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GIUSEPPE SPOTO

Roma Tre University, Italy e-mail: giuseppe.spoto@uniroma3.it ORCID: 0000-0001-8176-7809

Lab-grown meat and the Italian ban

La carne coltivata in laboratorio e il divieto italiano

The article analyses the advantages and disadvantages of in-vitro cultivation of meat, noting that the proposal to ban its trade by Italy, despite some shareable reasons behind it, appears to be an excessive measure of legal paternalism with negative effects on further research. According to the author, it would be more appropriate to approve a specific law that would regulate the production processes of cultured meat, ensuring correct consumer information and considering this product an alternative to the consumption of conventional meat, rather than a substitute. This would, however, require an introduction of a new product configuration and a distinct legal denomination.

Keywords: cultured meat, lab-grown meat, novel food legislation, consumer protection, legal paternalism, dietary considerations

L'articolo analizza i vantaggi e gli svantaggi della coltivazione della carne in vitro. Viene osservato che il divieto italiano, nonostante alcune legittime ragioni, appare essere una misura eccessiva di paternalismo giuridico che incide negativamente su ulteriori ricerche. A parere dell'autore, sarebbe più opportuno approvare un regolamento specifico che regoli processi di produzione di carni coltivate, garantendo una corretta informazione ai consumatori e riconoscendo questo prodotto come un'alternativa al consumo di carne convenzionale, e non come suo sostituto. Tuttavia, ciò richiederebbe una nuova qualificazione del prodotto e una denominazione giuridica separata.

Parole chiave: carne coltivata, alimenti, nuove regolazioni in materia di alimenti, tutela dei consumatori, paternalismo giuridico, considerazioni dietetiche

Introduction

This article is a reflection on the Italian law to ban the trade in laboratory-grown meat. An important clarification must be made here: at the time of its writing, the ban has been approved by both houses of Parliament, but law has not yet come into force. The point, however, is not to provide any judgment on a political choice, but to provide the scientific community with a reflection on legal paternalism and the problems of the trade in lab-grown meat in Europe. Some pros and cons must be considered if an objective analysis is to be proposed. Extreme defenders of the benefits that cultured meat will bring are wrong, but those who want to stop progress and research with the means of bans are also wrong. The article does not intend to criticize the Italian bill, which has some justifiable reasons or rationale behind, it but aims to reflect on the concrete effectiveness of the ban policies. It also aims to prompt the scientific community to reflect on the most appropriate legal instruments by answering some questions: are legal paternalism measures effective in a global market? Are mutual recognition and the precautionary principle always valid principles? How can local producers and the livestock sector be protected without violating international trade rules? These are questions that apply to every country.

1. Legal paternalism

According to the *Nanny State Index 2023* which measures the degree to which regulatory interventions inspired by legal paternalism have been adopted, Italy is among the countries most open to individual consumer choices in the food and alcoholic beverage market. Out of the ranking of thirty countries that sees Turkey in the first place among the least tolerant countries in 2023, followed by Norway, Italy is in third-last place, just ahead of the Czech Republic and Germany, which are respectively in the second-last place and at the back of the list of countries that most guarantee freedom of consumption choice.

The research, coordinated by C. Snowdon under the auspices of the IEA, has produced the *Nanny State Index* annually since March 2016, focusing on lifestyles, bans, and more generally the policies of individual states with the consumption of three categories of goods: alcoholic beverages; e-cigarettes and tobacco; food and soft drinks. The states scoring highest in the ranking resort

¹ The comments refer to bill A.S. 651 passed by the Italian Senate on 19 July, 2023 and approved by the Chamber of Deputies without amendment on November 26, 2023.

to paternalistic policies through high taxation or the use of direct measures to curb the consumption of such goods, while the states scoring lowest favor clear information on labels, without intervening on prices and leaving consumers more freedom of choice. Poland ranks among the top 10 countries, exactly the ninth, thus placing itself among the countries with the most paternalistic measures, preferring consumer protection based on controls and bans. The Irish proposal to change the labeling rules for alcoholic beverages (and in particular wine) by adopting labels similar to those used for cigarettes and tobacco products should also be mentioned in the context of the discussion on this issue.

Returning to Italy, if we look at the published data, we observe a high tolerance for alcohol and tobacco products, while a more restrictive policy for electronic cigarettes and the consumption of soft drinks. However, if we consider the recent political decision to ban the trade in lab-grown meat, it is reasonable to believe that the approach will change in the future. This proposal, which has animated the scientific debate on an update of the regulatory model considered most useful and in a middle between paternalistic and libertarian choices, seems to apply different weights and measures depending on the types of goods, revealing a new variable about the sector of the most innovative Lab Grown Food production techniques.

