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Novel Foods and EU Law: Facing Ethical Lines

Abstract. Although the EU regulations on novel foods came into force in the 1990s, the threat of a famine and food crisis in Europe has appeared to such an extent only in recent years. The concept of novel foods, which can address challenges, is nevertheless associated with several ethical issues. In the individual aspect, it is the possibility of using widely innovative methods to produce food that successfully replaces meat or provides an alternative to sugar. On a broader scale, it is a replacement of products that are too expensive for the environment (i.e., greenhouse effect, deforestation) to provide an additional, entirely separate source of nutrition. This paper seeks to answer the research question regarding the role of law in the process of developing the concept of novel foods, with particular reference to whether and how the law addresses the ethical challenges that are posed by the novel foods. In addition to the main conclusions (multi-faceted dimension of novel foods, ethical and moral barriers to overcome), future prospects are also presented.

Keywords: novel foods, cultivated meat, ethics, law, environment

JEL Classification: Q18, Q56, K32, K38, I31, Q54, I18

Introduction

Demographic, technological, and structural changes in a globalized world bring up the question of solidarity, blurring the promise that each generation may hope to inherit a better world than the last. The European Union's core values of democracy, rule of law and fundamental rights should support the aforementioned promise. The EU legislature currently faces unprecedented challenges. Consequences of the Covid-19 crisis and the Russian war in Ukraine have shown that permanent and established supply chains can be broken overnight and cause food shortages. The same effect applies to fires, droughts, hurricanes or global warming and the loss of ecosystems and biodiversity. Remedies have to be taken immediately (Reflection paper, 2019).

Therefore, when it comes to food, alternative sources should be found and developed. New technologies have given rise to innovative methods and together with these – new moral issues to be dealt with. As for lab-grown meat, which could replace farm-raised meat, it is not only a question of whether people should abstain from meat, but also how they react to the novelty of this type of food.

The EU is introducing various programs and policies to promote climate neutrality, for example the Green Deal, which is described as one key to a climate-neutral and sustainable EU. Reducing carbon emissions from agriculture is one of the points of this program. This will give in-vitro meat startups more opportunities to launch innovations related to so-called alternative meats.

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Literature review

"The development of cultured meat is not merely an interesting technological phenomenon, but something we may be morally required to support" (Hopkins and Dacey, 2008). The philosophy of nutrition or the moral effects of different foods (Nietzsche, 2001) must be considered. Despite a long tradition of ethical and moral concern relating to food and eating (Coff, 2006), the reviewed academic literature contains little reference to the ethical aspects of novel foods (Maranas and Suthers, 2020; Welin, 2013). Some authors (Buffa et al., 2010) addressed the problem of the role of ethics regarding organic food products rather in the line of people's changing lifestyles. Others focused on genetically modified food production in the ethical context (Comstock, 2010).

Food ethics is also about animal suffering (Jamieson, 1998), intensive livestock farming and environmental concerns (Ilea, 2009) which is more and more visible when examining relevant reports (FAOSTAT, 2023; Reflection paper, 2019; EFSA Novel Food Guidance, 2016). Novel food, as a legal category, is a subject of academic interest (Leśkiewicz, 2022); nevertheless, a comprehensive description of the ethical aspects of novel foods, especially in-vitro meat, is still lacking.

Having analyzed the academic literature, a lack of sufficient and comprehensive overview of the environmental impact of the traditional meat and cell-culture-derived meat production was identified. This article takes the less-explored approach of looking into the ethical and legal perspectives of the analyzed matter. It takes ethics as a central concern and discusses global (environmental), individual (consumer choice) and legal issues related to ethics. The law has a structuring function and is responsive towards changes. The integration of several perspectives in one paper is both justified and innovative.

Theoretical framework

The main scientific goal of this paper is to analyze the concept of novel food and its legal aspects in the context of ethical challenges facing humanity today. The analysis of the sources of law were based on the purposive (teleological) theory of EU law (Majkowska-Szulc, 2013) and the legal-dogmatics research method. As it was important for the results of the study to examine reports on the environmental impact of meat production, as well as reports on the extent of malnutrition and the global value of the meat production market, the study also included the following research methods: content analysis and comparative methods. Content analysis was essential to determine the presence of certain words, themes, or concepts within given qualitative data. Moreover, the comparative method served to investigate the relationship between the ethical concerns identified and the corresponding legal issues. In addition, research regarding the public's perception of novel foods was substantial.

