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The effect of the EU's novel food regulations on firm investment decisions

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Abstract

In this study, we assess the effect of the European Union's novel food regulations on firms' incentives to invest in such products. We adopt a conceptual framework based on real option value theory, which underpins an empirical analysis of a detailed dataset comprising 326 applications submitted under both the 1997 EU novel food regulation and its 2018 replacement. We investigate the dynamics of novel food applications under these regulations and disentangle the determinants of successful cases. Our results show a relatively stable number of applications over the years, with a spike after the introduction of the 2018 regulation, which sought to simplify and centralise the approval process. This upsurge can be interpreted as a reduction in the real option value of postponing investments, attributable to the introduction of a transitional regime and of 5-year data protection measures. However, the new regulation did not shorten the authorisation process, with the expected benefits of centralisation compromised by operational bottlenecks and a lower chance of approval. Finally, we find that approvals under the 2018 regulation are more likely when applicants are private entities from non-EU countries and have substantial experience with novel foods. Our empirical evidence suggests that the new regulation may be insufficient to speed up and streamline the novel food assessment process, which is inevitably constrained by EU food safety principles. This, in turn, may discourage future investments.

KEYWORDS

EU food legislation, EU food policy, food innovation, novel food regulation, real option models

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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 et al., 2021). Within the food system, there is a demand for new healthy, functional and locally less well-known foods, which have the potential to align environmental benefits with the intake of essential micronutrients (Belluco et al., 2017; Hermann, 2009; Marberg et al., 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 (Willett et al., 2019; Zilberman et al., 2022). These technologies allow companies to produce food from unconventional sources such as vitamin K from menaquinone or Antarctic krill oil, which is rich in phospholipids from *Euphausia superba* (EFSA-NDA, 2012–2014; Vapnek et al., 2020). A shift towards less animal-sourced foods is increasingly acknowledged as an important solution to feeding the world's growing population more sustainably, and fostering innovation in the food industry has the potential to facilitate a more planet-friendly diet. Recent literature shows that novel foods[1] (NFs) such as insects, seaweed and cultured meat could lead to significant environmental benefits while guaranteeing the intake of essential micronutrients (Parodi et al., 2018). For example, if European consumers replace animal-sourced foods with these novel foods, the environmental impacts might be reduced by more than 80% while meeting nutritional requirements (Mazac et al., 2022).

Innovation is essential for food companies to be competitive in the world market (Zilberman et al., 2022). However, the advent of new technologies has created concerns about adverse effects on human, environmental, animal and plant health, which trigger the need for standardised regulations (Vapnek et al., 2020). In the EU, a series of incidents of foodborne diseases in the late 1990s drew even more attention to the need to establish general food safety principles and requirements at the policy level (Hyde et al., 2017; Wesseler & Kalaitzandonakes, 2019).

In 1997, the EU introduced a Novel Food Regulation (NFR), Regulation (EC) 258/97, to keep up with the rapid evolution of the food sector. This legislation 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, lack of binding timelines and discrimination against non-EU food products and producers (Grimsby, 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 1 January 2018.

The EU NFR offers a good case study of a regulation aimed at simplifying procedures with a more centralised approach. To date, however, most analyses of the EU NFR have focused on the length of the decision process, highlighting how a decentralised and heterogeneous procedure managed by multiple authorities may result in longer processing times for applicants (Millstone & Van Zwanenberg, 2002). Existing studies have accordingly suggested that

[1]Notice that we indicate as 'Novel Food' all the food that 'had not been consumed to a significant degree by humans in the EU before 15 May 1997, when the first Regulation on novel food came into force', following the definition proposed by the European Commission European.EC, (2023) Therefore, this terminology should not be intended from a cultural or ethnic perspective but from a purely European Commission technical regulatory specification.

the simplified processes resulting from the new NFR might lead to leaner processes, thereby shortening the authorisation procedure (Pisanello & Caruso, 2018; Scarpa & Dalfrà, 2008). For example, Hyde et al. (2017) found that the average length for authorising an NF under Regulation (EC) 258/97 was about 3.3 years, ranging from 0.7 to almost 10 years. Similarly, Grimsby (2020) found an average authorisation process length of 3.8 years.

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 in which findings can be interpreted. Therefore, the first contribution of this study is to define a theoretical framework for a consistent assessment of firms' investment decisions in a market subject to evolving regulatory settings. Building on the insights gained from the literature on real options (Dixit & Pindyck, 1994), we present a conceptual investment model that establishes the role of regulations (such as the NFR) and liabilities in influencing the timing of introduction of a novel food product to the market. We hypothesise that regulations may foster investment opportunities, thereby increasing applications for novel food products. This outcome could be achieved by reducing the expected irreversible approval costs, the expected length of the approval process and uncertainty. Moreover, we suggest that expected performance indicators play a crucial role in informing companies' beliefs and behaviours. Therefore, it is essential to identify and quantify these indicators and understand how they might be affected by changes to improve future policy revisions.