The Lab Grown Food category encompasses a wide variety of products: lab-grown meat (also improperly called "synthetic meat") and plant-based products or "non-meat." They emulate the taste and texture of meat,² but are food made entirely from plant-based ingredients. There are also "single-cell" products that use single-cell organisms such as bacteria, fungi, yeasts, and algae to derive functional compounds for the food industry.

In addition to the objective of protecting the health of consumers when faced with food that has not been fully tested, there is certainly the legislator's intention to preserve the traditional agri-food heritage, emphasizing the differences to other production systems and enhancing the qualitative characteristics of the Italian meat market. However, limiting the scope of the ban exclusively to cell cultures or tissues deriving from vertebrate animals cannot be justified, since such a specification would leave out of its scope all non-vertebrate animals used in food such as molluscs, octopus, cuttlefish, squid and crustaceans in general. From this point of view, for the reasons mentioned above, it is therefore clear that the predominant interest underlying the ban is primarily aimed at preserving "traditional" forms of domestic livestock farm-

² E. Sirsi, *Della carne degli animali e del consumo etico*, "Agricoltura Istituzioni Mercati" 2018, no. 1, pp. 33–70.

ing, forgetting other species of animals that may also reach our tables.³ The declared objectives of protecting the health of consumers that would justify the application of the ban based on the precautionary principle therefore remain in the background, while the protection of specific interests of the producers' category is more evident, which certainly raises some perplexity. Pending more precise information on consumer health from the scientific community, the appeal to the precautionary principle underlying the legislative measure introducing a ban on the consumption and marketing of meat grown in laboratories cannot, however, be considered conclusive. The measures introduced can be reviewed and modified, once the situation of scientific uncertainty has been defined, taking on sharper and more precise contours. However, precisely about the precautionary principle, invoked to protect consumers, another critical element of the law should be pointed out, considering that the ban not only concerns the sale but extends to any form of production of meat grown in a laboratory. Thus, if we adhere to a restrictive interpretation of the ban, the provision takes on a far broader scope than the aims set out in the preamble, ending up in preventing any kind of private research on the matter.

It is necessary to clear the debate of any kind of prejudice and consider all the aspects at stake. Examining the advantages and disadvantages of the adoption of the measure, which at the moment seems to show numerous criticalities not only in terms of concrete regulatory effectiveness regarding a category of goods that has not yet entered the market in Europe. However, this topic is mainly aimed at excluding companies from a new and large market, despite the broad forecasts in terms of profits and growth worldwide.⁴

³ In an early version, the heading of Article 2 of the bill introduced "Divieto di produzione e commercializzazione di alimenti e mangimi sintetici – Prohibition of the production and marketing of synthetic food and feed." Subsequently, the phrase: "alimenti e mangimi sintetici – synthetic food and feed" was replaced with "alimenti e mangimi costituiti, isolati o prodotti a partire da colture cellulari o da tessuti derivanti da animali vertebrati – food and feed consisting of, isolated from or produced from cell cultures or tissues derived from vertebrate animals." This amendment is to be considered pejorative and, notwithstanding the critical nature of the term "synthetic meat" to refer to cell cultures and biological material, the wording of the original text, provided it was accompanied by a clearer preliminary definition aimed at better specifying and circumscribing the scope, would certainly have been preferable to the wording approved by the Senate, which proves to be a harbinger of greater problems of interpretation. Perhaps it would have been more appropriate if the legislator had proposed the definition referred to in EU Regulation 2015/2283 on novel foods, which is contained in Art. 3(2)(vi) without stumbling into misunderstandings and bungling.

⁴ P. Benanti, *La carne sintetica tra biotecnologie e società*, "Aggiornamenti Sociali" 2018, no. 6–7, pp. 475–482. See the reflection on a difficult relationship of technological innovation and its impact on society: L. Costato, *Innovazione tecnologica, agricoltura*

Rather than an absolute ban that will result in bending the logic of free trade, cultured meat should be authorized at the European level. At the same time, certain measures could be taken to protect the quality of meat production from Italian farms.

We can start to support the need for an action at the regulatory level to qualify this in vitro production not as meat, however, as an alternative product with a distinct and specific legal denomination. It is possible to develop the most appropriate legal instruments to mitigate the negative effects of the application of the principle of mutual recognition without leaving breeders behind or falling out of the market that will certainly expand worldwide in the upcoming years.

