

# How innovation-friendly is the EU novel food regulation? The case of cellular agriculture

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## ABSTRACT

The Novel Food Regulation provides the central legal framework for regulating food innovation in the European Union (EU). Its suitability for transformative innovation, such as cellular agriculture, has recently come under intense political and scientific scrutiny. This paper systematically analyzes how the Novel Food Regulation affects the development of cellular agriculture in the EU. It employs an original analytical framework that captures its influence on the functionality of the innovation system as well as the potential for “legal disruption” caused by technological development. It triangulates a detailed legal analysis with empirical data, collected through EFSA’s stakeholder consultations, expert interviews, as well as an original stakeholder survey. Results show mixed effects of the regulation on the innovation system for cellular agriculture: whilst the transparent and robust procedures by EFSA contribute to *knowledge diffusion* and *legitimation*, the complex authorization process hampers *entrepreneurial experimentation*, *resource mobilization* and *market formation*. The regulation’s narrow focus on food safety and the potential for political interference in the authorization process create a risk for legal disruption. We argue that the creation of well-designed “regulatory sandboxes” could facilitate the identification of solutions that actually contribute to food system sustainability and innovation, without compromising food safety.

## 1. Introduction

Cellular agriculture refers to various methods of food production that involve the cultivation of cells, typically from animals or plants, in controlled environments, with the purpose of producing cell tissues, as in the case of cell-based meat (also known as “cultivated” or “cultured” meat), or specific compounds, as for precision fermentation (Donaldson and Carter, 2016; Eibl et al., 2021; Post et al., 2020). Considering the increased global demand for proteins (Aiking and de Boer, 2020), cellular agriculture products are deemed significant in the shift toward more sustainable food systems (Bhat et al., 2015; Davis et al., 2024; Fytisilis et al., 2024; Kumar et al., 2021; Luiz Morais-da-Silva et al., 2022; Newman et al., 2024; Post et al., 2020). However, key technological and economic challenges still need to be overcome (Chriki and Hocquette, 2020; Fernandes et al., 2022; Trinidad et al., 2023).

Over the past few years, a global innovation system for cellular agriculture has evolved to comprise an increasing number of companies, products, and technologies (Guan et al., 2021; Ye et al., 2022). As of June 2023, 159 companies were active globally in the field of cell tissue cultivation (Good Food Institute, 2023a) and 62 in precision

fermentation (Good Food Institute, 2023b). The cell-based meat sector alone has raised 2,8 billion dollars between 2016 and 2022 (Good Food Institute, 2023c) while companies working with precision fermentation have collectively raised more than 1 billion between 2021 and 2022 (Good Food Institute, 2023b).

Regulation is one of the key factors shaping the evolution of this innovation system (Broucke et al., 2023; Lähteenmäki-Uutela et al., 2021; Post et al., 2020; Scaffardi, 2020; Stephens et al., 2018; Wood et al., 2023), besides other aspects such as consumer acceptance (Asioli et al., 2022; Davis et al., 2024; Giacalone and Jaeger, 2023; Lin-Hi et al., 2022; Monaco et al., 2024; Siegrist and Hartmann, 2020) and socio-economic conditions (Chiles et al., 2021; Davis et al., 2024; Dueñas-Ocampo et al., 2023; Gagnon et al., 2023; Luiz Morais-da-Silva et al., 2022; Zarbà et al., 2022).

In the European Union (EU), the Novel Food Regulation (EU) No 2283/2015 (hereafter “NFR”) provides the central regulatory framework for food innovation (Lietzow et al., 2020; Vapnek et al., 2021). It covers categories of foods that were not consumed to a significant degree within the Union before the 15th of May 1997, including products of cellular agriculture (Broucke et al., 2023; Ronchetti et al., 2024). Novel

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foods must undergo an authorization procedure before being placed on the market. This procedure consists of two separate steps: a scientific risk assessment conducted independently by the European Food Safety Authority (EFSA) and a political risk management decision. The risk assessment aims to demonstrate that the product is safe and its intended use does not mislead the consumers, nor is it nutritional disadvantageous. Once the risk assessment is concluded, the Commission prepares a draft implementing regulation taking into consideration the general conditions for approval of novel food, the scientific opinion of the EFSA, relevant legal provisions including the precautionary principle and any other legitimate factor relevant for the application under consideration. The final decision on the authorization is taken by the Standing Committee on Plants, Animals, Food and Feed (PAFF), composed of EU member states' representatives.

As of December 2024, several extracts from cell cultures of plant cells to be used in food supplements, as well as compounds produced via precision fermentation, have been authorized as novel foods in the EU; a first application for a cell-based meat product has been submitted in July 2024 (see Section 2). Other authorizations, including for cell-based meat products, have been granted in several jurisdictions around the globe, notably Singapore (Ives, 2020), the United States (Douglas, 2023) and Israel (Aleph Farms, 2023), with applications pending in Switzerland (Morrison, 2023a) and Australia (Food Standards Australia-New Zealand, 2023).

The suitability of the NFR to regulate animal proteins grown via cellular agriculture has recently become a hot topic in EU policy. Following a ban on the production and commercialization of products of cellular agriculture adopted in Italy in December 2023 (Legge n. 172/2023: Article 2), the governments of Italy, France Austria and nine other countries submitted a note to the Council of the EU in January 2024 that urged the adoption of a more comprehensive regulatory framework to evaluate the significant implications of products of cellular agriculture on the lifestyle of Europeans and the potential effects on their health and safety (Note to the Council 5469/1/24 REV 1, 2024). Similar propositions are highlighted in the European Protein Strategy adopted in October 2023 by the European Parliament, where the NFR is seen as not fit for purpose for assessing the ethical, social, environmental and economic challenges posed by cellular agriculture (European Parliament, 2023).

At the same time, interest groups (Morrison, 2023b) and researchers are increasingly questioning whether the NFR slows down innovation, pointing to the length and cost of the authorization procedure (Holle, 2018; Lähteenmäki-Uutela et al., 2021) and the overarching scope of the NFR (Monaco and Purnhagen, 2022). Similar concerns have also been expressed by stakeholders in the UK where the government has named a more innovation-friendly novel food framework a strategic priority after Brexit (Deloitte LLP, 2023). According to Article 1(2), the main purpose of the NFR is to ensure the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests. However, the promotion of innovation and sustainability can be considered an implicit objective of the NFR (Monaco and Purnhagen, 2022), as highlighted in Recital 29 of the NFR: "New technologies and innovations in food production should be encouraged as they could reduce the environmental impact of food production, enhance food security and bring benefits to consumers as long as the high level of consumer protection is ensured".

This paper presents the first systematic analysis of the impact of the NFR on the cellular agriculture innovation system. It employs an original analytical framework, that combines approaches from innovation research and legal sciences. It triangulates legal analysis with stakeholders' perceptions gathered through EFSA's stakeholder consultations, own qualitative interviews and an original survey.

It thus makes a substantive contribution to the literature on food innovation and its role in the food system transformation, as well as a conceptual contribution to the literature on innovation systems and legal disruption. It makes original proposals on how regulation could

unshackle the potential of cellular agriculture for the transformation of food systems, notably by proposing the creation of "regulatory sandboxes" for *ex officio* and self-assessment.

