Cultivated meat beyond bans: Ten remarks from the Italian case toward a reasoned decision-making process

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Commentary

Cultivated meat beyond bans: Ten remarks from the Italian case toward a reasoned decision-making process

Michele Antonio Fino,[1,*] Bruna Anzà,[2] Lorenzo Bairati,[1] Ilaria Bertini,[3] Bartolomeo Biolatti,[1] Stefano Biressi,[4] Francesca Tiziana Cannizzo,[5] Laura Cavallarin,[6] Luciano Conti,[4] Marco Deriu,[7] Cesare Gargioli,[8] Barbara Loera,[9] Luca Lo Sapio,[10] Daniele Marchisio,[2] Lorenzo Pallante,[7] Simona Stano,[10] Luisa Torri,[1] Alessandro Bertero,[11,12,*] and Diana Massai[7,12,*]

[1]University of Gastronomic Sciences, Pollenzo-Bra, Italy
[2]Department of Applied Science and Technology, Politecnico di Torino, Torino, Italy
[3]The Good Food Institute Europe, Forest, Belgium
[4]Department of Cellular, Computational and Integrative Biology (CIBIO), University of Trento, Trento, Italy
[5]Department of Veterinary Science, University of Turin, Torino, Italy
[6]Institute of Sciences of Food Production (ISPA), National Research Council, Grugliasco, Italy
[7]Department of Mechanical and Aerospace Engineering, Politecnico di Torino, Torino, Italy
[8]Department of Biology, Tor Vergata Rome University, Roma, Italy
[9]Department of Psychology, University of Turin, Torino, Italy
[10]Department of Philosophy and Education Sciences, University of Turin, Torino, Italy
[11]Department of Molecular Biotechnology and Health Sciences, Molecular Biotechnology Center "Guido Tarone", University of Turin, Torino, Italy
[12]These authors contributed equally
*Correspondence: m.fino@unisg.it (M.A.F.), alessandro.bertero@unito.it (A.B.), diana.massai@polito.it (D.M.)
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Cultivated meat has become a polarizing topic in the political discourse worldwide. Italy was the first country to pass legislation to ban cellular agriculture products. A thoughtful reflection on this experience reveals the urgent need for rigorous, cross-sectoral research and regulatory diligence for the advancement of the field.

Hurdles, policies, and polarization in cultivated meat

Over the past decade, the concept of cellular agriculture, most notably cultivating meat and seafood from animal cells, has moved from science fiction to real-world sales, albeit niche, in some countries.[1] The ability to produce animal proteins, while reducing the environmental impacts, welfare concerns, and risks of antibiotic resistance and zoonosis associated with intensive animal farming, moves ever closer.[2] However, scaling up this technology to allow for wider commercial availability continues to face challenges,[3] with missed milestones shattering inflated expectations. Accordingly, private investment in the field has slowed.[4]

Although this is not unexpected for a novel technology going through the Gartner hype cycle (Figure 1), for cellular agriculture to reach the "plateau of productivity," it must not only overcome obstacles of the biotechnological and engineering sort but also those that are social and political in nature. Several countries are embracing and supporting cellular agriculture with clear regulatory frameworks and/or public investments, yet despite the current lack of authorization for any cultivated meat or seafood in the European Union, in December 2023, Italy promulgated a statute (law 172/2023) that bans the production and commercialization of cell-cultured products.[5] This decision was not based on a scientific consensus but rather on an inconsistent application of the precautionary principle. This law fulfilled the requests of the leading farmers' association in Italy, Coldiretti, which campaigned against what they referred to as synthetic meat "to stop a dangerous drift that jeopardizes the future of livestock and the entire "Made in Italy" food chain."[6] Coldiretti argued that cultivated meat "is dangerous for the environment, it is unsafe for human health, it limits consumer freedom, it favors the interests of few monopolies, and it breaks the bond between food and nature."[6] These, among other claims, lack substantive evidence in the scientific and social sciences literature. US states—Florida and Alabama—have followed this example, and similar proposals are currently under discussion in Arizona and Tennessee as well as in several European Union countries, including Austria, France, Hungary, and Romania. Should this path expand to other geographical areas, it may stifle the field, preventing it from reaching its full potential, not as the result of research demonstrating the unsafety, unreliability, or inefficiency of cellular agriculture, but as the outcome of a preventive ban (Figure 1).

