Relationship between regulations and firm investment decisions: the case of novel foods in the European Union

Alessandro Varacca[2], Beatrice Cortesi[1,2], Maximilian Kardung[1], Claudio Soregaroli[2], Justus Wesseler[1]

[1] Agricultural Economics & Rural Policy Group, Wageningen University, Wageningen, The Netherlands
[2] Department of Agricultural and Food Economics, Università Cattolica del Sacro Cuore, Piacenza-Cremona, Italy

Abstract

In this study, we investigated the relationships between ex ante regulations and innovations via firm investment decisions. We first present a conceptual framework based on the option value theory. We then exploited this model to provide an interpretative framework for the results of an empirical analysis in which we assessed the authorization procedures of the EU novel food regulation. Our findings were based on a novel detailed dataset of 289 applications submitted under both the former (Regulation 258/97) and current EU novel food regulation (Regulation 2283/2015), in which we gathered information on the number of applications, duration of the authorization procedure, and determinants of approval of novel food applications. We found relatively stable applications across the years, with an upsurge following the enforcement of the current novel food regulation, which is explained by a reduction in option value. We also found a decreasing trend in the ceiling value for the expected duration of the relevant procedures. However, this upper limit appears irrelevant in determining investment decisions. Finally, our results suggest that compared with public entities, private entities and applying for regulatory approval of NF ingredients instead of a product have higher success.

Keywords: Novel Food Regulation, EU Food Policy, EU Food Legislation, Real Option Models, Food Innovation.

1. Introduction

Food security, food safety, and environmental sustainability stand out as objectives for food system governance (Directorate-General for Research and Innovation of the European Commission et al., 2022), which should aim to efficiently regulate access to new products in the market (Smith, Wesseler &Zilberman, 2021). Within the food system, markets are shifting toward new healthy, functional, and ethnic foods, which have the potential to align environmental benefits with the intake of essential micronutrients (Belluco et al., 2017; Hermann, 2009; Marberg, van Kranenburg, Korzilius, 2017, Parodi et al., 2018).

Market changes and the development of new food processing technologies are associated with innovation in the food sector, with large potential impacts (Willet, Rockström, Loken & Springmann, 2019; Zilberman et al., 2022). New food technologies allow companies to produce food from unconventional sources such as vitamin K from menaquinone or Antarctic krill oil rich in phospholipids from *Euphausia superba* (Vapnek & Purnhagen, 2020). As shifting diets towards less animal-source foods are increasingly acknowledged as an important solution to feed the world's growing population, fostering innovation in the food industry becomes a key stage in the search for a planet-friendly diet. Recent literature shows that novel foods such as insects, seaweed and cultured meat could lead to great environmental benefits while guaranteeing the intake of essential micronutrients (Parodi et al., 2018). For example, if European consumers replace animal-source foods with these novel foods (NFs) in their diets, the environmental impacts might be reduced by more than 80% while meeting nutrition and feasible consumption constraints (Mazac et al., 2022).

Innovation is an essential instrument for food companies to face competition in the world market (Zilberman et al., 2022). However, the importance placed on consumer protection and food safety is higher in Europe than in the rest of the world. The advent of new technologies creates concerns about adverse effects on human, environmental, animal, and/or plant health, which trigger

the need for standardized regulations (Vapnek and Purnhagen, 2020). In addition, the series of incidents of foodborne diseases in the late 1990s drew even more attention to the need to establish general food principles and requirements at the policy level (Wesseler and Kalaitzandonakes, 2019; Hyde et al., 2017).

In 1997, the EU introduced a NF regulation (NFR), Regulation (EC) 258/97, to keep up with the rapid evolution of the food sector. This represented an attempt to define, control, and uniformly regulate the entry of NF products into the EU market. However, as this first legislative attempt had resulted in several complaints about compliance costs; the lack of binding timelines, which resulted in delays; and the discrimination against non-EU food products and producers (Grimsy, 2020; Holle, 2018; Hyde et al., 2017), the EU decided to reform the NFR to address these criticisms. The 1997 NFR was thus repealed and replaced by Regulation (EU) 2015/2283, which was enforced on January 1, 2018. The EU considers any new food products as NFs that had not been consumed to a significant degree by humans in the EU before May 15, 1997, when the first regulation on NF was first enforced (European Parliament and Council, 2015).

Although many studies have analyzed the advantages and shortcomings of the EU NFR, only a few empirical investigations have delved into the development of the EU NFR. Hyde et al. (2017) found that the average length for authorizing a NF under Regulation (EC) 258/97 was 1,194 days, ranging from 267 to 3,523 days. Grimsby (2020) used data from applications and notifications as a background for semistructured interviews with successful applicants and experts. Through their research, they found that the decentralized nature of the old NFR reduced the possibilities for data protection and thwarted innovation. They also found no systematic differences in the size of companies that applied to the two regulations. Finally, an average authorization process length of 3.8 years was calculated.

Notwithstanding some interesting insights into the performance of the EU NFR, such as highlighting the length of the authorization process as a key indicator of regulatory efficiency, the abovementioned studies (Hyde et al. (2017); Grimsby (2020)) do not propose a sound interpretative

framework or a solid dataset to attempt to generalize such insights beyond the food sector. Thus, we are interested in assessing how evolving regulations relate to the level of innovation within a sector. In this work, we aimed to characterize this relationship in the context of the evolving NFR. Specifically, we draw from the literature on the economics of safety (Shavell, 1984a; 1984b) and present a theoretical framework that establishes the role of ex ante regulations and ex post liabilities in influencing the opportunity costs of a NF introduction. Therefore, we measured innovation as the degree to which firms invest in new products (Kardung et al., 2021). Our conceptual model postulates that ex ante regulations may foster investment opportunities (i.e., more applications for NF products) by lowering the expected irreversible approval costs, decreasing the expected length of the approval process, and curbing uncertainty. We also posit that, because companies rely on expected performance indicators to inform their beliefs and behaviors, it is important to qualify, quantify, and understand such indicators within the abovementioned theoretical framework.

We empirically analyzed the development of authorization procedures under Regulation (EC) 258/97 and Regulation (EU) 2015/2283, considering the changes between the two regulatory regimes. The relationships of these regulations with firm investment decisions were investigated by addressing three main research questions (RQs), which we excerpted from our theoretical setup: (RQ1) How is the yearly number of NF applications evolving over time? (RQ2) How is the duration of the NF authorization procedure developing over time? (RQ3) Which applicant characteristics increase the probability of success for a NF application? While RQ1 addressed the total number of applications, which is directly linked to firm investment decisions and the level of innovation, RQ2 and RQ3 investigated factors influencing such decisions and incorporated them into the conceptual model. We investigated the RQs while considering possible trends and whether the more centralized approach of the current NFR had led to a change in any of the abovementioned indicators.

The paper is structured as follows: Section 2 provides a detailed description of our theoretical framework, Section 3 illustrates how NF have been regulated in the EU, while Section 4 describes our dataset and presents the empirical analysis addressing the NFRs in the EU. Finally, Section 5

presents the main results of our statistical analysis, while Section 6 discusses the implications of such results within the boundaries of our conceptual model. Finally, we present our conclusions in Section 7.

2. Theoretical Framework: Ex ante Regulation and Firm Investment Decisions

We start from the theoretical framework introduced by Shavell (1984a, 1984b) and others on the economics of safety, where the major problem for regulators is to set the optimal levels of ex ante regulations and ex post liabilities (Kolstad et al., 1990). Considering that both dimensions will determine firms' decisions to invest in novel products or services, the balance between companies' initial commitments (i.e., compliance with ex ante regulations) and future uncertainties (i.e., compliance with ex post liabilities) must be carefully addressed and understood from a theoretical perspective.

Ideally, ex ante regulations are unnecessary in the presence of flawless court procedures and rulings under a clear and well-designed framework for ex post liabilities (Shleifer, 2010). In this case, private companies would be incentivized to invest in product safety under the penalty of full accountability and consequent economic losses. However, liability via courts does not work perfectly (Shleifer, 2010). As Kolstad et al. (1990), Shleifer (2010), and many others have indicated, there exist several layers of uncertainty that would make an ex ante regulation necessary to balance out the pitfalls of the court system (Shleifer, 2010). Moreover, ex post liabilities are not independent from the enforced ex ante regulation. For example, with reference to the food industry, once a NF is approved by the competent authority and placed on the market, ex post liabilities do not necessarily concern safety alone but are often related to non-compliance with legal requirements. Examples include cases in which traces of the novel product are detected in marketed food when the former is only approved for feed use or research purposes, or not approved for import. This noncompliance may result in market recalls, compensation payments, and loss of reputation.