Ethical aspects of novel foods. The case of cultured meat

What are novel foods?

The "novel foods" concept is not entirely new. Throughout history, new foods have arrived in Europe from all over the world. Bananas, tomatoes and a wide range of spices – all originally arrived in Europe as novel foods. In other words, "novel" means "new", "innovative", "not used so far". The current trend is therefore a historical rerun, except that this time it is more difficult: with the advancement of technology and the increased scope of areas regulated by law, novel foods must meet the requirements of each of these areas.

Ethics – general remarks

As a preliminary consideration, it is worth indicating which key ethical assumptions appear closest to the subject matter. Since the discussion focuses on consequences, the most appropriate approach would be consequentialism[2]. Teleological theories, such as consequentialism, subject the value of actions to the extent to which they achieve their intended goals. In this case, the goals would be welfare, pristine environment, human and animal dignity (Wenz, 1984).

In the context of ethics, public health, medical law or environment, acts that impose risk upon others are acceptable only when criteria for informed consent have been met. The informed consent principle requires that people should be provided with all available information about the risks to which they are being exposed. In many environmental and public health contexts, criteria emphasize the optimization of risk-benefit trade-offs. "Science" has determined a particular theory of moral action that opts for optimization rather than informed consent. According to the general consensus, science should be neutral with regard to moral claims about food safety risks (Thompson, 2001).

There are situations where consumers need not only choice, but also information to seek alternatives. The most obvious case concerns people with food allergies or special dietary needs. Novel foods should also be included as such because of their function – they provide a dietary alternative. This information allows the interested party to exit, to look for an option. Exit is a key criterion for a consent-based food system (Thompson, 2001).

In seeking to answer the question of when people began to reflect on morality or food ethics, the issue is as old as morality itself. In the course of history, several approaches to this matter can be distinguished. During ancient times, Greeks focused on the problem of temperance, while Jewish ethics concentrated on distinction between legitimate and illicit food. During the nineteenth century, more attention began to focus on the production and distribution of food. "Due to the increasing distance between the production and consumption of food and the massive introduction of novel food products, consumer dependence on food providers has increased considerably. The moral implication of this development is that a food ethic based on the binary logic of contamination will more and more have to rely on

[2] Consequentialism, as a mature, independent ethical position is linked to the development of modern utilitarianism. Classical utilitarians such as Jeremy Bentham (1789-1958), John Stuart Mill (1861-1959) and Henry Sidgwick (1907) are prototypical representatives of consequentialism. However, the precursors of utilitarianism were already 19th century philosophers such as Richard Cumberland (1631-1718), Francis Hutcheson (1694-1746), John Gay (1699-1745), David Hume (1711-1776), Claude Adrien Helvétius (1715-1771), Cesare Beccaria (1738-1794), William Paley (1743-1805), William Godwin (1756-1836).

labelling practices" (Zwart, 1999). The concept of informed choice is a modern ethical food concern. The remaining considerations can be categorized as follows: human right to food, moral obligation, animal welfare, concern for the environment, and artificial-natural opposition. Hippocrates long ago pointed out that a truly human existence is not about passive consumption. Food products provided by nature must be improved and refined by active cultivation. And this seems to be a fully moral task (Zwart, 1999).

Individual dimension

A concept of ethics, namely consumer autonomy, is linked to the age-old desire to develop a personal moral identity (Zwart, 1999). The preference for natural or cultured meat may be derived from moral reasons (e.g., cultural, religious values), biases (e.g. food neophobia), health reasons or even by anticipated taste or price[3]. Should morality be the dominant motivation, it would be very difficult or even impossible to change consumers' preferences (Hartman and Siegrist, 2020). For instance, the fact that no animal suffering is involved could dispel fears, while for others, repulsion at the perceived "unnaturalness" might prevail. In other cases, the aspect of providing information to consumers about what they are consuming is vital.

Thanks to new technologies, it has become possible for people who reject meat consumption for, say, ethical reasons, to eat an artificial meat substitute, while mostly preserving the nutritional values of real meat. However, as a complete novelty, such food may not meet with widespread public acceptance.

Consumers' opinion about food technologies is usually based on heuristic processes rather than on elaborate information processing (Hartman and Siegrist, 2020). Not everyone is familiar with nutrition, the environmental impact of production, or the production process itself.

