CHAPTER 5

Innovating Food, Shaping Trust: Insights from a Consumer Survey on EU Novel Foods and Cell-Based Meat Regulation

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Summary

1 Innovation in the Agrifood Sector and the Linkages between the Market, Consumer Choice, and Regulatory Solutions: Novel Foods as a Case Study[1]

Against the backdrop of climate change, the depletion of natural resources, and a continuously growing global population,[2] building resilient and sustainable food systems has become critically important. Ensuring food security—defined as the guarantee of access to adequate, nutritious, and sufficient food for all, including future generations[3]—requires a profound paradigm shift. It is no longer sufficient to merely enhance the capacity of food

1 While this chapter has been jointly written by the coauthors, Sections 1, 2, and 5 were written by Giulia Formici, and Sections 3 and 4 by Giacomo Degli Antoni and Marco Faillo.

2 FAO, IFAD, UNICEF, WFP, and WHO, *The State of Food Security and Nutrition in the World 2024. Financing to end hunger, food insecurity and malnutrition in all its forms* (Rome 2024).

3 Emily Webster, Ankita Gupta and Ruth Ambros (eds), *Transnational Food Security* (Routledge 2020); Luigi Costato, Ferdinando Albisinni, and Theodore Georgopoulos (eds), *European and Global Food Law* (3rd edn, Wolters Kluwer 2025).

systems to meet evolving dietary needs, both in terms of quality and quantity. What is fundamentally demanded is the promotion of sustainable food production methods that minimise the environmental impact of the agrifood sector on biodiversity, natural resources such as air, soil, and water, while also addressing socioeconomic inequalities.[4]

In recent decades, significant technical and scientific advancements have been made to pave the way for the development of unprecedented food products and production methods. These improvements offer valuable tools to support the transition toward more sustainable food systems.[5] Innovations such as the 'Internet of farming' and Artificial Intelligence,[6] New Genomic Techniques,[7] and Novel Foods[8] are emerging as potential drivers of transformative solutions to challenges such as climate change, pollution, food waste,[9] environmental degradation, and resource scarcity.

However, innovation brings both potential and risk, raising new questions and concerns particularly around the need to foster scientific progress while safeguarding consumer health. In other words, it is crucial to guarantee that new foods or food production techniques entering the market do not pose risks to human health, the environment, and/or animal welfare.

Striking an appropriate balance between food safety, food security, food sustainability, and innovation necessitates thoughtful regulatory and policy interventions. Lawmakers and policymakers are increasingly called upon to craft comprehensive strategies as well as sophisticated normative frameworks to govern technological advancements in the agrifood sector. These legal mechanisms may significantly influence consumer acceptance and freedom of choice

4 Francesco Rossi Dal Pozzo and Vito Rubino (eds), *La sicurezza alimentare tra crisi internazionali e nuovi modelli economici* (Cacucci 2023); Simone Pitto, *La rilevanza costituzionale e globale della sicurezza alimentare. Una lettura olistica e comparata della food security* (Editoriale Scientifica 2024).

5 Stefano Sforza, 'Food (In)Security: The Role of Novel Foods on Sustainability' in Lucia Scaffardi and Giulia Formici (eds), *Novel Foods and Edible Insects in the European Union* (Springer 2022); AIDA-IFLA (ed), *Innovation in Agri-Food Law Between Technology and Comparison* (Wolters Kluwer 2019).

6 See Corazza in this Volume. Valeria Paganizza, 'Artificial Intelligence in the Food Sector' in Luigi Costato, Ferdinando Albisinni and Theodore Georgopoulos (eds), *European and Global Food Law* (3rd edn, Wolters Kluwer 2025).

7 See Errigo in this Volume.

8 See Grilli in this Volume; Daniele Pisanello and Giorgia Caruso, *Novel Foods in the European Union* (Springer 2018).

9 See Cerbone in this Volume.

while also affecting business investments—especially in terms of research and development—, ultimately shaping the entire food market.[10]

Within this broader scenario, Novel Foods constitute a particularly relevant and interesting case study. Focusing on the European Union (EU), the marketing of such foods is governed by Reg. (EU) 2015/2283,[11] which establishes a centralised pre-market authorisation procedure. This Regulation aims to ensure a high level of consumer protection, while simultaneously promoting innovation that contributes to food security and sustainability.[12]

Despite these legislative efforts, current regulation of Novel Foods remains under scrutiny and, in some cases, has faced criticism, prompting growing calls for reform.[13] This ongoing legislative and political debate has also been fuelled by certain specific categories of new foods—most notably insects-based products and cell-based meat[14]—which are at the centre of a lively discourse involving civil society, stakeholder organisations, media, politicians, and the academic community. Therefore, the future of Novel Foods appears to be clearly intertwined with legislative decisions and regulatory approaches, both at the national and supranational levels, that have the power to influence the internal market and the strategic choices of key players in the sector. At the same time, public knowledge and trust in the regulatory system may serve as essential factors for lawmakers, helping to assess the need for reform and guiding efforts to better inform and educate citizen-consumers, thereby fostering more conscious consumer choices.

As part of the On Foods Project,[15] a survey was conducted in Italy involving a representative sample of adults, in terms of age, gender, and

10 Bernd Van Der Meulen, *Reconciling Food Law to Competitiveness. Report on the regulatory environment of the European Food and dairy sector* (Wageningen Academic Publisher 2009).

11 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods, amending Regulation (EU) 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) 258/97 of the European Parliament and of the Council and Commission Regulation (EC) 1852/2001 [2015] OJ L327/1.

12 ibid Recital 29.

13 Valeria Paganizza, 'I nuovi alimenti ("Novel Foods")' in Paolo Borghi and others (eds), *Trattato di diritto alimentare italiano e dell'Unione europea* (2nd edn, Giuffrè 2024); Alessandro Monaco, 'Data Protection under the Novel Food Regulation: Valuable Instrument or Barrier to Innovation? Insights from the Insect Sector' (2023) 18 European Food and Feed Law Review 172.