To stylize the firm investment decision problem, we postulate that a food company developing a novel product must submit it for approval in compliance with a relevant ex ante food regulation[1]. According to the seminal work of Dixit and Pindyck (1994) on real option models, the firm's decision to invest in a new product does not simply result from a positive difference between the present value of future revenues and costs. In fact, there can be a firm-specific incentive for delaying and postponing the investment. This opportunity cost is known as option value and only exists under three specific conditions: (i) the firm can flexibly time the investment decision; (ii) the firm faces irreversible investment costs (i.e., costs that cannot be recovered); and (iii) future investment profits must entail some degree of uncertainty. Under these conditions, we can define the real option value of investing, $F(V)$, as:

$$F(V) = max\, E\,[(V_T(B) - I_T)e^{-\rho T}] \qquad (1)$$

Equation (1) illustrates that investing at a future point in time, T, maximizes the expected (E) net future value discounted by an interest rate, ρ. The net future value is defined as the difference between the value of reversible net benefits at time T, $V_T(B)$, and the irreversible net costs at time T, (I_T). Therefore, investing at time $T = 0$ (present time) requires that the net present value ($V_0(B) - I_0$)) is greater than or equal not only to zero but also to the value of withholding the investment until a later point in time. Indeed, if the real option value is greater than the net present value of immediate investment, then delaying and postponing the investment until more information is available represent a better strategy. From a different perspective, for some critical value V^*such that $V^* - F(V^*) = I_0$, if $V_0 \geq V^*$, the firm's profit-maximizing decision is to invest immediately because the value of the investment V_0 net of its opportunity cost, $F(V^*)$, is larger than the net-irreversible costs. The model suggests that the critical value V^* must be, to some extent, larger than the investment costs by a factor

[1] We consider this type of company without loss of generality for the conceptual framework discussed in this section.

of $h > 1$ (i.e.: $V^*/I_0 = h > 1$), which is known in the literature as the hurdle rate. As the future benefits and costs of food production, ex post liabilities, and approval costs and length are uncertain, V^* (and consequently h) is unknown to the firm, although expectations can be built. Therefore, V^* can be understood as a latent quantity that must be characterized to produce optimal investment decisions. We can formalize the latter as follows:

$$V_0 \geq V^* = hI_0, \quad with\ h > 1. \qquad (2)$$

Regulations can influence the investment strategy depicted in equation (2) in several ways. For example, ex ante regulations can impact the value of net-reversible benefits and the magnitude of net-irreversible costs. As discussed by Soregaroli and Wesseler (2005) in the context of the coexistence of conventional and genetically modified crops, an ex ante regulation can indirectly impact the underlying stochastic processes of investment values, thereby influencing the magnitude of the hurdle rate. Wesseler et al. (2022) described the incentives to invest by combining the cost of complying with ex ante regulations and the risk of ex post liability using a continuous-time, discrete-state, real-option model. Although the authors used this model to assess the incentives for investing in products derived from genetically modified microorganisms in the EU market, we posit that the underlying conceptual framework can also be applied to investments in NFs. In that case, the investment strategy represented in equation (2) can be rewritten as follows:

$$V_0[E(B, \theta_{k3})E(P_{appr})] \geq V^* = h(\sigma_{reg})I[R_{k1}, E(A_{k2})], \quad with\ h(.) > 1, \qquad (3)$$

where the value of the reversible net benefit depends on the expected net benefit and the likelihood of facing ex post liabilities (θ_{k3}) in a given point in time (*k3)*, weighted by the expected probability of final approval of the NF (P_{appr}). Next, irreversible costs are defined as a function of research costs (R_{k1}), which represent the amount of money and time spent researching and developing a NF or food

ingredient[2], and expected approval costs (A_{k2}), which indicate how much money and time the firm must invest to undergo the approval process under the relevant regulation[3]. These costs also depend on the length of the research phase for the novel product (*k1*) and the expected length of the approval phase (*k2*), respectively. Wesseler et al. (2022) showed that changes in *k1* or *k2* have a high average marginal impact on the decision to invest. Hence, while preserving the necessary safety level, reducing the time length for approval, if possible, should decrease irreversible net costs and increase the incentive to invest. A similar argument is sustained by Renckens and Auld (2022) that the efficiency of third-party certifiers (when applicable) is also recognized as a likely contributor to A via *k2*.

Finally, regulations must be translated into norms and procedures, rules and rights must be implemented and enforced, and compliance must be monitored. Such activities belong to meso-level institutions (Ménard, 2014, 2018) or, using different terminology, to regulatory intermediaries (Abbott et al., 2017). These can be either public or private bodies that, by possessing capabilities that regulators may lack, can improve the effectiveness and efficiency of a regulatory framework (Abbott et al., 2017). In this respect, an excessive number of intermediaries can create a fragmented authorization process with administrative and approval bottlenecks that could reduce efficiency (i.e., higher A and *k2* [Hyde et al., 2017]) and increase uncertainty (i.e., larger σ_{reg}), which negatively impact firms' investments[4].

[2] In some cases, these costs might be close to zero because some products or ingredients might have already been used in markets outside the EU.

[3] The direct costs refer to the costs for preparing the dossiers and conducting tests to determine the product's or ingredient's safety.

[4] The state must not necessarily be involved in setting regulatory standards. The private sector has incentives to develop rules (standards) that companies must comply with as part of a certification scheme. These schemes can improve firms' participation in supply chains having a food standard, as they can reduce transactions costs among agents (Soregaroli et al., 2022). Moreover, standards can be efficiently managed in private forms using third-party certifiers, as documented by Lytton (2014) for fire safety, Zorn et al. (2014) for organic, and Castellari et al. (2018) for “GMO-free” products.

To sum up, model (3) highlights that an ex ante regulation can influence the way firms assess investment opportunities in several ways, impacting: a) the expected probability of non-compliance and therefore ex post liability; b) the expected probability of approval of products resulting from those investments; c) the expected irreversible approval costs; d) the expected time length of approval; and e) the overall uncertainty concerning the variables in the previous points. In particular, the lower the expected ex post liability, the lower the irreversible approval costs; and the lower the expected length of the approval process, the higher the incentives to invest in NF products, which leads to a higher number of applications. Similarly, lower uncertainty should make investors more confident about market- and regulation-related risks, which results in more applications. Conversely, the expected probability of approval trivially increases the net present benefits, thus providing an incentive to invest. Finally, we stress the importance of expectations. Companies can form their own expectations based on actual performance indicators or, for a new regulation, on expected future performances. Therefore, it is essential to define (and quantify) such indicators and understand their implications within the theoretical framework developed so far. We discuss these indicators and their interpretation in Section 3.2.

3. Regulating NFs in the EU

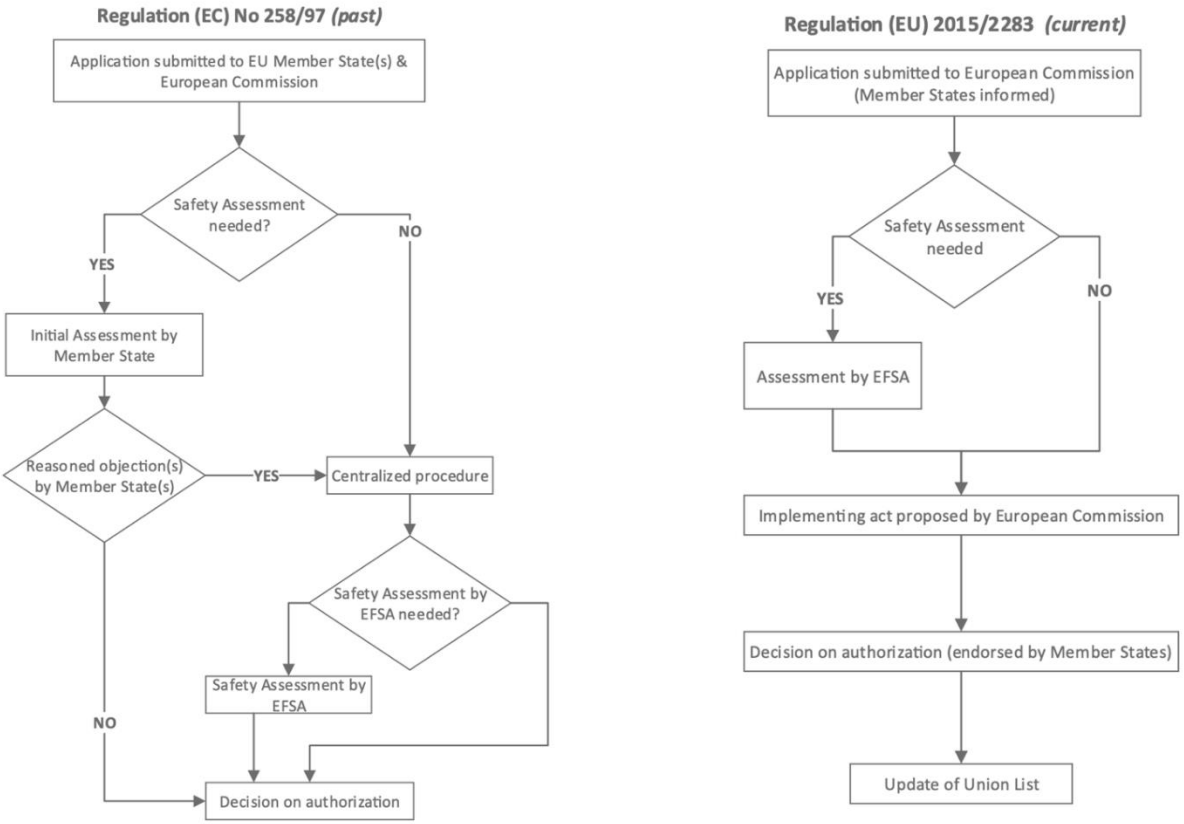
Regulation enables the homogenization of the safety and quality requirements requested by the EU, protecting consumers from the risk of consuming certain foods (de Magistris et al., 2014; Hyde et al., 2017). This is achieved by setting standardized risk assessment procedures defining an accepted range of authorization requirement, which may also decrease consumer neophobia toward NF products and increase acceptance (Frewer et al., 2011).

