

# **European Novel Foods Policy at a Critical Juncture:**

*Drawing lessons for future Novel Food Governance  
through a retrospective examination of Regulation 258/97*

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## **ABSTRACT**

*This paper presents a timely analysis of the European Union (EU) Novel Foods Regulation EC 258/97, identifying trends in the policy process and the applications that have been made under the regulation. The ways that the Novel Foods Regulation has functioned to govern new foods placed on the European market is considered, and a number of important trends are described. A historical account of EU policy regarding novel foods is presented, including an analysis of the changes to Novel Foods Regulation and an analysis of data drawn from the European Commission's own records of novel foods applications is conducted. The ways Novel Foods Regulation has functioned to govern new foods placed on the European market is revealed. A number of important trends in full applications are explored, along with substantial equivalence applications and unapproved foods that are placed on the market. This data is used to analyze the empirical legitimacy of the recent amendments to EU novel foods governance which will come into force in 2018, suggesting that change was needed, and supports the centralizing approach taken by the Commission. However, the analysis identifies potential risks and uncertainties in recent amendments to EU novel foods governance and considers the challenges of Brexit to the novel foods regime.*

(1) Whereas differences between national laws relating to novel foods or food ingredients may hinder the free movement of foodstuffs; whereas they may create conditions of unfair competition, thereby directly affecting the functioning of the internal market;

(2) Whereas, in order to protect public health, it is necessary to ensure that novel foods and novel food ingredients are subject to a single safety assessment through a Community procedure before they are placed on the market within the Community.

*Preamble, Commission Regulation 258/97.*

## INTRODUCTION

The regulation of the production and marketing of food, in the broadest sense, is a central activity of the European Union (EU).<sup>1</sup> Food regulation is harmonized so that food products can circulate freely in the single market. One area that is harmonized is the law governing how newly developed or newly discovered foods gain entry into the market. Whilst EU food law in general has been the subject of significant academic scrutiny, the law concerning these novel foods has been less widely covered.<sup>2</sup>

Regulation 258/97 of the European Parliament and of the Council of January 27, 1997, concerning novel foods and novel food ingredients, commonly referred to as the “Novel Foods Regulation” (NFR) provides a framework for the entry of new food products into the European market. Novel foods are defined as those that have “not hitherto been used for human consumption to a significant degree within the [EU].”<sup>3</sup> The preamble to the regulation sets out two goals.<sup>4</sup>

Recital (1) provides that national differences in novel foods regulation may damage the function of the internal market, and therefore an EU novel foods regulation is necessary to ensure that new foods are able to freely access the European Single Market.<sup>5</sup> Further, the necessity of ensuring that food can access the market reflects the EU’s significant emphasis and investment in food technology research and development.<sup>6</sup> The EU sees such investment as necessary to ensure

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<sup>1</sup> See, e.g., CAOIMHIN MACMAOLÁIN, *EU FOOD LAW: PROTECTING CONSUMERS AND HEALTH IN A COMMON MARKET* (2007); CAOIMHIN MACMAOLÁIN, *FOOD LAW: NATIONAL, EUROPEAN AND INTERNATIONAL PERSPECTIVES* (2015).

<sup>2</sup> Particularly following the removal of GMO’s from the scope of the regulation. Commission Regulation 1829/6, 2003 O.J. (327) 38.

<sup>3</sup> Commission Regulation 258/97, 1997 O.J. (L 43), 1(2), repeated by Commission Regulation 2015/2283 O.J. (327) 2(a). The ECJ in Case C-211/03, *HLH Warenvertriebs GmBh and Orthica VB v. Bundesrepublik Deutschland*, Case C-299/03 and Case C316/03-C318/03 2005 E.C.R. I-5141 83 confirmed that “human consumption” in this context means “ingestion by humans.”

<sup>4</sup> See Case C-236/01, *Monsanto Agricoltura Italia*, 2003 E.C.R. I-08105.

<sup>5</sup> Reflecting the preamble to the Treaty on the Functioning of the European Union, which commits the parties “to the progressive abolition of restrictions on international trade.” It is important to note that the “novel foods area,” where a single process will operate, is expanding to cover European Neighborhood countries. See e.g., Council Decision 2016/877, 2016 O.J. (L 145/24); see Tom Casier, *To Adopt or Not to Adopt: Explaining Selective Rule Transfer under the European Neighbourhood Policy*, 33 J. EUR. Integration 37 (2011).

<sup>6</sup> See Commission Regulation 2283, 2015 J.O. (29), which provides that “new technologies and innovations in food production should be encouraged.” As an example of the emphasis placed on research and development in the food sphere, see funding calls in the European Commission Horizon 2020 program. Horizon 2020, EURO. COMM’N, <https://ec.europa.eu/programmes/horizon2020/> (last visited July

food security, encourage greener environments, and provide economic and social benefits to consumers.<sup>7</sup>

Recital (2) provides that novel foods should be subject to scrutiny in order to protect public health and should not be allowed to enter the market if they are unsafe. This goal reflects the central rationale of the Directorate-General for Health and Consumers (DG SANCO)<sup>8</sup> the Directorate of the European Commission (“the Commission”), with responsibility for novel foods policy. The EU’s internal market will not work to benefit consumers unless there are appropriate protections for the public and for consumers.<sup>9</sup> These two goals, market access and consumer safety, are yardsticks that assess the success of novel foods policy in the EU.

Carrying out an assessment of whether the NFR has achieved these goals could not be timelier. Novel foods governance in Europe is in the process of being reshaped. The new Novel Foods Regulation 2015/2283 will come into force on January 1, 2018, and it is claimed that this will reinvigorate novel food governance and address some of the many perceived failings of the existing regulation. Furthermore, the United Kingdom’s (UK) probable exit from the EU<sup>10</sup> following the results of the referendum of June 23, 2016, will leave the EU without a Member State that has made a key contribution to both the development and implementation of novel foods policy. Therefore, novel foods policy in Europe (and in the UK) is at a critical juncture. This paper seeks to inform and critically comment upon policy and legal developments, providing insight into future developments by examining the past. Although a valuable policy impact assessment was carried out by the European Commission in 2007, this paper’s analysis was conducted for a specific purpose and does not provide a complete landscape of the application process. However, this important gap is addressed below.

This paper analyses the EU’s past novel foods policy through the lens of three datasets, full applications for approval submitted during nearly twenty years of operation of the NFR, substantial equivalence applications submitted during the nearly twenty years of operation of the NFR, and unapproved novel foods that have been placed on the market. The detailed and rich dataset on the operation of a key European food policy is used to consider whether the policy goals identified in the recitals have been achieved. Combining this analysis with an account of the

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8, 2017). *See also* MASSIMILIANO GRANIERI & ANDREA RENDA, *INNOVATION LAW AND POLICY IN THE EUROPEAN UNION: TOWARDS HORIZON 2020* (2012).

<sup>7</sup> Commission Regulation, 2283, 2015 J.O. (29).

<sup>8</sup> For discussion of the evolution of D-G SANCO, *see* Erik Millstone & Patrick Van Zwanenberg, *The Evolution of Food Safety Policy-making Institutions in the UK, EU and Codex Alimentarius*, 36 *SOC. POL’Y & ADMIN.* 593, 603–04 (2012).