14 Giulia Formici, Maria Cecilia Mancini and Lucia Scaffardi (eds), *Cell-Based Meat in the European Union and Beyond. An Interdisciplinary Study* (Springer 2025).

15 Project funded by the European Union under the Next Generation EU initiative, National Recovery and Resilience Plan (NRRP)—Mission 4, Component 2, Investment 1.3—Ministerial Call No. 341 of 15 March 2022 issued by the Ministry of University and

macro-geographical area of residence.[16] Among its objectives, the survey also aimed to explore: a) consumer awareness and understanding of the existing Novel Foods discipline in the EU and b) citizen-consumer preferences regarding how such rules should ideally be shaped. The study paid particular attention to the roles and responsibilities of different institutional actors, including national and supranational authorities as well as independent agencies. It also investigated the relevance of scientific evaluations vis à vis political considerations, especially in relation to ethics and socioeconomics.

While numerous surveys on Novel Foods and cell-based meat focus on consumer acceptance and behaviour, the abovementioned survey specifically addressed regulatory aspects, a topic that remained underexplored in existing literature.

The present contribution reflects upon several findings from the survey, centring on the following research questions:

1. To what extent are Italian consumers familiar with the current EU legislative framework on Novel Foods and its main characteristics?
2. What is the level of knowledge regarding the regulatory landscape surrounding cell-based meat in Italy?
3. What are citizen-consumer preferences concerning the regulatory approaches on Novel Foods and, more specifically, cell-based meat? In particular, which institutions do consumers believe should be responsible or empowered in this regulatory process?
4. What role is attributed to science and which aspects should be properly considered when assessing possible risks associated with Novel Foods in general and cell-based meat more specifically?

Ultimately, this analysis seeks to offer valuable '*Novel* food for thought' and insights for both private and public actors, helping to evaluate citizen-consumer knowledge, preferred regulatory solutions, and trust regarding Novel Foods within the EU. These findings could inform legislative and policy initiatives aimed at improving regulatory procedures—especially with regards to which entities should be involved in the risk assessment and risk management phases during the authorisation process at the EU level—while also enhancing trust

Research; Project Code PE00000003, Ministerial Decree No. 1550 of 11 October 2022 granting the funding, project title: 'ON Foods—Research and innovation network on food and nutrition Sustainability, Safety and Security—Working ON Foods'.

16 Alongside the authors of this chapter, the following scholars contributed to the design and development of the survey: Nicola Bergamaschi, Maria Chiara Errigo, Maria Cecilia Mancini, Simeon Benedict Rolla, and Lucia Scaffardi.

in Novel Foods and identifying which concerns (eg human health, environment, animal welfare) are most salient to consumers.

Accordingly, Section 2 of this chapter reviews the current state of EU Novel Foods legislation, with specific attention to the peculiar debate surrounding the marketing of cell-based meat. The Section serves as a foundation for understanding the methodological choices characterising the survey as well as the questions elaborated and included in the analysis, as detailed in Section 3. The empirical evidence collected is explained and evaluated in Section 4. The chapter concludes by offering critical perspectives and suggestions for future regulatory developments and stakeholder engagement rooted in the survey's results.

2 The Novel Foods Discipline in the European Union and the Regulatory Debate on Cell-Based Meat

As anticipated, the marketing of Novel Foods in the EU is governed by Reg. (EU) 2015/2283. Entered into force in January 1, 2018, it defines as 'novel' those food products that meet both of the following criteria: a) they have not been consumed to a significant degree by humans within the EU prior to May 15, 1997 (the date the first EU regulation on Novel Foods entered into force)[17] and b) they fall under one of the ten categories listed in Article 3 of the Regulation, among which 'food consisting of, isolated from, or produced from material of mineral origin'; 'foods consisting of, isolated from, or produced from cell cultures or tissue derived from animals, plants, microorganisms, fungi, or algae'; and traditional foods coming from third countries are included.[18]

Therefore, according to this legislative framework, the vast Novel Foods list includes, on the one hand, foods that are innovative per se—either due to new processing methods or unconventional sources—and, on the other hand, foods considered 'new' from a strictly European perspective, based on geographical and temporal criteria.

17 Regulation (EC) 258/97 of the European Parliament and of the Council of 27 January 1997 concerning Novel Foods and Novel Food ingredients [1997] OJ L43/1.

18 Article 3, para 2, lett b). See Lucia Scaffardi, 'A Peculiar Category of Novel Foods: Traditional Foods Coming from Third Countries and the Regulatory Issues Involving Sustainability, Food Security, Food Safety, and the Free Circulation of Goods' in Lucia Scaffardi and Giulia Formici (eds), *Novel Foods and Edible Insects in the European Union* (Springer 2022); Hanna Schebesta and Kai Purnhagen, *EU Food Law* (OUP 2024).

Foods falling within the scope of this Regulation are subject to a complex pre-market authorisation procedure, aimed at ensuring not only the smooth functioning of the internal market but also a high level of protection of human health and consumer interests (Article 1, para 2). In fact, Novel Foods can be legitimately marketed only if they do not pose safety risks to human health, on the basis of the scientific evidence available (Article 7, lett a).[19] Consequently, in the absence of authorisation, the commercialisation of the Novel Food is prohibited across the EU.

The authorisation procedure established by the Novel Foods Regulation is long and complex. Operators wishing to commercialise a Novel Food have to initiate a centralised and fully harmonised procedure with the European Commission.[20] The Commission receives the application and carries out a preliminary 'formal' validity check (Article 11, para 1). Crucially, it is the responsibility of the applicant to prepare a scientific dossier, providing 'scientific evidence that the Novel Food does not pose a risk to human health' (Article 10, para 2, lett e).

The application is then transferred to the European Food Safety Authority (EFSA), an independent EU authority which is tasked with conducting a risk assessment to evaluate the product's food safety.