2. The ban: pros and cons

The positive aspects of the development of cultured meat consumption certainly include the prevention of zoonoses. There is no doubt that many human infectious diseases are transmitted by animal pathogens and that the cultivation of meat in laboratories and protected environments could counter these dangers more easily.⁵ However, the argument cannot be commonly used for all livestock farms because these fears are very low in Europe, since, with few exceptions, the rules laid down at the EU level provide for very high food safety standards and controls⁶ that reduce the dangers of zoonoses, although do not neutralize them entirely.

Furthermore, if we consider the generally applied principles of food safety, there are several shareable objectives behind the ban that cannot be overlooked, as the elements used for cultivation contain hormonal growth factors that could be harmful to consumers.⁷ This is an extremely sensitive point that must not be overlooked because the presence of growth hormones

e alimentazione: una sfida risalente, "Diritto Alimentare" 2019, no. 2; F. Albisinni, *Diritto agroalimentare innanzi alle sfide dell'innovazione*, "BioLaw Journal – Rivista di BioDiritto" 2020, no. 2, pp. 25–42.

⁵ F. Cusano, F. Pedace, *I "novel food" possono essere un rimedio alle zoonosi?*, fedealismi.it, 2021, no. 16, p. 22; E. McNamara, C. Bomkamp, *Cultivated meat as a tool for figthing antimicrobial resistance*, "Nature Food" 2022, no. 3, pp. 791–794.

⁶ L. Paoloni, *Benessere animale e filiera sostenibile*, "Rivista di Diritto Alimentare" 2021, no. 3, pp. 37–41.

⁷ On the risk of a lowering of protection levels in connection with possible enlargements of international trade rules: G. Bonora, *Sul difficile nodo della carne trattata con ormoni nel "Transatlantic Trade and Investment Partnership" (TTIP)*, "Rivista di Diritto Agrario" 2016, no. 1, pp. 123–137. For an in-depth look at the different European approach to food

in the culture medium is a factor in itself that is sufficient to monitor the marketing of laboratory-developed meat more closely.

From this point of view, the political choice of a specific ban on the trade in lab-grown meat may therefore be understandable, however, many other arguments lead one to criticize the choice of preventing the full development of private enterprise freedom in this area. In my opinion, in the absence of clear scientific evidence of a danger to consumer health, the legislative ban would be contrary to Article 41 of the Italian Constitution, which guarantees the freedom of private economic initiative. The reference to the precautionary principle⁸ would not allow this relief to be overcome, since it should be remembered that its application must always be within the limits of temporariness, proportionality, and reasonableness of the ban.

3. Laboratory-grown meat and sustainability goals

The question of whether laboratory-grown meat offers a more sustainable alternative to conventional meat production in terms of its nutritional contribution to consumers' diets and, above all, in terms of its impact on the environment, merits further investigation. In the first respect, it is not possible to equate the products from a nutritional point of view, so the conventional meat diet remains preferable, given that the qualitative contribution also depends on the farming model and the type of feed given, which influence the growth and development of the animal. The lower nutrients in cultured meat could perhaps be compensated for in the future by enriching the final product and filling any deficiencies with additional elements, but this argument is now definitely a point in favor of conventional food.

More complex, however, is the issue of environmental impact,⁹ because there is conflicting data on the actual sustainability of cultured meat, although most scholars tend to consider this type of production more advantageous than conventional livestock farming.

safety compared to the US: F. Bruno, *Il diritto alimentare nel contesto globale: USA e UE a confronto*, Padova 2017.

⁸ For an in-depth look at the precautionary principle and the Early Warning System in Europe: V. Paganizza, *Il sistema di allarme rapido degli alimenti e i mangimi (RASFF): co-municazione e collaborazione per la gestione del rischio*, Padova 2023; L. Petrelli, *Il sistema di allarme rapido per gli alimenti e i mangimi*, "Rivista di Diritto Alimentare" 2010, no. 4.

⁹ N. Ferrucci, S. Schiavon, *Inquinamento zootecnico: una rivalutazione del ciclo biologico nelle nuove prospettive della ricerca tecnica*, "Rivista di Diritto Agrario" 2002, no. 1, p. 121.

According to the 2006 and 2019 FAO reports "Livestock's Long Shadow" livestock production is directly responsible for 14% of total greenhouse gas emissions, in addition to the enormous consumption of water. Due to the increase in population, it is evident that the problems of environmental impact will increase exponentially unless different production methods are adopted and viable alternatives are offered. In this context, cultured meat represents an alternative example for reducing the environmental impact of livestock farming. However, while it can easily be argued that developing only a portion of an animal's muscle tissue in vitro is an operation that has less environmental impact than growing a "whole" animal over time, regarding methane emissions from enteric fermentation of ruminates and consumption of soil and water, the energy requirements to operate bioreactors and to implement large-scale in-vitro meat production are not environmentally neutral, either.