Studies show that how cultured meat is described affects the perception of naturalness or lack thereof (see: Barnett and Bryant, 2018; Hartman, Siegrist and Sütterlin, 2018; Barnett et al., 2015). When considering spontaneous reactions, there can be a perception of unnaturalness and a feeling of disgust. For those who state that in-vitro meat is devoid of naturalness, consider the following perspective: Let us go back to the very beginning. How did life on Earth – our life – start? With a single cell, which was a very natural event. Likewise, cell-derived meat originates from a single cell, just like the plants that we usually eat. Can we compare bread or wine to in-vitro meat? The production of these products involves processing ingredients and the ingredients come from natural components. The production of cultured meat is probably less unnatural than raising farm animals in intensive confinement systems, injecting them with synthetic hormones, and feeding them artificial diets made up of antibiotics and animal wastes.

General dimension

"The technology of cultured meat can be seen as such a solution to certain environmental and animal ethics problems" (Welin, 2013). With the rapid growth of the global population, which is expected to reach almost 10 billion by 2050, innovation and expansion of the food

[3] What should be borne in mind is if a country introduces more strict control for slaughtering, it results in (traditional) meat prices increasing and consequently consumers will buy cheaper imported meat.

system will need to occur to feed many more people over time (Report: The state of food security, 2023).

The meat value chain includes the ecological relation of production with aspects of the biophysical environment as well as the social relation of production. Biotechnology can be criticized because of its effects on a social scale, for example, because of the increasing dependence of farmers worldwide on a limited number of international economic operators (for example - due to the production of novel foods). While the replacement of primitive slaughtering practices by more sophisticated food production technologies can be recognized as moral progress, humanity's authority over both animal and plant forms of life has grown considerably. This may raise suspicions, especially about its long-term effects, not only for safety reasons, but also in terms of biodiversity, species extinction and other global moral issues. Taking the position that it is a moral obligation not to cause damage, consequently, there is also a responsibility to prevent global change-induced health problems. There is a strong moral obligation to act with the purpose of stabilizing the climate.

Livestock farming is putting significant pressure on the environment. Globally, the livestock sector emits 15% of all human-induced greenhouse gas emissions. Methane, whose global warming potential is 25 times greater than that of carbon dioxide, makes up 44% of the animal industry's total emissions. This sector accounts for 70% of all agricultural land amounting to 30% of Earth's land surface, thereby contributing to deforestation and over 8% of global human water use. In addition, fecal waste is a leading cause of water and air pollution (Maranas and Suthers, 2020). If an alternative to the current meat production systems is not found, the situation will only worsen given the fact that meat demand is expected to increase globally by 73% by 2050 (see: Horizon 2020: A cost-effective production, 2020). It is therefore essential to find a sustainable alternative that, combining the most advanced technologies with environmental protection, meets future demand. As an example of a given alterative, cultivated meat production uses much fewer resources: 99% less land, 75% less water and 90% fewer greenhouse gas emissions than similar meat products (The Good Food Institute Europe, 2022). Other research shows that beef has the highest potential for reducing greenhouse gas emissions (Fig. 1).

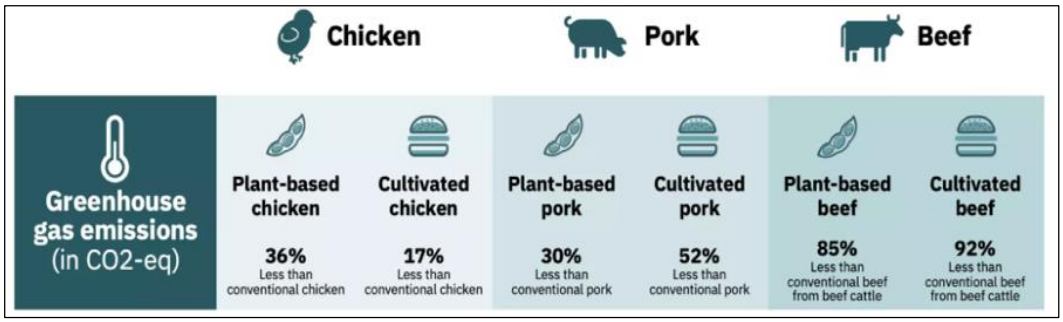

Fig. 1. Greenhouse gas emission reduction potential of plant-based meat and cultivated meat in comparison with specific types of farm-raised meat (chicken, pork, beef).