Nevertheless, EFSA's opinion does not mark the conclusion of the authorisation process, nor does it constitute the sole factor determining the final decision. Rather, EFSA evaluation is followed by a separate risk management phase, involving different actors and a broader range of considerations. In fact, the Commission is responsible for drafting a proposed implementing act, authorising (or rejecting) the Novel Food (Article 12). This act must take into account not only EFSA's scientific food safety assessment—which is non-binding—but also relevant provisions of EU law, 'including the precautionary principle' (Article 12, para 1, lett b) as well as 'any other legitimate factors' (Article 12, para 1, lett d). Although the Regulation does not define these 'other legitimate factors' in detail, it is important to note that while 'irrational fears or purely

19 Other conditions are: 'b) the food's intended use does not mislead the consumer, especially when the food is intended to replace another food and there is a significant change in the nutritional value; c) where the food is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer'.

20 The authorisation 'shall start either on the Commission's initiative or following an application to the Commission by an applicant', art 10.

emotional reactions … cannot be considered legitimate factors',[21] certain non-scientific considerations may indeed be relevant during the risk management phase. These can include economic, social, ethical, and environmental considerations, as acknowledged in Recital 19 of Reg. (EC) 178/2002.[22]

Finally, the Commission's proposed implementing act must be voted on by a qualified majority in the Standing Committee on Plants, Animals, Food, and Feed (commonly referred to as the PAFF Committee), which involves Member States' representatives. Once approved, the authorised Novel Food is included in the public Union List, together with any specific requirements regarding labelling, conditions of use, or post-market monitoring obligations (Article 9).

It is worth highlighting that this Regulation—unlike others, such as the one concerning cultivation of Genetically Modified Organisms—fully covers the procedural aspects, thereby excluding national legislators from intervening in this domain.[23] This interpretation is reinforced by the exclusion from the current legal framework of the flexibility clause included in the previous 1997 Regulation (Article 12), which allowed Member States to restrict or suspend the marketing of an authorised Novel Food within their national territory in the event of emerging health or environmental risks. As will be discussed later in relation to cell-based meat, the strong, centralised approach adopted in the

21 Annalisa Volpato, 'Novel Foods in the EU Integrated Administrative Space: An Institutional Perspective' in Lucia Scaffardi and Giulia Formici (eds), *Novel Foods and Edible Insects in the European Union* (Springer 2022).

22 Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1, better known as General Food Law Regulation; Recital 19 states: 'It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical, and environmental factors and the feasibility of controls'.

23 Discussion should include the possibility of invoking arts 53–54 of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1. On this point Giulia Formici, 'Meating the Future: alcune riflessioni sulla necessità di promuovere un attento dibattito regolatorio in materia di c.d. carne sintetica' (2023) 2 Forum di Quaderni Costituzionali 15, 18; Guido Bellenghi and Luca Knuth, 'EU Food Law and the Politics of the Internal Market: The Challenge of Cultivated Meat' (2024) 17(3–4) Review of European Administrative Law 39; Vito Rubino and Francesco Rossi Dal Pozzo, 'The Regulatory Framework for the Authorisation to Produce and Market Cultured Meat in the EU' (2024) 19 European Food and Feed Law Review 199.

2015 legislation has significant implications for assessing the compatibility between certain unilateral national actions and EU law.

In conclusion, the 2015 Regulation's innovative structure and relative success—despite some weaknesses and areas for improvement[24]—can be attributed in part to the dual-phase process it establishes. This process separates risk assessment and risk management, assigning them to distinct institutional actors. At the same time, the procedure maintains a meaningful role for Member States through their participation in the PAFF Committee, notwithstanding the centralised nature of the authorisation pathway. Furthermore, the explicit inclusion of decision-making criteria beyond food safety allows for broader considerations (eg economic, social, ethical, and environmental) which are particularly relevant when evaluating highly innovative food products. These aspects have undoubtedly helped to prevent—at least thus far—major tensions between EU-level decisionmakers (particularly the Commission and Member State representatives), as well as between scientific risk assessments and subsequent risk management decisions, which have so far consistently aligned with EFSA's opinions.[25]

Nonetheless, this trend now appears to be at a critical juncture. Attempts by some Member States to deviate from the full harmonisation imposed by Reg. (EU) 2015/2283 are multiplying, particularly in relation to sensitive and potentially divisive Novel Foods, such as insect-based products for human consumption[26] and cell-based meat.

Particularly on the latter category of Novel Foods, the EU is currently experiencing a lively and complex regulatory debate. To date, cultured meat has neither been authorised nor marketed following the abovementioned procedure. Recently, two applications were submitted to the European Commission concerning cultivated duck meat (*foie gras*) and cultivated beef fat.[27] Although these authorisation procedures are still in their very early stages, political and legislative discussions around the effectiveness and suitability of the existing Novel Foods legal framework have intensified, giving rise to fragmented national approaches which potentially create conflicts between the supranational and national regulatory levels.

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24 Martin Holle, 'Pre-market Approval and its Impact on Food Innovation: The Novel Foods Example' in Harry Bremmers and Kai Purnhagen (eds), *Regulating and Managing Food Safety in the EU* (Springer 2018).

25 Volpato (n 21).

26 Paganizza (n 13) 814.

27 Lucia Scaffardi and Giulia Formici, 'Cell-Based Meat' in Luigi Costato, Ferdinando Albisinni, and Theodore Georgopoulos (eds), *European and Global Food Law* (3rd edn, Wolters Kluwer 2025).

In particular, Italy has adopted national legislation banning the production and marketing of cell-based foods deriving from vertebrate animals.[28] France, Romania, and Hungary are attempting to follow suit, with legislative proposals under discussion in their national Parliaments.[29] These 'centrifugal forces' have prompted a crucial dialogue (and in some cases confrontation) with the European Commission, within the framework of the TRIS Directive procedure.[30] In Hungary's case, the Commission, supported by several Member States, declared in its opinion about the compliance of the proposed national ban with the EU law, that such provisions are incompatible with the Novel Foods Regulation.[31] Whether this clear stance will ultimately halt these unprecedented national attempts to circumvent the centralised authorisation procedure established by Reg. (EU) 2015/2283 remains to be seen.

