the EU area, it was decided in 2019 that it is a novel food. The company must apply for authorization and provide evidence on safety and nutritional impact. For the novel food status in Europe, it was irrelevant that the product is on the market outside the EU since November 2017, with no adverse effects reported (UK Food Standards Agency.).

The company Nova Meat produces plant-based 'beef' steaks and 'pork' skewers by 3D printing technology, which gives the possibility to control the texture and appearance of food products. Their meat-mimicking products are made from several different plant-based ingredients including pea isolate, rice isolate, olive oil, and brown seaweed extract. A salmon-mimicking 3D printed product is also in the plans. The company plans to have the 'beef' and 'pork' products in restaurants in 2020 and in industrial production in 2021. In Europe, 3D printed foods are deemed novel foods because of their production process, regardless of whether the ingredients are novel (Baiano 2020). Product names such as "beef 2.0" or "pork 2.0" are not allowed on plant-based products, see chapter 3 below.

2.4. Macroalgae foods

In comparison to terrestrial plants, macroalgae grown in seas and lakes have important benefits: they do not require land, irrigation, fertilizers or pesticides to grow (Øverland et al., 2019). Most brown macroalgae have relatively low protein content, but red and green algae may contain over 30% of protein of their dry weight (Øverland et al., 2019). Moreover, the quality of macroalgal protein is good for human and animal nutrition as the proportion of essential amino acids of total amino acids is usually close to 40% and relative to that of soy and corn (Maehre et al., 2014).

The variety of the macroalgae species that can be utilized as food and feed is limited by the established aquaculture methodology and the possibilities of sustainable harvesting of the wild macroalgae stocks (Borges et al., 2020; Campbell et al., 2019). At the moment, most of the cultivated macroalgae biomass in Europe is brown macroalgae, which have a low protein content compared to some red and green algae

(Campbell et al., 2019; Øverland et al., 2019). However, as aquaculture techniques are under development, green algae such as *Ulva* spp. are gaining interest in Europe.

Although macroalgae have not been widely utilized as food in Europe, some commonly used native European species can be found in the Novel Food Catalogue categorized as "not novel", meaning that their use as food is authorized based on their usage already before 1997. These include for example several species of orders *Laminariales* and *Fucales* as well as the red algae *Chondrus crispus* and *Palmaria palmata* (Table 2). However, the edible green algae are poorly covered in the Novel Food Catalogue. Of the native European species, *Enteromorpha* sp. and *Ulva lactuca* are listed as not novel foods, but more species of the order *Ulvales* need to be authorized in the future, as the order contains several potent crop species for aquaculture, and many of these species have history as food and feed in different parts of the world. It would benefit the industry if these were added to the positive list of species allowed. Despite the approved use of selected species of macroalgae, the novel food status is not clear for any protein isolates or concentrates from these approved macroalgae species.

Table 2
Macroalgae species that have long history of safe use and are listed in the EU Novel Food Catalogue or by CEVA. *Consumed in EU countries before 1997.