The second part of this study exploits the conceptual framework discussed above to empirically analyse the development of the authorisation procedures under Regulation (EC) 258/97 and Regulation (EU) 2015/2283, considering the changes between the two regulatory regimes. Specifically, we address three main research questions (RQs): (RQ1) How is the annual number of NF applications evolving over time? (RQ2) How is the duration of the NF authorisation procedure developing over time? (RQ3) Which applicant characteristics increase the probability of success for an NF application? While RQ1 addresses the total number of applications, which is directly linked to firm investment decisions and the level of innovation in a market, RQ2 and RQ3 investigate the factors influencing such decisions as conceptualised into our theoretical model. We investigate the research questions while considering possible trends and whether the more centralised approach of the current NFR has led to a change in any of the abovementioned indicators.

The paper is structured as follows: Section 2 offers an overview of the core features of the NFR in the EU and illustrates the main novelties introduced with the new regulatory regime. Section 3 presents a detailed description of our theoretical framework. Section 4 describes the dataset used in the study and presents the empirical analysis. Section 5 discusses the main results, which are then discussed in Section 6 within the context of our conceptual model. Finally, Section 7 presents concluding remarks.

2 | REGULATING NFs IN THE EU

The first EU NFR (Regulation [EC] No 258/97) was adopted in 1997. In 2002, shortly after the implementation of the original regulation, the European Commission opened consultations to monitor the effectiveness of the authorisation process on NF, identify shortcomings and propose a revised regulation. In this regard, the impact assessment carried out by the European Commission in 2008 identified three main critical aspects of the former NFR: (a) the excessive complexity of the decentralised authorisation procedure between EU Member States and the

TABLE 1 Authorisation processing times for Reg. (EC) 258/97.

Step	Actor	Process time limit
Risk assessment		
Verification of the validity of the dossier	Member States	1 month
Initial assessment	Member States	3 months
Other Member States and European Commission comment on initial assessment	Member States/European Commission	2 months (can extend to 4 months if objections are raised)
EFSA safety assessment (if needed)	Scientific Committee for Foodstuff/EFSA	No time limit
Risk management		
Implementation of the draft	European Commission	No time limit
Final decision deliberation	European Commission	3 months

EU; (b) the duplication of efforts arising out of a system where authorisation was linked to the applicant and (c) the delays caused by having to resort to the same authorisation procedure both for NFs and traditional foods from third countries.

The first EU NFR was replaced by Regulation (EU) No 2015/2283 in 2018. The new regulation introduces several changes to the authorisation procedure but neither fundamentally alters its ultimate goals nor its basic two-step approach (Tables 1 and 2). Regarding the former, the new NFR reaffirms the importance of ensuring '*the free movement of safe and wholesome food*' as a means to contribute to '*the effective functioning of the internal market while providing a high level of protection of human health and consumers' interests*' (NFR, Article 1.1). Reaffirming such goals confirms the validity of the framework goals determined ex ante by the EU General Food Regulation (Regulation (EC) No 178 (2002)), whose role is to set the open-ended framework goals for the EU Safety domain (Vos, 2010).

With respect to standards, the new regulation maintains the two-step risk assessment and risk management authorisation procedure in line with the risk analysis principle, as set out in the EU General Food Regulation (Article 6). However, several features were extensively revised in the current NFR to better accommodate stakeholders' preferences for simplification with the view to stimulating innovation and research on NFs, among other things. The first element concerns the introduction of a more centralised authorisation procedure for the purposes of reducing the approval duration and its connected costs. The current system involves four main actors: the applicants, the European Food Safety Authority (EFSA), the EU Member States and the European Commission. The applicants can be the European Commission itself or any legal or natural person (e.g. individuals, business operators, industry associations, consultancies), situated within or outside the EU, that apply to the European Commission (Article 10.1 NFR) to authorise an NF on the EU market. According to the current NFR, the EFSA is the only actor in charge of the risk assessment stage, and it carries out the safety assessment upon the request of the European Commission (NFR Article 10.3). This feature is one of the main novelties of the current NFR: Member States no longer engage in an initial risk assessment. This change has limited the role of Member States, leading to a more centralised process. For example, under the former NFR, the assessment conducted at the Member State level often led to objections from other Member States; consequently, the EFSA often ended up rerunning the risk assessment, which doubled the decision-making period (Volpato, 2022).

TABLE 2 Authorisation processing times for Reg. (EU) 2015/2283.