The EC aims to have transparent and clear policies, starting with a formal definition of NF. According to Regulation (EU) 2015/2283 (L 327, p. 2–7), the term “novel food” refers to (I) “any food that was not used for human consumption to a significant degree within the Union before May

15 1997" and (II) falls under one of the categories expressed in Article 3 of the NFR (EU, 2015; Pisanello & Caruso, 2018), namely food from microorganisms, fungi, and algae; NFs derived from plants; NFs from animals, including insects; and food from novel production processes, including nanofoods. Examples of novel products are foods derived from new production processes such as ultraviolet or high-pressure treatment, foods isolated from animals or their parts (e.g., insects, oil from Antarctic krill, and peptides from fish [EFSA, 2012]) or from microorganisms, fungi, or algae (e.g., algae oil from *Ulkenia* sp. [EFSA, 2014]). Agricultural products traditionally consumed outside the EU are also considered NFs, such as noni fruit juice and chia seeds.

NFs and NF ingredients must undergo an EU-level assessment before they are released to the EU market (Figure 1). Under both regulations, the authorization procedure is performed in two steps: risk assessment (RA) and risk management (RM). The NF is evaluated during RA on the basis of its compliance with European safety criteria (EFSA, 2000). In RM, the EC decides whether to authorize a product for the EU market (Pisanello et al., 2018).

Figure 1: Main steps of the authorization process of novel food under the past and current EU NFRs



Source: Ververis et al. (2020)

3.1 Comparison of former and current EU NFR

The steps, actors involved, and timings of the authorization procedure changed from the former to the current NFR (Tables 1 and 2). Under the former NFR, three major authorities played a role in the process at the EU level: the member states (MSs), the Scientific Committee for Foodstuff or EFSA, and the EC. The EFSA and EC lead the process in the current NFR, while MSs only endorse the authorization decision. In the former NFR, the application dossier was initially assessed by the competent authority at the MS level, and the EFSA carried out an additional assessment. In most cases, the application had to be assessed twice (EPRS, 2015). In the current NFR, safety evaluation and RA are performed entirely by the EFSA. In both NFRs, the RM phase is carried out by the EC.

The new NFR also improved the synchronization of legal and technical procedures across all MSs, guaranteeing homogeneity in the process (Ververis et al., 2020).

The new NFR introduced a streamlined notification procedure for traditional foods from third countries to further simplify authorization. The simplified procedure applies to foods with a "history of safe food use in a third country" for at least 25 years (EU, 2015).

The two regulations also differ in creating the "Union list" of NFs and their definitions. Under the previous NFR, the definition of NF and its specifications were general, resulting in different interpretations across MSs (Coppens, 2013). The current NFR updates its definition of NF, which tries to better *"keep up with scientific advances"* as titled in the document released by the European Parliamentary Research Service (2015) and providing more clarity on the interpretation of the definitions and concepts within Regulation 258/97 (Coppens, 2013). In addition, the former NFR addressed foods and food ingredients containing genetically modified organisms (GMOs). In 2003, a separate regulation was adopted exclusively to regulate GMOs, removing them from the definition in the current NFR. A further change is creating a Union list, including all authorized NFs under Regulation (EC) 258/97, which increases transparency.

In summary, the authorization procedure of the current Regulation (EU) 2015/2283 has fewer steps than the past NFR, fewer actors involved, and a more centralized approach.

Table 1: Authorization process time - Reg. (EC) 258/97

Step	Actor	Process time limit
Risk assessment		
Verification of the validity of the dossier	MS	1 month
Initial assessment	MS	3 months
Other MS and EC comment on IA	MS/ EC	2 months (extendible to 4 months when objections are raised)
EFSA safety assessment (if needed)	SCFF/EFSA	No time limit
Risk management		
Implementation of the draft	EC	No time limit
Final decision deliberation	EC	3 months

Table 2: Authorization process time - Reg. (EU) 2015/2283

Step	Actor	Process time limit for novel food or food ingredients	Process time limit for traditional food from third countries
Risk assessment			
Verification of the validity of the dossier	EC	1 month	1 month
Dossier transmitted to EFSA and MS	EC	1 month	
EFSA safety assessment (if needed)	EFSA	9 months (+ possible clock stops)	4 months
Risk management			
Implementation of the draft and final decision deliberation	EC	7 months	6 months

3.2 Assessing investment decisions under the EU NFR

Following the theoretical framework encoded in model (3), firms' investment decisions in marketing NFs in the EU under the evolving NFR can be assessed. The number of NF applications received by the EU is the first and most straightforward indicator of such decisions. Through RQ1, we explored the evolution of such applications, focusing on whether Regulation 2015/2283 has, since 2018, created an incentive for new applications because of the leaner authorization process. We expect the easier application process to reduce (or create expectations for a reduction of) both A and *k2* while reducing the uncertainty of the procedures, thus resulting in more applications. For this reason, measuring the evolution of *k2* over time and comparing it with the trend in submissions represent another key RQ for understanding the dynamics of NF applications. Indeed, observing a negative (positive) tendency for *k2* would imply lower (higher) irreversible net costs that, under time-invariant A (i.e., no changes in the NFR), would then translate into more (less) applications over time. We investigated this interdependence in RQ2. The NFR may also play an important role in determining the size of the hurdle rate. The more a regulation opens to uncertainties in its procedures or the longer the expected length of the approval process, the larger the variance parameter σ_{reg} and thus the higher the hurdle rate. Therefore, if Regulation 2015/2283 was successful (or was expected to be successful)

in making the application process more efficient, we would predict lower uncertainty and, consequently, more applications (RQ1).

We finally addressed the probability of approval of a NF, P_{appr}. Our interest in this parameter is twofold: On the one hand, we aimed to understand which firm characteristics predict a higher chance of successful application. This insight would provide the regulator with valuable information to revise the authorization process so that certain cohorts of food companies may improve their approval rate. At the same time, firms themselves may benefit from these results by anticipating the likely decision and better characterizing their option value. On the other hand, we also aimed to disclose whether the implementation of Regulation 2015/2283 has contributed to boosting the authorization rate, in accordance with firms' characteristics. In that case, higher P_{appr} values would require a comparatively lower V_0 to match or exceed V^*, thus incentivizing investments. We answer these questions in RQ3.

4. Materials and Methods

4.1 Data

We collected our data from the EC's official decision documents on each NF and the Union list of all authorized NFs. In addition, for each NF, we collected information from the EFSA Register of Questions and the Scientific Journal of EFSA on the exact dates of its authorization procedure steps, such as the dates of application submission and the final decision. We identified the decision status of each application, which can be authorized, refused, withdrawn, under evaluation, or under consideration. Our dataset included 289 applications, of which 165 were submitted under Regulation

(EC) 258/97; and 124, under Regulation (EU) 2015/2283[5] (see Table 3). We recorded all applications submitted between November 1997 and December 2020 and monitored the approval status until September 2021. The EC has currently authorized 168 and refused 13 of the 289 applications. Thirty-four have been withdrawn, and the approval of another 63 is still ongoing[6].

[Table 3 about here]

Table 3 shows the five most important countries in terms of the total number of applications under both NFRs. Our data show that under Reg. 258/97, most EU applications were submitted from

[5] Besides the submissions for authorization, we found more than 400 applications for notification under the former NFR and more than 50 applications under the current regulation. A NF must be a substantial equivalent of a product already authorized under the NFR for a notification application. In this case, the authorization procedure is shorter and does not entail all the steps that would be required if a NF product entered the market for the first time. We did not include these submissions in our analysis to ensure comparability.