Source: GFI & CE Delft lifecycle assessment 2021.

In addition, the consumption of traditional meat poses certain health hazards. These risks include public health threats from zoonotic diseases that can arise from close proximity of

humans and livestock, such as avian flu. Currently, public perception has also increased and epidemics, such as influenza or COVID-19 are associated by people with the use of animals for food. Public safety is also affected by antibiotic resistance arising from its overuse during breeding. Parasites can be transmitted in uncooked foods, and other types of food-borne diseases may be caused by bacterial contamination introduced during slaughter and rendering.

Replacing meat production with large-scale animal culture industry would eliminate the public health risks associated with animal husbandry, antibiotic use, and slaughter. Cultured meat would lower the risk of global pandemics associated with industrial livestock production. And this may lead to another – more sanitary – impact of novel foods production. The environmental and public health impact of meat production is therefore very significant. This is one of the main reasons why the food market is seeking more sustainable alternatives to traditional animal protein.

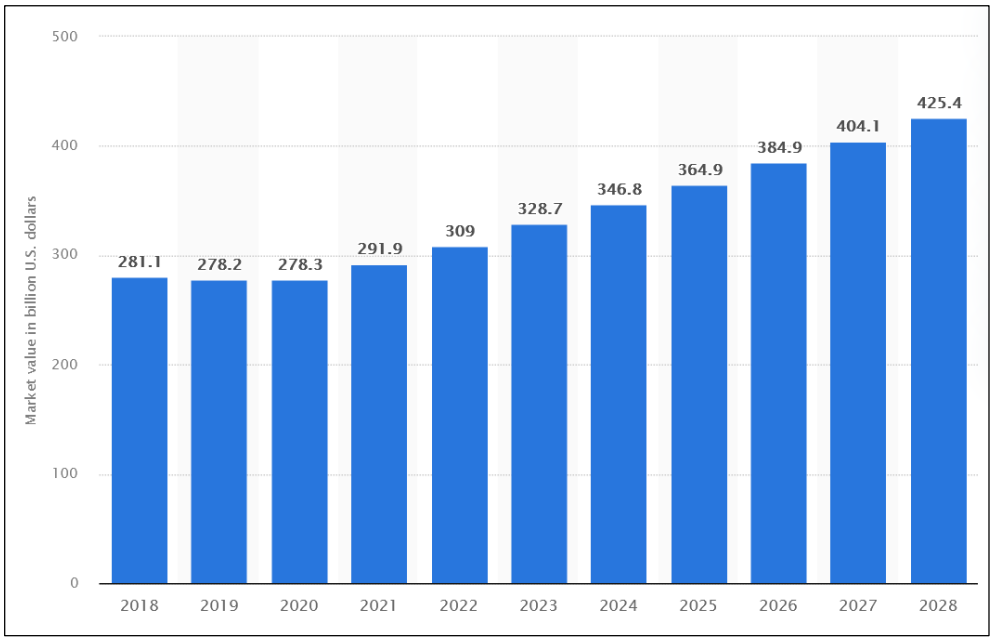

Fig. 2. Revenue of the processed meat worldwide in 2018 to 2028 (in billion U.S. dollars)

Source: Revenue of the processed meat worldwide in 2018 to 2028, published by M. Shahbandeh, Aug 29, 2023 https://www.statista.com/statistics/911596/ forecast-global-market-value-of-processed-meat/.

The scale of "human-meat dependency" is also shown by the fact that 76 grams of meat protein is consumed (on average) per person per day, which equals 202,000 million tons per year. What is more, the global market of processed meat was valued at $278.3 billion in 2020. In 2023 the revenue generated by processed meat worldwide amounted to $328.7 billion and is estimated to reach $425.4 billion by 2028 (Fig. 2). The process of producing animal protein by cell culturing will create a new market to satisfy this consumer demand for animal protein. On the other hand, it must be borne in mind that the introduction of a new product, which is equivalent to food produced on a large scale in a Member State, may create undesirable

competition from the point of view of producers and may endanger its national economy (Sokołowski, 2020). An integrated, single market is a value, but there are few that can escape in today's polarized world from an identity-based approach, which, after all, is openly demonstrated by some EU Member States.