Step	Actor	Processing time limit for novel food or food ingredients	Processing time limit for traditional food from third countries
Risk assessment			
Verification of the validity of the dossier	European Commission	1 month	1 month
Dossier transmitted to EFSA and Member States	European Commission	1 month	
EFSA safety assessment (if needed)	EFSA	9 months (+ possible clock stops)	4 months
Risk management			
Implementation of the draft Opinion from PAFF Committee Final decision deliberation	European Commission	7 months	6 months

However, EU Member States continue to play a key role in the authorisation procedure through the Standing Committee on Plants, Animals, Food and Feed (PAFF), which is composed of representatives from Member States. According to the latest NFR, once the European Commission concludes the risk management step, the European Commission cannot directly authorise the placing of a NF in the EU market; instead, it submits an authorisation draft to the PAFF Committee which is subject to an examination procedure (NFR Articles 12–30). The PAFF Committee may, by a qualified majority, oppose the European Commission decision, delivering a binding negative opinion on the draft. Further, applicants may withdraw their applications if they foresee an adverse recommendation by the EFSA or a rejection at the Standing Committee level to reduce costs (see e.g. Smart et al., 2015 for the case of GMOs).

Another innovation introduced by the new NFR concerns authorisations, which are now generic by default. They are valid for all food operators unless an applicant requests data protection for up to 5 years (NFR, Article 26). In the former regulation, the scenario was reversed: the European Commission's authorisation of an NF was individual—only the specific applicant was allowed to place the NF in the EU market. Subsequent applicants interested in producing the same NF would need an additional administrative notification, thus multiplying efforts for already-authorised products (European Commission, 2008).

Finally, another main difference in the new regime concerns the introduction of a distinction between the ordinary procedure for NF authorisation and the simplified procedure for the authorisation of traditional foods from third countries (i.e. food from primary production with a history of safe food use in at least one country for at least 25 years). Under the current NFR, an applicant who intends to place a traditional food from a third country on the EU market may opt for a simplified procedure.

3 | THEORETICAL FRAMEWORK: EX ANTE REGULATION AND FIRM INVESTMENT DECISIONS

To stylise the firm investment decision problem, we postulate that a company developing a novel food product must submit it for approval in compliance with the relevant food regulation. 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 investment costs and the net present value of future benefits. For an investment to be made, this difference must be greater than the value of withholding and postponing the investment (real option value). This difference is in most cases larger than zero if: (i) the firm can flexibly time the investment decision; (ii) the firm faces irreversible investment costs (costs that cannot be recovered) and (iii) profits from future investment entail some degree of uncertainty resulting in a negative net-present-value.

Under the above conditions, the investment strategy can be represented as follows:

$$V_0 \geq hI_0, \quad with\ h > 1 \tag{1}$$

where, for an investment to be made at time $T = 0$, the present value of the (reversible) net future benefits V_0 must be greater than the net irreversible costs of the investment I_0 augmented by a hurdle rate h. The hurdle rate is always greater than 1 and represents the degree to which net present benefits must be greater than the respective irreversible costs for an investment to be profitable. If the condition in Equation 1 is not satisfied, then delaying and postponing the investment until more information about the future is available represents a better strategy.

Regulations can influence the investment strategy depicted in equation (1) 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 (1) can be rewritten as follows:

$$V_0\left[E\left(B, \theta_{k3}\right)E\left(P_{appr}\right)\right] \geq V^* = h\left(\sigma_{reg}\right)I\left[R_{k1}, E\left(A_{k2}\right)\right], \quad with\ h(.) > 1 \tag{2}$$

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 $\left(P_{appr}\right)$. 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 indicates 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 in the product and in the target market. A similar argument is sustained by Renckens and Auld (2022), who argue that the efficiency of third-party certifiers (when applicable) is also recognised as a likely contributor to A_{k2} via *k2*.

[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.

TABLE 3 Factors influencing NF investment decisions in a target market within a regulatory framework and their expected impact (in parentheses).

Net present value of future benefits V_0	Hurdle rate, h	Net irreversible costs, I
Expected net benefit	Uncertainty in the business environment: • Regulatory framework (−) • Markets (−)	Research costs: • Length of the research phase for the novel product (−) Expected approval costs: • Expected length of the approval phase (−)

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 authorisation process with administrative and approval bottlenecks that could reduce efficiency (, higher A_{k2} and $k2$ [Hyde et al., 2017]) and increase uncertainty (, larger σ_{reg}), which negatively impact firms' investments.[4] Mechanically, larger σ_{reg} translates to a higher hurdle rate and, consequently, to a higher threshold for net future benefits. Therefore, lower uncertainty of failure (downside risks) should make investors more confident about market- and regulation-related risks, thereby leading to more applications (Wesseler & Zhao, 2019).

To sum up, model (2) 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. Table 3 summarises the main influence factors through which regulations can steer investment decisions for an NF in a market via V_0, h and I. 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 and target markets, 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 4.

[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., 2012 for organic, and Castellari et al. (2018) for 'GMO-free' products.

4 | DATA AND METHODS

4.1 | Empirical strategy

Following the theoretical framework encoded in model (2), firms' investment decisions in marketing NFs in the EU under the evolving NFR can be empirically 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 (EU) 2015/2283 has, since 2018, created an incentive for new applications. We expect the easier application process to reduce (or create expectations for a reduction of) both A_{k2} and $k2$ while curbing 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_{k2} (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 (EU) 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 alone would provide the regulator with valuable information to revise the authorisation 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 characterising their option value. On the other hand, we also aimed to disclose whether the implementation of Regulation (EU) 2015/2283 has contributed to boosting the authorisation 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 incentivising investments. We answer these questions in RQ3.