What clearly emerges from these attempted or already in place national legislations are the multiple and delicate questions surrounding cell-based meat and concerning not only food safety but also environmental sustainability, socioeconomic implications, animal welfare, and ethical considerations—including compliance with religious dietary rules—, and the protection of cultural identity.[32] These concerns are mirrored in the regulatory discourse, with several Member States questioning the adequacy of the existing legal framework and its ability to fully address such multifaceted and complex challenges. Scientific uncertainties still characterising various aspects of cell-based meat

28 Law 172 of 1 December 2023, *Disposizioni in materia di divieto di produzione e di immissione sul mercato di alimenti e mangimi costituiti, isolati o prodotti a partire da colture cellulari o di tessuti derivanti da animali vertebrati nonche' di divieto della denominazione di carne per prodotti trasformati contenenti proteine vegetali* (Official Gazzette General Series 281 of 1 December 2023).

29 Maria Giulia Corazza and Giulia Formici, 'Cell-Based Meat in the European Union—A Regulatory Crossroads' in Giulia Formici, Maria Cecilia Mancini, and Lucia Scaffardi (eds), *Cell-Based Meat in the European Union and Beyond. An Interdisciplinary Study* (Springer 2025).

30 Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services [2015] OJ L241/1; Diana Cerini, 'From farm to fork' vs. 'from factory to lab': riflessioni su sostenibilità sociale e benessere animale a partire dalla L. 172/2023 in materia di alimenti e mangimi da colture cellulari' (2025) Rivista di Diritto Alimentare 76.

31 Notification 2024/0394/HU—Draft act prohibiting the production and placing on the market of laboratory-grown meat ('a laboratóriumi hús')—Delivery of a detailed opinion pursuant to Art. 6(2) of Directive (EU)2015/1535, <https://technical-regulation-information-system.ec.europa.eu/en/notification/26066> accessed 10 April 2025.

32 Giulia Formici, Maria Cecilia Mancini and Lucia Scaffardi (eds), *Cell-Based Meat in the European Union and Beyond. An Interdisciplinary Study* (Springer 2025); Carlos Ricardo Soccol and others (eds), *Cultivated Meat. Technologies, Commercialization and Challenges* (Springer 2024).

production and consumption[33] have in fact led a group of Member States to advocate for an EU-wide moratorium, along with the development of specific, *ad hoc* supranational legislation.[34]

The described highly polarised political and regulatory debate has, in many cases, fostered confusion and disinformation within civil society.

Accurate knowledge on the EU legislative framework is therefore crucial for reorienting the debate within proper, science-based boundaries, free from ideologically-driven distortions that can mislead public opinion. Such knowledge is the indispensable starting point for a much-needed dialogue among civil society (including citizens-consumers but also food business operators), policymakers, lawmakers, and the academic community. This discussion is essential for shaping future regulatory approaches and potential reforms, which will significantly influence how innovation, food safety, and food security are governed and balanced.

Building on these premises, the idea emerged to conduct a survey exploring citizens' or consumers' awareness as well as their regulatory perceptions and preferences.

3 The Methodological Approach and Survey Structure

To analyse both the awareness of current EU regulations on Novel Foods and individuals' preferences regarding how such regulations should ideally be shaped, we used original data collected through online surveys. The dataset includes a sample of 2,102 individuals representative of the adult Italian population in terms of gender, age, and macro-geographical area of residence (North-West, North-East, Center, and South).

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33 Numerous documents, among which FAO and WHO, *Food Safety Aspects of Cell-Based Food* (Rome 2023), underline the need for further research in this innovative field in order to better understand lights and shadows, potentialities and risks in terms of food safety but also environmental sustainability and potential socio-economic effects. Hanna Tuomisto and Tony Ryynänen, 'Environmental Impacts of Cultivated Meat' in Carlos Ricardo Soccol and others (eds), *Cultivated Meat. Technologies, Commercialization and Challenges* (Springer 2024); Davide Lanzoni and others 'Biotechnological and Technical Challenges Related to Cultured Meat Production' (2022) 12(13) Applied Sciences 6771; Maria Cecilia Mancini and Federico Antonioli, 'The Future of Cultured Meat Between Sustainability Expectations and Socio-Economics Challenges' in Rajeev Bhat (ed), *Future Foods. Global Trends, Opportunities, and Sustainability Challenges* (Academic Press 2021).

34 *CAP's role in safeguarding high-quality and primary farm-based food production—Note from the Austrian, French and Italian Delegations*, 5469/2024-REV1 <https://data.consilium.europa.eu/doc/document/ST-5469-2024-REV-1/en/pdf> accessed 10 April 2025.

3.1 *Awareness of the Regulatory Framework*

Awareness of the regulatory framework and its various dimensions was assessed through a set of targeted questions.

The first question aimed to gauge basic knowledge of whether any EU regulation on Novel Foods exists: 'To the best of your knowledge, is there a regulation governing the placing on the market of Novel Foods in the European Union?' (Possible responses: yes; no; or I don't know).

A second question explored familiarity with the existence of a pre-market authorisation process: 'To the best of your knowledge, is there a pre-market approval process for Novel Foods in the European Union?' (Possible responses: yes; no; or I don't know). For respondents answering affirmatively, a follow-up question was asked: 'To the best of your knowledge, at what level does this pre-market approval take place?' (Possible responses: at the EU level; at the level of individual Member States; at both levels; I don't know).

The final general question investigated respondents' knowledge of EFSA's role in this context: 'To the best of your knowledge, is there an independent body in the European Union responsible for the scientific risk assessment of the food safety of Novel Foods?' (Possible responses: yes; no; or I don't know).

In addition, we included two questions specifically addressing cell-based meat, as a particular category of Novel Foods: 'To the best of your knowledge, has the European Union adopted specific legislation regulating the placing on the market of cell-based meat?' *and* 'To the best of your knowledge, has Italy adopted specific legislation regulating the placing on the market of cell-based meat?' (Possible responses: yes; no; or I don't know for both).

3.2 *Preferences for Regulatory Approaches*

Preferences regarding how the regulation of Novel Foods should be designed were explored through a series of questions targeting different aspects of the regulatory process.