Macroalgae	Common name	Legal status	Reference
Brown algae			
Alaria esculenta	Dabberlocks	EU/Not novel*	EU Novel Food Catalogue
Ascophyllum nodosum/ Ascophyllum laevigata/ Fucus nodosus	Rockweed	EU/Not novel*	EU Novel Food Catalogue
Eisenia bicyclis	Arame	EU/Not novel*	EU Novel Food Catalogue
Fucus serratus	Saw wrack	EU/Not novel*	EU Novel Food Catalogue
Fucus spiralis	Spiral wrack	EU/Not novel*	EU Novel Food Catalogue
Fucus vesiculosus	Bladderwrack	EU/Not novel*	EU Novel Food Catalogue
Himanthalia elognata	Sea spaghetti	EU/Not novel*	EU Novel Food Catalogue
Laminaria digitata	Oarweed	EU/Not novel*	EU Novel Food Catalogue
Laminaria longicruris		EU/Not novel*	EU Novel Food Catalogue
Saccharina japonica/ Laminaria japonica		EU/Not novel*	EU Novel Food Catalogue
Saccharina latissima/ Laminaria saccharina	Sugar kelp	EU/Not novel*	EU Novel Food Catalogue
Sargassum fusiforme	Hijiki/Hizikia	EU/Not novel*	EU Novel Food Catalogue
Undaria pinnatifida	Wakame	EU/Not novel*	EU Novel Food Catalogue
Red algae			
Chondrus crispus	Irish moss	EU/Not novel*	EU Novel Food Catalogue
Gracilaria verrucosa		EU/Not novel*	EU Novel Food Catalogue
Lithothamnium calcareum	Mäerl	EU/Not novel*	EU Novel Food Catalogue
Porphyra tenera	Nori	EU/Not novel*	EU Novel Food Catalogue
Porphyra lacinata	Nori	CEVA/Used before 1997	CEVA (2019)
Porphyra umbilicalis	Nori	CEVA/Used before 1997	CEVA (2019)
Pyropia leucostica	Nori	CEVA/Used before 1997	CEVA (2019)
Porphyra dioica	Nori	CEVA/Used before 1997	CEVA (2019)
Porphyra purpurea	Nori	CEVA/Used before 1997	CEVA (2019)
Porphyra yezoensis	Nori	CEVA/Used before 1997	CEVA (2019)
Palmaria palmata	Dulse	EU/Not novel*	EU Novel Food Catalogue
Green algae (macroalgae)			
Enteromorpha sp.	Anori, Green laver	EU/Not novel*	EU Novel Food Catalogue
Ulva lactuca	Sea lettuce	EU/Not novel*	EU Novel Food Catalogue
Ulva sp.	Sea lettuce	CEVA/Used before 1997	CEVA (2019)
Monostroma nitidum	Green nori	EU/Not novel*	EU Novel Food Catalogue

In France, the Algae Technology and Innovation Centre (Centre d'Étude et de Valorisation des Algues; CEVA) has published a list of macroalgae species used for food consumption in France (CEVA, 2019). This list contains several species that are not listed in the EU Novel Food Catalogue. Table 2 shows the macroalgae that are allowed as food in the EU as they are non-novel. The table is based on the information in the Novel Food Catalogue and CEVA list of edible macroalgae.

Although many macroalgae species have long history of consumption in the EU member countries, macroalgae aquaculture in the EU has been minor and the existing macroalgae industry relies heavily on harvesting of wild growing macroalga populations (Mac Monagail et al., 2017). However, increasing demand of sustainable algal biomass requires production by aquaculture. A major bottleneck in the production of macroalgae are shortcomings in regulatory procedures for establishing the macroalgae aquaculture sites and for evaluating their environmental impacts. One issue with macroalgae is the accumulation of heavy metals, which depends on cultivation site (García-Seoane et al., 2020; Lähteenmäki-Uutela et al., 2021).

2.5. Insect foods

The European insect sector sees food and feed law as one of the main factors impacting its growth. According to IPIFF, the sectoral lobby, "efforts are ongoing to broaden the opportunities available" (IPIFF 2018). To help the insect sector particularly with the European Novel Food Regulation, IPIFF has published its briefing paper (IPIFF 2019) and created a database of studies on the safety of insects.

For some years, some EU Member States have allowed insects as food and created national rules. The new European Novel Food Regulation and its centralized authorization procedure became applicable in the beginning of 2018. It applies to whole insects, insect parts, insect flour, or insect extracts to be marketed in the EU. A *transitional period* for whole insects and their preparations has been applied in the UK, Denmark, the Netherlands and Finland as these countries interpreted that whole insects were not included in the old novel food regulation, and the new Novel Food Regulation (Article 35.2) states that if foods were lawfully marketed by January 1, 2018 in a Member State, and a novel food application or notification was submitted by January 1, 2019, they are allowed until the Commission decision on the application or notification comes. Belgium, Austria and Czech Republic have also continued to allow insect foods based on their own rules. This means that several insect species continue be sold as food in the EU area without novel food authorization, but only in some of the EU countries. In a legal case brought to the Supreme Administrative Court in France by company Entoma, the European Court of Justice resolved that whole insects and their preparations were indeed *not* covered by the old Novel Food Regulation. For food products made of whole insects, the transitional period granted by the new Novel Food Regulation therefore applies. This means that for companies that were in the insect business and legally marketed their products on January 1, 2018 and for which an application or notification was made by January 1, 2019, the transitional period, i.e., the permit to continue with the marketing, should apply across the EU.