<sup>9</sup> *See generally* Iain Ramsay, *Regulation and the constitution of the Single Market: the Role of Consumer Law*, 50 *CANADIAN BUS. L. J.* 322 (2010).

<sup>10</sup> The UK government notified the European Council of its intention to withdraw in accordance with Treaty of European Union art. 50 on 29<sup>th</sup> March 2017. Further, it is not clear whether the UK will remain a member of the EEA, and therefore a part of the European Single Market, (a so-called “soft-Brexit”), although this seems unlikely, or whether the UK will no longer be a member of the single market (a so-called “hard-Brexit”). For general discussion of the effect of Brexit on UK Food Policy, *see* Tim Lang & Victoria Schoen, *FOOD, THE UK AND THE EU: BREXIT OR BREMAIN* (2016), <http://foodresearch.org.uk/wp-content/uploads/2016/03/Food-and-Brexit-briefing-paper-2.pdf>. The possibility that different parts of the UK could have different relationships with the EU, and the consequences for novel foods policy are not addressed in this paper.

development of novel foods policy in the EU and a theoretical examination of the need for novel foods regulation, allows this paper to consider the empirical legitimacy of the changes to the NFR, whether the criticisms of the NFR are justified, the risks and opportunities of the new regime, and the potential challenges posed by the new regulation and the probable British exit from the EU.

## I. METHODOLOGY

This paper focused on the analysis of open access data on the operation of the NFR, collected and made available by the European Commission (EC), specifically the data collated by DG SANCO. The EU publishes a record of all full applications for novel foods approval<sup>11</sup> and all substantial equivalence notifications.<sup>12</sup> The data was gathered in early 2014. The status of the applications was analyzed as it appears in the data kept by the EU.

The data contained in these records was coded in accordance with the characteristics of the approval or notification.<sup>13</sup> After the data was coded, descriptive analysis was performed using Microsoft Excel. Where data was missing, the applications have been omitted from this analysis.

The full applications dataset consists of 145 applications. Of the 145 applications, the majority of applicants are large agri-food or biotech businesses (e.g. Monsanto, Cargill, Novartis, Coca-Cola, and Kellogg's). However, applications have been made by or on behalf of academic researchers and primary producers. Some applications are submitted by the food business itself, and some are submitted by agents on its behalf. The agent may be a food consultant or a legal practitioner. Applications are submitted from both inside and outside the EU, with 82 applications made by legal entities based within the EU (mostly businesses), and 63 applications made by legal entities based outside the EU. The most common base for non-EU organizations was the USA, with 30 applications submitted by U.S. businesses, followed by Switzerland with almost half of that number (n=14). The substantial equivalence dataset consisted of 296 applications. These applications were submitted by a variety of businesses, with more Small and Medium-sized Enterprise (SME) applications than the full applications dataset.

Data concerning notifications of novel foods placed on the market without approval was captured from the Rapid Alert System for Food and Feed (RASFF) database<sup>14</sup> on March 31st, 2014. Competent authorities within Member States must make notifications of unapproved foods on the market to the Commission.<sup>15</sup> This is

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<sup>11</sup> EUR. COMM'N NOVEL FOOD, [http://ec.europa.eu/food/food/biotechnology/novelfood/app\\_list\\_en.pdf](http://ec.europa.eu/food/food/biotechnology/novelfood/app_list_en.pdf) (last visited June 17, 2017).

<sup>12</sup> *Id.*

<sup>13</sup> Internal consistency was ensured with coding performed by multiple coders, with agreement reached regarding appropriate codes.

<sup>14</sup> Details on RASFF database, a mechanism for storing and sharing information regarding non-compliance with food regulation established by Commission Regulation 178, 2002 J.O. (50), <https://webgate.ec.europa.eu/rasff-window/portal/> (last visited June, 17 2017). For a discussion of RASFF, see Richard Hyde & Ashley Savage, *Cross-Border Concerns: Perils and Possibilities*, 2 E-JOURNAL OF INT'L & COMP. LABOUR STUDS. (2013).

<sup>15</sup> There are currently 28 Member States of the EU, although this number will drop to 27 when the UK leaves the EU.

then placed on the database. The database was created pursuant to Regulation 178/2002, and has only been in operation since 2004. Therefore, data regarding unapproved food on the market was only analyzed over a ten-year period (January, 2004 to March, 2014). This data was coded using Microsoft Excel and a descriptive analysis was performed.

## II. NOVEL FOODS POLICY IN THE EU

### *A. Developing Novel Foods Policy in the European Union*

It is necessary that a policy on the introduction of novel foods into the market is adopted. Whilst it is possible to adopt an approach which allows free entry of novel foods into the market, most jurisdictions have chosen to implement some form of regulatory regime.<sup>16</sup>

The NFR was adopted on January 27, 1997, to provide a harmonized procedure for novel foods marketing to allow market access and protect public health through the uniform safety assessment of foods that are placed on the European market.<sup>17</sup> Prior to this Member States were responsible for approving novel foods.<sup>18</sup> Some Member States had complex processes, and some had none. Therefore, it was necessary to harmonize mechanisms for novel foods approval to ensure that novel foods could circulate freely in the single market.

Almost as soon as the NFR came into force, it faced significant challenges and criticisms resulting in substantive changes to the scope and assessment process and a failed legislative proposal for amendments (discussed below in 3.1 and 3.2). In December 2013, the Commission adopted a legislative proposal to amend the NFR for the second time, which was approved in accordance with the ordinary legislative procedure on November 25, 2015, and is due to come into force on January 1, 2018.

### *B. The NFR*

When the NFR was established in 1997, “novel foods” was defined as foods and food ingredients with no significant history of consumption in the EU (prior to 1997) which fell under the six categories outlined in Table 1.<sup>19</sup>

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<sup>16</sup> See e.g., Juan Sun, *The Regulation of Novel Food in China: The Tendency of Deregulation* 6 EUR. FOOD & FEED L. REV. 442 (2015); Anu Lähteenmäki-Uutela, *Foodstuffs and medicines as legal categories in the EU and China* (Doctoral thesis, University of Turku 2009) <https://oa.doria.fi/handle/10024/52491>; James H. Maryanski, *Special Challenges of Novel Foods*, 45 FOOD DRUG COSM. L.J. 545 (1990); Marion Healy, Simon Brooke-Taylor & Peter Liehne, *Reform of food regulation in Australia and New Zealand*, 14 FOOD CONTROL 357 (2013); *Australia New Zealand Food Standards Code Standard – Novel Foods*, 2013, 1.5.1 (Aust.); In Canada, see Food and Drugs Regulation B.28.001-B.28.003, C.R.C. c. 870 (Can.).

<sup>17</sup> Guido Kayaert, *The European Market for Food Products*, 51 FOOD & DRUG L.J. 717, 721 (1996).

<sup>18</sup> See, e.g., the UK Food Safety Act 1990 section 18(1)(a) which provides that “Ministers may by regulations make provision . . . for prohibiting the carrying out of commercial operations with respect to novel foods . . .”; See J. Robert Bradgate & Geraint G Howells, *Food Law in the United Kingdom*, 46 FOOD DRUG COSM. L.J. 447 (1991) 459–60. However, rather than making regulations under the Act a voluntary scheme operated in the UK until the implementation of Directive 258/97 (Discussed briefly in Rosa K. Pawley, *Genetically Modified Foods*, in *Molecular Biology and Biotechnology* 262–65 (2000).