First, we aimed to understand which institutions respondents consider most appropriate to be involved in the authorisation procedure for Novel Foods, and what roles they should play. To this end, participants were asked to indicate which institutions they would like to see involved in a hypothetical EU-level authorisation process:

> 'If you were to imagine an EU-level (European Union) authorisation procedure for Novel Foods, which institutions would you like to see involved? You may select more than one answer'. (Possible answers: European Parliament; European Commission; independent agency composed of experts; Member States; other).

We then examined which of these institutions respondents believed should have final decision-making power. The question was:

> 'Among the following institutions, which one do you think should have final say in authorising a Novel Food across the entire European Union?' (Possible answers: European Parliament; European Commission; independent agency composed of experts; unanimous agreement of Member States; majority vote of Member States).

Along the same lines, we investigated public attitudes toward the degree of autonomy and discretionary power individual countries should have within this regulatory framework. Respondents were presented with the following scenario:

> 'Imagine the following scenario: the commercialisation of a Novel Food has been authorised by the European Union. This authorisation, valid throughout the EU, was approved by a majority of Member States' representatives following a favourable scientific opinion from an expert agency. In this case, would you want individual Member States to have the power to autonomously prohibit the commercialisation of this Novel Food within their own national borders?'(Possible answers: yes; no; I don't know).

If the answer was 'yes', respondents were then asked to explain their reasoning by responding to the following questions:

- 'Would food safety for Novel Foods be better guaranteed?' (Possible answers: yes; no)
- 'Would the economic interests of those operating in the agrifood sector be better protected?' (Possible answers: yes; no)
- 'Would environmental sustainability be better safeguarded?' (Possible answers: yes; no)
- Respondents could also provide a narrative response providing additional thoughts.

We also investigated preferences regarding the role independent expert agencies should play in the authorisation process. First, we asked whether the scientific assessments made by such bodies should be considered binding or non-binding:

> 'Imagine that, as part of an EU-level authorisation procedure for Novel Foods, an independent agency composed of experts is tasked with

> assessing the food safety of the product for consumer health. In your opinion, what should be the value of this scientific opinion?' (Possible answers: Binding—EU institutions must follow this opinion; Non-binding—EU institutions may decide otherwise, also considering other interests such as environmental impact, economic considerations, or animal welfare.)

Next, we asked which areas respondents believe should fall under the responsibility of an independent scientific agency. Respondents were asked to state how interested they were in the technical-scientific opinion of the independent agency regarding: i) safety of the Novel Food for consumer health; ii) environmental sustainability; and iii) impact on animal welfare. (Possible answers: 1 = I am not interested in the opinion; 2 = I am somewhat interested in the opinion; 3 = I am very interested in the opinion.)

Finally, to specifically explore attitudes toward the regulation of cell-based meat, as a particularly interesting category of Novel Foods, we included two scenario-based questions. The first asked:

> 'Imagine the following scenario: the commercialisation of cell-based meat has been authorised by the European Union. This authorisation, valid throughout the EU, was approved by a majority of Member States' representatives following a favourable scientific opinion from an expert agency. In this case, would you want individual Member States to have the power to autonomously prohibit the commercialisation of this Novel Food within their own national borders?' (Possible answers: yes; no; I don't know.)

If respondents chose 'yes', they were asked to specify their reasons by choosing among the following:

- I would not trust the scientific opinion of the independent agency regarding the food safety.
- I am concerned that cell-based meat could have a negative environmental impact.
- I am concerned that this product could negatively affect animal welfare.
- I am concerned that this product could have a negative economic impact.
- Other (please specify).

The second question presented a different decision-making scenario:

> 'Imagine the following scenario: an independent European agency composed of experts has issued a favourable opinion regarding the food safety

of cell-based meat for consumers' health. Now the European Union must decide whether to authorise its commercialisation. What should it do?

- It should authorise its commercialisation across the entire EU.
- It should authorise its commercialisation across the EU, but allow individual Member States to ban its sale within their borders.
- It could ban its commercialisation across the EU, considering other factors besides food safety for consumers' health (eg, environmental impact, economic impact, animal welfare).
- It could still ban its commercialisation across the EU.

3.3 *Survey Structure*

As further detailed below, the survey was organized into six Parts and respondents were divided into two groups. Questions assessing respondents' awareness of current EU regulations (described in Section 3.1 of this chapter) were included in Part 3 of the questionnaire and were asked to all survey participants. Conversely, questions about individuals' preferences regarding how such regulations should be designed (Section 3.2 above) were included in Part 5 of the survey and administered only to half of the sample.

In fact, for half of the sample, the questionnaire included—between Parts 3 and 4—detailed information about the EU marketing authorisation process. This information was provided in order to analyse its potential effects on attitudes toward Novel Foods. For respondents who received this information, we did not ask how they would design the regulation; instead, we asked for their evaluation of the existing regulatory framework, about which they had just been informed.

As a result, when analysing awareness of the EU Regulation on Novel Foods, we considered the entire sample of 2,102 individuals. In contrast, when analysing preferences regarding the characteristics of the Regulation and, consequently, of the authorisation process, we focused only on the half of the sample that had not received the background information about this topic (ie Part 3a of the survey). It is worth noting that this sub-sample is also representative of the adult Italian population in terms of age group, gender, and macro-geographical area of residence—just like the full sample and the other sub-sample that received the authorisation process background information. Moreover, to increase comparability between the two sets of questions, in the next Section of this Chapter, we discuss what the data revealed about the awareness of the Regulation, both considering the full sample of subjects and the sub-sample of respondents who also answered the questions on preferences for regulatory approach (Group A).