Applications for EU novel food authorization have been submitted for all the edible insect species that are at the focus of research and business attention. None have yet been authorized yet (situation March

2021, Table 3). General applications for authorizing house cricket (*Acheta domesticus*), migrating cricket (*Locusta migratoria*) or black soldier fly (*Hermetia illucens*) have not yet reached EFSA assessment. Neither has the general application for mealworm (*Tenebrio molitor*). As discussed above, the submission of these general applications impacts the EU markets as transitional measures apply to insects on which the regulatory process is ongoing.

The three first applications to pass the first validity and completeness checks by the European Commission and EFSA were the applications on dried banded cricket (*Gryllodes sigillatus*) and dried mealworm (*Tenebrio molitor*) by the French company Micronutris (currently Agronutris) and whole and ground lesser mealworm (*Alphitobius diaperinus*) larvae products by the Dutch company Protifarm. These were put forward to EFSA for assessment in July 2018 (IPIFF 2019, p. 6). All request the protection of proprietary data. This means that for five years after possible authorization, other marketers would not be allowed to use the proprietary data if EFSA sees that this data was necessary to prove safety. The EFSA requested for additional evidence for all three applications. The first EFSA opinion (EFSA 2021) on novel insect foods finally arrived on *Tenebrio molitor* in January 2021, based on the application from French company Agronutris. Proprietary data was considered necessary for reaching the opinion. Opinions on the dried banded cricket application by Agronutris and on the lesser mealworm application by Proti-Farm are also expected soon. The Commission ultimately decides on all additions to the EU list of authorized novel foods, and after the EFSA opinion, this takes a few more months. The Commission is not bound by the EFSA opinion. The authorization processes seem to take approximately three years.

For insects that have a 25-year history of safe food use in third countries, the notification procedure might also be applicable. Cricket cultivation for food use, for example, began in Thailand in 1997 (Halloran et al., 2016). Notifications based on traditional use have not yet been made on insects (situation March 2021). If a valid and complete notification is made to the Commission, the product can be put to market if Member States or EFSA find no "duly reasoned safety objections" within the set 5-month timeframe. Products that have a record of traditional use are typically not highly processed, i.e. that are the products of primary production (IPIFF 2019, p. 12). Third countries as institutional applicants might notify their traditional foods in order to open the EU market for their companies (IPIFF 2019, p. 14).

3. European law on food marketing

The general marketing and food marketing rules apply to all food products. The main piece of food law is the Food Information Regulation EU/1169/2011, which contains labelling rules that apply to all food. The objectives of the regulation are related to the protection of consumers as well as to the internal market and removing obstacles for trade (Ohm Rørdam 2013). The ingredients of the food product must be listed in a descending order based on weight, GMO foods must be labelled (if they contain at least 0.9% GM materials), allergens must be specifically highlighted, and nutrition information must be provided. If the product name is for example cricket bar or bladder wrack snack, the percentage amount of cricket or bladder wrack must be given. Any untruthful and misleading marketing claims are prohibited in labels, leaflets, and advertising (Food Information Regulation, Article 7). With cultured meat products, it is not yet clear if the production process must be labelled. Proponents feel that if a label is required, it should not resemble a warning (Norton 2015, p. 174). The same discussion concerns 3D-printed foods. Tran (2016) and Baiano (2020) see that information on the production process should be given.