[6] The first observation in our dataset is "Stevia rebaudiana Bertoni" from November 5, 1997, and the last application is for "6-siallylactose sodium salt" from September 22, 2020. The first NF ever to be approved, "phospholipids from egg yolk," was authorized in the year 2000 in the EU.

Table 3: Novel food applications for the top five applicant countries under Reg. 258/97 and Reg. 2015/2283 by decision status

Country	EU/ Non-EU	Number of Applications		Authorized Applications		Open Applications		Withdrawn Applications		Refused Applications	
		Reg. 258/97	*Reg. 2015/2283*	*Reg. 258/97*	*Reg. 2015/2283*	*Reg. 258/97*	*Reg. 2015/2283*	*Reg. 258/97*	*Reg. 2015/2283*	*Reg. 258/97*	*Reg. 2015/2283*
United Kingdom	EU	23	3	17	1	0	2	5	0	1	0
Belgium	EU	18	7	14	2	0	4	2	0	2	0
France	EU	16	10	9	3	0	6	6	0	1	0
Germany	EU	15	12	13	0	0	10	2	0	0	2
Denmark	EU	5	10	4	5	0	3	1	1	0	0
Others	EU	36	42	26	15	0	20	9	2	1	0
Total	EU	113	84	83	26	0	45	25	3	5	2
USA	Non-EU	15	17	12	10	0	4	2	0	1	2
Switzerland	Non-EU	15	5	12	1	0	4	3	0	0	0
Japan	Non-EU	7	3	7	1	0	2	0	0	0	0
Canada	Non-EU	6	0	3	0	0	0	1	0	2	0
Israel	Non-EU	4	1	4	1	0	0	0	0	0	0
Others	Non-EU	5	14	4	4	0	8	0	0	1	0
Total	Non-EU	52	40	42	17	0	18	6	0	4	2

entities in the United Kingdom, followed by Belgium, France, and Germany. The non-EU countries with the highest numbers of applications are the United States, followed by Switzerland, Japan, and Canada. Globally, EU actors accounted for roughly 70% of the submitted dossiers under the former NFR and approximately 67% under Reg. 2283/2015. Since the introduction of the novel NFR, most submissions within the EU came from Germany, followed by Denmark, the Netherlands, France, and Belgium. As for non-EU countries, the United States, Switzerland, and Japan remain home to most applicants. These figures are consistent with the report of Charlebois (2020), who found the United Kingdom, the United States, and Germany to be leaders in terms of the global food innovation index.

To provide an overview of the development of NF authorizations, Table 3 also breaks down the total number of applications under the different regulations by decision status. The number of authorized NFs under the new NFR is obviously lower because the most recent regulation has been in place for only 3 years. Therefore, because several applications are still under evaluation by the EC (under Regulation 2283/2015), we do not have information on the approval statuses of these NFs. At the time of analysis, 84 of 124 NFs were awaiting a decision. Consequently, the empirical strategy presented in the following sections was purposedly designed to answer RQ1 through RQ3 while dealing with this lack of information. On the other hand, all the applications under Regulation 258/1997 have been fully processed and have received either authorization or rejection/withdrawal. Under Regulation 2283/2015, only seven applications have been refused or withdrawn so far, while under the former NFR, such a figure accounted for roughly 24% of all applications.

For each submission, we next measured the length of the authorization process as the number of days from the application submission date to the final decision (either authorization, withdrawal, or refusal) by the EC. We constructed the length of each authorization process by taking the arithmetic sum of the days from submission to decision.

Finally, we gathered information on each applicant at the year of submission from the information provided on the EC's decision documents. Specifically, we collected information on whether the applicant is an EU resident, the type of NF application (NF as a whole food product or ingredient or both), whether the applicant is a private or public entity (i.e., universities, research institutes, or non-profit organizations), whether they have filed more than one submission throughout the entire 1997–2021 period, and whether the relevant scientific authority is in the same country as the applicant. Table 4 presents an overview of these additional variables.

Table 4: Applicant's characteristics available from the collected data

Variable	Levels	Proportion
Type of novel product	Novel food	20%
	Novel food ingredient	80%
	Novel food and novel food ingredient	16%
	GMO	3%
	Traditional food from a third country	5%
Type of company	Private	98%
	Public	2%
EU/Non-EU Country	EU	68%
	Non-EU	32%
Spatial relation to the competent authority	The same country as the competent authority	33%
	A different country as the competent authority	67%
Number of novel food applications submitted	Single	47%
	Multiple	43%

4.2 Empirical strategy

4.2.1 RQ1: Number of applications and introduction of Regulation (EU) 2015/2283

The first stage of our empirical work addresses RQ1, in which we assessed the yearly number of applications for NF products and investigated how the introduction of Regulation (EU) 2015/2283 affected them. We designed a Bayesian hierarchical model (Gelman et al., 2013; McErleath, 2020 and references therein) to decompose the time series of NF submissions into three additive

components. We postulate that the yearly count of NF applications results from a fixed offset component, α, plus a time-dependent coefficient that linearly depends on (i) the observations in previous years, θ_t, and (ii) a dynamic shock following the introduction of the new NFR, β_t. Mathematically, the model can be expressed as follows:

$$
\begin{aligned}
n_t &\sim \text{poisson}(\lambda_t) \\
\log(\lambda_t) &= \alpha + \theta_t + \beta_t \times \mathbb{I}[t \geq 2018] \\
\alpha &\sim \text{normal}(\mu_\alpha, \sigma_\alpha) \\
\theta_t &\sim \text{normal}(\mu_\theta + \rho_\theta \theta_{t-1}, \sigma_\theta);\ \rho_\theta \in (-1,1) \\
\beta_t &\sim \text{normal}\big(\mu_\beta + \rho_\beta \beta_{t-1}, \sigma_\beta\big);\ \rho_\beta \in (-1,1),
\end{aligned}
\tag{4}
$$

where λ_t expresses the yearly rate of NF applications (McCullagh & Nelder, 2019), $\mathbb{I}[\cdot]$ represents an indicator function taking on a value of 1 when its argument is true, μ_α and σ_α express prior hyperparameters for the offset, and μ_θ and μ_β indicate initial mean deviations from the offset. The remaining terms, ρ_θ and ρ_β, are the autoregressive coefficients, whereas σ_θ and σ_β represent variance hyperparameters for the corresponding dynamic prior distributions. We provide further details on the model structure and functioning, estimation procedures, inferential calibration, and prior definition for all the latent quantities in the Methodological Appendix. In short, β_t represents our parameter set of interest, indicating the additional rate of applications resulting from Regulation (EU) 2015/2283. The fact that β_t depends on its previous values has two uses, one technical and the other conceptual. On the technical side, the autoregressive component of β_t helps identify the effect of Regulation (EU) 2015/2283 from the trend component, θ_t. From a conceptual perspective, modeling both θ_t and β_t autoregressively provides a generalization to a simpler model in which the dynamic effects would be independent across periods. This dependence might reflect future expectations about the business of the authorization pipeline: as more products are being submitted

for evaluation, capacity constraints might compromise the ability of the competent authority to process applications within a reasonable amount of time, thereby discouraging new candidates from submitting new NFs. However, because we give both ρ_θ and ρ_β zero-centered weakly informative prior distributions (see Methodological Appendix), whether the autoregressive structure holds will depend on the data.

4.2.2 RQ2: Proportion of decisions within T *years*

We next investigated RQ2 by analyzing how the proportion of applications that received a decision (either approval or rejection) within 1, 2, 3, or 4 years has changed since the introduction of Regulation 258/97 in January 1997. Specifically, we fitted a linear, quadratic, and flexible (i.e., LOESS regression) model and plotted the resulting trend lines to discuss specifications and their implications. We calculated each proportion as the sum of applications approved within $k \times 365$ days in year t divided by the total number of applications within the same year t. Our time series starts at $t = 1997$ and terminates at $T = 2021$, while, as anticipated above, $k \in \{1,2,3,4\}$ years. When at any time $t = 2016$ (i.e., $2021 - max(k) + 1$) or beyond, we observed applications with no decision by 2021 and imputed the missing application length using $366 \times (T - t)$. This means that whenever the evaluation was still ongoing, we defined the length of the process as exceeding the considered time window. For each value of k, the most recent year we consider depends on k itself. For example, take $k = 4$. As we are looking for NFs that took no more than 4 years to evaluate, we could not include years beyond 2016, as the data for approval covering a whole year ended with the calendar year 2020.