4.2 | Data

We collected our data from the European Commission's official decision documents on each NF and the list of all authorised NFs in the EU. 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 authorisation procedure, such as the dates of application submission and the final decision. We identified the decision status of each application, which can be authorised, refused, withdrawn, under evaluation, or under consideration. Our dataset included 326 applications, of which 165 were submitted under Regulation (EC) 258/97; and 161, under Regulation (EU) 2015/2283.[5]

We recorded all applications submitted between November 1997 and December 2022. However, since our primary information sources are not uniformly updated, our empirical analysis ends in December 2021. In other words, while we keep track of existing products until

[5]In addition to the submissions for authorization, we found more than 400 applications for notification under the former NFR and more than 50 applications under the current NFR. An NF must be substantially equivalent to a product already authorised under the NFR to qualify for a notification application. In this case, the authorization procedure is shorter and does not entail all the steps required when an NF product enters the market for the first time. We did not include these submissions in our analysis to ensure comparability.

December 2022, the applications we analyse are only those submitted by the end of 2021. The European Commission has currently authorised 171 and refused 13 of the 326 applications. Forty have been withdrawn, and the approval of another 97 is ongoing.[6] For more details concerning applications across different countries and characteristics of applicants see the Appendix S1.

4.3 | Estimation

4.3.1 | Number of applications and the 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:

$$\begin{aligned} n_t &\sim \text{poisson}(\lambda_t) \\ \log(\lambda_t) &= \alpha + \theta_t + \beta_t \times \mathbb{I}[t \geq 2018] \\ \alpha &\sim \text{normal}(\mu_\alpha, \sigma_\alpha) \\ \theta_t &\sim \text{normal}(\mu_\theta + \rho_\theta \theta_{t-1}, \sigma_\theta); \rho_\theta \in (-1, 1) \\ \beta_t &\sim \text{normal}(\mu_\beta + \rho_\beta \beta_{t-1}, \sigma_\beta); \rho_\beta \in (-1, 1) \end{aligned} \tag{3}$$

where λ_t expresses the yearly rate of NF applications, $\mathbb{I}[\cdot]$ represents an indicator function taking 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 function, estimation procedures, inferential calibration and prior definition for all the latent quantities in the Appendix S2. 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, modelling both θ_t and β_t autoregressively provides a generalisation to a simpler model in which the dynamic effects would be independent across periods. However, because we give both ρ_θ and ρ_β zero-centred weakly informative prior distributions (see Appendix S2), whether the autoregressive structure holds will depend on the data.

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

4.3.2 | Proportion of decisions within T years

We next investigated RQ2 by analysing 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 (EC) 258/97 in January 1997. Specifically, we fitted a flexible (i.e. LOESS regression) model and plotted the resulting trend lines to discuss their implications. Since our goal is to uncover how *k2* changed over time vis-à-vis the number of submissions following the implementation of Regulation (EU) 2015/2283, using a locally adaptive model allows to pick up breakpoints in these global trends, provided that enough data are available after the posited shift. For this reason, while a general pattern can be traced out for applications fully processed within 1, 2, 3 or 4 years, specific information on the effect of the new NFR only makes sense for those that received a quick assessment (i.e. within 1 year). We calculated each proportion as the sum of applications approved within $(k-1\times 365, k\times 365)$ days, where $k\in\{1,2,3,4\}$, in some year t divided by the total number of applications within the same year from $t=1997$ up to $T=2022$. At any time $t=2017$ or beyond, had observed applications received no decision by 2022, we imputed the corresponding missing application length using $(365+1)\times(T-t)$. In other words, if an evaluation were still ongoing, we defined the length of the process as exceeding the considered time window. 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 2017, as the data for approval covering a whole year ended with the calendar year 2021.

4.3.3 | 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 authorised. These variables are presented in Table A2 of the Appendix S1. Reflecting the discussion in Section 3, our analysis involved estimating a Bayesian logit model, where we regressed authorisation decisions on a dummy identifying which submissions occurred under Regulation (EU) 2015/2283, plus all the covariates in Table A2 of the Appendix S1. 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 Appendix S2).

5 | RESULTS

Figure 1 shows the estimates for all the time-dependent parameters in model (3), suggesting that the yearly number of applications remained relatively steady between 1997 and 2009, and then exhibited a slightly higher variability from 2010 to 2021. Nevertheless, the spike in applications after the introduction of Regulation (EU) 2015/2283 in 2018 stood out, captured by the dynamic parameter β_t. However, our estimates indicate that this temporary surge was fleeting, as it was followed by a stabilisation in the number of applications, reaching a higher level compared to the pre-2018 period. In the next section, we will thoroughly examine the implications of these findings under the conceptual framework developed in section 3.