In this chapter, we will specifically focus on three EU legal issues that are central with alternative protein products marketing: names of vegan/vegetarian products, nutrition and health claims, and environmental claims. Through names and claims, marketers can convince consumers and build their brands.

Table 3
Insects for which a European novel food application has been made.

Scientific name	Common name	Legal status 2021
Tenebrio molitor, proprietary data by Agronutris	Mealworm	EFSA's favourable opinion arrived in January 2021
Gryllodes sigillatus, proprietary data by Agronutris	Banded cricket	Under EFSA's assessment since 2018
Alphitobius diaperinus, Proprietary data by Protifarm	Lesser mealworm	Under EFSA's assessment since 2018
Tenebrio molitor, general application	Mealworm	
Hermetia illucens	Black soldier fly	
Acheta domesticus	House cricket	
Locusta migratoria	Migrating cricket	

3.1. Names of vegan/vegetarian products

European regulation on the names of foods is based on three main sources: the Food Information Regulation, specific standards on specific foods, and the Quality Schemes for protecting products of specific geographical location and traditional specialties. The Food Information Regulation applies to all food marketing. *It is mandatory to display the name of food on the package*. There are three types of food names defined in EU law: the legal, customary, and descriptive name. If a legally defined name exists, it should be used (e.g. honey). Only a small number of food names are legally defined within EU regulations, and if there is no definition on EU level, the legal definitions provided by the Member State in question must be used. If these do not exist either, a customary name should be used. Customary name is defined as a name that is accepted without further explanation by consumers in the Member State where the product is sold. Finally, a descriptive name should be used if no customary name exists. The name should describe the product in a manner that helps consumers understand the nature of the product and distinguishes the product from other products with which it might be confused. (Ohm Rørdam 2013). Furthermore, EU food standards place restrictions and rules on the composition and quality of foods, as well as establishing general labelling requirements. These are related to the protection of specific words, such as beef meat, pig meat, chicken, hops, milk, and cheese (European Commission 2008; Case C-1 95/14, Teekanne 2015). These words are defined in the regulation and protected, for example, against substitution by similar ingredients.

The increasing market of synthetic and plant-based 'substitute' products does not fall easily within the existing framework of EU food law. Much of the existing legislation dates to the establishment of the Common Market and the development of CAP, related to the aim to protect economic interests of important agricultural sectors (Bolton 2017). It was also considered important to protect consumers from food fraud and unknowingly buying inferior substitute products (Ohm Rørdam 2013). The new 'substitute' market of vegan and vegetarian products, however, are aimed at consumers who are specifically searching for products with alternative characteristics, for reason such as health, environment, or animal welfare.

As mentioned, certain food names are legally reserved for food with certain composition. This is the case with milk products, with the words milk, cheese, cream, and others, reserved for products derived from mammary secretions. The naming of vegan dairy substitutes has been discussed by the European Court of Justice, which ruled in the 2017 'TofuTown' decision that the reserved dairy names cannot be used even when combined with clarifying designators such as 'vegan' or 'plant-based'. The justification for the decision was that in matters related to the Common Agricultural Policy (CAP), the EU treaties give the Union wide discretion to pursue the objectives defined by the CAP. In this case, the objectives relate to improving the economic conditions for the

production and marketing of dairy products. According to the Court, this is in the interest of both producers and consumers. In relation to consumer protection, the Court ruled that any additional descriptions or explanations on the labels could not prevent confusion in the mind of the consumer *with certainty* (Case C-422/16, Verband Sozialer Wettbewerb eV v. TofuTown.com GmbH, 2017). In effect, the Court ruled that in relation to *milk products*, the general EU rules against misleading consumers are insufficient. The EU regulation on the names of milk products grants exceptions for products 'the exact nature of which is clear from traditional usage'. Examples include 'almond milk' and 'coconut milk'.