## 2. Theoretical framework

Regulation is a major factor for the development of many innovations, especially in the context of sustainability transformations (Becher, 2024; Dries, 2019; Haggard et al., 2008). At the same time, innovation can have major effects on regulation, for example when a technology introduces new risks or alters the socio-technical configurations within a sector (Cortez, 2014). A "mismatch" between regulatory interventions and the actual risks posed by a technology may lead to persistent non-compliance and paradoxical effects (Guha et al., 2023)

Assessing the impact of regulation on innovation systems requires a multidisciplinary effort that includes an empirical perspective. Legal research often lacks this empirical perspective and fails to capture the complex effects of regulation on innovation systems (Grinblat, 2021; Reinhardt, 2023). Innovation systems analysis, on the other hand, can be blind to the concrete regulatory trajectories and institutional realities, leading to broad and generic policy recommendations (Bening et al., 2015).

For our analysis, we developed an original analytical framework, that combines insights from legal science and innovation systems research. This framework, which we name Regulatory Analysis of Innovation Systems (RAIS), captures both a "static" perspective, i.e. the immediate impact of the regulatory framework on the innovation system, as well as a "dynamic" perspective, i.e. impact of innovation on the regulatory framework and the potential legal disruption. We believe, that the RAIS can provide a helpful tool also for analyzing the role of regulation in other areas (Fig. 1).

### 2.1. Static perspective – regulatory impact on the innovation system

In the short run, any innovation process occurs within a set regulatory framework. Starting from Schumpeter, evolutionary economics has shown the complexity and non-linearity of the innovation process, which is characterized by a co-evolution of knowledge, organizational structures and institutions (Autio et al., 2014). It is a central insight of innovation research, that the development and diffusion of innovation must therefore be analyzed in a systemic manner. The Technological Innovation Systems (TIS)-framework proposed by Bergek et al. (2008) offers an easily accessible heuristic frame of analysis. It has become a major building block of sustainability transition research (Bergek et al., 2015; Köhler et al., 2019), and has been applied in various contexts, including those in the agri-food sector, at various scales.

The focus of the TIS framework lies on the functionality of innovation systems, not their configuration. At its core, it proposes a systematic analysis of seven "functional dynamics", i.e. seven processes that are seen as essential for the system's performance: *Knowledge Development and Diffusion, Guidance of Search, Entrepreneurial Experimentation, Market Formation, Legitimation, Resource Mobilization and Development of Positive Externalities*.

In the RAIS framework, the TIS-functions provide the basis for a fine-grained analysis of the regulatory impact on the innovation system. We identify key salient features of the novel food framework to assess the impact of each feature on the seven functions described in the TIS-framework. This assessment encompasses any relevant legal sources, including European and national case law, "soft law" and legal literature as well as stakeholder perspectives gathered through qualitative interviews and a quantitative survey.

### 2.2. Dynamic perspective – innovation's impact on regulation and legal disruption

Whilst the TIS-analysis allows for a comprehensive and thorough

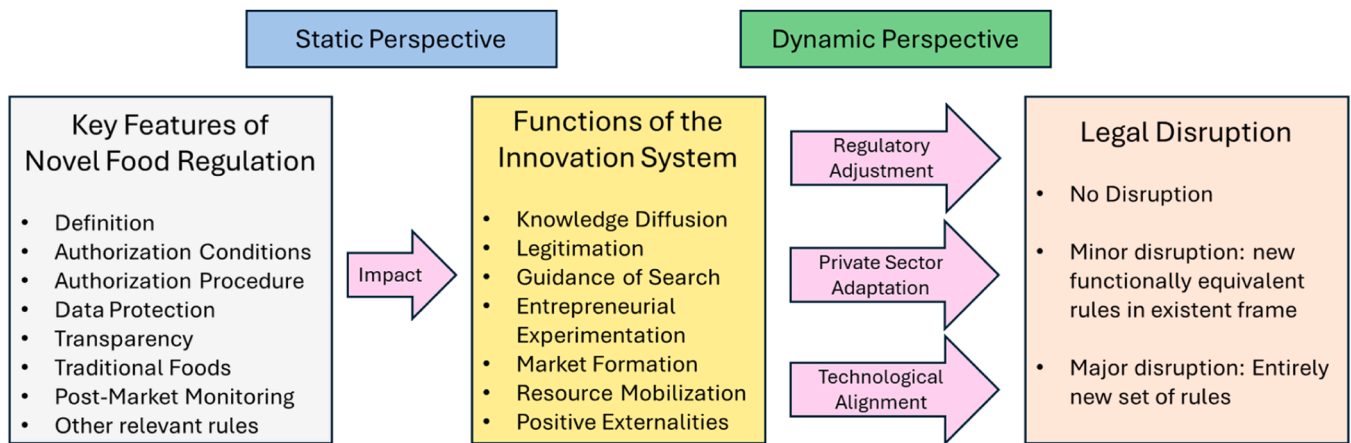


Fig. 1. Elements and sequence of the RAIS analysis.

analysis of the impact of a given regulatory framework on the innovation system, it does not capture the dynamic co-evolution process of innovation and institutions, that is characteristic of innovation system development. It is clear, that regulatory frameworks correspond to established practices at a given point in time and do not foresee all new developments (Cortez, 2014). Innovation-friendliness is just one of several paradigms of risk regulation, besides for example precaution or democratization (Eisenberger, 2016). “Institutional alignment” therefore constitutes a typical challenge in the early phase of innovation system development (Bergek et al., 2008).

From a dynamic perspective, innovation leads to various degrees of legal disruption (Purnhagen, 2021; Twigg-Flesner, 2016): no disruption, if a regulatory framework is fit to accommodate an innovation; minor disruption, where key features of a regulatory framework stay the same, but some rules have to be adapted by functionally equivalent ones; and major disruption, where a totally new set of rules has to be created.

In the RAIS framework, we propose three main elements that determine the degree of legal disruption:

**Regulatory adjustment:** Depending on various parameters, regulation may adapt to new technological realities. This may happen through evolutionary administrative and judicial interpretation and/or through more-or-less flexible legislative changes. The responsiveness of the institutional structures behind the regulation plays a large role in

that respect.

**Private sector adaptation:** To achieve a better institutional alignment, private sector actors have to build the capacity to articulate their concerns (Bergek 2008). At the same time, private actors may seek to evade regulatory obstacles, e.g. through alternative legal constructions, moving operations to other jurisdictions or other circumvention tactics.

**Technological alignment:** Depending on the concrete attributes of an innovation and the socio-technical configurations, the innovation may still generally fit within the regulatory framework (for example, if an innovation only entails different business models). Technology may also help private actors to better align with their regulatory obligations.

### 3. Materials and methods

#### 3.1. Legal analysis

In Table 1 we describe the salient features of the novel food framework that guide our RAIS of the cellular agriculture innovation system.

For each of these salient features, we analyze the impact on the various functions of the cellular agriculture innovation system, as proposed in the TIS framework. We include all available legal sources, i.e. court cases, but also guidance documents and literature in legal journals and commentaries, as well as public information on novel food

Table 1  
Salient features of the NFR.