Next, Figure 2 visually represents the results from the flexible regression models presented in Section 4.3.2 for the four cut-off periods (1, 2, 3 and 4 years). The first plot indicates that the European Commission did not change the proportion of NF applications they

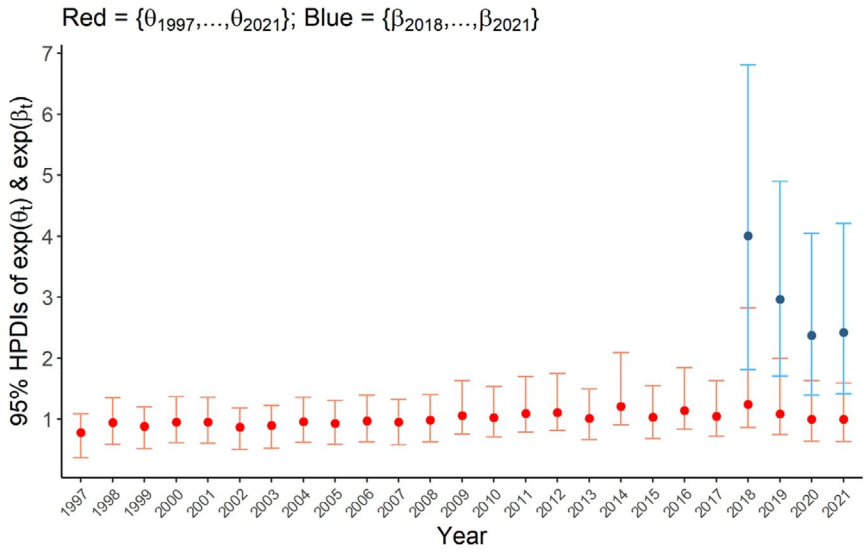

FIGURE 1 Highest posterior density intervals (HPDI) based on a Bayesian hierarchical model for the time-dependent coefficient of applications (in red) and additional rate of applications from the introduction of Regulation (EU) 2015/2283 (in blue). 95% HPDIs represent the interval of the posterior distribution where 95% of the probability lies. The dots indicate the median of the posterior (the maximum a posteriori [MAP] values), representing our point estimates.

decided upon within 1 year from 1998 to 2021 (Figure 2, top left).[7] However, we can clearly see how the relatively flat trend before 2018 seems to change and take a negative trajectory after the introduction of Regulation (EU) 2015/2283. On the other hand, the second plot (Figure 2, top right) indicates a moderate increase in the proportion of NF applications decided upon between 1 and 2 years. Indeed, the LOESS smoothed line increased and then decreased, primarily owing to the lower proportions in 2018 and 2019, which seems to replicate the trend observed for the products processed within 1 year. Nevertheless, the latter still suggests that the proportion of applications that received a decision within 2 years increased on average from almost zero in 1998 to roughly 30% in 2020. The LOESS model in the third panel (Figure 2, bottom left) highlights an interesting pattern in the proportion of application authorised/rejected between 2 and 3 years. In this case, the data trace out a decreasing trend following 1998 which then reverse in the following years, peaking in the early 2010s. The process then seems to slow down approaching the more recent period, where the average share readjusts to values close to those of the earliest periods. However, since the data are, in this case, rather noisy, a clear-cut interpretation of this trend remains challenging and requires extra caution. Finally, the fourth plot (Figure 2, bottom right) suggests little changes in the proportion of applications decided upon within 4 years, owing to a slight improvement between the late nineties and 2010–2013 followed by a decline towards the end, which is attributable to the proportion drop started in 2013. This observation aligns with the previous cases. We further elaborate on these results in Section 6, connecting our theoretical background to our empirical findings.

Figure 3 reports the posterior parameter estimates for the Bayesian logistic regression model described in Section 4.3.3. To facilitate interpretation, we transformed the estimated coefficient so that each variable could be discussed in terms of relative odds (i.e. odds ratios).

[7]Note that we left out year 1997 because only one application was submitted that year. It was successfully processed between 2 and 3 years.