<sup>19</sup> Commission Regulation 258/97, art. 1(2), (1997) J.O. (L 43) 1.

**Table 1: The Six Categories of Novel Foods Covered by the NFR 1997**

Covered by NFR in 1997	Removed from NFR by Regulation 1829/2003	Class (a): foods and food ingredients containing or consisting of genetically modified organisms
		Class (b): foods and food ingredients produced from, but not containing, genetically modified organisms
	Remaining in the NFR to date	Class (c): foods and food ingredients with a new or intentionally modified primary molecular structure
		Class (d): foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae
		Class (e): foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals
		Class (f): foods and food ingredients to which a currently unused production process has been applied, and that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism, or level of undesirable substances

To market a novel food, the applicant must prepare a dossier adhering to guidelines specified in the Commission Recommendation (European Commission, 1997). This dossier is then submitted to a competent authority in a Member State. The Member State has 90 days to complete a safety assessment and, if no objections are found, will forward the application to the Commission for Union approval. The Commission then circulates the application to all Member States, who have 60 days to raise science-based objections. If no objections are raised, the Member State will inform the applicant of the opinion, and if approved, the product can be marketed across the EU. If objections are raised by one or more Member States, the application may be forwarded to European Food Safety Authority (EFSA) for an additional assessment.<sup>20</sup> The EFSA safety assessment is then considered by Member States at the Standing Committee for the Food Chain and Animal Health and a decision is made by a qualified majority vote.

A novel food may be marketed through a simplified *notification procedure* if it is considered to be “substantially equivalent”<sup>21</sup> to a similar product already available on the EU market. The applicant requests an opinion from the Member State authority

<sup>20</sup> Before EFSA was established in 2003, if a Member State raised an objection, the Standing Committee for Food (constituted with representatives from all Member States) made a decision on a qualified majority vote with advice from the Scientific Committee for Food (*see* Bevan E. B. Moseley, *The safety and social acceptance of novel foods* 50 INT’L J. OF FOOD MICROBIOLOGY 25, 29 (1999)).

<sup>21</sup> The concept of substantial equivalence means that the product in question is substantially equivalent to an existing food or food ingredient with respect to composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein (Commission Regulation 258/97, art. 3(4), (1997) O.J. (L 43) 1). In C-236/01 *Monsanto Agricoltura Italia*, *supra* note 4, the ECJ concluded that a product not substantially equivalent to human health would not be equivalent, and that the precautionary principle applied to the assessment of potential risks to health. Therefore, a GMO could not be substantively equivalent to a non-GM product already on the market, or even a GMO that had previously been through a safety assessment.

to establish substantial equivalence and then notifies the Commission directly. An open access online register of these notifications is available through an EU portal.<sup>22</sup>

### *C. Amendments to the NFR Since 1997*

The NFR has been amended three times since 1997 (see Figure 1). The first two amendments came in 2003 following the significant public backlash against Genetically Modified (GM) crops and foods.<sup>23</sup> First, Regulation 1882/2003 empowered the Standing Committee on Food Chain and Animal Health, set up by article 58 of Regulation 178/2002,<sup>24</sup> to assist the Commission before approval of a novel food.<sup>25</sup> However the more significant change came with Regulation 1829/2003, which reduced the scope of the NFR by removing GM foods from the definition of novel food (see Table 1). The third and final amendment was made in 2008 by Regulation 1332/2008, removing food enzymes from the NFR.<sup>26</sup> In addition to these legislative amendments, the NFR was subject to the EU's "good governance" agenda: the General Food Law Regulation established the centralized EFSA, a scientific body with a remit for food safety.<sup>27</sup> Since its establishment, EFSA has been playing an ever-increasing role in novel food governance<sup>28</sup> (for example, through provision of scientific opinions on applications or on matters related to novel foods such as animal cloning for food production).

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<sup>22</sup> *What is Novel Food?*, EUR. COMM'N, [http://ec.europa.eu/food/food/biotechnology/novelfood/notif\\_list\\_en.pdf](http://ec.europa.eu/food/food/biotechnology/novelfood/notif_list_en.pdf) (last visited June 17, 2017).

<sup>23</sup> See David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law*, 30 YALE J. INT'L L. 81, 86–90 (2005) (an account of the events leading to the implementation of changes to the NFR). For a contemporary account of the proposal for what became Regulation 1829/2003, see, e.g., Joanne Scott, *European Regulation of GMOs and the WTO*, 9 COLUM. J. EUR. L. 213 (2003).

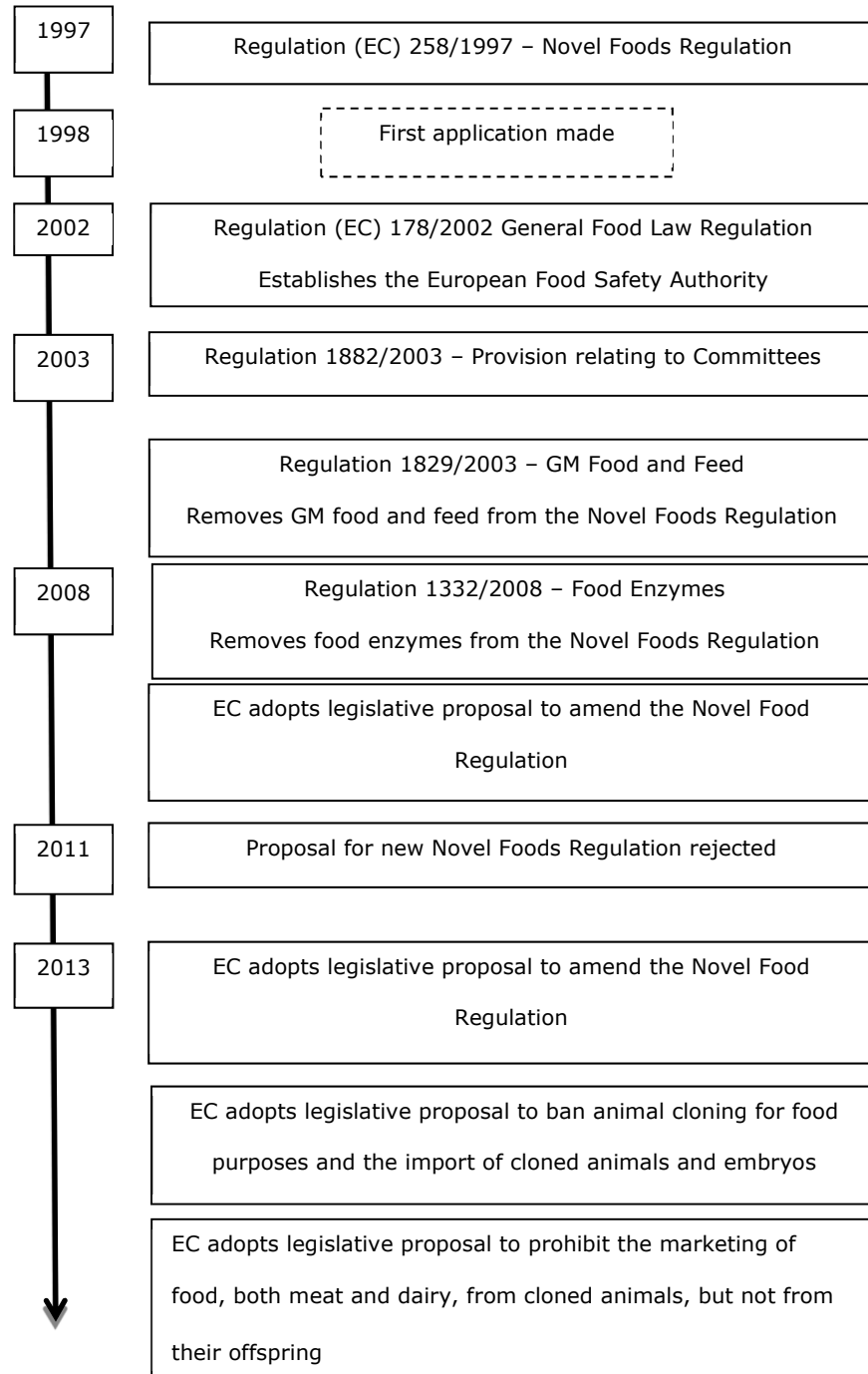
<sup>24</sup> Commission Regulation 178, 2002 J.O. (L 268) 1 (laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ('the General Food Law Regulation').