Meat products have different rules compared to dairy products. Although the specific names for beef, pig meat, and chicken are protected, as is the word *meat* itself, the names referring to shapes and composition of meat products (steaks, sausages, and burgers) are not. The EU Commission seems to believe that general marketing rules suffice for 'meaty' names (Pisanello & Ferraris 2018; Sochirca 2018). In April 2019, a French socialist MEP Eric Andrieu brought an amendment to the Commission's proposal for the reform of the Common Agricultural Policy (COM/2018/0394) before the European Parliament's Committee on Agriculture and Rural Development. The core of the amendment was to limit the use of the words 'steak', 'sausage', 'escalope', 'burger' and 'hamburger' for animal-based products only. The amendment gained support at the Committee but was rejected by the whole EU Parliament in a vote on October 23, 2020. The justifications for the amendment were stated to relate strictly to consumer protection – with Andrieu emphasizing that the meat industry's lobbyists were not behind the suggestion (Boffey 2019). Various NGOs such as Greenpeace (ibid.) and member states expressed concern over the proposed amendment. For example, in the UK the House of Lords sent a letter to the Minister of Agriculture, raising concerns that instead of protecting consumers, the suggested regulation may in fact reduce consumer clarity and hinder the growth of the vegan and vegetarian market (House of Lords 2019). The House of Lords also turned attention to the benefits of plant-based diets for health and environment, and question whether the regulation may make it more difficult for consumers to reduce the amount of meat in their diets. Furthermore, there seems to be little evidence that consumers are being misled by existing designators for vegetarian products. A recent study of 1003 consumers found that only 4% had been misled by vegetarian products (Forsa Institute 2019). The House of Lords states that "without evidence of a problem, legislative action […] is unnecessary and would undermine EU policy objectives on climate change, the environment and public health" (House of Lords 2019). The ban would have caused costs and various harms for the brands already on the market in EU countries using terms such as sausages and burgers for their vegan or vegetarian products. Tension between the cultural, legal, and vernacular definitions of certain foods would have grown larger with the ban (Gambert 2019).

It can be argued that there now exists discrepancy between different market sectors that puts companies producing vegan alternatives to dairy in an unfair position on the market compared to those producing alternatives to meat. In making their case before the court, the company TofuTown appealed to the equality argument which the court dismissed, stating that the existence of different rules for each sector do not constitute a valid basis for discrimination (Carreño & Dolle 2018). Thus, conversely, the 'TofuTown' ruling indicated that protection for dairy names was not itself a sufficient justification for implementing regulation protecting meat designators. Pisanello & Ferraris (2018) have argued that the current EU legislation is not consistent in its aim to protect consumers, with the court indicating that the consumer requires extensive protection in relation to milk products, but not in relation to meat and fish. Questions of fairness might be extended also to the overprotection of consumers. As consumer studies suggest that banning specific names from alternative products is unlikely to transform consumer behavior, the animal-based product industries seem to have little to gain from the naming rules (DeMuth 2019). Restrictions against customary usage of terms might instead strengthen the pushback against the livestock industry (Malone & McFadden 2019). At the same time, the naming rules that are already operating in the vegetarian and vegan markets.

As legally defined 'meaty' names do not exist on the EU level, companies have turned to the law of the Member States, and in the absence of those, to customary names. It has been debated whether words such as 'schnitzel' or 'wurst' are traditionally attributed to animal products only. This will eventually be decided on a case-by-base basis by national or EU level courts (Carreño & Dolle 2018), and court cases are on-going in various Member States. France banned 'meaty' names for plant-based products, the new French food labelling law taking effect in the beginning of 2021 (bib_FoodNavigator_com_18_June_2020FoodNavigator.com, June 18, 2020). Beyond Burger, for example, should be renamed in France. In Finland, the company Pouttu wanted to call its product 'plant meat' but was prohibited (Raeste, 2019). Differences in national rulings and the unclear legal status related to 'meaty' names can cause uncertainty for companies that are on the vegetarian/vegan market.