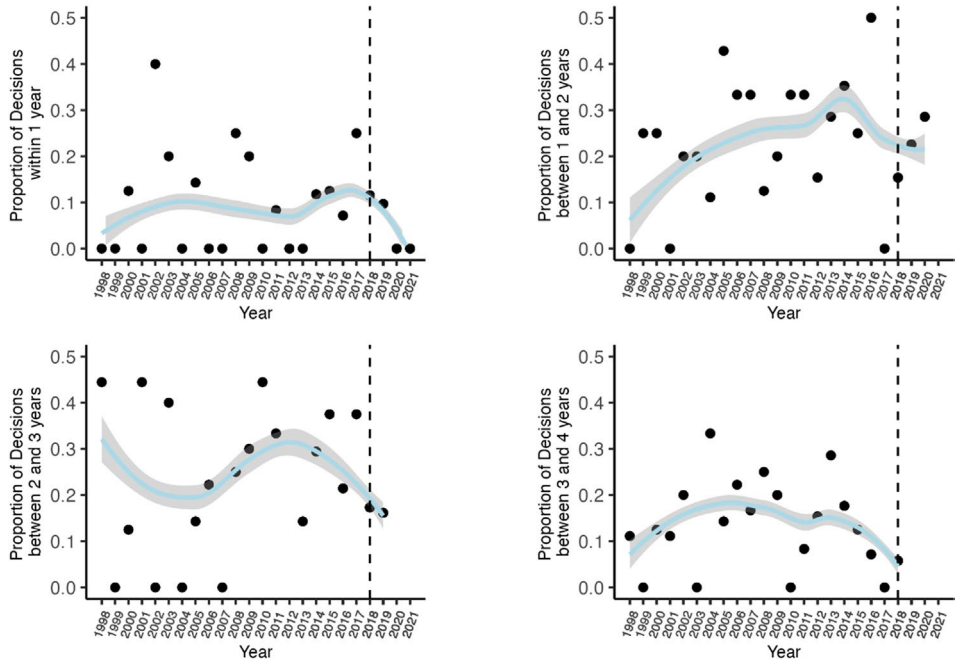

FIGURE 2 Proportion of applications that received a decision within 1, 2, 3 or 4 years as defined in section 4.3.2. The vertical dashed line indicates the implementation of Regulation (EU) 2015/2283.

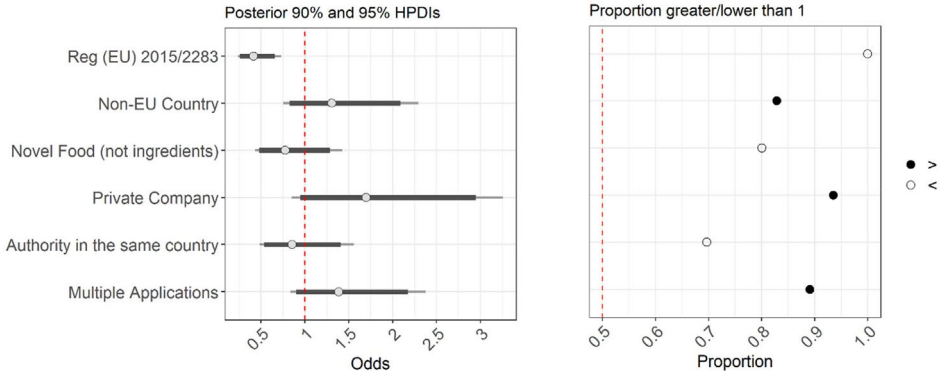

FIGURE 3 Panel 1 (left): Highest posterior density intervals (HPDI) based on a Bayesian logit model on the probability that a novel food is authorised. Panel 2 (right): Proportion of the estimated parameter values below/above 1. The thick (thin) lines indicate 90% (95%) HPDIs, which represent the interval of the posterior distribution where 90% (95%) of the probability lies. The grey circles indicate the median of the posterior (the maximum a posteriori [MAP] values), which represent our point estimates.

First, ceteris paribus, both the calculated 90% and 95% highest posterior density intervals (HPDIs) for the variable indicating applications under Regulation (EU) 2015/2283 indicate that the odds of approval under the novel legislation are approximately 0.5 times lower than under Regulation (EC) 258/97.

Conversely, our estimates are less clear-cut regarding the remaining covariates. In this respect, the point estimate (grey circles) in panel 1 of Figure 3 suggests that the odds of receiving approval for products submitted by private companies are approximately 1.5 times

higher than the odds for applications by public institutions. 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 by public companies) and above 1 (indicating higher chances of approval for NFs submitted by private companies). Similarly, applicants from non-EU countries and those with multiple applications might be more likely to receive authorisation. 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 and NF products that are not ingredients, 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 (Figure 3, panel 2). In the case of NFs submitted by private companies or along with other applications from non-EU Countries, we found that the values of the corresponding odds ratio would be higher than 1, with roughly 90% probability. This information complements the HPDI and helps corroborate the estimated directionality of the variables represented in Figure 3.

6 | DISCUSSION

6.1 | Number of submissions

The investment decision model outlined in Section 3 provides insights to interpret the observed hike in applications after the introduction of Regulation (EU) 2015/2283. The real option value of an investment decision is central in this interpretation. We can argue that, despite the several innovations already in the pipeline, the high hurdle rate encouraged firms to postpone their time-to-market investment decisions. However, after the introduction of Regulation (EU) 2015/2283 firms expected that the proposed new NRF would have guaranteed higher efficiency with a shorter 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 length of the whole regulatory process. Therefore, the high count of submissions observed in 2018 may signal a reduction in the value of waiting, which favours immediate 'go' decisions.