<sup>25</sup> Commission Regulation 1882, 2003 J.O. (L 284) adapting to Council Decision 468, 1998 J.O. (184) the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in the European Community Treaty annex II, art. 251 (70).

<sup>26</sup> Commission Regulation 1332, art. 23, 2008 J.O. (L 354).

<sup>27</sup> Commission Regulation 178, *supra* note 24.

<sup>28</sup> For a general account of the role of EFSA, see ALBERTO ALEMANNI & SIMONE GABBI, FOUNDATIONS OF EU FOOD LAW AND POLICY: TEN YEARS OF THE EUROPEAN FOOD SAFETY AUTHORITY (2014).

**Figure 1: Amendments and Revisions to the NFR, 1997–2014**



Despite these amendments, the food industry, third country exporters, consumer groups, and researchers have levied significant procedural and substantive criticisms against the NFR with pressure for fundamental reform starting in the early 2000s.<sup>29</sup> One notable concern was that the NFR was designed to address GM foods,<sup>30</sup> yet once GM foods were removed from the NFR in 2003, the regulations were not appropriately amended. This led to concerns that the NFR imposed too high a level of scrutiny on foods that were not as risky as the GM foods that the drafters intended to target. For example, during the discussion of the NFR at the 2006 WTO Sanitary and Phytosanitary Measures Committee meeting, Colombia, Ecuador, and Peru argued the NFR was designed primarily to deal with new technologies (such as GM) yet this legislation was affecting their ability to export small exotic traditional foods to the EU.<sup>31</sup>

The most common criticisms levied against the NFR center on regulatory uncertainty, significant costs, and long approval times, all of which are claimed to threaten innovation.<sup>32</sup> In public consultations, an overwhelming majority of the food and food-related industries called for a centralized authorization system to depoliticize and speed up the process.<sup>33</sup> For example, Pen & Tec Consulting of Spain stated that “[d]ecentralised procedures are slow and bureaucratic. Centralised procedures are faster, more efficient and fairer.”<sup>34</sup> An element of this criticism about costs and approval times focuses on the inequitable nature of this burden.<sup>35</sup> It is claimed that the huge cost involved marginalizes small applicants from underdeveloped countries, and only large companies with stable research budgets are able to consider applying as they can afford to collate the necessary scientific evidence required for regulatory approval. However, in a 2006 public consultation that involved 60 interested parties, one of the two consumer groups, the European Consumers’ Organization, raised concerns that the drive to speed up the process to stimulate innovation may compromise consumer protection.<sup>36</sup>

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<sup>29</sup> See European Commission ‘Draft Report on Impact Assessment for a Regulation Replacing Regulation (EC) No 258/97 on Novel Foods and Novel Food Ingredients, COM (2007) 872 Final (2008), [http://ec.europa.eu/food/food/biotechnology/novelfood/documents/novel-food\\_impact\\_assessment\\_en.pdf](http://ec.europa.eu/food/food/biotechnology/novelfood/documents/novel-food_impact_assessment_en.pdf). The criticisms are explored by Bruno Scarpa & Stafania Dalfra, *Regulating the Novel Foods Sector: Moving Forward*, 3 EUR. FOOD & FEED L. REV. 292, 292–95 (2008).

<sup>30</sup> This can be seen from the prominence of GM in the initial Commission proposal (*Proposal for a Council Regulation (EEC) on novel foods and novel food ingredients*, 1992 O.J. (C 190/3) recital (5) and art. 7) and the Opinion of the Economic And Social Committee (*Opinion of the Economic And Social Committee on the proposal for a Council Regulation (EEC) on novel foods and novel food ingredients*, 1993 O.J. (C 108/2).

<sup>31</sup> WTO, Summary of Discussions by the SPS Committee including debate on EU’s novel food regulation (Mar. 30, 2006), <http://www.reading.ac.uk/foodlaw/news/in-06001.htm>.

<sup>32</sup> See Chris Jones, *The Novel Food Regulation: Revisions Required - A View from a Regulator*, 7 EUR. FOOD & FEED L. REV. 81, 82 (2012) (“[T]he system is too lengthy and cumbersome and it is outdated.”).

<sup>33</sup> See European Commission, *supra* note 29.

<sup>34</sup> Directorate-General for Health and Consumers, ‘Responses to the Online Consultation on the revision of Novel Food regulation’ 2007 EC J.O. (L258) art. 97 (European Commission 2006), [http://ec.europa.eu/food/food/biotechnology/novelfood/resp\\_consult\\_258\\_97\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/resp_consult_258_97_en.htm).

<sup>35</sup> Anu Lähteenmäki-Uutela, *European Novel Food Legislation as a Restriction to Trade in 106th Seminar of the EAAE*, Presentation at the 106th EAAE Conference (Oct. 25-27, 2007).

<sup>36</sup> See Directorate-General for Health and Consumers, *supra* note 34.