As far as energy consumption is concerned, it has to be said that there has been no shortage of studies aimed at calculating the increase in usable surface area for purposes other than breeding, and consequently the possibility of developing energy-efficient systems through bioenergy production. ¹¹ Thus, the emissions associated with the use of fuel and electricity required to run in-vitro meat production could be offset by using renewable energy sources obtained by reclaiming land taken from traditional farming methods.

On the other hand, the large-scale production of in vitro meat, if intended not to supplement the consumption demand of conventional meat, but to fulfill more generic purposes of complete replacement or considerable reduction in production, together with the reduction of meadows and pastures needed for livestock farming, could generate negative impacts on rural biodiversity.

In truth, there are many other reasons to consider that lead one to look with circumspection at the large-scale marketing of cultured meat, but which do not justify an outright ban a priori and the adoption of such stringent countermeasures. Moreover, it should be pointed out that even in the absence of an express ban, cultured meat would not automatically be able to enter the

¹⁰ For a more precise review of the data see: https://www.fao.org/news/story/it/item/197623/icode/ [accessed on 27.09.2019] and regarding the cited studies see H. Steinfeld, P. Gerber, T. Wassenaar, V. Castel, M. Rosales, C. de Haan, *Livestock's long shadow: environmental issues and options*, Rome 2006, especially from p. 79 onward.

¹¹ H.I. Tuomisto, M. Joost Teixeira de Mattos, *Environmental Impacts of Cultured Meat Production*, "Environmental Science & Technology" 2011, no. 45, pp. 6117–6123; M.J. Post et al., *Scientific, sustainability and regulatory challenges of cultured meat*, "Nature Food" 2020, no. 1, pp. 403–415; D. Humbird, *Scale-up economics for cultured meat*, "Biotechnology and Bioengineering" 2021, no. 118, pp. 3239–3250.

European market until after the completion of a long and complex process of controls required for any new foodstuff. In fact, it should be noted that the ban refers to a good that is not yet on the market in Europe, even if it is already in circulation in non-European markets.

If we think of the rules about full information on the ingredients used to arrive at the finished product, it is clear that there are numerous aspects that need to be investigated, and in the face of which the rules on novel foods are inadequate. However, extending the ban to any form of cell culture production tout court, ending up disincentivizing and hindering the research sector in this field, risks turning it into a boomerang against the very breeders and operators in the meat supply chain that we would like to protect with such a measure.

On closer inspection, this is a different product category that should not be seen as a substitute for meat from traditional livestock farms.

Laboratory-grown meat could serve a different function, supplementing the traditional diet of omnivorous consumers, and providing access to new types of protein supply to a wider audience that does not normally consume meat, thus including vegetarians and vegans.¹²

However, this last point also merits further investigation because cultures often use substances derived from animals, and from a technical point of view, foetal bovine serum, obtained during the slaughter process, is used to stimulate cell growth and proliferation. Now, if one wants to ensure the possibility of offering additional protein diets to those who do not consume meat for ethical reasons in the future, it would not be expedient to block the advancement of research and the refinement of viable alternative techniques. For example, it is worth mentioning that experiments based on alginate, obtained from seaweed, are being studied, which would overcome the problems of finding foetal bovine serum. However, this aspect introduces further elements of criticality if the contribution of vegetable derivatives to animal ingredients is high. In other words, if cultured meat were to become a hybrid product mixed with vegetable ingredients, there would be a further problem for consumers in relation to the final product purchased, which would no longer accurately reflect the object of demand. There is therefore a need for a distinction that must always be maintained, in terms of product categories, between cultured meat and processed products containing plant proteins. It is equally obvious that a distinction should be made between cultivated

¹² M. Reynolds, *Lab-Grown Burgers have a Secret Ingredient: Plants*, "Wired" 2023, no. 3–4, https://www.wired.co.uk/article/hybrid-meat-blended-burgers-upside-foods-ivy-far-m-technologies [accessed on 12.10.2023].

meat containing a percentage of vegetable protein and products that do not contain any percentage of animal protein. The Italian bill not only forbids cultivated meat, but it also has the objective of prohibiting the use of legal denominations, which in some way could lead back to or associate with meat products that have been exclusively obtained from vegetables. At the same time, it allows such denominations when animal proteins prevail over vegetable proteins, without prejudice to the overriding need not to mislead the consumer as to the composition of the food.