<b>Novel Food Definition</b> Art. 3(2)(a) NFR	The novel food definition defines the scope of application of the NFR. It includes food that was not consumed to a significant degree within the Union before 15th May 1997 and that falls under one of the ten novel food categories.
<b>Authorization conditions</b> Art. 7 NFR	Novel foods can be authorized if they are safe, if their intended use does not mislead the consumers, especially when they replace other foods and there is a significant change in nutritional value, and if the novel foods do not differ from those foods in a way that normal consumption would be nutritionally disadvantageous for the consumers.
<b>Authorization procedure</b> Artt. 10–13 NFR	The authorization procedure, divided into a risk assessment and a risk management procedure is meant to ascertain that the approval criteria are met, based on scientific data provided by the applicant. The EFSA is the gatekeeper in the risk assessment, while risk management lies in the hands of political authorities, which make a final decision on the authorization.
<b>Data protection</b> Artt. 26–27 NFR	Authorizations under the NFR are in principle generic, but, upon request by the applicant, data protection can be granted on proprietary scientific studies that were considered critical for the good outcome of the authorization. Such data cannot be used for the benefit of a subsequent application for a non-renewable period of five years. This practically results in an exclusive right of the applicant to place the product on the market for five years, unless other companies obtain their own authorization presenting their own proprietary data.
<b>Transparency / Information dissemination</b>	Different instruments serve to disseminate information on novel foods. EFSA’s scientific opinions are always made public; consultation procedures conducted by member states’ competent authorities over novel food status of products are also publicly available; approved novel foods are listed in the Union List of Novel Foods.
<b>Traditional foods from third countries</b> Art. 14 NFR	A novel food can be approved through a simplified notification procedure, when a history of safe food use of at least 25 years can be demonstrated in a third country, the novel food is derived from primary production and it does not fall under the novel food categories (i), (iii), (vii), (viii), (ix) and (x).
<b>Post-Market Monitoring</b> Art. 24 NFR	The NFR does not prescribe general post-market monitoring of novel foods. The Commission may impose post-market monitoring requirements for food safety reasons, taking into account the opinion of the EFSA.
<b>Other relevant rules</b>	Apart from the NFR, other regulatory provisions and political initiatives may influence the innovation system for cellular agriculture, in particular rules on subsidies and labelling.

**Table 2**

Products of cell cultures and precision fermentation authorized as novel foods in the EU.

Products of precision fermentation	Products of cell cultures
L-Alanyl-L-Glutamine	<i>Ajuga reptans</i> extract from cell cultures
Ice Structuring Protein type III HPLC 12	Dried extract of <i>Lippia citriodora</i>
3'-Sialyllactose (3'-SL) sodium salt (microbial source)	<i>Echinacea angustifolia</i> extract
Lacto-N-tetraose ("LNT") (microbial source)	<i>Echinacea purpurea</i> extract
Lacto-N-tetraose ("LNT") (produced by derivative strains of <i>E. coli</i> BL21(DE3))	Apple fruit cell culture biomass
2'-Fucosyllactose/Difucosyllactose mixture (2'-FL/DFL') (microbial source)	
3-Fucosyllactose (3'-FL') (produced by a derivative strain of <i>E. coli</i> BL21(DE3))	
3-Fucosyllactose (3'-FL) (microbial source)	
3-Fucosyllactose (3'-FL') (produced by a derivative strain of <i>E. coli</i> BL21(DE3))	

authorization procedures. (Table 2, Table 3)

As of December 2024, five products of cell culture from plant cells have been authorized as novel foods in the EU, all of them to be used in food supplements. Nine novel foods produced via precision fermentation have been approved and included in the Union List of Authorised Novel Foods. No authorization for dairy proteins through precision fermentation or cell-based meat has been granted yet. A first application for a cell-based meat product has been submitted by the company Gourmey in July 2024 and is currently in the evaluation phase (Good Food Institute, 2024). A second application concerning a cultivated fat was submitted by Mosa Meat in January 2025 (Mosa Meat, 2025).

### 3.2. Stakeholder perceptions

In a second step, we triangulate the legal analysis with stakeholder perceptions. We use qualitative data and quantitative data from an original survey conducted as part of this project.

#### 3.2.1. Qualitative data

Qualitative data was drawn from the official report on the EFSA's Colloquium on "Cell culture-derived foods and food ingredients" in May 2023 (EFSA, 2024a) as well as from the published statements made by industry representatives in the subsequent ad-hoc meeting in October 2023 (EFSA, 2023). Both events explicitly aimed to collect stakeholder perspectives on how novel foods produced via cell tissue cultivation and precision fermentation should be assessed by the EFSA, and resulted in new indications for the preparation of dossiers concerning these products being included in the new Guidance for Novel Food Application published in September 2024 (EFSA, 2024b).

We also consider interviews with stakeholders conducted in various research projects concerning the NFR between 2020 and 2024. Altogether, thirty-one qualitative interviews were taken into consideration. Sixteen interviews were conducted to assess the regulatory framework applicable to products obtained through mycelium fermentation, seven interviews concerned dairy alternatives produced through precision fermentation, and five interviews focused on insect-based novel foods. Finally, three interviews with stakeholders active in the field were specifically conducted to discuss the quantitative survey conducted as part of this research project.

#### 3.2.2. Quantitative data

Insights from the qualitative interviews and the results of the doctrinal legal analysis were used to develop a survey entitled "Innovation and the Novel Food Regulation", distributed among stakeholders in the EU novel food sector in June 2023. The aim of the survey was to

collect the perceptions on the NFR and the appreciation for potential changes. The distribution of the survey was not limited to actors in the cellular agriculture sector to avoid uncertainties about definitions and get a broader picture from all stakeholders active in the EU novel food sector.

The survey was distributed to five samples of stakeholders and then enlarged through snowball technique. The survey was initially distributed to (1) all EU companies listed in the database of the Good Food Institute, an organization globally active on the promotion of alternative proteins, (2) members of the organization "Cellular Agriculture Europe", (3) all companies part of the IPIFF, the consortium of EU insects producers, (4) to members of the Verband für Alternative Proteinquellen e. V. and (5) to all companies and start-ups with whom we collaborated in previous research projects.

The total number of participants was N=88. Most replies came from representatives of start-ups (n=24), established companies (n=25) and academia (n=17). Public authorities (n=6) and industry groups (n=3) were also represented. Other participants can be broadly categorized as consultants and experts in the sector (n=13). The respondents were mainly active in Europe, and the larger group of respondents operated in Germany (n=26). When asked to indicate the scope of their expertise, n=41 referred to plant-based products, n=28 biomass fermentation, n=23 insects, n=26 cell tissue cultivation and n=27 precision fermentation. Most of the respondents have never been directly involved in an authorization procedure in the EU (n=59).

## 4. Results

### 4.1. Legal analysis and qualitative interviews

Table 3 summarizes the results of the legal and qualitative analyses.

### 4.2. Survey results

The results from the legal and qualitative analysis were largely confirmed by our original survey.

#### 4.2.1. Stakeholders perception of the NFR

The survey investigated stakeholders' perception of the NFR features and the appreciation of some suggestions for potential changes developed throughout this research project.