Perhaps the most prominent criticism of the NFR addresses equity concerns about non-tariff barriers. If an applicant can demonstrate that food has a history of use within the EU prior to 1997, the food will not require authorization. However, foods with history of use outside the EU require authorization and must therefore go through the regulatory process. Food businesses who wish to place such foods on the market must go through the full approval process, demonstrating a history of safe food use.<sup>37</sup> This has resulted in a non-tariff trade barrier to countries outside the EU who try to market traditional foods, particularly for what is deemed to be exotic foods from the Global South.<sup>38</sup> Trade with the EU could play an important role in alleviating poverty in under-developed countries and encouraging investment in export supply chains, resulting in environmental and nutritional benefits from stimulation in innovation in tropical agri-biodiversity.<sup>39</sup>

Lastly, there have been disagreements about the role of science and the public policy process involved in novel food approvals. Industry organizations have called for a centralized authorization procedure as a means to depoliticize the NFR. However, this is in contrast with the views of consumer groups who have argued that regulators should take into account a broader range of factors, rather than just science, when determining Community acceptance of novel foods.<sup>40</sup>

#### *D. The Failed 2008 Legislative Proposal*

Shortly after the removal of GM foods from the NFR, the Commission recognized the need to refocus the NFR, address the concerns of non-EU countries about non-tariff trade barriers, and create a more favorable legislative environment for innovation.<sup>41</sup> Between 2002 and 2006, the Commission consulted Member States, held informal discussions with stakeholders, and initiated a public consultation. Finally, in January 2008, the Commission announced a legislative proposal to amend the NFR.<sup>42</sup> However, this proposal was not supported by the European Parliament due to ethical objections and public resistance to animal cloning in the food system.<sup>43</sup> Arguably, animal cloning presented the greatest challenge to the novel foods regime since the NFR's inception in 1997.<sup>44</sup> In the same month that the Commission

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<sup>37</sup> Anne Constable et al. *History of safe use as applied to the safety assessment of novel foods and foods derived from genetically modified organisms*, 45 *FOOD & CHEMICAL TOXICOLOGY* 2513 (2007).

<sup>38</sup> Michael Hermann, *The impact of the European Novel Food Regulation on trade and food innovation based on traditional plant foods from developing countries*, 34 *FOOD POLICY* 499 (2009); Lähteenmäki-Uutela, *supra* note 35; Nicole Coutrelis, *Regulatory Obstacles to the International Trade of Human Foods*, 1 *EUR. FOOD & FEED L. REV.* 220 (2006).

<sup>39</sup> Lähteenmäki-Uutela, *supra* note 35.

<sup>40</sup> Directorate-General for Health and Consumers, *supra* note 34.

<sup>41</sup> *Draft Report on Impact Assessment for a Regulation Replacing Regulation (EC) No 258/97 on Novel Foods and Novel Food Ingredients*, COM (2007) 872 final (2008).

<sup>42</sup> See Ina Gerstberger, *The Proposal for a Revised Novel Food Regulation - An Improvement for the Worse*, 2008 *EUR. FOOD & FEED L. REV.* 213; see also Scarpa & Dalfra, *supra* note 29, at 296–99.

<sup>43</sup> See *Recommendation for Second Reading, Explanation of Votes*, EUR. PARLIAMENT, <http://www.europarl.europa.eu/sides/getDoc.do?type=CRE&reference=20100707&secondRef=ITEM-009&language=EN&ring=A7-2010-0152#3-179> (last visited July 3, 2017).

<sup>44</sup> Ludvine Petetin, *The Revival of Modern Agricultural Biotechnology by the UK Government: What Role for Animal Cloning*, 6 *EUR. FOOD & FEED L. REV.* 296 (2012); Luis Gonzalez Vaque, *The Cloning of Animals for Farming Purposes in the EU: From Ethics to Agri-Food Law*, 4 *EUR. FOOD &*

announced the new proposal, the European Group on Ethics in Science and New Technologies (EGE) issued its opinion on the ethical aspects of animal cloning, claiming that animal cloning for food production purposes could not be justified.<sup>45</sup> In July 2008, EFSA issued its first opinion on animal cloning stating that there was no indication that cloned animals present any greater food risk than those reared through traditional breeding, although it did recognize that cloning presented significant risks to animal welfare.<sup>46</sup> In September 2008, based on social and ethical concerns, the European Parliament adopted a resolution calling on the EU to ban cloned animals and their offspring from food.<sup>47</sup> Disagreement between the Commission, Council, and Parliament on the issue of cloning led to stalemate, and the proposal was not adopted at the final Conciliation Committee meeting in March 2011.<sup>48</sup>

### *E. Regulation 2015/2283 on Novel Foods*

Following the failure of the 2008 package, in December 2013, Commissioner for Health Tonio Borg announced three new legislative proposals.<sup>49</sup> Two proposals addressed the ethical concerns related to animal cloning and banned animal cloning in the food system, importation of clones, and marketing of food from clones (although the progeny of clones do not fall under the scope of these proposals). The third proposal amends the NFR. Recognizing the challenges the NFR faced since its inception, Borg noted the new proposal would provide “legal certainty on these emotive issues.”<sup>50</sup>

Through the legislative process the proposals became Regulation 2015/2283 on Novel Foods.<sup>51</sup> The regulation reflects the EU focus on food innovation as a driver of economic development, and as with 258/97, attempts to balance innovation with

FEED L. REV. 223 (2014); Maria Weimer, *The Regulatory Challenge of Animal Cloning for Food - The Risks of Risk Regulation in the European Union*, 1 EUR. J. RISK REG. 31 (2010).

<sup>45</sup> EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES, ETHICAL ASPECTS OF ANIMAL CLONING FOR FOOD SUPPLY – OPINION NO. 23 (2008).

<sup>46</sup> *Opinion of the Scientific Committee of the on the 'European Food Safety Authority, Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer and their Offspring and Products Obtained from those Animals'*, 767 ESJF J. 3 (2008), <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2008.767/epdf>.

<sup>47</sup> *European Parliament urges commission to ban animal cloning for food supply*, CORDIS NEWS, (Sept. 4, 2008), [http://cordis.europa.eu/news/rcn/29825\\_en.html](http://cordis.europa.eu/news/rcn/29825_en.html); Conrad Brunk & Sarah Hartley, *Issues of Governance in Animal Biotechnology*, in DESIGNER ANIMALS: MAPPING THE ISSUES IN ANIMAL BIOTECHNOLOGY 236 (Conrad Brunk & Sarah Hartley eds., 2008).

<sup>48</sup> See 2008/0002(COD) - 29/03/2011 Final decision by Conciliation Committee, <http://www.europarl.europa.eu/oeil/popups/summary.do?id=1147521&t=e&l=en> (last visited July 3, 2016).

<sup>49</sup> *Proposal for a Regulation of the European Parliament and of the Council on Novel Foods*, COM (2013) 0894 final (Dec. 18, 2013); *Proposal for a Council Directive on the placing on the market of food from animal clones*, COM (2013) 0893 final (Dec. 18, 2013); *Proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes*, COM (2013) 0892 final (Dec. 18, 2013).

<sup>50</sup> Press Statement, Tonio Borg, Comm'r for Health, Press Room Statement on Cloning & Novel Food (Dec. 18, 2013), [http://europa.eu/rapid/press-release\\_SPEECH-13-1081\\_en.htm](http://europa.eu/rapid/press-release_SPEECH-13-1081_en.htm).