3.2. Nutrition and health claims

Nutrition and health claims on foods are allowed in the EU if they are approved by the EFSA according to the Nutrition and Health Claim Regulation (EC/1924/2006). Rules for nutrition claims are listed in the Annex of the Regulation. in the Annex of the Regulation. In order to get a health claim approved, an application to the EU Commission must be made. Protection for proprietary data is possible similarly to the novel food application procedure. The EU register on the nutrition and health claims made on foods contains all the allowed nutrition claims, the authorized health claims, and the rejected health claims.

Here, we look at the nutrition and health claims that microalgae and macroalgae products can legally carry. One important benefit with microalgae and macroalgae is that in addition to being 'alternative proteins', they contain essential fatty acids, i.e. alpha-linolenic acid (ALA, an omega-3 fatty acid) and linoleic acid (LA, an omega-6 fatty acid), and they are the only plant-based sources of the omega 3 acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Marketing claims related to these fatty acids should be highly interesting for consumers as their intake is vital for human health. Commission Regulation 116/2010 added the rules on omega-3 nutrition claims to the Annex of Regulation EC/1924/2006: "a claim that a food is a source of omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,3 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 40 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal. A claim that a food is high in omega-3 fatty acids, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least 0,6 g alpha-linolenic acid per 100 g and per 100 kcal, or at least 80 mg of the sum of eicosapentaenoic acid and docosahexaenoic acid per 100 g and per 100 kcal"

The following health claims are authorized for fatty acids (the conditions for the use of these health claims are given in the EU Register):

- Essential fatty acids are needed for normal growth and development of children
- Alpha-linolenic acid contributes to the maintenance of normal blood cholesterol levels
- Linoleic acid contributes to the maintenance of normal blood cholesterol levels
- DHA contributes to maintenance of normal brain function
- DHA contributes to the maintenance of normal vision
- DHA contributes to the maintenance of normal blood triglyceride levels
- Docosahexaenoic acid (DHA) maternal intake contributes to the normal brain development of the foetus and breastfed infants.

- Docosahexaenoic acid (DHA) intake contributes to the normal visual development of infants up to 12 months of age.
- Docosahexaenoic acid (DHA) maternal intake contributes to the normal development of the eye of the foetus and breastfed infants.
- DHA and EPA contribute to the maintenance of normal blood pressure
- DHA and EPA contribute to the maintenance of normal blood triglyceride levels
- EPA and DHA contribute to the normal function of the heart

For macroalgae/seaweed as a group of organisms or for specific macroalgae/seaweed species, no health claims have been authorized. For sodium alginate and *Ulva*, a health claim "seaweed fibres support body detoxification" was applied along with some alternative claim wordings, but the claim was rejected: "non-compliance with the Regulation because on the basis of the scientific evidence assessed, this food is not sufficiently characterised for a scientific assessment of this claimed effect and the claim could not therefore be substantiated" (EFSA opinion 2011 9 (4): 2083). Also the claim "Algatrium® promotes your antioxidant response: a singular nutritional substance that has scientifically demonstrated in humans a stimulation of the own cells antioxidant defences" was rejected (EFSA opinion Q-2008-705, Commission Regulation 1168/2009).

The EU requirements for health claims are demanding. In the US, for example, in addition to authorized health claims based on significant scientific agreement, 'qualified' health claims are allowed that are supported by a less demanding level of scientific evidence. In Europe, communicating preliminary evidence to consumers is not possible.

3.3. Environmental claims

As buyers in green/sustainable public procurement as well as private companies and consumers are setting various environmental and ethical criteria on foods they purchase, standards and labels on foods that fulfil these criteria have been developed. There are no general EU food law rules for carbon claims, environmental claims, or ethical claims: the general prohibition of misleading marketing communications applies.

What the EU has for low-carbon and other environmentally friendly foods is the Organic Food Regulation (EU/2018/848). The new regulation will, after a delay, start to apply in the beginning of 2022. Producers can decide whether they want to comply with the strict demands of the regulation and then carry the organic food label. Limitations on the use of artificial fertilizers, herbicides and pesticides are central in organic food. The list of authorized additives is shorter than with normal food. As organic food is a specifically defined regulatory category, any resource-efficient or environmental-friendly production cannot be called organic. The word or prefix "bio" is also reserved for organic food only. Regardless of their potential environmental benefits, genetically modified foods are excluded from the EU definition or organic foods.