**Novel food definition:** Uncertainty on the novel food status of products is considered an issue by 54% of the participants that indicated "cell tissue cultivation" and "precision fermentation" among their main areas of expertise. This percentage is even higher than for all participants, of which 46.5 % were concerned about uncertainty on the status.

**Conditions for authorization:** 69.3% of the respondents strongly agree or agree that the novel food authorization procedure increases the Legitimation of innovative food products. Most respondents to the survey (67%) believe that potential sustainability benefits should be considered in the authorization procedure.

**Authorization procedure:** Respondents consider the costs and the duration of the procedure as the major obstacle to placing novel foods on the market (Fig. 2).

The great majority of participants (70.4%) expressed concerns over excessive political interference, with no significant differences between participants who had participated in the procedure and participants who did not (Fig. 3).

**Data protection:** The perception of the data protection clause and the subsequent exclusivity period is fragmented among respondents. Whilst 22.7% of the respondents consider it "valuable", and 18.2% "very valuable", 25% have a neutral opinion, 9.1% consider it as "non-valuable" and 11.4% as "no valuable at all". Notably, participants working for established companies valued the data protection clause more positively than start-uppers (Figs. 4 and 5).

Survey participants had the opportunity to comment on specific

**Table 3**  
RAIS analysis.

Salient feature	Legal Analysis:	Impact on Innovation System
<b>Definition</b> Article 3(2)(a) NFR	<p>The novel food status of a product is normally clarified through national consultation procedures, which vary considerably between member states (Molitorisová et al., 2021; Niewald, 2023). The results of the consultations are collected in the Novel Food Catalogue. The novel food status of a food can be contentious and has been subject of judicial procedures at EU (CJEU, 2023; 2016; 2020) and national level (Sosnitzer and Meisterer, 2023).</p> <p>For cellular agriculture products uncertainty may arise when genome modification techniques are applied during the production process (e.g. ingredients produced using modified microorganisms), potentially leading to their categorization as genetically modified organisms (Lensch et al., 2022; Ronchetti et al., 2024).</p> <p>The novel food category (vii) covering new production processes may act as a catch-all provision (CJEU, 2009) and thus introduce considerable uncertainty for technological developments in the production process (Grube et al., 2015; Kostenzer, 2021).</p>	<p>Negative effect on <i>Entrepreneurial Experimentation</i>, <i>Resource Mobilization</i> caused by uncertainty.</p> <p>Indirect effect on <i>Guidance of Search</i>, as actors may turn to solutions that do not fall under the NFR.</p>
<b>Authorization Conditions</b>	<p>The authorization confirms that the novel food does not pose safety risks for human health, that it is not nutritionally disadvantageous for consumers compared with a food it intends to replace, and that it is not misleading.</p> <p>The criteria for approval do not evaluate any benefits that the novel food might bring e.g. in terms of sustainability.</p>	<p>Positive effect on <i>Legitimation</i> and, subsequently, <i>Market Formation</i>.</p>
<b>Authorization procedure</b>	<p>Whilst by law, the procedure should be finished in 17 months, on average it lasts more than three years (Kostenzer, 2021; Grimsby, 2020; Varacca et al., 2024), as the stop-the-clock clause (article 22 NFR) is used regularly by EFSA to require additional information from the applicants. This poses particular problems for start-ups that have to meet milestones set by investors (Cellular Agriculture Europe, 2023). Notification obligations for studies pose additional risks for delays (Torre, 2023). Details on the preparation of the dossier are defined in the EFSA's Guidance for Novel Foods application, which has been updated in September 2024 (EFSA, 2024b). The new guideline includes specific instructions on the preparation of dossiers concerning cellular agricultural products.</p> <p>The authorization procedure for novel foods accommodates the obligations set by Regulation (EU) No 1381/2019 on the transparency and sustainability of the EU risk assessment in the food chain. According to this Regulation, the EFSA cannot discuss in advance the specifics of applications or comment on the proposed study design but only answer questions on the published guidelines and provide general advice. General advice, however, is often not enough for innovators (Torre, 2023), especially for new technologies such as cellular agriculture (EuropaBio, 2023). Additionally, Regulation (EU) No 1381/2019 introduced an obligation to notify studies included in the dossier before they are conducted.</p> <p>The final decision on authorization is taken by the PAFF committee and it is political. So far, no novel food has been rejected by the PAFF committee, but procedures have been significantly delayed (Verzijden and Buijs, 2020). Procedural requirements are even stricter than in the regulation of Genetically Modified Organisms (GMOs) (Verzijden and Buijs, 2020). GMOs cases show a real risk of political rejection despite positive risk assessment (Davison and Ammann, 2017). Applicants have limited possibilities to challenge the EFSA assessment or the Commission decision (Kostenzer, 2021).</p>	<p>Negative effect on <i>Entrepreneurial Experimentation</i> and <i>Resource Mobilization</i>.</p>
<b>Data protection</b>	<p>Data protection is almost always granted when requested by applicants. Whilst exclusivity may constitute an incentive for innovators (Grimsby, 2020), its true benefits are debatable due to the limited duration of 5 years and the possibility for competitors to apply for the same product (Holle, 2018; Monaco, 2023). Exclusivity may slow down the development of specific novel foods' subsectors and delay the publication of important scientific results (Holle, 2018, 2014; Monaco, 2023; Simpson, 2016).</p>	<p>Positive effect on <i>Resource Mobilization</i> for the beneficiaries, negative effect on <i>Knowledge Development and Diffusion</i>, <i>Market Formation</i> and potentially <i>Legitimation</i>.</p>
<b>Transparency / Information dissemination</b>	<p>The characteristics of the novel food, its conditions of use and specific labelling requirements are specified in the Union List of Authorised Novel Foods.</p> <p>All scientific opinions of EFSA are published in the <i>EFSA journal</i>.</p> <p>The Novel Food Catalogue (European Commission, 2023a) is regularly updated with the results of the consultations on the novel food status of products at the member states level.</p>	<p>Positive effect on <i>Knowledge Development and Diffusion</i> and <i>Development of Positive Externalities</i>.</p>
<b>Traditional food categories</b>	<p>The traditional food category requires a demonstrated use of at least 25 years and thus does not affect cellular agriculture products.</p>	<p>No effect</p>
<b>Post-Market Monitoring</b>	<p>Specific labelling requirements can cause minor inconvenience as they do not allow for inclusion of IP-protected terms (Ballke, 2019). Unlike for GMOs, there are no general additional labelling or traceability requirement for novel food. There are no general obligations for post-market monitoring of novel foods.</p>	<p>Positive effect for <i>Market Formation</i> and <i>Legitimation</i></p>
<b>Other relevant rules</b>	<p>Cellular agriculture does not receive funding under the Common Agricultural Policy or research funding under EIP-AGRI.</p> <p>The opportunity to use meat and dairy denominations when labelling products of cellular agriculture may contribute to their widespread adoption (Seehafer and Bartels, 2019). In the EU, the use of dairy-like denominations is reserved for animal products, as established by case C-422/16 (CJEU, 2017). This restriction would novel foods obtained through precision fermentation (Bánáti, 2020; Domke, 2018; Ronchetti et al., 2024).</p> <p>The use of meat-like denominations is not regulated at EU level (Bánáti, 2020;</p>	<p>Negative effect <i>Resource Mobilization</i></p> <p>Negative effects on <i>Market Formation</i></p>

(continued on next page)

Table 3 (continued)

Salient feature	Legal Analysis:	Impact on Innovation System
	European Parliament, 2021), but is subject to national restrictions, e.g. in France ( <i>Décret n° 2024-144</i> , 2024), Italy ( <i>Legge n. 172/2023</i> ) and Germany ( <i>Leitsätze der Deutscher Lebensmittelbuch-Kommission vom 10 2024</i> ). In October 2024, the Court of Justice of the European Union clarified that member states must not simply prohibit the use of meat-like denominations for plant-based products. However, Member States may positively define names for food products ( <i>CJEU, 2024</i> ).	