<sup>51</sup> See Patrick Coppens, *The Revision of the Novel Foods Regulation: Forget about Cloning and Nanotechnology, Let's Focus on the Scope*, 4 EUR. FOOD & FEED L. REV. 238 (2013); Christian Ballke, *The New Novel Food Regulation - Reform 2.0*, 5 EUR. FOOD & FEED L. REV. 285 (2014).

consumer protection.<sup>52</sup> The regulation will come into force on January 1, 2018,<sup>53</sup> although the regulation contains transitional provisions that govern applications for approval under Regulation 258/97 that have not been determined by this time.<sup>54</sup> The regulation lays out a prohibition on the marketing of unapproved novel foods (rather than leave the treatment of unapproved foods to the member states)<sup>55</sup> and creates a centralized authorization system.<sup>56</sup> It also introduces an EU list of generic novel food authorizations,<sup>57</sup> allowing businesses to judge whether their food falls within the generic list. The regulation provides clear timelines which aim to reduce the length of the authorization process from an average of three and a half years to 18 months,<sup>58</sup> aimed at ensuring innovation have a quicker path to market. The regulation also aims to incentivize innovation by providing applicants with an authorization to market the novel food for five years before it can be produced and marketed by others taking advantage of the possibility of placing substantially equivalent food onto the market.<sup>59</sup> Lastly, the regulation provides a simplified assessment process for placing traditional foods from third countries on the EU market provided that a history of safe food use in a non-EU state can be demonstrated,<sup>60</sup> responding to some criticisms that the novel foods approval process is a barrier to trade in traditional foods from the global south.

In addition, the proposal updates the definition of novel foods.<sup>61</sup> The expanded definition of novel foods enlarges the reach of the regulations, and in particular ensures that “food consisting of, isolated from or produced from material of mineral origin,”<sup>62</sup> “food consisting of, isolated from or produced from animals”<sup>63</sup> (and not just “food ingredients isolated from animals”<sup>64</sup>) and “food consisting of engineered

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<sup>52</sup> See Commission Regulation 2015/2283, 2015 O.J. (L 327) 1. The regulatory framework adopted mirrors the EU approach to regulation adopted. For example, Regulation 1924/2006 on nutrition and health claims made on food, places the role of approving novel foods at the European rather than national level.

<sup>53</sup> Commission Regulation 2015/2283, art. 34, 2015 O.J. (L 327) 1, 21.

<sup>54</sup> Commission Regulation 2015/2283, art. 35, 2015 O.J. (L 327) 1, 21.

<sup>55</sup> See Commission Regulation 2015/2283, art. 6(2), 2015 O.J. (L 327) 1, 9 (“[O]nly novel foods authorised and included in the Union list may be placed on the market within the Union.”). However, the sanctions for placing unapproved novel foods on the market remain for the Member States to determine.

<sup>56</sup> Commission Regulation 2015/2283, Chapter III, 2015 O.J. (L 327) 1, 11.

<sup>57</sup> Commission Regulation 2015/2283, art. 5, 6 & 8, 2015 O.J. (L 327) 1, 9–10.

<sup>58</sup> See Commission Regulation 2015/2238, art. 11(1), 12(1), 2015 O.J. (L 327) 1, 12 (EFSA has 9 months to provide an opinion and once this opinion is given the Commission has seven months to draft and submit an implementing act).

<sup>59</sup> Commission Regulation 2015/2283, art. 26(1), 2015 O.J. (L 327) 1, 18; See Martin Holle, *The Protection of Proprietary Data in Novel Foods - How to Make It Work*, 5 EUR. FOOD & FEED L. REV. 280 (2014).

<sup>60</sup> Commission Regulation 2015/2283, chapter III section II, 2015 O.J. (L 327) 1, 13–16.

<sup>61</sup> Commission Regulation 2015/2283, art. 3(2)(a), 2015 O.J. (L 327) 1, 7–8.

<sup>62</sup> Commission Regulation 2015/2283, art. 3(a)(iii), 2015 O.J. (L 327) 1, 7.

<sup>63</sup> Commission Regulation 2015/2283, art. 3(a)(v), 2015 O.J. (L 327) 1, 8.

<sup>64</sup> Commission Regulation 258/97, art. 1(e), 1997 O.J. (L 43) 4.

nanomaterials”<sup>65</sup> are covered by the novel foods regulation, and must be entered into the Union list before it can be placed on the market. The inclusion of “food consisting of, isolated from or produced from animals” is particularly important for food derived from insects,<sup>66</sup> as it has previously been the case that whole insects sold as food could enter the market without going through the novel foods process, but ingredients isolated from insects had to be assessed under the novel foods procedure. From 2018, whole insects will have to undergo the process under Regulation 2283/2015.<sup>67</sup>

The existing simplified notification procedure based on the concept of substantial equivalence would be redundant, and applicants are to rely on the generic list to market an already authorized novel food in the EU, judging whether their product is equivalent to a food product on the list.<sup>68</sup> The responsibility for making that judgment is placed on operators, although they may consult the Member State “where they first intend to place the novel food.”<sup>69</sup>

The new regulation seeks to remedy some of the issues identified as problematic in regulation 258/97. However, in order to assess the new regulatory regime, and consider whether the changes will enable European novel foods policy to better meet its twin goals of consumer protection and market access, it is necessary to consider how regulation 258/97 functioned, and what this reveals about the future functioning of the 2015/2283.

### III. THE ROLE OF NOVEL FOODS IN SOCIETY

Food and diet play an important role in the construction of national and cultural identity, with diet being a persistent and shared characteristic.<sup>70</sup> Writers therefore define cuisine by geographical area (Italian, Indian, etc.), even though it is known that what is consumed changes over time.

Food develops through a process of trial and error, with ingredients used and combined. Cuisine is not fixed, but instead develops through the incorporation of culinary trends from diffuse and diverse sources.<sup>71</sup> New foods are introduced into the foodscape, becoming part of national diets. As Allison James notes, “cuisine bears the traces of trade, travel and, increasingly, of technology, so that food could more correctly be said to be constitutive of global rather than local cultures.”<sup>72</sup> Food

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<sup>65</sup> Commission Regulation 2015/2283, art. 3(a)(viii), 2015 O.J. (L 327) 1, 8.

<sup>66</sup> See Anu Lahteenmaki-Uutela & Nicole Grmelova, *European Law on Insects in Food and Feed*, 1 EUR. FOOD & FEED L. REV. 2 (2016).

<sup>67</sup> Commission Regulation 2015/2283, 2015 O.J. (L 327) 1, 2. Of course, where the whole insect has a history of safe food use in a third country the process under Commission Regulation 2015/2283, chapter III section II, 2015 O.J. (L 327) 1, 13 may be used.

<sup>68</sup> Commission Regulation 2015/2283, art. 4, 2015 O.J. (L 327) 1, 9. (“Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation.”).

<sup>69</sup> Commission Regulation 2015/2283, art. 4(2), 2015 O.J. (L 327) 1, 9.

<sup>70</sup> See Allison James, *How British is British food?*, in *FOOD, IDENTITY AND HEALTH* (Patricia Caplan ed., 1997).

<sup>71</sup> Theodore C. Bestor, *How Sushi went Global*, in *THE CULTURAL POLITICS OF FOOD AND EATING* (2005); See also James, *supra* note 70 (the development of high class ‘English’ cuisine in the 19th Century, which was heavily influenced by developments in French cooking).

<sup>72</sup> James, *supra* note 70, at 73.

evolves, with new ingredients introduced and utilized. Potatoes originated in South America; maize and tomatoes in Central America; and these once “novel foods” in Europe, now form an important part of the diet.<sup>73</sup> Of course, these foods were introduced at a time long predating the NFR.