Some of the authors have previously called for self-regulation in the biotechnological and technical field to mitigate the risk of a broader ban.[7] However, it is clear that the current polarization of the discourse on cellular agriculture has deeper roots. From a scholarly perspective, we argue that this stems from the fragmented approach to cellular agriculture research adopted by experts in different domains (social, economic, food, health, biotechnological, and environmental) along with the scarcity of publicly funded open-access research. This siloed approach has hindered the ability to develop a unified, multidisciplinary framework necessary for effective

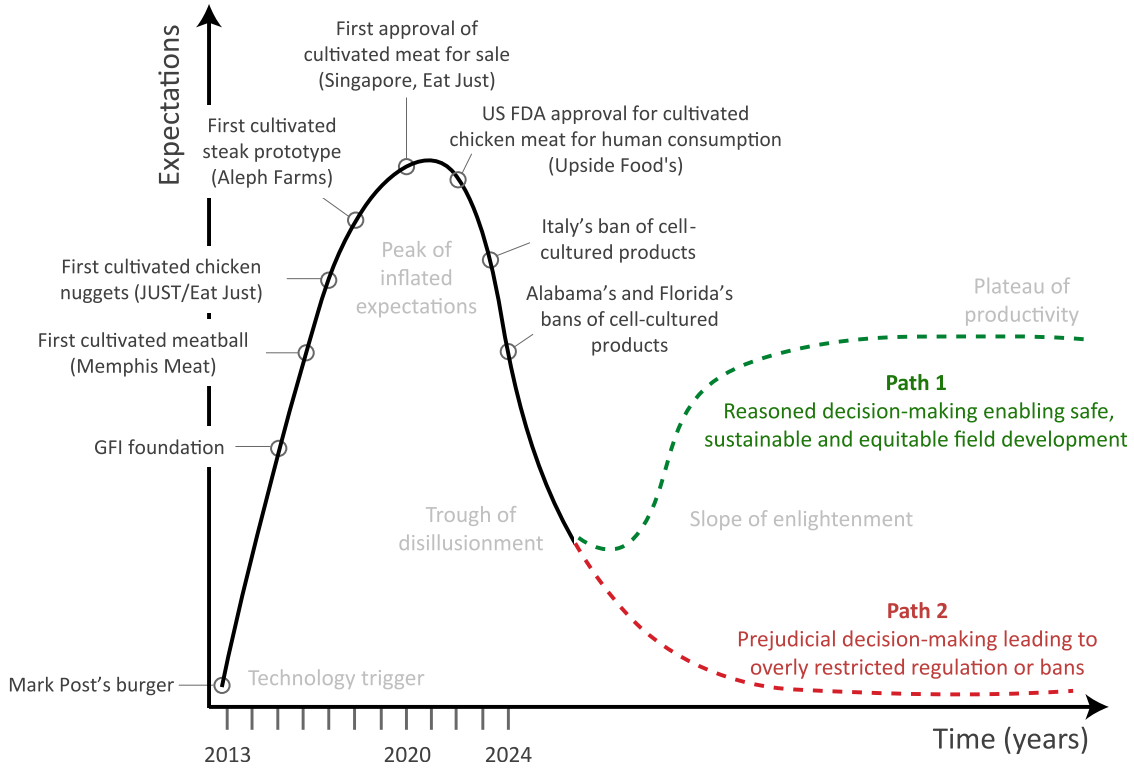

Figure 1. Gartner hype cycle for the cellular agriculture sector, with selected milestones and roadblocks
Although this graphical description does not capture all of the nuances of the technology development, we use it to illustrate two possible paths depending on the premises of the political discourse and the resulting decisions affecting the advancement of the field globally and/or locally.

communication with non-experts (i.e., customers and voters) and stakeholders (i.e., farmers, regulatory bodies, and politicians). In the discussions leading up to the Italian ban, technical, social, and humanities arguments were presented in isolation, which allowed detractors to target critical points in each area separately. Meanwhile, non-detractors seeking clarity across all fronts found little cohesive information to address their concerns comprehensively.

Ten remarks toward a reasoned decision-making process

In response to this challenge, as representatives of diverse technological, social, and humanities disciplines, we have engaged in a cross-sectoral discourse and distilled ten remarks as starting points for a constructive discussion. While our reflections inherently stem from our direct experience in the Italian landscape, they will hopefully inspire similar reflections elsewhere.