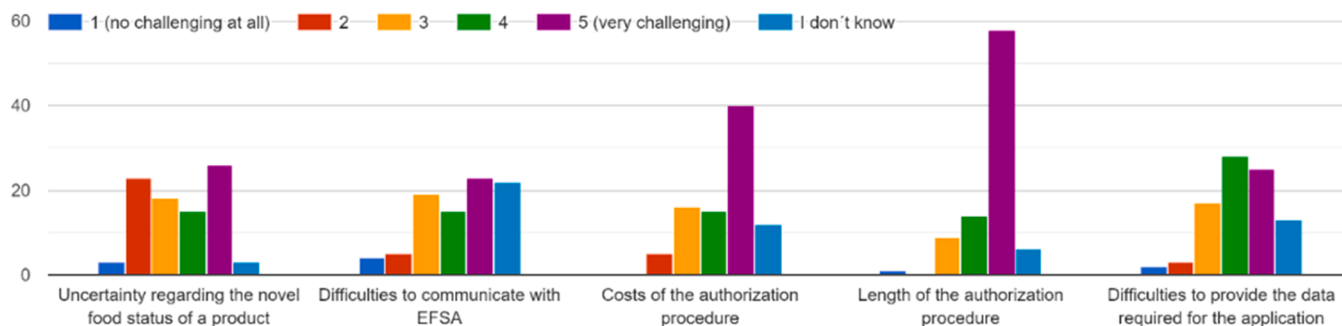


Fig. 2. Challenges under the NFR

In your opinion, how challenging are the following aspects of the Novel Foods authorization procedure? Rate them from no challenging at all (1) to very challenging (5).

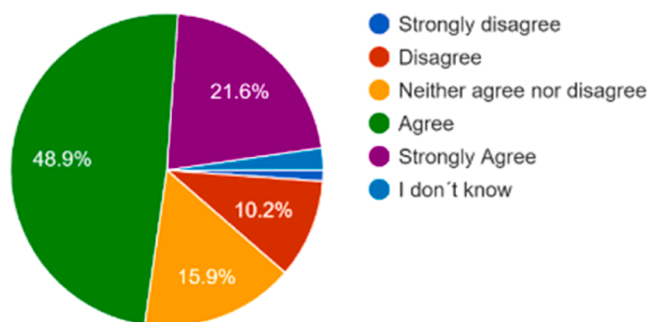


Fig. 3. Political interference in the authorization procedure

Do you agree with the following statement? "I am afraid of excessive political interference in the authorization procedure of novel foods".

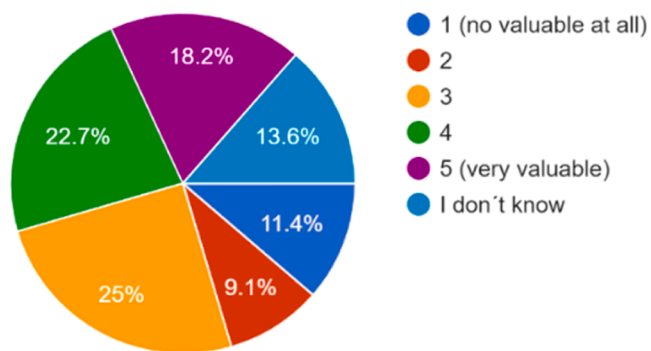


Fig. 4. Do you think that the data protection clause is a valuable tool to promote innovation in the EU? Rate it from 1 (no valuable at all) to 5 (very valuable).

issues with regard to data protection. Respondents highlighted that the duration of the protection does not reflect the length and costs of the procedure and how the clause essentially leads to the duplication of invested resources by other companies, cutting off small-size companies and slowing down the adoption of innovations like cell-based meat or precision fermentation: "5 years isn't very long given how long it takes a

company to prepare safety data", "(...) forces the applicant to repeat an additional approval process for an already approved food, resulting in wasted time and money", "It is restrictive for the whole space, because it means only initiatives with substantial funding can access the market", "Slowing down acceptance of general public in novel foods".

4.2.2. Potential improvements of the NFR

To better understand the key pressure points and develop proposals for improvement, survey participants also assessed potential changes to the NFR framework and were briefly asked about their perception of other jurisdictions.

The majority of respondents would welcome the opportunity to discuss the dossier with the EFSA staff before submission (81% of the total number of participants, and 89% of the respondents who have direct experience with a novel food authorization procedure).

A possibility to organize non-commercial tastings would be greatly appreciated (70.4% positive evaluations) by stakeholders. Currently, there are no EU-wide guidelines on how to organize tastings of non-approved novel foods. Only the Dutch competent authority has released guidelines for the non-commercial tastings of products of tissue cultivation ( *Rijksoverheid, 2023*).

A hypothetical opportunity to place a novel food on the market before receiving the final authorization, with appropriate warning signs and limitations, was appreciated by 48.8% of the participants. The introduction of a mandatory licensing mechanism for novel foods covered by data protection has received positive evaluations only from a minority (45%) of participants ( *Fig. 6*).

Respondents also had the opportunity to suggest mechanisms to foster innovation under the novel food framework. The suggestions focused again on pre-submission consultation with the EFSA ("pre-submission dialogue with EFSA", "The Commission should formalise an avenue for companies to open substantive dialogue with EFSA prior to safety dossier submission"), on the possibility to amend the specifics of the authorizations to reflect the technological advancements ("EFSA should ensure the authorisation process includes routes for safety dossiers to be amended to reflect technological progression and innovation in product development") and on the creation of databases of pre-approved substances.