Novel foods approval governs foods that are introduced by trade, travel, or technology, controlling the admission of foods into the foodscape that were not present in 1997. The mixing of “new” foods with existing foods creates something novel, which eventually becomes part of the cuisine. The novel foods process has the potential to impede the development of European cuisines, holding them in an idealized 1997, where anything introduced following this point is seen as untraditional and not part of the European cuisine. This classificatory othering of novel food ingredients has the potential to stifle development of new “traditional” foods by preventing market admission, where experimentation could lead to the development of new food traditions. This is why the presence or absence of the food on the European market in 1997 is so hotly contested;<sup>74</sup> if it can be shown that a food was on the market in 1997, that food or ingredient can continue to permeate food culture(s) naturally, percolating through the traditional means. For this reason, the treatment of traditional foods from outside Europe has proved controversial. Mixing of foods on a global scale has been a constant trade story throughout human history. However, mixing is significantly more difficult following the introduction of the novel foods process under regulation 258/97.

Of course, technological development can lead to risk, and governance of that risk is an inevitable consequence of the development of risk societies and regulatory states.<sup>75</sup> However, the novel foods approval process is argued to have incorrectly balanced the risks of food compared to rewards of increased diversity in European diets, particularly following the removal of GMOs from the scope of the regulations.<sup>76</sup> Some argue that the novel foods regulation contributes to a cultural, rather than scientific, conception of food risk—calling “novel” food risky despite the foodstuff having been consumed by humans without causing injury. Of course, cultural perceptions of safety are central to human perceptions of risk.<sup>77</sup> However, such cultural perceptions may lead to a novel foods regime that is too unwilling to let new products onto the market, leading to stasis in the foodscape. This argument must be analyzed, and consideration given to whether it is addressed by Regulation 2015/2283.

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<sup>73</sup> See HENRY HOBHOUSE, *SEEDS OF CHANGE: FIVE PLANTS THAT TRANSFORMED MANKIND* 191 (1985).

<sup>74</sup> See Case C-383/07, *M-K Europa GmBH & KG v. Stadt Regensburg*, 2009 E.C.R. I-115 (the facts underpinning the judgment).

<sup>75</sup> Karen Yeung, *The Regulatory State*, in *THE OXFORD HANDBOOK OF REGULATION* 64 (Robert Baldwin et al. eds., 2010).

<sup>76</sup> See above section C(III).

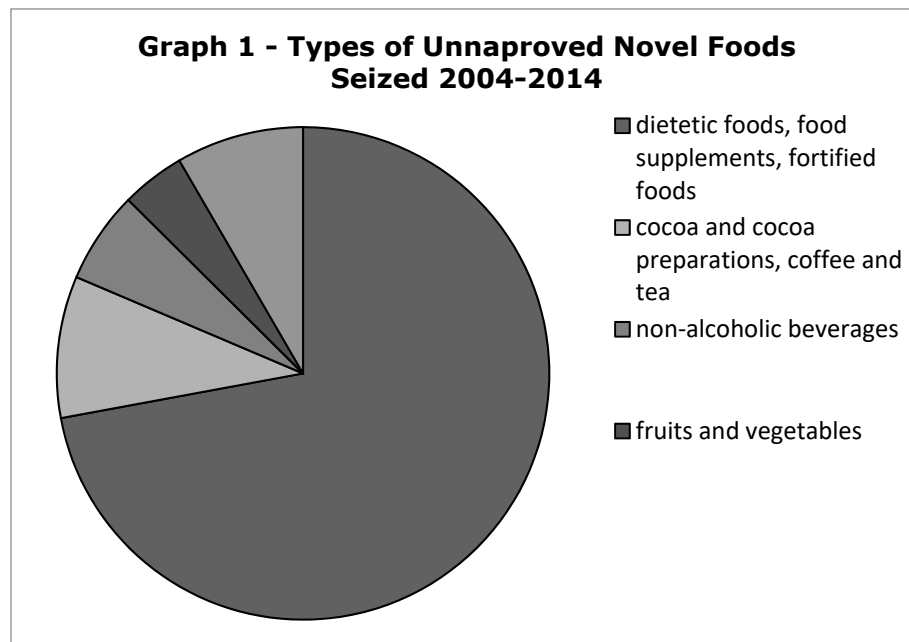
<sup>77</sup> Lyne Letourneau et al., *GM Foods Regulation: Coming to Terms with the Lay Conception of Risk*, 2 *FOOD STUDS*. 15 (2013).

#### IV. NOVEL FOOD POLICY ANALYSIS

Examining three datasets allows consideration of whether the novel foods policy, as set out in Regulation 258/97, has achieved its goals. Three key insights can be drawn from the data: the policy has failed to protect the public, the policy has failed to encourage innovation, and the policy of centralization is generally supported.

##### *A. The Policy Has Failed to Achieve the Consumer Safety Goal*

Since 2002, 215 notifications have been placed on the RASFF database concerning unauthorized novel foods appearing on the market in the EU. Graph 1 shows the types of unapproved foods that were discovered by regulators and taken off the market, with Table 2 showing the amount and percentage of total seizures.



**Table 2: Classes of Unapproved Foods Taken off the Market**

Food Type	Number of Seizures	Percentage of Seizures
alcoholic beverages	1	0.47%
cereals and bakery products	4	1.86%
cocoa and cocoa preparations, coffee and tea	20	9.30%
confectionery	1	0.47%
dietetic foods, food supplements, fortified foods	155	72.09%
fats and oils	1	0.47%
food additives and flavorings	1	0.47%
fruits and vegetables	9	4.19%
herbs and spices	6	2.79%
non-alcoholic beverages	13	6.05%
nuts, nut products and seeds	1	0.47%
other food product / mixed	1	0.47%
soups, broths, sauces and condiments	2	0.93%
Total	215	

The majority of notifications, 155 (72 percent), relate to foods within the dietetic foods, food supplements, and fortified foods category. Some supplements are regulated under Directive 2002/46 on Food Supplements; however, those that fall within the novel foods category tend to be those that fall outside the scope of the Supplements Directive. The other types of unapproved novel food that find their way onto the European market include cocoa, tea and coffee (n=20, 9 percent), and non-alcoholic beverages (n=13, 6 percent).

This suggests that the public may come into contact with unapproved novel foods, raising safety concerns. Novel foods are appearing on the market in greater proportions than applications are being submitted, although it must be remembered that a number of the notifications may relate to the same novel foods which are found on the market repeatedly. Unapproved food that appears on the market may be seized by regulators and taken off the market. The presence of unregulated novel foods on the market raises questions about the reasons for such regulatory non-compliance. Are food businesses taking the risk and knowingly placing unapproved food products on the market because of the challenges of the regulatory system, or are businesses inadvertently contravening the requirements for approval, placing food on the market believing it is approved or not knowing that there are approval requirements?

The literature suggests there are a number of reasons why importers of novel foods may be ignoring the NFR. First, regulatory uncertainty and the absence of comprehensive and reliable information about the status of traditional novel foods



vis-à-vis the NFR;<sup>78</sup> second, investments in marketing and supply-chain development; third, uncertainty about the novel food status of the product;<sup>79</sup> fourth, high administrative burden and cost<sup>80</sup> as “when a law is impossible to live by, it is not obeyed”;<sup>81</sup> and fifth, divergent implementation in Member States.<sup>82</sup> Whilst these factors need further empirical investigation, there is clear evidence of policy failure. Evidence to support the perception among potential applicants that regulatory uncertainty has discouraged applications was collected from a workshop on NFR revisions in Brussels in 2005.<sup>83</sup> However, it is not clear that these factors drive importers to circumvent the NFR.