From a legal perspective, two main features introduced by Regulation (EU) 2015/2283 can help explain the hike registered in 2018 and confirm the fundamental role of the real option value in explaining firms' investment decisions in a target market: the transitional regime (Article 35(2)) and the introduction of data protection measures (Article 26). The transitional regime deals with foods that became 'novel' foods under the new NFR, that is, foods that were not considered as such or which had uncertain status (e.g. whole insects) under the previous NFR (Monaco, 2023). Firms were, in particular, given a fixed time window (i.e. until 1 January 2019) to file an authorisation request for those foods that were already placed on the EU market at the time the new NFR came into force to avoid losing the possibility to continue commercialising that product (EC implementing regulation 2017/2469, Article 8 (5)). Interestingly, the authorisations submitted in 2018 under the transitional regime amounted to 10 out of a total of 52, showing that the bulk of submissions related to new products to the market. This indicates that a clear legal framework with binding deadlines (Holle, 2018)—not only for the authorising authorities but also for firms—highly encourages the latter to bring their innovations to market promptly, as it strongly reduces the real option value.

Another legal novelty that could help explain the hike registered in 2018 is the introduction of a data protection regime. Under Article 25 of the new NFR, an applicant can request that '*newly developed scientific evidence or scientific data supporting the application*' not be used to

support subsequent applications for up to 5 years (see above, Section 2.2). According to the data, 25 out of 52 authorisations were submitted in 2018 under the data protection regime, which may indicate that applicants accelerated the number of authorisation requests with a view to preempt their competitors and establish themselves on the market as early as possible. In real option terms, this regime raised expected net benefits, making investors also more confident about market- and regulation-related risks.

At the same time, the decreasing and flattening trend observed from 2019 to 2020 seems compatible with a natural reduction of the stock of innovative NFs waiting in the pipeline. The additional rate of applications should be monitored over a few more years to determine whether the new NFR led to a structural change in the number of NF applications. Firms' expectations might not be met as time passes. In fact, from a research perspective, the costs and benefits of alternative regulatory frameworks may not be as apparent as they seem because of several nontrivial trade-offs. For example, decentralisation could improve the efficiency of a regulation owing to the monitoring and enforcement of specific rules and norms by third-party certifiers (Renckens & Auld, 2022) or, more generally, by the lack of regulatory capacity 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. It is also important to stress that the data registered for the 2020–2021 period could have been influenced by the COVID-19 pandemic through an incidental reduction of applications resulting from the lockdown measures during the emergency period. This could be particularly relevant for 2020, although one might expect the effect to spill over to 2021 and the following years. However, the extent to which the pandemic played a role in reducing or even flattening the rate of submissions can only be carefully examined once more data beyond 2021 become available.

To sum up, we argue that the dimensions identified in the investment decision model are worth monitoring for a sound comparative analysis of alternative regulations and, to follow up, we conducted an empirical investigation to quantify two of these aspects: the actual length of the approval process and the probability of approval.

6.2 | Length of authorisation process

Considering the length of the authorisation procedure, our empirical results show that the share of applications that received a decision between 1 and 2 years increased from nearly zero since the appearance of the first EU novel food regulation to approximately 40%–50% in 2014–2015, to then drop to roughly 30% in 2018. On the other hand, the proportion of authorisation procedures that lasted either less than 1 year or between two and three showed no significant improvement, primary owing to the shares towards the end of the series being roughly the same as those registered in the late 1990s. The same pattern applies to applications processed between 3 and 4 years. In this respect, calculating the proportion of application successfully processed within 4 years or less suggests that by 2018 roughly 50% of products received a decision within 1, 2, 3 or 4 years. A slightly lower proportion emerges by focusing on the share of decisions reached in 3 years or less. This dynamic highlights how, over the past 20 years, the European Commission has at least succeeded in guaranteeing an upper bound for the length of the application process (i.e. 3–4 years), while working towards speeding up the whole process (i.e. more applications processed between 1 and 2 years).

The improved length performance under the old NFR (up until approximately 2015), indicated an increased efficiency that 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. However, no substantial improvement occurred under Regulation (EU) 2015/2283, although this assessment is currently limited by data availability. Our analysis suggests that very few applications successfully went through the evaluation process within 1 year after the implementation of the new NFR. This trend seems to have reversed compared to the higher shares observed between 2013 and 2017, but it is at least consistent with early observations from the previous regulatory framework. A similar pattern is observed for applications processed within 1–2 years, albeit post-2018 data are, in this case, even more scant. Based on current information, it thus seems that the latest regulatory change has not yet solved the criticisms raised in the literature on the hefty duration of the authorisation process (and the resulting costs for the whole system; see Hermann, 2009; Hyde et al., 2017). In fact, our empirical analysis hints towards the opposite, which is surprising considering how Regulation (EU) 2015/2283 purports to simplify the authorisation procedures for novel food products. Yet, this lack of significant and rapid reduction in the length of the authorisation procedure could be explained by both regulatory and practical considerations.