TABLE 5.1 Survey structure

Part of survey	Type of questions/content	Groups completing	# of participants completing
1	Socio-demographic information	All	2,102
2	Respondents' attitudes and behaviours, including aspects such as risk preferences and impatience; trust in science, scientific research, and various institutions; political orientation; dietary habits; and levels of concern about environmental issues, health risks related to food, animal welfare, and rising prices of food and basic necessities	All	2,102
3	Definitions and background information on the concept of Novel Foods as defined by the European Union legal framework; participants' perceptions of Novel Foods and their awareness of the EU legal framework	All	2,102
3a	Detailed background information about the EU marketing authorisation process	Group B only	1,051
4	Respondents' attitudes and perceptions toward two specific and highly debated categories of Novel Foods: cell-based meat and insect-based flour products	All	2,102
5	Questions on how respondents would design the regulatory framework for marketing authorisation of Novel Foods	Group A only	1,051
5	Respondents' evaluation of the current regulatory system governing marketing authorisation of Novel Foods	Group B only	1,051
6	Respondents' views on the clarity of the information provided about Novel Foods and whether they perceive any political bias in the survey	All	2,102

As already underlined and in accordance with the abovementioned research questions, this Chapter does not focus on the effects of the additional background information that was shared with Group B.

The general contents of the survey's six Parts were as follows:

- Part 1 collected socio-demographic information.
- Part 2 focused on respondents' attitudes and behaviours, including aspects such as risk preferences and impatience; trust in science, scientific research, and various institutions; political orientation; dietary habits; and levels of concern about environmental issues, health risks related to food, animal welfare, and rising prices of food and basic necessities.
- Part 3 began with definitions and background information on the concept of Novel Foods as defined by the European Union legal framework. It then explored participants' perceptions of Novel Foods and their awareness of the EU legal framework, as described earlier.
- Part 3a provided detailed background information about the EU marketing authorisation process but was only shown to half the respondents.
- Part 4 examined respondents' attitudes and perceptions toward two specific and highly debated categories of Novel Foods: cell-based meat and insect-based flour products.
- Part 5 varied depending on whether respondents received information about the EU regulatory process for the marketing authorisation of Novel Foods, as previously discussed (Part 3a). For those who did not receive this information, the Part included questions on how they would design the regulatory framework. For those who did receive it, the part asks for their evaluation of the current regulatory system.
- Part 6 contained two questions assessing respondents' views on the clarity of the information provided about Novel Foods and whether they perceived any political bias in the survey.

4 Empirical Evidence

In this Section, we present the empirical evidence gathered from the survey results, focusing on both the respondents' awareness of current EU Regulation on Novel Foods and their opinions on how such a regulation should be shaped according to their preferences.

In particular, we analyse the frequency of the different response options selected for each question.

4.1 *Respondents' Awareness of Current EU Novel Foods Regulation*

The first key finding regarding regulatory awareness is that an absolute majority of respondents (51.33%) stated that they did not know whether an EU Regulation governing the marketing of Novel Foods existed. Meanwhile, 38.77% believed that such a Regulation did exist, while 9.90% stated that, to the best of their knowledge, no such Regulation exists.

When the same question was asked specifically about cell-based meat, the share of respondents who were unsure increased to 57.90%. Similarly, the proportion of negative responses rose to 12.84%, while the percentage of positive responses decreased to 29.26%. With specific reference to the existence of a legal framework adopted by Italy concerning cell-based meat, the responses showed a similar pattern: 25.07% believed such a regulation existed, 19.70% believed it did not, and 55.23% reported not knowing.

Knowledge about the existence of a pre-market approval process for Novel Foods in the EU was slightly higher: 40.82% of respondents believed that such a process existed, compared to 10.23% who believed it did not, and 48.95% who were unsure. Among those who correctly believed that a pre-market approval process exists, nearly half (45.69% of the total sample) thought that it takes place both at the EU level and the Member State level. Meanwhile, 24.94% believed it occurs only at the EU level, 15.03% only at the Member State level, with 14.34% who reported not knowing.

Finally, only 33.44% of respondents were aware that an independent body responsible for the scientific assessment of the food safety of Novel Foods exists in the European Union. Meanwhile, 11.56% believed that no such body exists, and 55.00% were unsure.

Overall, only 321 out of 2,102 respondents (15.27%) demonstrated an accurate understanding of the current EU Regulation on Novel Foods. For the purposes of this analysis, with respect to the question concerning the pre-market approval process, responses were considered correct if participants identified the pre-market approval process as taking place either 'only at the EU level' or 'both at the EU level and at the level of individual Member States'.

Figure 5.1 summarises data about regulation awareness as it emerges from the questions previously analysed.

The previous percentages refer to the full sample of 2,102 respondents, with no missing values for any of the questions. When the analysis is broken down by the two sub-samples of 1,051 respondents each—one group that answered questions about preferences regarding how the regulation should be shaped, and one that did not according to what is discussed in the previous

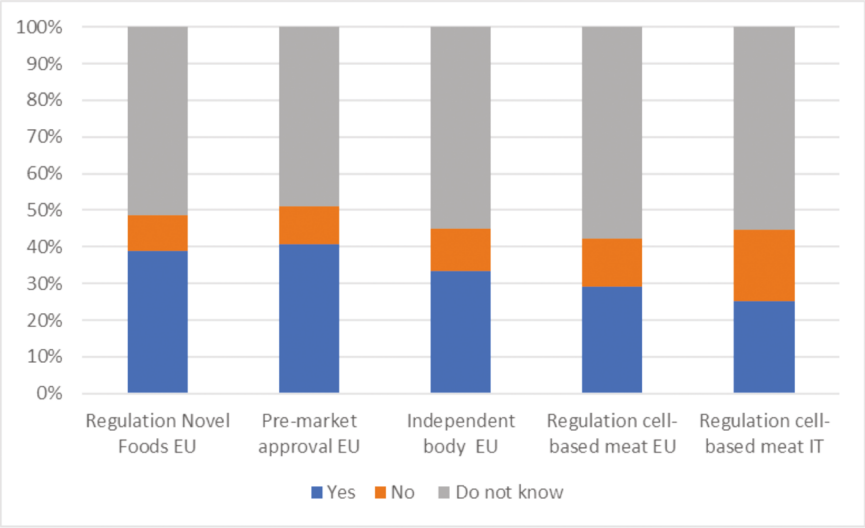

FIGURE 5.1 Regulation awareness

Section—we find that the response distributions are very similar across both groups.[35]

4.2 *Preferences on How Novel Foods Regulation Should Be Shaped*

With regard to the institution(s) to be involved in the authorisation procedure for Novel Foods, respondents—who could select more than one option—tended to favour an independent agency composed of experts (50.80%), followed by the European Commission (40.15%). The European Parliament and individual Member States were selected with the same frequency (38.77%) (Figure 5.2).