Safety: a balancing act. Research freedom is crucial for innovation, and heuristic exploration within laboratories is fundamental to fruitful research. Nevertheless, the transition from laboratories to production facilities must occur within a defined regulatory framework that adheres to international and national standards concerning not only food safety[8] but also animal welfare and environmental sustainability.[2] Despite the current EU legal frame on novel foods (based on Reg. EU 2015/2283), the Italian government's decision to ban cultivated meat signals a disregard for the competences conferred on the EU, as stated by the EU Commission.[9] Indeed, it contravenes the established procedure for the adoption of technical standards, set out in art. 6 of the EU Directive 2535/2015, and the reservation of competence in favor of the EU regarding the admission of novel foods to the internal market. Notwithstanding the legal ambiguity of the Italian regulatory framework, the Italian government has set a precedent for other countries.[10] These circumstances highlight how relevant it is that scientists collectively advocate for the upholding of existing regulations and principles. In all, research should involve the development of guidelines for promoting a balance between academic freedom and industrial regulation, ensuring that potential innovation is guided by ethical principles.

Semantics: addressing neologisms and food-technology neophobia. Wording like "cultivated" or "cultured meat," which is related to the biological origin of the cells and the production method, is not equivalent to "artificial" or "synthetic meat." These last terms are not only inaccurate but may carry a negative connotation for consumers.[11] The quest for suitable neologisms should strive to capture the novelty of this emerging food product, while considering the consumers' need for familiar words to overcome potential neophobia and the possible reluctance toward novel foods produced using novel technologies. A thoughtfully crafted neologism could mitigate neophobia and not harm consumers' openness to new food choices. Therefore, research should focus on semantics and develop a dedicated terminology that is more easily understandable by the general public. This involves defining a globally recognized denomination with the aim of objectively identifying

cultivated products, without misleading consumers.

Safeguarding information "hygiene." The use of inappropriate terms and linguistic-conceptual shortcuts to describe cellular agriculture products undermines individuals' capacity to form their own opinions.[12] This is reinforced by the dissemination of laboratory imagery that often misrepresents the scientific and productive realities. Furthermore, technical information and assessments should ideally come from experts in the field. It is imperative, within a democratic framework, to safeguard the integrity of information and to adopt appropriate communication strategies. Scientific communication should remain impartial and independent of partisan politics that may distort the picture of the state of the art. Research institutions should guarantee an apolitical and secular stance, ensuring the integrity of the information conveyed with communication based on data-driven evidence.

Embracing technology and sustainable production processes. The simplistic dichotomy between nature and technology fails to capture the evolution of modern production processes. In comparison to manual procedures, automation technology reduces contamination risks and increases control, safety, and traceability of processes. Combined with modeling approaches, it offers substantial advantages in terms of reproducibility, scalability, and sustainability, leading to higher bioprocess efficiency. To achieve large-scale cultivated meat production, automated bioreactors with controlled physico-chemical conditions are imperative to produce the required number of cells for manufacturing while minimizing feedstock, waste, manipulation, and operator-dependence. Nevertheless, the use of automated bioreactors is energy intensive and cultivated meat processing needs large amounts of water. This highlights the growing importance of transitioning to renewable energy sources and considering water recycling and reuse practices in the expansion of the cultivated meat industry.[13] Collectively, it is crucial to care about the narrative surrounding technology in order to allow research to be carried out, technology to be developed, and the feasibility of sustainable solutions to be verified.

Recognizing the potential of cellular agriculture. The world faces significant food challenges as the global population is expected to reach between 9 and 11 billion by 2050. Alongside this growth, there is a rising demand for protein. Many consumers, driven by health and environmental concerns, are seeking to reduce their consumption of animal-based products.[14] Cellular agriculture is not the only alternative protein solution, but it could represent a promising countermeasure to the proliferation of intensive farming practices.[15] Beyond mere substitution, cellular agriculture has the potential to complement conventional meat production; it can mitigate the environmental impacts associated with intensive farming and related gas emissions, water consumption, and land use[16]; it can enable optimized large-scale productions; it can enhance product safety control while catering to diverse consumer needs; it can foster improved and personalized diets for citizens, including functional foods. Additionally, in unique contexts such as space travel, cellular agriculture stands as an opportunity to provide fresh, tailored, self-sustaining, and palatable protein-rich food during long-duration missions.