Finally, when asked to evaluate jurisdictions other than the EU and their ability to favour innovation, 68% of the respondents agreed that other countries have more innovators-friendly frameworks in place,

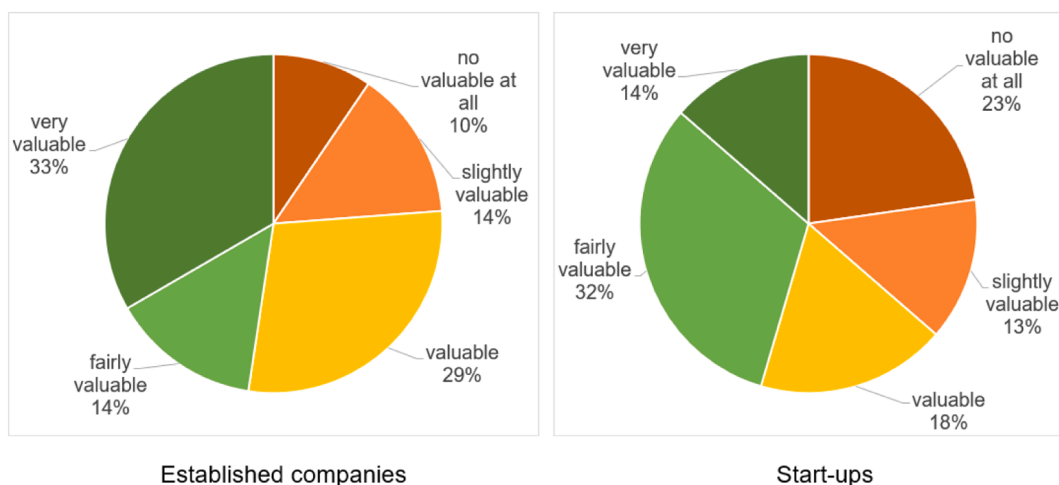


Fig. 5. Differences between established companies and start-ups in the perception of data protection.

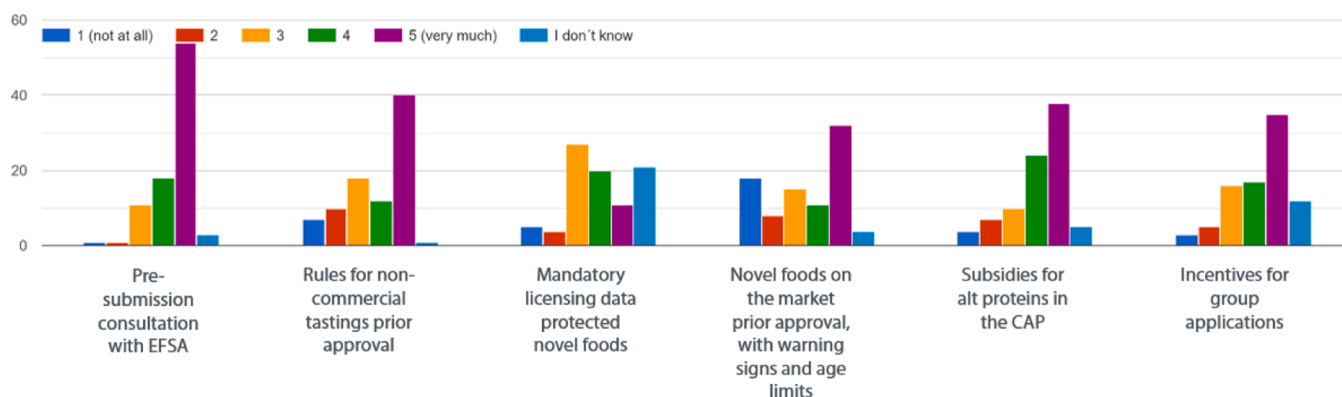


Fig. 6. Appreciation for potential amendments to the NFR.

while 27% stated that they do not have the experience to make such a claim. Only n=4 considered the EU not worse than other jurisdictions, n=2 of which have been involved in an EU authorization procedure. When asked to comment on their answers, respondents explained that they appreciate other frameworks like Singapore for their pre-submission consultations and risk-benefit approach.

### 5. Discussion

Our analysis shows negative and positive impacts of the NFR on the development of the cellular agriculture innovation system.

Negative impacts concern the *Entrepreneurial Experimentation*, *Market Formation* and *Resource Mobilization* functions. They are mainly related to the length of the authorization procedure and difficulties in communication with the EFSA.

Positive impacts mainly concern *Legitimation* provided by the rigorous and comprehensive authorization process. Overcoming neophobia seems crucial for food innovations, as consumer studies show strong biases against novel foods (Bryant and Barnett, 2018; Ledesma-Chaves et al., 2024; Monaco et al., 2024; Siegrist and Hartmann, 2020) and trust in food safety authorities is a key factor to overcome them (Muiruri and Rickertsen, 2024). The positive effect of the NFR authorization on *Legitimation* can be even stronger than for Genetically Modified Organisms (GMOs), as no subsequent labelling is required for novel foods.

*Legitimation* as well as *Knowledge Development and Diffusion* are also supported by the transparency of the NFR. The scientific opinions of the EFSA and the specifics of the authorization are made publicly available.

Data protection, conceived to support innovation, elicits mixed reactions from stakeholders, matching previous doubts about its effectiveness in the legal literature (Holle, 2018, 2014; Monaco, 2023; Simpson, 2016).

The NFR does not actively guide the search process of the innovation system, for example by recognizing sustainability benefits. However, the complex authorization procedure might discourage some stakeholders from pursuing technologies that require novel food approval (Varacca et al., 2024).

The survey results also point to potential improvements of the NFR. Interestingly, relatively minor changes to the framework received the highest approval. In particular, stakeholders would welcome rules that facilitate non-commercial tastings and the opportunity to consult with EFSA prior to submitting an application. Many stakeholders think that regulatory frameworks in other countries are more innovation-friendly and that sustainability benefits should be considered in the authorization procedure.

In the following, we discuss our results with a view to the dynamic evolution of regulation and the potential for legal disruption (Section 5.1). This leads us to a consideration of sustainability aspects of cellular agriculture in the broader context of food system transformation (Section 5.2). We argue that a reform of the NFR is not only advisable from a scientific point of view, but normatively required (Section 5.3). Regulatory sandboxing could provide a way to address many concerns.

#### 5.1. Potential for legal disruption

At the current stage of development of cellular agriculture, major

challenges still concern the technological development and the scale-up (Broucke et al., 2023; Santos et al., 2023). However, production costs for cell-based meat are decreasing (McKinsey & Company, 2023) and some projections already see potential market niches (Garrison et al., 2022). Thus, the suitability of the NFR for cellular agriculture might soon be tested at a greater scale.

It is clear, that any regulatory framework corresponds to the *status quo* of technology at a given point in time and does not necessarily “fit” all future technological advancements (de Boer and Bast, 2018; Johnson, 2021). Institutional alignment is a typical challenge for innovation system development, especially at an early stage. In the RAIS framework, we identify three main factors that influence the potential for legal disruption (cf. Section 2): regulatory adjustment, private sector adaptation and technological alignment.

Regulatory adjustment has already started. Following various stakeholder consultations, the EFSA has published a revised guidance for novel food applications, which contains specific provisions for products of cellular agriculture (EFSA, 2024b). Political initiatives are taken by individual member states, notably the Dutch rules on non-commercial tastings (Rijksoverheid, 2023). Even the action of hostile governments, such as in the case of the Italian ban, can be seen as a process of regulatory adaptation which can serve to enlarge the debate and ultimately favour the creation of ad-hoc, Europe-wide initiatives.