When focusing on preferences concerning the involvement of multiple institutions and considering only those explicitly listed in the response options (European Parliament, European Commission, independent agency composed

35 Only in the case of the question concerning the existence of an independent body responsible for the scientific assessment of the food safety of Novel Foods does the distribution of responses differ significantly (Two-sample Wilcoxon rank-sum [Mann-Whitney] test, Prob > |z| = 0.0133). In this case, a higher percentage of respondents in the sub-sample that was also asked about regulatory preferences declared that such an authority exists (35.97% vs. 30.92%). This difference is almost entirely offset by a lower percentage of respondents in that same group who were unsure about the existence of such an authority (52.52% vs. 57.45%).

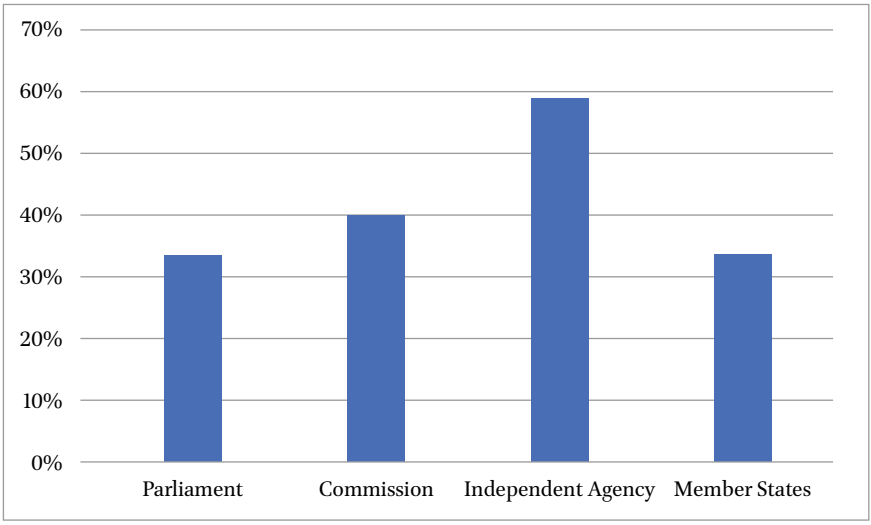

FIGURE 5.2 Preference for the involvement of EU institutions in the approval of Novel Foods (Multiple answers allowed)

of experts, Member States), 8.56% of respondents indicated a preference for the involvement of all these institutions in the authorisation process. Among those favouring a centralised procedure at the EU level, 18.55% of respondents opted for a procedure involving at least both the European Commission and the European Parliament, while 4.95% selected *only* these two institutions. 20.46% of respondents favored a procedure involving both the European Commission and an independent agency. Looking at exclusive preferences for a single institution, 6.76% of respondents favoured solely the European Parliament, 9.51% selected only the European Commission, 25.98% chose only an independent agency, and 6.76% preferred only the Member States.

Regarding the institution that should have the final say in authorising a Novel Foods across the entire EU, respondents' preferences once again leaned toward an independent agency composed of experts, selected by a relative majority (33.78%). This is followed by the requirement of unanimous agreement among Member States (21.50%), a majority vote among Member States (15.79%), the European Commission (15.41%), and the European Parliament (13.51%).

The roles of Member States and independent agencies were further explored through specific questions. Concerning Member States, an absolute majority of respondents (51.28%) expressed the view that individual Member States should have the authority to unilaterally prohibit the commercialisation of Novel Foods within their own national borders, even when an

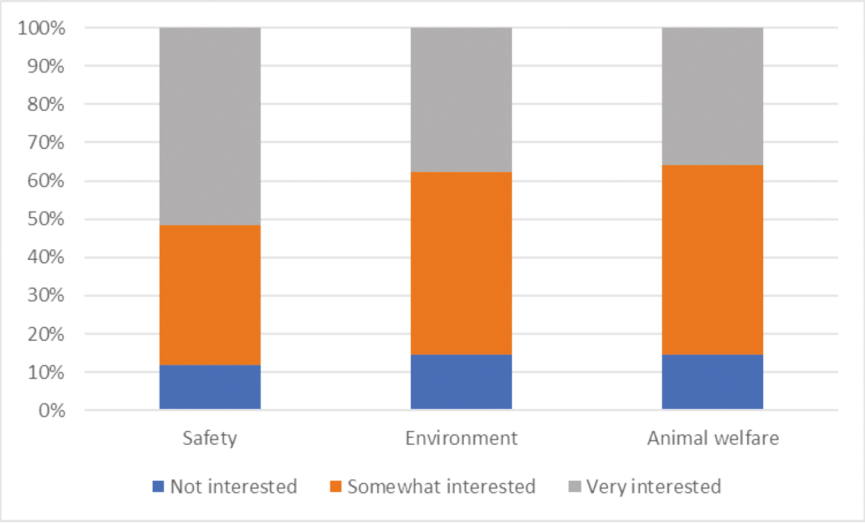

FIGURE 5.3 Aspects you would like the independent agency to express technical-scientific opinion

EU-wide authorisation has been granted by a majority of Member States' representatives based on a favourable scientific opinion from an expert agency. Specifically, respondents believe that such power at the national level would better ensure food safety (according to 84.23% of those supporting this position), better protect the economic interests of stakeholders in the agrifood sector (80.52%), and better safeguard environmental sustainability (71.61%). Conversely, 21.50% of respondents oppose granting such authority to individual Member States, while 27.21% expressed no opinion.

As for the role of an independent authority providing EU-wide assessments, 65.94% of respondents would prefer the agency's assessment of product safety for consumer health be binding in the context of the EU-level authorization procedure for Novel Foods, compared to 34.06% who favor a non-binding role. Furthermore, when asked which issues should be evaluated by an independent panel of experts, respondents expressed higher approval of the option for technical scientific opinions regarding the food safety of Novel Foods for consumer health over opinions regarding environmental sustainability or the impact on animal welfare. These were also considered relevant but to a lesser extent, as reflected in respondents' answers shown in Figure 5.3.