Ensuring trust in novel food evaluation. The sale of novel foods is subject to approval by the relevant authorities worldwide. In the EU, risk assessment of a novel food is the task of the European Food Safety Authority (EFSA), while risk management is the task of the EU Commission, which makes its decisions based on the precautionary principle. It is imperative to address claims that question the adequacy of EFSA's determinations, particularly those that advocate a shift of responsibility for risk assessment into political hands, which could compromise the scientific integrity of the process. EFSA's role is well established and has been in place for over two decades (Reg. EU 2002/178). Undermining it could challenge other authorities, including the US Food and Drug Administration (FDA), where risk assessment and risk management are not separated. In addition, equating the approval pathway for novel foods with that for pharmaceuticals (i.e., requiring pre-clinical and clinical studies[14]) is unfounded and disregards the regulatory nuances specific to each product category. Foods and drugs are held to different standards because they serve fundamentally different purposes. Paradoxically, while drugs can be approved despite known side effects, EFSA approves novel food products only when it is proven that they do not cause unintended or adverse effects. To reinforce trust in novel food evaluation, it is crucial to emphasize the distinction between the scientific rigor of risk assessment and the broader policy considerations that rightfully fall within the domain of political decision-making. Accordingly, a recent proposal from the Hungary to impose a ban on cultivated meat products similar to the Italian one was opposed by the EU Commission on grounds of being "unjustified, since it could pre-empt the harmonized authorization procedure for novel foods at EU level, which includes a scientific assessment by EFSA."[17]

Monitoring intellectual property initiatives and monopoly risks. Cellular agriculture draws on research and well-established techniques from biotechnology, tissue engineering, and fermentation and is not based on patents from large companies. Concerns about intellectual property and the risk of monopolies are currently unfounded. Such claims are the result of an alarmist and misleading narrative that often wrongly equate cell-based products with genetically modified organisms (GMOs). Nevertheless, there is a significant push to patent specific aspects, and it is crucial to monitor this trend carefully because of the potential risk of slowing down the innovation process and restricting access to knowledge advancement. This could be particularly true in countries with fewer resources. Consistent support for public research is essential to mitigate the inequity risks associated with private patents and potential monopolies.

Ensuring regulatory stability and evidence-based decisions. Public research efforts and related technology transfer on novel foods require regulatory stability and evidence-based decisions, conditions that cannot be overlooked without significantly hampering countries' progress. Cautionary tales from the recent past are Italy's bans on human embryonic stem cells (hESCs)—which led many researchers to relocate[18]—and GMOs—Italian farmers now import millions of metric tons of GMO soy that they are prohibited from cultivating domestically due to these regulations.[19] To avoid similar impacts in the cellular agriculture field, it

is imperative to reconsider the prohibition on cultivated meat enshrined in the Italian statute 172/2023. While this statute lacks any real legal effects due to procedural flaws in its adoption, as noted in the EU Commission statement of 29 January 2024, the law fosters the damaging perception that cultivated meat is banned, which adversely impacts investments and research in the sector.

Preserving individual freedom in food choices. In absence of ethical concerns, the freedom to make dietary choices must not be restricted by any majority, as it reflects the individual and inviolable right to determine one's own identity.[20] Institutions are responsible for ensuring food safety and comprehensive information, however they cannot make decisions about what is right or wrong to consume in place of individual citizens. If the institutions assess that a food is safe, even the majority of citizens cannot decide whether or not individuals can eat it. On the other hand, it is crucial to ensure accurate communication and labeling consistent with the food's characteristics. To guarantee effective freedom of choice, it is essential to provide educational support through public initiatives in order to raise awareness of novel products.

Safeguarding freedom in research and enterprise. Freedom of research and enterprise, when consistent with ethical standards, should not be subject to partisan political positioning, but should be upheld as an unquestionable value shared by all political actors. Access to progress is a fundamental human right, in accordance with art. 27(1) of the Universal Declaration of Human Rights, art. 3 of the Treaty on the EU, art. 14(1) of the American Convention on Human Rights, and others. This underlines the importance of unity and cooperation among different political forces to protect, guarantee, and support freedom of research and enterprise over time.

In conclusion, the current discourse on cultivated meat underscores the necessity for rigorous, multidisciplinary research, and regulatory diligence, evaluating both its prospective advantages and concerns. Notwithstanding the potential conclusion that cellular meat is not a viable avenue of scientific exploration, this intersectoral approach is crucial for evaluating the ethical and social implications of such innovation. This will ultimately guide the development of appropriate legal frameworks and supportive guidelines for global decision-makers.

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AUTHOR CONTRIBUTIONS

M.A.F., A.B., and D.M. wrote the first draft. All other authors provided intellectual input and edited the manuscript and are listed alphabetically.

DECLARATION OF INTERESTS

A.B. is an inventor of cellular agriculture patents and a shareholder and scientific advisor of SoundEats Inc. S.B. and L.C. are inventors of a patent on cellular agriculture and scientific advisors of Bruno Cell srl.

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