Animal welfare is another aspect of moral responsibility[4] that burdens everyone, especially developed countries. Not only does meat production cause suffering, it is also inefficient because only part of the slaughtered animal is eaten. In the case of a pig or chicken, the edible part is about 70%, and in the case of a cow, 50%. Cultured meat would be able to replace these practices and thus lead to a significant alleviation of suffering and the use of almost 100% of the meat produced. In the future, meat could be produced partly as cultured meat through tissue engineering and partly through the practice of breeding animals that live well and are killed in a non-painful manner. A world with less suffering is a better world.

EU law and cultivated meat

Why novel foods?

The law, following social change, has a structuring role. European Union consumers are increasingly interested in foods with distinct parameters and specific qualities. This is motivated by economic, social, and environmental factors and, more specifically, by the need to look for alternative sources of protein to meat due to the growing world population and the negative environmental impact of intensive meat cultivation.

The role of law

The arguments referring to the purposes of a legal provision are often associated with the qualifying terms 'teleological' and 'purposive'. Purpose is a non-legal element, such as needs, interests or values. The legal philosopher Rudolf von Ihering was one of the first to take these extra-legal elements into account. From his perspective, law is an instrument for performing power and interests; the purpose of the norm should be found rather than its concepts. (Von Ihering, 1914). As the legal framework has to deal with new, unknown and unconsumed food products, the essential step is providing safety. This paper focuses on a selection of the most relevant legal acts regulating novel foods in the context of European Union law. Table 1 shows a comparison of the identified ethical challenges with corresponding replies from EU law (selected legislation, soft law, policies).

The following acts have been selected: the Treaty on the Functioning of the European Union (TFEU), Regulation 2015/2283 of 25 November 2015 on novel foods (Regulation on novel foods) with its implementing acts[5], Regulation 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food

[4] See more of philosophers who wrote about the moral status of animals: Peter Singer (1975) *Animal Liberation* and many others.

[5] To facilitate the entry into force of the Regulation on Novel Foods, the Commission has adopted implementing acts that set out the administrative, technical and scientific requirements which should be included in a novel food application: Regulation 2020/1772 of 26 November 2020 amending Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on Novel Foods, Official Journal of the European Union L 398/13, 27.11.2020.

Safety Authority and laying down procedures in matters of food safety (Regulation on Food Law), Regulation 1169/2011 of 25 October 2011 on the provision of food information to consumers (Regulation on Labelling).

The principles

The right to food was first indirectly recognized in 1948 in the Universal Declaration of Human Rights (UDHR), as a part of the human right to an adequate standard of living. This right has since been developed by EU law. According to TFEU, the EU supports the following areas: protection of human heath [Articles: 168 (protection of public health); 114 (single market) and 153 (social policy) of the TFEU], consumer interests [Article 4(2)(f), 12, 114 and 169 of TFEU and Article 38 of the Charter of Fundamental Rights of the European Union], food safety [Articles: 43, 114, 168(4) and 169 of the TFEU], internal market [Articles: 4(2)(a), 26, 27, 114 and 115 of the TFEU] and animal welfare [Article 13 of the TFEU].

Relevant legal provisions have the form of regulations and are therefore directly applicable. Regulation as an instrument harmonizing the law has been chosen not only to achieve sufficiency but also the effective protection of consumer health and to ensure the free movement of safe novel foods within the EU (Articles 26-28 of the TFEU). This is confirmed by the Regulation on Novel Foods. "The purpose of novel food Regulation is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests." [Article 1(2) of Regulation on Novel Foods]. Moreover, a high level of protection and improvement of the quality of the environment are among the objectives of the Union (Article 11 and 191-193 of the TFEU).

According to TFEU, the EU has the power to act in all environmental policy areas, such as air and water pollution, waste management and climate change. The same act has established the internal market as an area without internal borders in which the free movement of goods, persons, services, and capital is ensured. Everything produced in the EU is either a good or a service. As has already been emphasized, it is the nature of the common internal market that has led to the acceptance procedure for novel foods taking place at EU level. Acceptance of a given food in one Member State opens the possibility for the product to be placed on the entire internal market. Another common value is human health and the obligation to provide a high level of protection. The primary responsibility for health protection and, above all, for health systems remains with the Member States. However, the EU plays an important role in improving public health, in preventing and treating disease and in reducing sources of risk to human health, and in harmonizing health strategies between Member States. Efficient consumer policy guarantees the proper and effective functioning of the single market.