Finally, we address two questions that allowed us to broaden our analysis concerning cell-based meat. The first question appears to confirm the importance that respondents attribute to independent scientific agencies, while also highlighting the role of individual Member States. Specifically, respondents

were asked what the EU should do in a hypothetical scenario where an independent European agency composed of experts issued a favourable opinion regarding the safety of cell-based meat for consumers.

In this context, a relative majority of respondents (49.95%) believed that the EU should authorise the commercialisation of cell-based meat across the Union, while allowing individual Member States to ban its sale within their own borders. A significantly smaller proportion of respondents believe that the EU should authorise commercialisation across the entire Union without exceptions (19.52%); ban commercialisation altogether based on considerations beyond food safety (eg environmental impact, economic consequences, animal welfare) (18.10%); or simply ban commercialisation throughout the EU (15.43%).

As was the case with Novel Foods more generally, an absolute majority of respondents (53.62%) believed that individual Member States should retain the authority to unilaterally ban the commercialisation of cell-based meat within their national borders, even when an EU-wide authorisation has been granted based on a favourable scientific opinion from an expert agency. Those who held this view justified their position by stating that they would not trust the scientific opinion of the independent agency regarding the product's safety (33.39%)—a finding that somewhat contradicts the importance attributed to such agencies in other parts of the survey. Others cited concerns about the potential negative economic impact (26.82%), environmental impact (14.03%), or effects on animal welfare (12.26%).

5 Unpacking the Survey: Civil Society and the Future of Novel Foods Regulation

Based on the empirical evidence examined, several key conclusions can be drawn.

First of all, the survey clearly reveals limited awareness of the current EU Novel Foods Regulation among the average citizen-consumer. This emerges from both the respondents' lack of knowledge about the existence of this specific EU legislation and the incorrect belief that such a legislative framework exists at all. These findings highlight the need for lawmakers and policymakers to implement targeted information strategies and public communications campaigns to increase awareness and to correct misunderstandings about the regulatory solutions currently in place. If the EU, national governments, and food business operators want to encourage public participation and stimulate

debate concerning reform of the Novel Foods discipline, adequate public education is a crucial prerequisite. The observed lack of awareness of regulatory aspects can also offer useful insights for companies interested in the production and marketing of Novel Foods, helping them to design communications strategies aimed at enhancing consumer acceptance through greater knowledge and transparency about the regulatory process.

When it comes to cell-based meat, the awareness gap becomes even more evident, with regard not only to EU legislation but also to national solutions. Considering the highly polarised debate already underway in different Member States, a limited level of knowledge and understanding of the regulatory framework currently in place could ultimately foster fear, misinformation, and the spread of fake news. Moreover, it is worth underlining that the public's scant awareness does not only concern the Novel Foods Regulation but also the role of EFSA, whose existence (and, consequently, function and purpose) appears to be surrounded by uncertainty.

Secondly, if we consider the authorisation process and how it should be shaped, the empirical evidence interestingly underscores two main findings:

a) A significant share of respondents recognised the central role played by independent experts and, consequently, scientific evaluations. This may prompt reflection on the need to reform the existing risk assessment process by expanding it beyond food safety considerations and analysis. In fact, one potential legislative reform and intervention is the integration into the current authorisation process of not only independent evaluations of food safety, but also assessments of other key aspects, such as environmental effects and animal welfare impacts.

b) A noteworthy segment of respondents identified the European Commission and independent agencies as legitimate actors in the authorisation process, thus suggesting widespread acceptance of the current multilevel, biphasic governance structure. In other words, when given multiple choices, respondents mainly expressed their preference for shared decision-making. Nonetheless, another aspect is worth examining: differently from what the current Novel Foods Regulation establishes, a large proportion of respondents supported the possibility for Member States to exercise individual powers to ban or restrict the marketing of new foods within their national borders, even if these products are already authorised at the EU level. This dynamic surprisingly holds true when cell-based meat is investigated as well: a total opposition—in the form of an outright ban—to this innovative food is supported by a minor number of respondents. Nonetheless, a relative majority expressed preference for

EU-level authorisation with Member State discretion to limit the sale in their territory; in this case, the reasons behind this choice indicate less clear-cut confidence in the independent agencies' scrutiny.

In conclusion, what we can infer from this evidence is, on the one hand, the important role accorded to science—by also potentially recognising scientific opinions expressed during the regulatory process as binding for risk managers. On the other hand, the role of Member States is reaffirmed, reinforcing the importance of national risk governance. Although only apparently contradictory, these findings perfectly reflect the constant tension that emerges when innovation enters the regulatory domain. In this case, while the need to affirm and reinforce scientific, independent assessments clearly emerges from respondents' positions, the demand for a final political decision—also at the national level—was simultaneously expressed. This could represent the perceived necessity to counterbalance the attribution of powers to independent authorities that lie outside the framework of democratic legitimacy, and therefore to mitigate potential technocratic drifts.[36] This duality concretely illustrates the complex regulatory choices and emerging trends that arise when innovation must be governed, thus revealing the pressing challenge of defining a balance point between 'politicisation of science' and 'scientification' of political decision-making.[37] Such complex challenges impose serious and profound reflection on democratic representation and, in a broad sense, public involvement in sensitive decision-making processes.

Ultimately, this survey highlights the complexity of regulating innovation. It emphasises the crucial role of knowledge in reducing polarisation and rebuilding credibility in both regulatory processes and scientific evaluations. At the same time, it points to the need to effectively integrate scientific assessments with political considerations: this could lead to a reconfiguration of the roles played by different actors and a rethinking of the governance of emerging technological advancements in a way that ensures solutions and decisions are both scientifically sound and socially acceptable and grounded in political considerations.

36 Laura Salvi, 'Agri-Food Law and Innovation through the Lenses of Better Regulation' in AIDA-IFLA (ed), *Innovation in Agri-Food Law Between Technology and Comparison* (Wolters Kluwer 2019), 28.

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