The private sector is building up capacities to articulate political demands through global and regional organizations, such as the Good Food Institute, Cellular Agriculture Europe or Food Fermentation Europe in the EU or the APAC Regulatory Coordination Forum in Asia. These organizations provide regulatory advice to their members and articulate common concerns towards regulators. This capacity seems essential, as the NFR framework - by design - does not allow for evasion strategies. No novel food must be placed on the EU market without an authorization, and there is no mutual recognition in place with other jurisdictions. Whilst the knowledge and data generated in authorization processes in US, Australia, Singapore, Israel and Switzerland may be practically helpful for the EU NFR procedure, the international discussion on harmonization of authorization standards in the Food and Agriculture Organization (FAO) is only at an initial stage (FAO and WHO, 2023).

As for technological alignment, an improved understanding on the specific challenges can be expected as more and more products come to market. Technological advances may also streamline authorization procedures, for example by integrating AI tools in risk assessment (Fu et al., 2023) or tissue culture models (Fytasilis et al., 2024). As most cellular agriculture technologies aim to produce homogenous products (cells or molecules), safety assessments may eventually become more straightforward. The “one product – one authorization” approach of the NFR, however, could provide an obstacle to the necessary incremental innovation processes. Existing NFR authorizations such as the apple fruit cell culture biomass (Commission Implementing Regulation (EU) 2023/2847) show a high degree of specificity, for example referring to the specific apple variety used for deriving the cell lines, and other specific aspects of the cultivation process. This raises the question if new authorizations are required for any subsequent improvements of the process. Already, the capacities of EFSA are seen as constrained (EuropaBio, 2023). Examination *ex officio* by the EFSA of at least some of these aspects was named as a potential improvement by stakeholders.

Regulatory adjustment, private sector adaptation and technological alignment alleviate the pressure for legal disruption in the medium term. Our survey confirms that most stakeholders do not put the robust NFR-framework in question. The most immediate concerns for stakeholders, namely length of procedure and communication with EFSA, could be improved without major legislative changes.

The biggest potential for disruption arises from political element of the NFR authorization. The current political discussion around cell-based meat could create unfavorable changes for the sector. The case of GMOs shows that EU and member states’ authorities eventually do

not authorize scientifically “safe” products because of political reasons (Davison and Ammann, 2017; Mohorčič and Reese, 2019).

## 5.2. Sustainability

The current political debate on cellular agriculture in the EU concerns potential safety risks, but also the broader societal implications of cellular agriculture. It can be compared to other debates about biotechnology, notably GMOs (Mohorčič and Reese, 2019). The Italian ban of cellular agriculture, for example, is openly based on the precautionary principle to avoid potential safety risks but also a preference for natural solutions, traditional agriculture and local gastronomic heritage (Legge n. 172/2023: Article 1).

Scientific literature points to significant potential environmental and animal welfare benefits of cellular agriculture that could make it an important element of the food system transformation (Bhat et al., 2015; Davis et al., 2024; Kumar et al., 2021; Newman et al., 2024; Post et al., 2020). Whilst many technical challenges remain unsolved (Chriki and Hocquette, 2020), cell-based meat and dairy proteins produced via precision fermentation could significantly reduce problems related to animal production. (Fesenfeld et al., 2023). Beyond proteins, other molecules such as oils or sugar may be produced in more efficient pathways (Davis et al., 2024). Cellular agriculture could also play a role in the production of ingredients with high nutritional value or complement traditional agricultural to improve its resilience (Soice and Johnston, 2021). An innovation friendly NFR may also be important for technologies, such as algae (Severo et al., 2024) and products based on waste from the agri-food industry (Martuscelli et al., 2023).

Regulation must also consider potential risks of cellular agriculture. Innovation research increasingly scrutinizes the prevailing “innovation bias”, i.e the framing of major policy challenges as innovation challenges (Pfothenauer et al., 2019), and asks for policies that lead to “better” innovation (Pfothenauer, 2023). Cellular agriculture could replicate sourcing patterns of animal agriculture, reinforce existing power asymmetries in the food system and does not contribute to a change in dietary habits (Gruber, 2022; Holmes et al., 2022; Howard, 2022). Previous predictions of biotechnology’s contribution to sustainability have shown to be questionable and the proposed solutions raise questions about technological control and their effects on vulnerable groups (Fischer and Rock, 2023). These considerations also matter from a business point of view. Consumer studies suggest, that sustainability benefits will be key for marketing cellular agriculture products (Lanz et al., 2024), but consumers are aware of potential negative aspects in this regard (Kühl et al., 2024).

Our analysis shows that the NFR does not actively guide the innovation system’s search process. This is consistent with the NFR’s primary focus on safety, consumer information and the Common Market. An inclusion of sustainability criteria in the safety approval for novel foods seems premature and would entail further hurdles for the *Entrepreneurial Experimentation* that is necessary to identify viable solutions. Food safety is only a necessary but not sufficient condition for sustainable innovation. The current paradigm of food safety can be described as “myopic” as it does not consider environmental or public health effects of products (Pollans and Leib, 2019). Further regulation must set incentives for sustainable and healthy solutions and address the questions of technological control and societal implications of cellular agriculture.

The NFR’s key role lies in legitimizing food innovation and providing transparency to avoid distrust and monopoly dynamics. This may require a more nuanced approach to data protection. Whilst exclusivity can be an important incentive in competitive environments (Grimsby, 2020), an open innovation approach that incentivizes cooperation and transparency may be more appropriate, given the fundamental societal implications and huge technological challenges of cellular agriculture (Dabic et al., 2022; de Amstalden, 2024; Holmes et al., 2022).

### 5.3. Normative considerations

Given the universally acknowledged urgency of food system transformation, the innovation-friendliness of the NFR may also be framed as a normative problem. Is the approach of the NFR consistent with fundamental constitutional principles of the EU?

Like any other intervention, the rules of the NFR must be measured against the fundamental freedoms and the principle of non-discrimination of EU primary law. The scope of the NFR has been criticized for being overinclusive and discretionary: the novel food definition is based on the arbitrary date of its first adoption in 1997 and was not revised when the NFR was reformed in 2015 (Holle, 2018). The lack of scientific rationale was even acknowledged at the political level (European Parliament, 2014). The risk factors that trigger the application of the legislation, namely novelty and unnaturalness (Monaco and Purnhagen, 2022), are not based on scientific evidence but rather mimic consumers' biases regarding novel foods (Monaco et al., 2024).

Interventions in fundamental freedoms must be justified and proportionate (Zarbà et al., 2020). In recent years, the existence of an "innovation principle" in EU primary law has become subject of the scientific legal debate: the European Commission has operationalized this principle through check-lists and design suggestions in its Better Regulation Toolbox, last updated in 2023 (European Commission, 2023b). Legal scholarship has raised questions about its compatibility with other fundamental principles of the European legal order, notably democracy (Ducuing, 2022), sustainable development (Reins and Ala-Lahti, 2024) and the precautionary principle (Garnett et al., 2018). Beyond this dogmatic debate, however, there is consensus that the precautionary principle can only justify restrictions in case of scientific uncertainty and to prevent health-related or environmental risks. Its application must not only consider the risks of a new technology, but also the risks of not allowing it. Precautionary and innovation principle thus apply simultaneously to guide risk-risk trade-offs in the urgent and dynamic context of the climate change (Callies 2021). The existing food system causes real, and not just hypothetical, damage to environmental integrity and public health that must be weighed against the risks and potentials of emerging technologies such as cellular agriculture.