4.2.3 RQ3: Probability of approval and its determinants

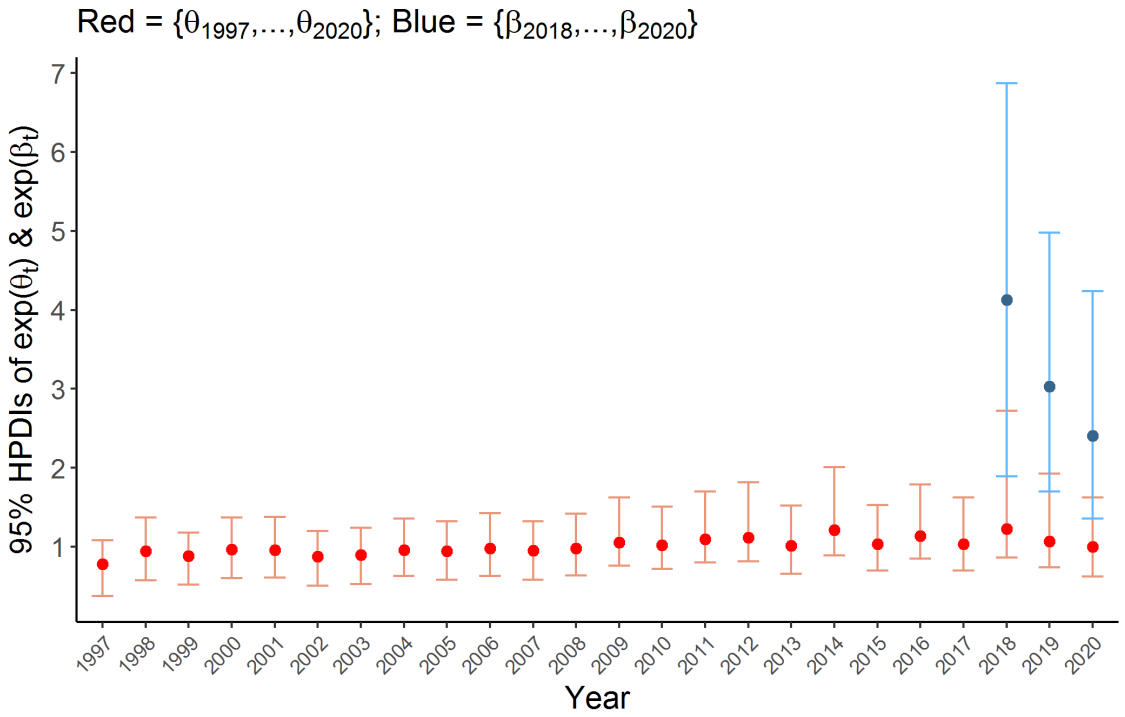
We finally addressed RQ3 by assessing the association between the different characteristics of the applicants and the probability that a NF would be authorized. These variables are presented in Table

4. Coherently with the discussion in Section 3, our analysis involved estimating a Bayesian logit model, where we regressed authorization decisions on a dummy identifying which submissions occurred under Regulation (EU) 2015/2283, plus all the covariates in Table 4. As with the count model introduced in Section 4.2.1, we set up a prior distribution for each parameter in the conditional mean function via calibration (see the Methodological Appendix).

5. Results

Figure 2 shows the estimates for all the time-dependent parameters in model (4), which suggest that the yearly number of applications remained relatively steady between 1997 and 2009, and then exhibited a slightly higher variability from 2010 to 2020. However, the spike in applications after the introduction of Regulation (EU) 2015/2283 in 2018 stood out, captured by the dynamic parameter β_t. However, since β_t appears to enter a decreasing phase in the following 2 years, our estimates suggested that this upsurge was only temporary. We will carefully discuss the implications of these findings for RQ1 in the next section.

Figure 2: Highest posterior density intervals (HPDI) based on a Bayesian hierarchical model for the time-dependent coefficient of applications (in red) and additional rate of applications from the introduction of Regulation 283/2015 (in blue)

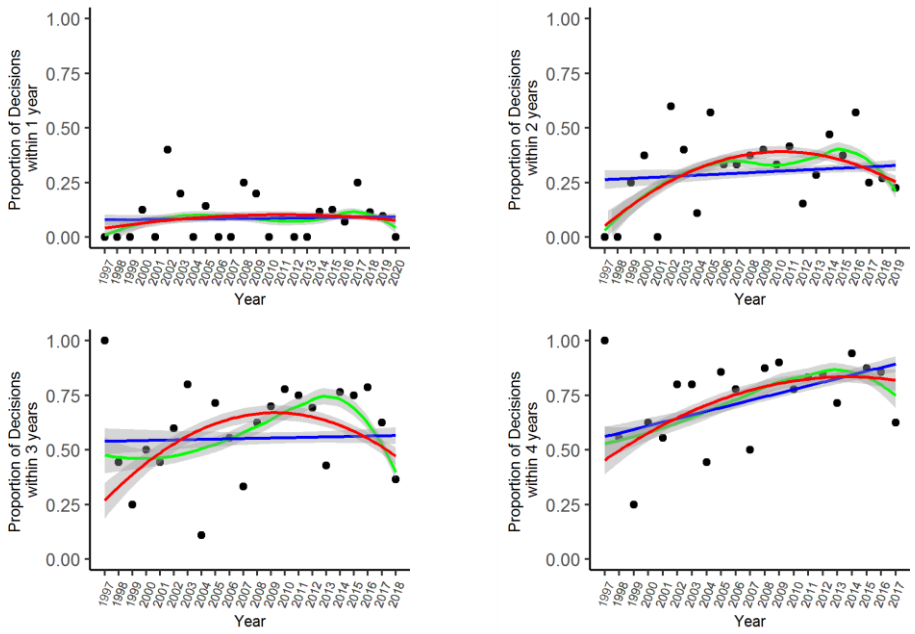


Note: 95% HPDIs represent the interval of the posterior distribution where 95% of the probability lies. The dots indicate the median of the posterior (the maximum a posteiori [MAP] values), which represent our point estimates.

Next, Figure 3 visually represents the three flexible regression models presented in Section 4.2.2 for the four cutoff periods (1, 2, 3, and 4 years). These simple models were aimed at eliciting the underlying trend using various degrees of adaptiveness to the data: linear (blue line), quadratic (red line), and LOESS smoothed (green line). The first plot indicates that the EC did not change the proportion of NF applications they decided upon within 1 year from 1997 to 2020 (Figure 3, top left). The second (Figure 3, top right) and third plots (Figure 3, bottom left) indicate only a subtle increase in the proportions decided upon within 2 to 3 years. The linear lines slope slightly upward, while the quadratic and LOESS smoothed lines first increased and then decreased, primarily owing to the low proportions in 2018 and 2019. The fourth plot (Figure 3, bottom right) shows a general increase in the proportion of decisions decided upon within 4 years. However, the nonlinear lines show a decline toward the end, which was caused by the lower proportion in 2017. The plot shows no observations

from 2017 onward. We further elaborate on these results in Section 6, where we connect our theoretical background to our empirical findings.

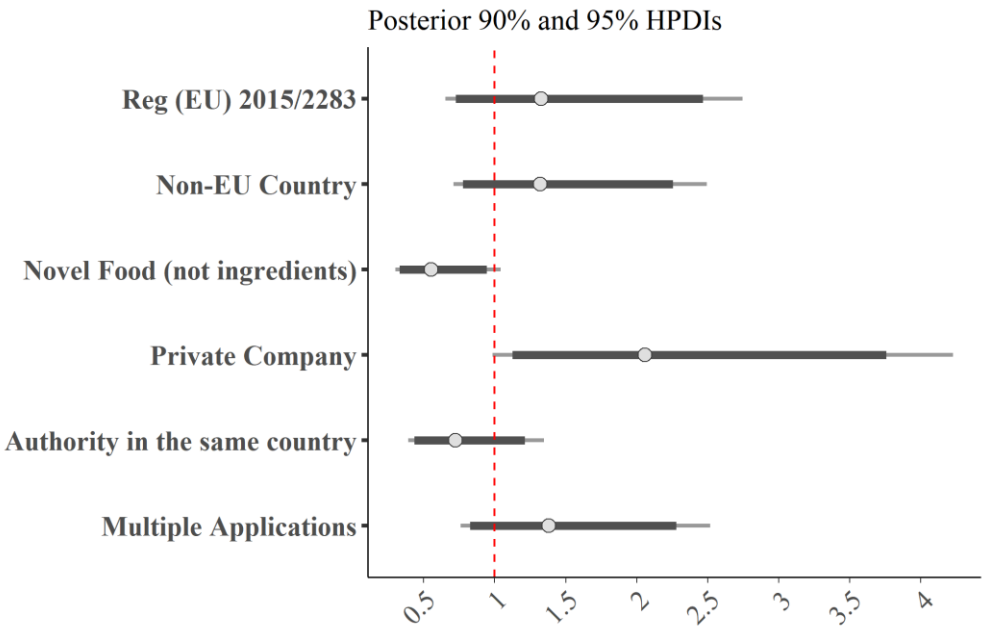
Figure 3: Proportion of applications that received a decision within one, two, three, or four years



Note: The blue (red, green) line represents the linear (quadratic, flexible) model.