On the one hand, the revision of the NFR mainly focused on centralising and streamlining the authorisation procedure as much as possible *within* the strict limits set by the risk analysis principle (EU General Food Regulation Article 6) and the precautionary principle (EU General Food Regulation Article 3.12). Thus, the new NFR could neither alter the two-step risk assessment and risk management procedure nor depart from the goal to ensure that the free movement of food would not trump defining values such as protecting human health and consumer interests. Given such constraints, significantly shortening the authorisation procedure remains unlikely.

On the other hand, the application boost after the introduction of the new NFR in 2018 might have created a bottleneck in the authorisation pipeline, creating practical problems such as administrative burden and inefficiency. This finding further stresses the importance of monitoring the number of applications per year, which could be strictly connected to expectations about the length of the process and, ceteris paribus, the European Commission processing capacity. If so, the decline in investments after the 2018 hike would be further justified. In this context, meso-institutional layers, such as the European Commission administrative bodies responsible for 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 also be dynamic: as the actors involved grow accustomed to new procedures and gain experience in submitting, managing and processing NF applications, the time to decision could accelerate, as witnessed for the older NFR. Subsequent monitoring of the length of the approval process would be helpful to determine whether the new authorisation process introduced by Regulation (EU) 2015/2283 on how Member States, the European Commission and the EFSA interact will prove to be effectively less efficient vis-à-vis the former NFR or, rather, after an initial bottleneck in the pipeline and administrative inefficiencies unrelated to the NFR, it will prove equally or more efficient.

Finally, it is once again worth stressing that part of the trends observed in Figure 2 and discussed throughout this section might result from the interplay between the above mechanisms and the COVID-19 pandemic. In this respect, not only could the emergency restrictions have delayed the evaluation of NF products submitted in 2020–2021, but also the handling of pending applications could have been affected by the extraordinary measures implemented at the EU level. Unfortunately, the extent to which these exogenous factors impacted the parameters of (2) remains difficult to quantify.

6.3 | Probability of approval

By examining the authorised applications to the EU NFR, we observed a difference in the NF approval rate between the old NFR and Regulation (EU) 2015/2283. Controlling for applicant characteristics, we estimated this difference to be approximately −20%, with the more recent NFR associated with a lower chance of approval. Following our investment decision model, the lower chances of approval might dampen investors' expectations, leading to a further reduction in new applications. Further qualitative analysis would be helpful to determine the reasons and causes behind the authorisation refusals in order to detect common patterns or shortcomings that could prove useful in the potential future monitoring and revision of the actual NFR.

Finally, it should be kept in mind that the probability of acceptance under the new NFR might be biased by its short enforcement period, as several applications made since 2018 are still pending. More-problematic applications will likely undergo a longer authorisation process because the EFSA may request additional data from applicants. Whether a long-lasting decision could bring to a higher or lower acceptance rate remains unknown.

7 | CONCLUDING REMARKS

In this study, we investigated the relationships between regulations and innovations via firm investment decisions. Our results suggest that the relatively stable number of NF applications between 1997 and 2017 suddenly spiked after the implementation of Regulation (EU) 2015/2283 in 2018. Following our theoretical model, we interpret this upsurge as a reduction in the real option value of postponing investments that were already in the innovation pipeline. This lower real option value resulted from stakeholders' expectations of improved efficiency due to the new NFR fostered by the introduction of a transitional regime and of a 5-year data protection measures.

We also demonstrate a decreasing trend in quick authorisation procedures (i.e. within 1 or 2 years), paired with a stagnant dynamic in applications successfully processed within 3–4 years. Moreover, while the overall speed of the process showed signs of improvement in the later years of the old NFR, there seem to be no substantial improvements under Regulation (EU) 2015/2283. Although the latter was explicitly aimed at simplifying the authorisation procedures, we argue that the extent to which such improvement could occur was necessarily limited by the boundaries of the NF regulatory framework, specifically the precautionary and risk analysis principles. On the other hand, the recent surge in applications may have also generated operational bottlenecks, yielding underwhelming waiting times under the new NFR. Finally, our empirical evidence suggests that the approval rate dropped by about 20% under Regulation (EU) 2015/2283 compared to the previous NFR, even after controlling for applicant characteristics. We expect these dynamics to negatively impact invertors' expectations and increase uncertainties, leading to higher chances of postponing investments in novel foods.

It is worth stressing that our research was limited by the publicly available data on NFs. Although the European Commission lists them in the so-called 'Union list' of NFs, this list only provides the name and specifications of each product without mentioning the date of application or authorisation, or the name of the applicant. Although we thoroughly collected timing data for each NF from among different sources (the European Commission website, EFSA Register of Questions and the relevant literature), the dataset still has a few gaps, as it is not mandatory to release the dates of the various procedural authorisation 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 (EU) 2015/2283 should be re-evaluated 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 among expected length, liability and uncertainty, it is difficult to identify which determinant contributed most to the observed dynamics in the number of applications. It may also be possible to compare the same or similar products authorised under different legislations, such as in Canada, the United States, or even the United Kingdom after 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 discrimination against non-industrialised countries. This approach would provide critical information to harmonise food policies with respect to reducing approval costs without undermining food safety.

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