In order to promote the interests of consumers and to ensure a high level of consumer protection, the European Union must contribute to protecting the health, safety and economic interests of consumers. Furthermore, the European Union must promote consumers' right to information and education and their right to organize themselves to protect their interests. Consumer protection is to be considered in all relevant policy areas covered by EU legislation.

Nevertheless, not all issues concerning novel foods are regulated by EU legislation. It is the responsibility of Member States to lay down rules on sanctions for the introduction of novel foods in a manner that is not in line with EU policy as well as to adopt measures to ensure implementation of EU law (Sokołowski, 2020).

The regulations

Food Law

A top-down approach has been taken to the analysis of the EU regulations. Therefore, it is necessary to start with the Regulation on Food Law.

Since the Regulation on Novel Foods came into force in January 2018, the process for scientific risk assessment of a novel food application has been centralized. The European Food Safety Authority (EFSA), established by Regulation on Food Law, performs risk assessments on the safety of a novel food upon request by the European Commission (EFSA Novel Food Guidance, 2016). Under the procedure for authorizing and updating the Union list of novel food, EFSA is requested to give its opinion if the update is liable to influence human health. In its opinion, it must assess, inter alia, all the characteristics of the novel food that may pose a safety risk to human health, and consider the possible effects on vulnerable groups of the population. In particular, EFSA verifies that when a novel food consists of engineered nanomaterials, the most up-to-date test methods are used to assess their safety. Once common requirements are met, a product introduced into the EU may freely cross the borders of the internal EU market. The approval process will involve a thorough and evidence-based assessment of the safety and nutritional value of cultured meat and is estimated to take at least 18 months.

Since novel food is, in fact, food enriched with the prefix meaning ‘innovative’, it must, by definition, at the same time fall under the general requirements of food law and the special requirements of novel food. “Food” (or “foodstuff”) means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans (Article 2 of Regulation on Food Law). Following this consideration, one may ask whether an in-vitro meat is “entitled” to be defined as “meat”. The definition of meat can be found in Regulation 853/2004 laying down specific hygiene rules for the hygiene of foodstuffs (Regulation on Foodstuff Hygiene). Generally, "meat" means edible parts of animals, including blood [Annex I, point 1.1. of the Regulation (EC) No 853/2004 of 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]. There seems to be no obstacle for cellular meat to fall under the mentioned definition. According to EU law, the novel foods’ definition contains two factors: a specific period of time and a comprehensive list of categories. According to law, novel food is the food not used in the European Union for human consumption to a significant degree before 15 May 1997 and one which falls under at least one of the 10 listed categories. Cell culture-derived food is a novel food unless the technique used to culture it falls under the scope of Regulation on genetically modified food and feed. It is presumed that in-vitro meat would fall under the category of food consisting of, isolated from or produced from cell culture or tissue culture derived from animals or plants [see: Article 3(2a) (vi) of the Regulation on Novel Foods]. It should be noted that so far, no application for a novel foods status has been registered under EU law.

Labelling

Changes in the food chain have accompanied humans since the beginning of time. When hunting or gathering food, people used to assess all the food risks themselves. Today, when we reach for any product on a store shelf, we can only get information about such risks from the food label. The extension of the consumption chain from the former two-part (me-food) to multiple-part (me-producer/distributor/operator-food) chain had to entail changes, including legal ones. It can be argued that, as never before, consumer knowledge depends on

the food operator or distributor who places the food on the market. The legal obligation to inform consumers about what they are eating is imposed on them. Only in this way can each of us individually consider the ethical aspects of nutrition. Ethics meanders here between the right to information and the collision of values.

"In order to achieve a high level of health protection for consumers and to guarantee their right to information, it should be ensured that consumers are appropriately informed as regards the food they consume. Consumers' choices can be influenced by, inter alia, health, economic, environmental, social, and ethical considerations" (Recital 3 of the Regulation on Labelling). Indeed, unjustified and inaccurate information restricts the circumstances for the consumer to make an informed and free choice, infringing his or her right to full information about a foodstuff. Consequently, it may infringe the basic economic interests of the consumer, the safeguarding of which, together with the guarantee of food safety, is a fundamental objective of food law. It is precisely because of this collision of values that rational intervention by the legislature seems necessary. It should be noted, however, that food safety as a fundamental objective of food law always takes priority.