Finally, Figure 4 reports the posterior parameter estimates for the Bayesian logistic regression model described in Section 4.2.3. To facilitate interpretation, we transformed the estimated coefficient so that each variable could be discussed in terms of relative odds (i.e., odds ratios). First, *ceteris paribus*, the calculated 90% highest posterior density intervals (HPDIs) for the variables "private company" and "novel food (not ingredients)" indicate that the odds of receiving approval status when submitting applications for NF ingredients is, on average, 1.5 times higher than the odds of receiving approval status for other NFs, whereas the odds of approval for private companies are, on average, twice as high as the odds for public institutions.

Figure 4: Highest posterior density intervals (HPDI) based on a Bayesian logit model on the probability that a novel food is authorized



Note: The thick (thin) lines indicate 90% (95%) HPDIs, which represent the interval of the posterior distribution where 90% (95%) of the probability lies. The dots indicate the median of the posterior (the maximum a posteiori [MAP] values), which represent our point estimates.

Conversely, our estimates are less clear-cut regarding the remaining covariates. In this respect, the point estimate in Figure 4 suggests that the odds for applications under Regulation (EU) 2015/2283 are approximately 1.2 times higher than the odds for applications under the older NFR. However, the estimated association is rather imprecise, as shown by the HPDIs encompassing both values below 1 (indicating higher chances of approval for NFs submitted under the older NFR) and above 1 (indicating higher chances of approval for NFs submitted under the new NFR). Likewise, applicants from non-EU countries and those with multiple applications might be more likely to receive authorization. Again, the uncertainty in these estimates is too high to draw reliable conclusions. Similar reasoning applies to applicants from the same country as the competent authority, although the point estimate is now below 1. As our model provides a full posterior distribution of the odds ratios, we can calculate useful summary quantities other than the 90% and 95% HPDIs. For example, we can calculate the proportion of the estimated parameter values

below/above 1. In the case of NFs submitted under Regulation (EU) 2015/2283, we found that the values of the corresponding odds ratio would be higher than 1, with 78% probability. Lastly, we also computed the predicted posterior probability of approval for both regulations, which was 66% for the older NFR and 79% for the new NFR, indicating a 12% difference (95% HDPI: 9% to 16%).

6. Discussion

6.1 Theoretical implications

The theoretical framework presented in Section 2 provides useful interpretative insights for assessing the relationship between the evolution of a regulation and the level of innovation. The EU NFR offers a good case study of a regulation aimed at simplifying procedures with a more centralized approach. So far, most studies about the EU NFR have focused on the length of the decision process, highlighting how a decentralized and heterogeneous procedure managed by multiple authorities may result in longer processes for the applicants (Millstone, Zwanenberg, 2002), thus suggesting that the simplified processes resulting from the new NFR might lead to leaner processes, thereby shortening the authorization procedure (Scarpa and Dalfrà, 2008; Pisanello and Caruso, 2018). However, other authors have extended the discussion beyond the mere duration aspect, recommending that researchers consider other drivers. For example, Hermann (2009, p. 505) highlights that "*costs, complexity, length and uncertain outcomes of NFR procedures have led to uncertainties about the likelihood of successful applications and discouraged firms of the sector to file applications*." However, although terms such as "length of the process," "likelihood of success," "uncertainty," and "expectations" appear in the abovementioned literature, they lack a coherent framework to interpret their findings. Therefore, the first contribution of this study is the theoretical background for a consistent assessment of firm investment decisions under evolving regulatory settings.

Investigating RQ1 provides an opportunity to apply the conceptual framework outlined in Section 2. Consistent with the structure of model (3), our empirical findings suggest that expectations impact firm investment decisions. Indeed, firms seek to anticipate the unfolding of the new technical and bureaucratic requirements and adjust their investment decisions accordingly. In particular, the spike in applications after the introduction of Regulation 2283/2015 suggests that firms believed that the proposed new NRF would guarantee higher efficiency through the main drivers of product innovation: shorter length of the approval process, reduced irreversible approval costs (research, application, and registration costs, all influenced by their lengths), higher probability of approval, and lower uncertainty surrounding the whole regulatory process. Recognizing that these dimensions are worth monitoring for a sound comparative analysis of alternative regulations, we conducted an empirical investigation to quantify two of these aspects (i.e., the actual length of the approval process and the probability of approval), thus providing useful insights for companies willing to invest in NFs (see Section 6.2).

Another way of interpreting these figures within the boundaries of our theoretical setup is that despite the several innovations already in the pipeline, their high option value encouraged firms to postpone their time-to-market investment decisions. The spike in new applications observed in 2018 may therefore signal a reduction in the opportunity cost of immediate investments. Following this interpretation, the reduction in the number of applications during the following 2 years was likely due to a natural reduction of the stock of innovative NFs waiting in the pipeline. (From a different perspective, the additional rate of applications should be monitored over a few more years to determine whether the NFR led to a structural change in the number of NF applications.)

However, expectations might not be confirmed by practice as time moves on. In fact, from a researcher's perspective, the costs and benefits of alternative regulatory frameworks may not be as obvious as they seem because of several nontrivial trade-offs. For example, decentralization could improve the efficiency of a regulation owing to the monitoring and enforcement of specific rules and norms by third-party certifiers (Renckens and Auld, 2022) or, more generally, by the lack of

capacities of the regulator that intermediaries can fill effectively at a lower cost (Abbott et al., 2017). At the same time, economic and political transaction costs could emerge for creating and managing such bodies, whether public, private, or in the form of coalitions (Ostrom,1990). Therefore, empirically monitoring the performance of alternative regulatory frameworks becomes important in the research agenda to understand relationships with efficient company decision-making.

6.2 Practical implications

We begin by focusing on the length of the authorization procedure (RQ2). Our results show that the share of applications that received a decision within 4 years increased from approximately 50% in 1997 to approximately 80% in 2017. By contrast, we observed that decisions made within 2 to 3 years only showed minor improvements. This increase highlights how, over the past 20 years, the EC has at least succeeded in guaranteeing an upper bound for the length of the application process. For the old NFR, this improved efficiency could be explained by the experience gained by the actors submitting, managing, and processing NF applications over the period the regulation had been in force. In light of the criticisms raised in the literature on the hefty duration of the authorization process (and the resulting costs for the whole system [Hermann, 2009; Hyde et al., 2017]), our findings suggest that the sluggishness of these procedures could be offset by reducing the degree of uncertainty regarding the maximum expected length. However, based on the steady number of applications, this reduced uncertainty does not appear to encourage investments. This observation is a possible indication that the 4-year upper bound is still perceived as too long for impacting firms' decisions to invest. In other words, firms still expect an unreasonably long procedure that discourages the submission of new NFs through a higher option value.

We expected improvements in the length of the authorization process from the simplification of the authorization process of the new NFR. However, considering the applications submitted in the first 3 years of implementation, the new NFR did not appear to introduce substantial changes in the observed timings. The proportions of the applications that received a decision within 1, 2, or 3 years

appeared unaffected based on the linear trend in the length of the authorization process. Moreover, inclusion of quadratic and flexible functional forms shows that the applications submitted in recent years exhibited even poorer performances. The new NFR had no impact on the proportions of decisions decided within 1 year, which could be expected, but the proportion of the decisions made within 2 or 3 years decreased. Therefore, EU policymakers appeared not to have achieved the aspired shortening of the authorization time yet. This shortcoming could have also influenced investors' expectations, setting the course of new NF applications back to the pre-Regulation 2283/2015 levels.

One plausible explanation for the steadiness of the length of the authorization process could be the application boost after the introduction of the new NFR in 2018, which might have created a bottleneck in the authorization pipeline, increasing administrative inefficiencies. This further stresses the importance of RQ1, as the effect on the number of applications per year could be strictly connected to expectations about the length of the process and, *ceteris paribus,* the EC processing capacity. If so, the steady decline in investments after the 2018 hike would be further justified. In this context, meso-institutional layers, such as the EC administrative bodies, in translating, monitoring, and enforcing the rules and norms become essential drivers of the costs and benefits of alternative regulatory arrangements (Ménard, 2018). Moreover, these costs and benefits could be also dynamic in that, as the actors involved get accustomed to new procedures and gain experience in submitting, managing, and processing NF applications, time to decision could accelerate, as witnessed for the older NFR.