For organic macroalgae production, there are specific EU rules (Commission Regulation 710/2009). The collection of wild algae is considered as organic production provided that the growing areas are suitable from a health point of view and of high ecological status as defined by Water Framework Directive 2000/60/EC, the collection does not affect significantly the stability of the natural ecosystem or the maintenance of the species in the collection area, and harvesting can be carried out without causing a significant impact on the aquatic environment. Organic algae aquaculture at sea may only utilize nutrients naturally occurring in the environment, or from organic aquaculture, preferably located nearby as part of a polyculture system. This means that organic macroalgae production cannot be integrated with non-organic fish cultivation. (Lähteenmäki-Uutela et al., 2021).

For insects, the EU process for creating rules for organic production has been delayed. Naturland, the international association for organic agriculture, has created its own regulation for organic insect production (Naturland, 2020).

4. Analysis and discussion

There is inherent tension between fostering sustainable innovations and protecting the environment and consumers from potential unexpected risks brought on by novel technologies or products. Our main argument is that EU food law should not hinder the transition to more sustainable foods. We claim it may currently block or delay the production and marketing of some innovative alternative proteins. This may slow down economic growth and create inequality and unfairness between marketers, in addition to slowing down sustainability transition.

There are several promising technologies and innovations for replacing animal-based proteins in diets, and these alternatives are interesting also for European consumers. As stated in the Farm to Fork Strategy (European Commission 2020) "new technologies and scientific discoveries … will benefit all stakeholders". The goal of food law, as all law, is to increase justice. With food law, consumer protection is the main goal, and providing equal opportunities and legal certainty for entrepreneurs is important for promoting food innovation and trade within the European single market (General Food Regulation of the EU). Food marketing law should guarantee the right of consumers to receive accurate information as well as the right of entrepreneurs to distinguish their products from others through fair competition. Any consumer law must balance the interests of risk-averse and risk-seeking consumers. Regulators need to take a holistic view in pursuing sustainability and health goals along with other societal goals including SME activity and rural livelihoods. Emotions easily intertwine with science-based calculation when regulating food. Novel foods may evoke suspicion, discomfort, disgust, or fear. Cultural traditions and habits may overweigh even the most pressing environmental and health concerns, and protectionism may overweigh global responsibility.

The main European food regulations impacting the transformative potential of alternative proteins are the Novel Food Regulation, the GM Food Regulation, the Food Information Regulation, the Nutrition and Health Claim Regulation, and the Organic Food Regulation. In transitions language, these regulations are part of the 'landscape' that shapes how the 'niches' of food innovation proceed into the sociotechnical 'regime'.

- - The Novel Food Regulation is procedurally and scientifically demanding, particularly for SMEs, and also applies to traditional foods from third countries. The Regulation dampens the transformative potential of novel foods in Europe. Several microalgae and macroalgae are non-novel in the EU, which eases their way into the markets. The unclear novel food status of some potential green macroalgae species is a hindrance. All insects are novel, and none have yet been authorized. The transition periods granted by at least some Member States allow some insect species to be marketed provided that the whole insect is used.
- - The GM Food Regulation is procedurally and scientifically demanding, and it forces GM labelling. The Regulation dampens the transformative potential of food GM technology in Europe. In addition to crops and fruit, GM Food Regulation applies to genetically modified microbes, microalgae, and to cells used for cultured meat.
- - The naming and labelling rules for plant-based products have caused controversy and made some investments futile as some products have had to change branding strategies on the way.
- - The rules on health claims are very strict and the process is demanding, particularly for SMEs.
- - Organic food is the (only) European Union regulatory category that allows the branding of an alternative protein product as environmentally friendly. Organic food does not allow GMOs.