When it comes to novel food, it is subjected to the general labelling requirements laid down in the Regulation on Labelling and other relevant labelling requirements in EU food law [Recital 33 of the Regulation on Novel Foods, Article 1(3) of the Regulation on Labelling]. Additional specific labelling requirements to inform the final consumer of particular characteristics of food, such as composition, nutritional value or nutritional effects and intended use of the food, which render the new food no longer equivalent to existing foods, or to inform the final consumer of the health effects on certain groups of the population. Moreover, Regulation on Novel Foods additionally provides for the establishment of a novel food catalogue. With the authorization, an entry is made in the list, which is of a constitutive nature. It also sets out information on the labelling requirements for the specific product.

Regulation on Novel Foods

Interestingly, the "directional" regulation, i.e., Regulation on Novel Foods, does not deal with the matter of ethics directly. It only mentions animal testing in an ethical context. Tests on animals should be replaced, reduced or refined. Therefore, within the scope of this regulation, animal testing should be avoided. Pursuing this goal could reduce possible animal welfare and ethical concerns regarding novel food applications (Recital 32 of the Regulation on Novel Foods). It is worth emphasizing that the welfare of animals is an important part of the Union values. In formulating and implementing the Union's agriculture, fisheries, transport, internal market, research and technological development and space policies, the Union and the Member States shall, since animals are sentient beings, pay full regard to the welfare requirements of animals, while respecting the legislative or administrative provisions and customs of the Member States relating in particular to religious rites, cultural traditions and regional heritage (Article 13 of the TFEU).

Regulation on Novel Foods deals with placing novel foods on the market within the EU. The regulations introduce conditions so that food business operators (the addressee) can bring new foods to the EU market, while maintaining a high level of food safety for European consumers. The indirect link to ethics concerns the aforementioned burden of the obligation to inform consumers about the food they choose to eat in order to make an informed choice.

The details of two regimes for placing novel foods on the market are beyond the scope of this paper (Articles 10-20 of the Regulation on Novel Foods). Briefly, it should be pointed

out that generally there are two modes: authorization or notification. Authorization is more difficult and concerns the novel food under which the in-vitro meat falls. Notification is easier and concerns traditional foods from third countries that have been in use for 25 years as a part of the customary diet of a significant number of people. "The effectiveness of food law provisions in the area of the protection of human life and health is best demonstrated by the lack of negative experiences related to the consumption of food" (Sokołowski, 2020). Only theoretically it is easier because it is often difficult to prove the history of safe use and evidence has only been gathered for a short time, so it is reasonable to assume that the number of notifications will be increasing.

Novel foods should be authorized and used only if they fulfil the criteria laid down in the Regulation on Novel Foods. Novel foods should be safe and if their safety cannot be assessed and scientific uncertainty persists, the precautionary principle may be applied. Their use should not mislead the consumer. Therefore, where a novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally less advantageous for the consumer.

Barriers to placing the novel foods are risks to food and safety. This is the legislator's guiding principle and stems, on the one hand, from the reactive nature of the law – diagnosing global problems and attempting to regulate mechanisms that hinder the degradation of the common good, such as the environment, while respecting individual consumer decision-making, which is expressed in the preservation of the right to make an informed choice. Since the EU legislation applicable to food is also applicable to novel foods, it should be noted that novel food regulations do not operate in a "legal vacuum". Cultivated meat is also food but it just needs to be marketed properly because it produces some aforementioned risks. The regulation is dedicated to novel food but also all other food regulations are applied. By language definition, "novel" lasts for a while and then becomes normal, conventional food. This is the goal of scientists, food business operators and legislators.

Soft law

Not only regulations but also soft law and EU policies create a framework in which ethical challenges are expressed. It is the EU's soft law, policies and programs that show the EU's line of thinking and direction of real action. Following the principles of the new Common Agricultural Policy (CAP) or the European Green Deal, the EU is consistently opting for climate neutrality, sustainable growth stopping global warming or focusing on alternative food sources such as novel foods and, in particular in this context, cultured meat (Reflection paper "Towards a sustainable Europe by 2030", 2019).