The NFR may also be challenged from a WTO law perspective (Downes, 2013; Hermann, 2009; Zarbà et al., 2023; Zarbà et al., 2024). It can create barriers for products whose safety have already been established in other WTO member states. In fact, the facilitated procedure applicable to traditional foods from third countries in Art. 14 NFR is a result of a dispute under WTO between the EU and Peru (Pisanello and Caruso, 2018; Scaffardi, 2022; World Trade Organization, 2006). In particular, the validity of data protection may be questioned, as imports of counterfeit or generic products could not be blocked for safety reasons if the Commission has positively confirmed the safety of a product for the EU market. Notably, data protection is not a recognized as an Intellectual Property right under the WTO's TRIPS agreement.

It is of course speculative, if and how actors in the cellular agriculture sector would actually raise normative claims against the NFR before the ECJ or in the (currently dysfunctional) WTO dispute settlement mechanism. Still, a reform of the NFR would alleviate the likelihood of disputes: in particular, the fast-track recognition procedure for traditional products from third countries could be extended to other novel food categories.

## 6. Conclusion

Until recently, the NFR was of limited general political relevance. Most authorizations did not raise public attention. The situation has changed with the dynamic development of technologies such as cellular agriculture, and the increased political attention for food system sustainability. The NFR may thus become a focal point in the broader discussion on policies to accelerate the food system transformation.

Overall, the NFR provides a robust framework for the development of

the cellular agriculture innovation system. The *Legitimation* conveyed by the authorization seems essential for disruptive food innovations such as cell-based meat. Still, the rigidity and length of the authorization process negatively affects *Entrepreneurial Experimentation* and *Market Formation* in the innovation system. The "elephant in the room" is the political element of the authorization procedure. A political backlash affecting approvals of products of cellular agriculture could threaten the sector's current dynamic development.

To respond to innovation and sustainability challenges of cellular agriculture, the EU lawmaker could consider the implementation of experimental regulation. Experimental regulation is named as a key approach for innovation-friendly regulation in the EU's Better Regulation Toolbox (European Commission, 2023b). It can be considered as the regulatory counterpart of the "living labs" approach that has become a key element of contemporary research policy. Regulatory sandboxes have become a key feature of regulation in other dynamic fields, such as finance, energy (European Commission, 2023c, 2023d) and, most recently, artificial intelligence (OECD, 2023). Various member states, such as Germany, are in the process of creating dedicated legal frameworks for experimental regulation, and regulatory sandboxing is at the heart of the UK's new National Vision for Engineering Biology (Department for Science, Innovation & Technology, 2023). Even the Italian government, whose negative stance on cellular agriculture has been extensively referred to throughout this paper, has recently allowed field trials for plants obtained through new genomic techniques (Defez et al. 2024).

A key element of regulatory sandboxes is the collaborative set-up in which the regulator and stakeholders together seek to design rules that lower regulatory barriers for testing technologies, while ensuring consumer safety (Ranchordas, 2021). Regulatory sandboxes could integrate some of the "low-hanging fruit" for NFR improvement identified in our survey, namely:

- Possibilities for pre-submission consultation with EFSA
- A fast-track procedure for recognizing third-country approvals
- Possibilities for non-commercial tastings und clearly defined conditions

Tastings seem particularly important, as consumer studies suggest, that they can boost the acceptance of cellular agriculture (Chong et al., 2024; Min et al., 2024; Tsvakirai et al., 2024).

In our opinion, experimental regulation could also concern the risk assessment process itself. Food innovation requires innovation in food safety assessment (Fytsilis et al., 2024). A regulatory sandbox could for example draw inspiration from the Generally Recognized As Safe (GRAS) self-determination for food additives in the US. In this procedure, innovative companies themselves conduct the risk assessment and may subsequently submit it to a review by the federal authority (Frestedt, 2018). Such a cooperative approach would allow the activation of know-how from the private sector and align with the general public-private approach of European food law (Purnhagen and Molitorisová, 2022).

Practical application of the self-affirmed GRAS in the US is subject to criticism, due to and a high number of "secret GRAS" products on the market and a lack of effective oversight (Faustman et al., 2021). Such concerns could be addressed by combining self-determination with stringent notification and surveillance obligations. Member states and EU can build on an established, strong, IT-enhanced cooperation in food safety (Molitorisová et al., 2022).

At the same time, sandboxing might also allow a more proactive role of the EFSA, for example by creating databases of authorized growth media of cells for food uses, taking inspiration from the Qualified Presumption of Safety (QPS) status granted to certain biological agents by the EFSA Panel on Biological Hazards (EFSA, 2022). The creation of such lists has been proposed in other jurisdictions by industry groups and stakeholders (Cellular Agriculture Australia, 2024)

Finally, regulatory sandboxes may also help to address the concerns regarding sustainability, control and societal implications of cellular agriculture, for example by setting adequate rules for data protection and transparency. It is clear, that experimental regulation in the area of public health can be critical and may also jeopardize public trust (Sherkow, 2022). However, considerable know-how on the design of sandboxes has been built up in recent years (Beckstedde et al., 2023). Well-designed sandboxes can open the impact of a technology for discussion and democratic control that can increase the legitimacy and effectiveness of regulation (Ranchordas, 2021). This would allow the EU to follow-up on its regulatory approach to other disruptive technologies such as AI, namely to set clear incentives for domestic innovation without giving up on a “rights-driven model” of technology regulation (Bradford, 2024). As in other areas of EU law, the concrete design of the sandboxes could also be left to member states, depending on their appetite for food innovation. The “competition between legal orders” to find the most adequate solutions, has been a key pillar for EU law since the beginning (Reich, 1992). It may be of renewed relevance in current times, where sustainability considerations increasingly challenge the paradigm of common market.

Of course, a more experimental and adaptive NFR alone is not sufficient to promote sustainable innovation and must be complemented by regulatory efforts to ensure benefits for the environment and public health, prevent monopolies and address societal implications. Concrete sandboxes, however, could initialize a more informed discussion on these issue by allowing real-life experience.

In the long run, a constitutional approach to food systems regulation may be warranted. This implies more clarity about the general values and governance mechanisms of the food systems transformation beyond individual technological solutions. The Sustainable Food Systems Framework promised in Annex 1 of the Farm-to-Fork Strategy (European Commission, 2021) might eventually provide such a clarification, but no proposal has been released so far.

Further research should concern a comparative analysis of regulatory developments in other countries, including emerging players like India and Korea, which have recently announced plans to regulate cellular agriculture. More research is also needed on relevant developments beyond food safety, for example questions related to intellectual property rights, and on the experiences derived from the implementation of regulatory sandboxes in the biotechnology sector.

#### Ethical statement – studies in humans and animals

The research did not involve any studies conducted on humans and/or animals. Therefore, no ethical approval was deemed necessary for this research.

#### CRedit authorship contribution statement

**Tilman Reinhardt:** Writing – review & editing, Writing – original draft, Project administration, Methodology, Formal analysis, Conceptualization. **Alessandro Monaco:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization.

#### Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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#### Data availability

Data will be made available on request.

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