Finally, by examining the authorized applications in the EU NFR (RQ3), we observed a difference in the approval rate of NFs between the old NFR and Regulation (EU) 2015/2283. Controlling for applicants' characteristics, we estimated this difference to be approximately 12%, with the more recent NFR being associated with a higher chance of approval. Although the estimates are quite imprecise, evidence shows that more successful authorizations were obtained under the new NFR, which could be a favorable factor for future investment decisions. Following model (3), if firms investing in NF products expect that the new regulatory framework would translate into higher chances of approval, the present value of the investment would increase relative to the option value,

which encourages new applicants to begin the submission procedures. Again, our conceptual framework provides the key to understanding the dynamics depicted in Figure 2. Although the hike in new applications after 2018 might have been reverting, it remains well above the long-term trend, at least on average (see the point estimates). In addition to the discussion provided in Section 6.1, we argue that this achievement could also be explained by the difference in approval rates generating lower option values.

However, it should be kept in mind that the higher probability of acceptance under the new NFR might be biased by the short length of time since its enforcement, as several applications made since 2018 are still pending a decision. More-problematic applications will likely undergo a longer authorization process because the EFSA may request additional data from the applicants.

7. Conclusions

In this study, we investigated the relationships between ex ante regulations and innovations via firm investment decisions. We first present a conceptual framework based on the option value theory. We then exploited this model to provide an interpretative framework for the results of the empirical analysis, in which we assessed the pre-market authorization procedure of the EU NFR. Our findings were based on a novel detailed dataset of 289 applications submitted under both the former (Regulation 258/97) and current EU NFRs (Regulation 2283/2015). To evaluate the efficiency and effectiveness of the two regulations, our empirical strategy was fitted into the general theoretical framework by focusing on the option value of investing in NF products while disentangling and assessing its main determinants.

Our results show a relatively stable number of NF applications over the years, with a spike after the introduction of Regulation 2283/2015 in 2018. This upsurge can be interpreted within our theoretical model as a reduction in the option value of postponing investments already in the innovation pipeline. This lower option value resulted from stakeholders' expectations of improved

efficiency due to the new NFR. We also show a decreasing trend in the length of the authorization process, especially for applications that received a decision within 4 years. Indeed, our data suggest that 4 years could now be considered a ceiling value for the expected duration of the relevant procedures. However, this upper limit appears irrelevant in determining investment decisions. The reason could be the high opportunity cost for applicants due to the lengthy waiting times: despite the reduction in uncertainty through a known worst-case scenario (i.e., 4 years), this expected latency could still be too high to reduce the option value. Owing to the limited data availability, however, there is not much we can say about the role of the new NFR, except that we did not witness any improvement in the proportion of applications that received a decision within 1 or 2 years.

Finally, our results suggest that being a private company and applying for approval of a NF ingredient are predictors of higher success in the authorization decision. The NF products submitted under the new NFR also showed a high rate of successful applications, which suggests that the policy reform has moved in the desired direction. This success also helps explain the higher number of applications after the implementation of Regulation 2283/2015 from an option value perspective: investors expecting a more favorable probability of receiving an authorization would face a higher present value and decide to invest. However, this indicator is likely biased upward, as it pertains to a subsample of applications that received a decision within a relatively short period.

Unfortunately, our research was limited by the publicly available data on NF. Although the EC lists NFs in the so-called "Union list" of NFs, this list only provided the name and specifications of each product without mentioning the date of application or authorization, or the name of the applicant. We collected timing data for each NF from among different sources (the EC website, EFSA Register of Questions, and the literature). However, the dataset has a few gaps, as it is not mandatory to release the dates of the various procedural authorization steps publicly. Future policies should include the release of this information.

Moreover, because of the initial stage of the new NFR and the resulting limited information regarding the status of the most recent applications, the efficacy of Regulation 2283/2015 should be

reevaluated in a few years. For further research, it would also be interesting to investigate the perceptions of NF producers concerning the different dimensions included in the theoretical framework and to compare the differences before and after the regulatory reform in the EU. For example, although the model distinguishes from the expected length, ex post liability, or uncertainty, it is difficult to identify which determinant contributed the most to the observed dynamics in the number of applications. Moreover, it might be possible to compare the same or similar products authorized under different legislations, such as Canada, the United States, or even in the United Kingdom after the Brexit. The impact of the new notification procedure for traditional foods from third countries on the performance of the new NFR should also be evaluated, especially concerning non-industrialized country discrimination. This will provide important information for harmonizing food policies with respect to reducing approval costs without undermining food safety.

References

Abbott, K. W., Levi-Faur, D., & Snidal, D. (2017). Theorizing regulatory intermediaries: The RIT model. The ANNALS of the American academy of political and social science, 670(1), 14-35.

Antle, J. M. (1996). Efficient food safety regulation in the food manufacturing sector. *American Journal of Agricultural Economics*, *78*(5), 1242–1247.

Belluco, S., Halloran, A., & Ricci, A. (2017). New protein sources and food legislation: The case of edible insects and EU law. *Food Security*, *9*(4), 803–814. https://doi.org/10.1007/s12571-017-0704-0

Bigliardi, B., & Galati, F. (2013). Models of adoption of open innovation within the food industry. *Trends in Food Science & Technology*, *30*(1), 16–26. https://doi.org/10.1016/j.tifs.2012.11.001

Brookes, G. (2007). *Economic impact assessment of the way in which the EU novel foods regulatory approval procedures affect the EU food sector*. Briefing paper for the Confederation of the Food and Drink Industries of the European Union (CIAA) & the Platform for Ingredients in Europe (PIE). https://www.pgeconomics.co.uk/pdf/novelfoods.pdf

Charlebois, S. (2020). Which countries are true food innovators? *New Food Magazine*. https://www.newfoodmagazine.com/article/128292/global-food-innovation/

Coppens, P. (2013). The revision of the Novel Foods Regulation: Forget about cloning and nanotechnology, let's focus on the scope. *European Food and Feed Law Review*, *8*(4), 238–246.

de-Magistris, T., Pascucci, S., & Mitsopoulos, D. (2015). Paying to see a bug on my food. *British Food Journal*. https://doi.org/10.1108/BFJ-06-2014-0222

European Commission. (2000). White paper on food safety, COM (1999) 719.

Directorate-General for Research and Innovation of the European Commission, Webb, P., Sonnino, R., Fraser, E. and Arnold T. (2022). Everyone at the Table: Transforming food systems by connecting science, policy and society, Publications Office of the European Union, Luxembourg, 2022

Dixit, A. K., and Pindyck, R.S. (1994). "Investment under Uncertainty," Economics Books, Princeton University Press, edition 1, number 5474.

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). (2012). Scientific opinion on the substantiation of a health claim related to krill oil and maintenance of joint comfort pursuant to Article 13 (5) of Regulation (EC) No 1924/2006. *EFSA Journal, 10*(12), 3003. https://doi.org/10.2903/j.efsa.2012.3003

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). (2014). Scientific opinion on the extension of use for DHA and EPA-rich algal oil from Schizochytrium sp. as a novel food ingredient. *EFSA Journal, 12*(10), 3843. https://doi.org/10.2903/j.efsa.2014.3843

European Parliament and Council (2015) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the

European Parliament and the Council and Commission Regulation (EC) No 1852/2001. *Official Journal of the European Union, L327*, 1–22.

European Parliament and Council of the European Union. (1997). Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. *Official Journal of the European Communities*, *L43*(40), 1–6.

European Parliamentary Research Service. (2015). Updating rules on novel foods to keep up with scientific advances. Briefing June 2015 Members' Research Service PE 564.383.

Frewer, L. J., Bergmann, K., Brennan, M., Lion, R., Meertens, R., Rowe, G., Siegrist, M., & Vereijken, C. (2011). Consumer response to novel agri-food technologies: Implications for predicting consumer acceptance of emerging food technologies. Trends in Food Science & Technology, 22(8), 442–456. https://doi.org/10.1016/J.TIFS.2011.05.005

Grimsby, S. (2020). New novel food regulation and collaboration for innovation. *British Food Journal*. https://doi.org/10.1108/BFJ-02-2020-0154

Hamilton, S. F., & Zilberman, D. (2006). Green markets, eco-certification, and equilibrium fraud. *Journal of Environmental Economics and Management*, 52(3), 627–644. https://doi.org/10.1016/j.jeem.2006.05.002

Hermann, M. (2009). The impact of the European Novel Food Regulation on trade and food innovation based on traditional plant foods from developing countries. *Food Policy*, *34*(6), 499–507. https://doi.org/10.1016/j.foodpol.2009.08.005

Holle, M. (2018). Pre-market approval and its impact on food innovation: the novel foods example. *In regulating and managing food safety in the EU* (pp. 291–330). Springer. https://doi.org/10.1007/978-3-319-77045-1_14

Hyde, R., Hartley, S., & Millar, K. (2017). European novel foods policy at a critical juncture. *Food and Drug Law Journal*, *72*(3), 472–505.