4. Novel food and authorization regimes

The issue of trade in cultured meat is closely linked to the Novel Foods Regulation. For this reason, it is appropriate to conduct a brief examination because the problems and fears underlying the ban are closely linked to this EU regulation, which is obsolete and inadequate to the new requirements. As a preliminary point, it should be recalled that the term 'novel food' is used both to indicate foods that are the result of new techniques and did not exist before, and to indicate foods that do not belong to the food habits of the European market, but are rooted in other countries and cultures, and can prove a historically established safe food use. Novel food is any food which had not been used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the date of any Member State's accession to the Union. This definition was introduced by EC Regulation No. 258/97 and was also confirmed in subsequent EU Regulation No. 2283 of 2015. The concept of "significant consumption" has also been reaffirmed by European case law (Court of Justice, 15 January 2009, C-383/07) and the date of 15 May 1997 continues to be the most important reference to assess the human consumption of novel foods.

Although a single term is used to indicate products of very different origins, this dichotomy comes to the fore when one considers the rules governing authorization regimes, given that more expeditious controls and a more simplified procedure are envisaged for foods traditionally consumed in third countries by a significant number of people over an established period of at least twenty-five years compared to foods that are entirely new.¹³

¹³ I. Canfora, Alimenti nuovi e alimenti tradizionali nel mercato dell'Unione europea dopo il regolamento 2015/2283, "Diritto Agroalimentare" 2016, no. 1, pp. 29–46; B. La Porta, Il Regolamento europeo in materia di novel food: riflessioni sugli "alimenti tradizionali dei Paesi terzi", "Cultura e Diritti" 2020, no. 1, pp. 182–189; G. Formici, Novel food tra esigenze di mercato, sicurezza alimentare e sviluppo sostenibile: la complessa disciplina degli alimenti

Now, without prejudice to the fact that a unitary general regulatory framework can often be useful, especially in the absence of specific rules, it is clear that bringing all novel foods together within the same regulatory framework is a solution that would deserve to be re-examined precisely in the light of the new problems associated with Lab Grown Food production techniques.

5. Freedom of research and transparency of information

Guarantees of proper protection of consumers and Italian farmers could be ensured by strengthening the rules on the labeling of novel foods, and by providing a more careful and complete description of the production processes used. It is clear that rather than introducing an absolute ban on the production and placing on the market meat grown in laboratories, a specific regulation on the subject would be needed. The appropriateness of a specific regulation, instead of a generic ban, would be justified by a multitude of reasons, both because it is not possible to apply the rules of the meat chain, as it is not a question of retracing the stages relating to the biological cycle of the animal and its slaughter, and because it is not possible to refer to the general labeling rules as these do not concern foodstuffs with only one ingredient and are therefore incompatible with cultured meat. Moreover, the principles of transparency and correctness of information¹⁴ would require a precise description of the substances used in the cultivation of bioreactors, scaffolds, and, more generally, the techniques used. While it is true that there is still insufficient clarity on production methods and risks to consumer health, this should not lead to a ban on any possible discussion on the subject, but to the most effective measures to balance the various interests at stake, without forgetting consumer protection. For this reason, the approval of such a far-reaching ban that leaves no room for scientific research which should be protected and encouraged, must certainly be condemned. The use of new biotechnologies should not be demonized, but wisely regulated and guided, without aprioristic prejudices. The case of cultured meat in Italy is a clear

tradizionali provenienti da Paesi terzi, "Biolaw Journal – Rivista di BioDiritto" 2020, no. 2, pp. 67–87; L. Scaffardi, *I novel food, un futuro ancora da definire*, "Biolaw Journal – Rivista di BioDiritto" 2020, no. 2, pp. 43–66.

¹⁴ It is clear that information can influence consumers, directing their choices towards food products: M.C. Mancini, F. Antonioli, *To What Extent Are Consumers' Perception and Acceptance of Alternative Meat Production Systems Affected by Information? The Case of Cultured Meat*, "Animals" 2010, no. 10, p. 656.

example of the problems underlying the relationship between science and law, as well as the conflict between politics and the scientific community. The debate on this point seems to lead to the conclusion that legal paternalism and political choices aimed at protecting the interests of few important categories do not always succeed in actually achieving the objectives set and solving the problems feared. It is useless to go down a road paved with good intentions and then, stopping scientific research, forget where that road ends up.

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