We claim that EU food law would encourage sustainable food innovation even better if these five laws and regulatory systems were modified in the following manner:

- - The novel food process should be fast and accessible to all companies.
- - The novel food status (whether a food is novel or non-novel) of all major alternative proteins should be clarified by the EFSA without request.
- - The GM food process should be fast and accessible to all companies.
- - Referral to customary names (e.g. burger) should be allowed for vegetarian and vegan products.
- - Health claim rules could include a category for 'preliminary evidence'.
- - Rules for organic insect production should be developed.
- - A category for ecological GM food could be created.

If public research organizations and authorities carried some of the burden of proof or cost for the novel food, GM food, and health claim processes for the most promising technologies and products, more alternative proteins would end up on supermarket assortments and into consumer diets. If regulators also acknowledge novel methods for testing food safety, they promote innovation in such methods and reduce the regulatory burden for food companies (de Boer & Bast, 2018). Big data analysis, for example, may be more revealing than animal tests (Marvin et al., 2017). Alternative protein products compete against animal-origin proteins but also against each other (see Sexton et al., 2019, p. 48). Sectoral lobbies demand regulatory actions that would benefit their sector. European regulators must remain impartial: they must guarantee food safety while ensuring that products with similar risks and similar societal impacts are treated equally.

The precautionary principle has guided EU environmental and food law for decades. Today, the global challenges with climate change and biodiversity loss raise questions about the hindrances that the precautionary principle may set for much-needed sustainable solutions. Caution and careful consideration may restrict the fast rollout of innovations with significant sustainability potential. Specifically considering the threats of climate change and biodiversity loss, there is an increasing pressure to foster sustainable innovations while maintaining an adequate level of risk regulation. The relatively novel 'innovation principle' presents a competing approach to the regulation of risk (Garnett et al., 2018). The principle was mentioned in the European Commission's Communication of May 15, 2018 on Research and Innovation and repeated in the proposed Regulation establishing Horizon Europe research program for 2021–2027 (European Commission 2018). The principle was also discussed at a "High-Level Conference on the Innovation Principle" in December 2019. According to the Commission, "the Innovation Principle is a tool to help achieve EU policy objectives by ensuring that legislation is designed in a way that creates the best possible conditions for innovation to flourish". According to the proponents of the innovation principle, the benefits of the innovations need to be weighed against known harm, rather than against unknown risks (Read & O'Riordan 2017, pp. 4–15). The idea is to accelerate economic growth through a faster adoption of technological advances. Critics have interpreted this to mean deregulation and the advancement of business goals at the expense of consumers and the environment. We claim that the innovation principle must be connected to environmental and other societal goals, if brought to the European regulatory framework. The non-discrimination principle and the proportionality principle will remain relevant. They will prevent unfair or overly burdensome regulatory requirements.

Whereas the innovative alternative protein, novel food and GM food start-ups often have global marketing strategies, each country has its own legal system and its own societal challenges and goals. Even if duplicate work in evaluating the safety and sustainability of innovative raw materials, processes and products cannot altogether be avoided, communication and collaboration between countries may ease the burden for both entrepreneurs and for authorities.

In addition to European food law discussed in this paper, the broader regulatory landscape for the agri-food system is highly important for the market potential and transformative potential of alternative proteins. European and global policies on primary production (such as agricultural/aquacultural subsidies) will impact the supply of alternative proteins vs. animal-based proteins, and policies on retail, public procurement, and/or consumption (e.g. sourcing criteria, advertising rules, value-added tax) will impact the demand for each type of food product. According to transition theorists, it is not enough if sustainable niches are promoted: governments must simultaneously withdraw support or even attack the unsustainable regimes (Kivimaa & Kern 2016; Rogge & Reichardt 2016). The relative policy support or policy hindrance for different types of food products may be decisive for their market access, market penetration and production upscaling. Politicians and regulators can and must interfere food markets to transform food systems and to change the assortments and diets. This includes action against animal-based production and consumption. All food system participants, including producers, marketers and consumers as well as civil society organizations representing various societal interests, must be involved in food system transition to ensure legitimacy and justice.

CRediT authorship contribution statement

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