Jones, C. (2012). The Novel Food Regulation: Revisions required—A view from a regulator. *Eur. Food & Feed L. Rev.*, *7*, 81.

Kardung, M., Costenoble, O., Dammer, L., Delahaye, R., Lovric´, M., Leeuwen, M. van, M'Barek, R., Meijl, H. van, Piotrowski, S., Ronzon, T., Verhoog, D., Verkerk, H., Vrachioli, M., Wesseler, J., & Zhu, B. X. (2020). D1. 1: Framework for measuring the size and development of the bioeconomy. Biomonitor: Horizon, European Commission, 2020. http://biomonitor.eu/news/d1-1-framework-for-measuring-the-size-and-development-of-the-bioeconomy/

Kolstad, C. D., Ulen, T. S., & Johnson, G. V. (1990). Ex Post Liability for Harm vs. Ex Ante Safety Regulation: Substitutes or Complements? *The American Economic Review*, 80(4), 888–901. http://www.jstor.org/stable/2006714

Lahteenmaki-Uutela, A. (2007). European novel food legislation as a restriction to trade (No. 691-2016-47375).

Lytton, T. D. (2014). Competitive third-party regulation: How private certification can overcome constraints that frustrate government regulation. Theoretical Inquiries in Law, 15(2), 539-572.

Marberg, A., van Kranenburg, H., & Korzilius, H. (2017). The big bug: The legitimation of the edible insect sector in the Netherlands. *Food Policy, 71*, 111–123. https://doi.org/10.1016/j.foodpol.2017.07.008

Mazac, R., Meinilä, J., Korkalo, L., Järviö, N., Jalava, M., & Tuomisto, H. L. (2022). Incorporation of novel foods in European diets can reduce global warming potential, water use and land use by over 80%. Nature Food, 3(4), 286–293. https://doi.org/10.1038/s43016-022-00489-9

Ménard, C. (2014). Embedding organizational arrangements: towards a general model. *Journal of Institutional Economics*, *10*(4), 567-589.

Ménard, C. (2018). Research frontiers of new institutional economics. *RAUSP Management Journal*, *53*(1), 3-10.

Millstone, E., & Van Zwanenberg, P. (2002). The evolution of food safety policy–making institutions in the UK, EU and codex alimentarius. *Social Policy & Administration, 36*(6), 593–609. https://doi.org/10.1111/1467-9515.t01-1-00306

Neuwirth, R. J. (2014). "Novel foods for thought" on law and policymaking in the global creative economy. *European Journal of Law and Economics, 37*(1), 13–50. https://doi.org/10.1007/s10657-013-9415-y

Ostrom, E. (1990). Governing the commons: The evolution of institutions for collective action. Cambridge university press.

Parodi, A., Leip, A., De Boer, I. J. M., Slegers, P. M., Ziegler, F., Temme, E. H. M., Herrero, M., Tuomisto, H., Valin, H., Van Middelaar, C. E., Van Loon, J. J. A., & Van Zanten, H. H. E. (2018).

The potential of future foods for sustainable and healthy diets. Nature Sustainability, 1(12), 782–789. https://doi.org/10.1038/s41893-018-0189-7

Pisanello, D., & Caruso, G. (2018). EU regulation on novel foods. In *Novel foods in the European Union* (pp. 1–29). Springer. https://doi.org/10.1007/978-3-319-93620-8

Scarpa, B., & Dalfrà, S. (2008). Regulating the novel foods sector: Moving forward. *Eur. Food & Feed L. Rev., 3*, 292.

Shavell, S. (1984a). A Model of the Optimal Use of Liability and Safety Regulation. *The RAND Journal of Economics*, 15(2), 271. https://doi.org/10.2307/2555680

Shavell, S. (1984b). Liability for Harm versus Regulation of Safety. *The Journal of Legal Studies*, 13(2), 357–374. https://doi.org/10.1086/467745

Shleifer, A. (2011). Efficient Regulation. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.1532802

Smart, R. D., Blum, M., & Wesseler, J. (2017). Trends in approval times for genetically engineered crops in the United States and the European Union. *Journal of Agricultural Economics*, *68*(1), 182–198. https://doi.org/10.1111/1477-9552.12171

Smith, V., Wesseler, J., & Zilberman, D. (2021). New Plant Breeding Technologies: An Assessment of the Political Economy of the Regulatory Environment and Implications for Sustainability. *Sustainability*, 13(7), 3687.

Soregaroli C., Wesseler J. (2005). “Minimum Distance Requirements and Liability: Implications for Co-Existence. In J. Wesseler, ed. Environmental Costs and Benefits of Transgenic Crops. Dordrecht and Norwell, Mass., Springer: Springer: 165-81.

Soregaroli, C., Varacca, A., Ricci, E. C., Platoni, S., Tillie, P., & Stranieri, S. (2022). Voluntary standards as meso-institutions: A Bayesian investigation of their relationships with transaction governance and risks. Applied Economic Perspectives and Policy.

Vapnek, J., Purnhagen, K. P., & Hillel, B. (2020). Regulatory and legislative framework for novel foods. https://doi.org/10.15495/EPub_UBT_00005178

Castellari, E., Soregaroli, C., Venus, T.J., Wesseler, J. (2018). Food processor and retailer non-GMO standards in the US and EU and the driving role of regulations. *Food Policy*. 78:26-37.

Ververis, E., Ackerl, R., Azzollini, D., Colombo, P. A., de Sesmaisons, A., Dumas, C., Fernandez-Dumont, A., Ferreira da Costa, L., Germini, A., Goumperis, T., Kouloura, E., Matijevic, L., Precup, G., Roldan-Torres, R., Rossi, A., Svejstil, R., Turla, E., & Gelbmann, W. (2020). Novel foods in the European Union: Scientific requirements and challenges of the risk assessment process by the European Food Safety Authority. *Food Research International*, *137*, 109515. https://doi.org/10.1016/j.foodres.2020.109515

Wagenberg, C. Van, Janssens, B., Kalk, C., & Sluis, A. Van Der. (2014). Guideline for making application dossiers for novel proteins: Novel food dossiers: From black box to tool box. Wageningen, LEI Wageningen UR (University & Research Centre), LEI 14-075. 52 pp.; 9 fig.; 15 tab.

Wesseler J., & Kalaitzandonakes N. (2019) Present and Future EU GMO Policy. In: Dries L., Heijman W., Jongeneel R., Purnhagen K., Wesseler J. (eds) EU Bioeconomy Economics and Policies: Volume II. Palgrave Advances in Bioeconomy: Economics and Policies. Palgrave Macmillan, Cham. https://doi.org/10.1007/978-3-030-28642-2_13

Wesseler, J., & Smart, R. (2014). Environmental impacts. In *Socio-economic considerations in biotechnology regulation* (pp. 81–95). Springer. https://doi.org/10.1007/978-1-4614-9440-9_6

Wesseler, J., & Zilberman, D. (2021). Biotechnology, bioeconomy, and sustainable life on land. In V. Beckmann (Ed.), Transitioning to sustainable life on land (pp. 407–427). MDPI.

Wesseler, J., Kleter, G., Meulenbroek, M., & Purnhagen, K. P. (2022). EU regulation of genetically modified microorganisms in light of new policy developments: Possible implications for EU bioeconomy investments . *Applied Economic Perspectives and Policy*. https://doi.org/10.1002/aepp.13259

Willett, W., Rockström, J., Loken, B., Springmann, M., Lang, T., Vermeulen, S., Garnett, T., Tilman, D., DeClerck, F., Wood, A., Jonell, M., Clark, M., Gordon, L. J., Fanzo, J., Hawkes, C., Zurayk, R., Rivera, J. A., De Vries, W., Majele Sibanda, L., … Murray, C. J. L. (2019). Food in the Anthropocene: the EAT–Lancet Commission on healthy diets from sustainable food systems. The Lancet, 393(10170), 447–492. https://doi.org/10.1016/S0140-6736(18)31788-4

Zarbà, C., Chinnici, G., & D'Amico, M. (2020). Novel food: The impact of innovation on the paths of the traditional food chain. *Sustainability, 12*(2), 555. https://doi.org/10.3390/su12020555

Zilberman, D., Reardon, T., Silvera, J., Luc, L., & Heiman, A. (2022). From the laboratory to the consumer: Innovation, supply chain, and adoption with applications to natural resources. PNAS 119 (23) e2115880119.

Zorn, A., Lippert, C., & Dabbert, S. (2012). Supervising a system of approved private control bodies for certification: The case of organic farming in Germany. *Food Control*, 25(2), 525–532. https://doi.org/10.1016/j.foodcont.2011.11.013