Table 1. Comparison of the identified ethical challenges with corresponding replies from EU law (selected legislation, soft law, policies).

Ethical issue	EU law (selected)
Concern for the environment	§ protection and improvement of the quality of the environment (Article 11 and 191-193 of the TFEU); § EU programmes and policies: Common Agricultural Policy, Green Deal, Farm to Fork, EU Climate ambition, Horizon 2020
Consequences of actions	§ food safety [Articles: 43, 114, 168(4) and 169 of the TFEU; Articles: 1, 7 of the Regulation on Food Law; Recital 9, 20 and 23 of the Regulation on Novel Foods]; § consumer's interests [Article 4(2)(f), 12, 114 and 169 of TFEU and Article 38 of the Charter of Fundamental Rights of the European Union]; § protection and improvement of the quality of the environment (Article 11 and 191-193 of the TFEU)
Prevention of damage	§ protection of public health (Article 168 of the TFEU); § food safety [Articles: 43, 114, 168(4) and 169 of the TFEU; Articles: 1, 7 of the Regulation on Food Law; Recital 9, 20 and 23 of the Regulation on Novel Foods]; § protection and improvement of the quality of the environment (Article 11 and 191-193 of the TFEU)
Prevention of hunger and malnutrition	§ well-being of citizens (Recital 1 of the Regulation on Novel Foods); § human dignity (Article 1 of the Charter of Fundamental Rights of the European Union); § Right to Adequate Standard of Living (Article 25 of the UDHR)[6]
Conscious (informed) choice	§ Recitals 20 and 33 of the Regulation on Novel Foods; Article 1(3) of the Regulation on Labelling
Animal welfare	§ Article 13 of the TFEU; Recital 32 of the Regulation on Novel Foods

Source: Author's own elaboration

The EU supports the aspiration to replace traditional meat with meat whose production is less environmentally damaging. Green Deal, Farm to Fork, EU Climate ambition – throughout all these programs, cultivated food has been identified as a promising potential alternative source of protein. Horizon 2020 is the EU's next step in implementing the Green Deal for Europe. The EU's flagship research and innovation program contains three projects in the 2023/2024 work program directly covering cultivated meat and fermentation-based foods. Other research shows that by 2030, cultivated meat's production costs could fall to just around €5 per kg (Report: TEA of cultivated meat. Future projections for different scenarios, 2021). To achieve this, both the public and private sectors will need to invest significant sums into research and development to overcome existing challenges. Enhancing taste, reducing prices, and delivering key infrastructure will be crucial.

[6] The right to food was first indirectly recognized in 1948 in Universal Declaration of Human Rights, as a part of the human right to an adequate standard of living. Afterwards, this right has been developed by EU law, however, due to the fact that it is not expressed directly, it must be derived from other (general) norms.

Conclusions

As this analysis shows, novel food puts into perspective those ethical aspects of food and nutrition with which we have always been confronted. Novel food is not only about the history of safe consumption and new production methods. It is also about introducing food to the market, labelling it, preserving free and conscious choice with respect for biodiversity and the environment. It is difficult to imagine progress towards a more sustainable, safer and more secure food system without new food technologies. Therefore, while considering the individual dimension of the subject matter, general skepticism regarding technologies in the food domain will remain a challenge. Indeed, not every consumer is ready to eat lab-grown meat and for many it will take time to get used to and overcome mental, as well as ethical, barriers. By shifting the conclusions to a more general dimension, it should be stated that the protection of the environment can be seen as both an objective and the means to it. The objective is to protect human life and health, since it is the environment in which human beings are functioning. By protecting the environment, people are affecting food safety.

Based on a teleological research theory, the main ethical issues with corresponding legal replies are the following: concern for the environment, consequences of actions, prevention of damage, prevention of hunger and malnutrition, conscious (informed) choice and animal welfare. Generally, the role of law in the ethical context is the realization of the right to food which protects the right of all human beings to be free from hunger and food insecurity. It is derived from such fundamental values as human dignity and well-being of citizens. Its relevance is increasing with the growing global demand for food.

We are about to experience a food-production phenomenon, which has already been set in motion. All possible measures, such as social campaigns, to raise consumers' awareness and confidence in novel foods should be adopted. A step towards the threats of today's world has already been taken. Let us go further with this idea preserving the precautionary standards that have been developed and looking with great hope for the future.

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