Some of the notifications relate to foods that have either subsequently been authorized or could have been authorized through the substantial equivalence process (particularly Noni (n=22)), whilst others relate to products which have been through the process and have been refused (for example *stevia rebaudiana* which was refused access to the market by Commission Decision 2000/196). Of course, as the decision of the Court of Justice of the European Union (CJEU) in *C-327/09 Mensch und Natur AG v Freistaat Bayern* shows a Commission Decision refusing to approve a food in a particular case does not bind a later food business,<sup>84</sup> but Member States are likely to take into account the refusal when deciding whether a food is an unapproved novel food and should therefore be taken off the market. Other information is available to assist regulators with this decision, including the novel foods catalogue maintained by DG SANCO.<sup>85</sup>

### *B. The Policy Has Failed to Support Market Access*

Whilst the presence of unapproved foods suggests policy failure in terms of consumer protection, evidence also suggests failure to support market innovation. The full approval process is lengthy, costly, and approves a narrow range of products. The substantial equivalence procedure is used by limited product types. Novel products, produced by either technological or market innovation, such as importing a new product from an overseas market, are hindered in their path to the EU marketplace.

#### *1. Time*

The process from submission of application to the receipt of approval takes a significant amount of time. Where the application is approved, the mean length of time between receipt of application by the national body and the approval being granted by Commission Decision is 1,194 days (approximately 40 months), with a

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<sup>78</sup> Hermann, *supra* note 38; Lähtenmäki-Uutela, *supra* note 35.

<sup>79</sup> See C383/07 M-K Europa GmbH & Co. KG v Stadt Regensburg, *supra* note 74.

<sup>80</sup> See Hermann, *supra* note 38, at 505 (Phytotrade spent over £15,000 on its baobab application).

<sup>81</sup> Lähtenmäki-Uutela, *supra* note 35, at 13.

<sup>82</sup> Hermann, *supra* note 38.

<sup>83</sup> *Id.*

<sup>84</sup> Case C-327/09 Mensch und Natur AG v. Freistaat Bayern, 2011 E.C.R. 1-2897.

<sup>85</sup> *Novel Food Catalogue*, EUR. COMM’N (Nov. 6, 2017), [http://ec.europa.eu/food/food/biotechnology/novelfood/novel\\_food\\_catalogue\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/novel_food_catalogue_en.htm), (catalogue will cease to exist with the implementation of Regulation 2015/2283).

range between 267 days<sup>86</sup> and 3,523 days.<sup>87</sup> Michael Hermann criticizes the length of time that a novel foods approval takes,<sup>88</sup> although he does not give specific details of time lag. This criticism is supported by the examination of this dataset.

## 2. Cost

There is widespread variation in cost between different Member States. In the UK, the cost of a full application is £4,000;<sup>89</sup> in the Netherlands, the cost is €25,838;<sup>90</sup> in Belgium, the cost is €3,718.50.<sup>91</sup> In addition to the formal fees, the cost of preparing the dossier, including engaging in scientific tests required to prove that the novel food is safe, means that gaining approval to place the food onto the market is expensive.

The influence of these costs on the decision-making of food businesses is suggested by the correlation in the Netherlands between the rise in the cost of submitting an application and the decrease in the number of applications received. Only 8 out of 31 total applications were made after the increase in Dutch fees on January 2, 2008. Before the increase in fees, 26 percent of all full approval applications were made to the Netherlands, whereas after the rise in application fees only 13 percent of applications were made to the Netherlands. This drop is statistically significant ( $P > 0.95$ ;  $\Phi$ -test), suggesting that the fee may have had some effect on the decision to make an application to the competent authority in the Netherlands.

The increased application cost may mean that businesses engage in deviant behavior, placing food products on the market without approval, or decide that it is not economically viable to incur the cost necessary to gain approval. This may occur since the NFR does not provide any marketing protection for the business who incurs the cost, as a novel foods approval does not function like intellectual property (IP) protection. Approval does not afford the applicant a market advantage in relation to a particular food product (although novel foods approval may, of course, sit alongside proprietary biotechnology for which there is IP protection, patent protection in particular).<sup>92</sup> Indeed, some businesses may be disadvantaged as competitors can use substantial equivalence to gain marketing approval. This disincentive can be seen in the case of echium oil, where the application was withdrawn when initially made in 2000 because of a request for an expensive human feeding study, but approved in 2006 when a new application was made by a different company, who was informed

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<sup>86</sup> Lipid extract from *Euphausia superba*, application for approval submitted to the competent authority in Finland on 11th May 2011, approved on 2nd February 2012.

<sup>87</sup> 2 leaf extracts from *Lucerne*, application for approval submitted to the competent authority in France on 20th February 2000, approved on 13th October 2009.

<sup>88</sup> Hermann, *supra* note 38.

<sup>89</sup> Commission Regulation 1997/1336, art. 4.1, (1997), Novel Foods and Novel Food Ingredients (Fees) Regulations 1997.

<sup>90</sup> Warenwetregeling vaststelling van tarieven voor retributies levensmiddelen 2008 article 24.

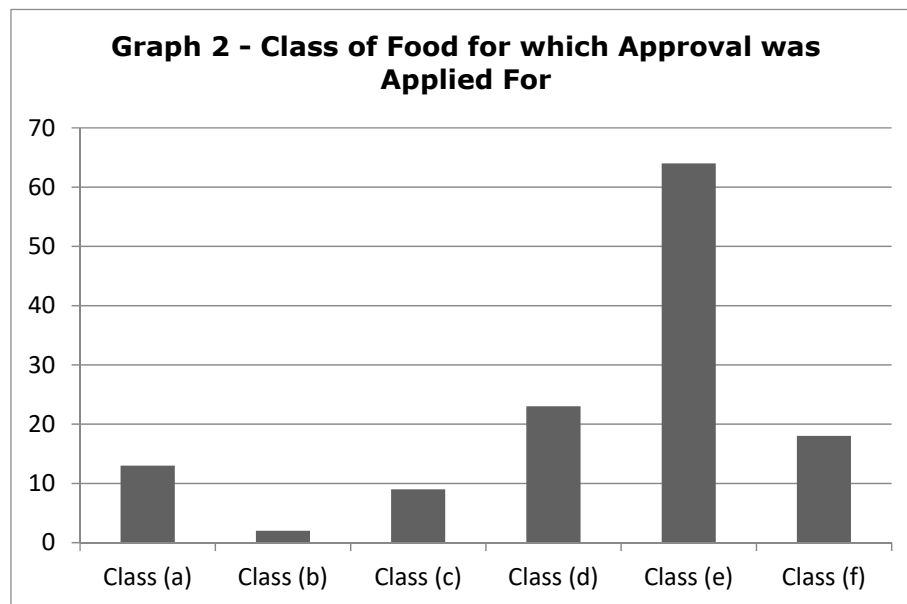
<sup>91</sup> *Health, Food chain safety, and Environment*, FED. PUB. SERV., [http://www.health.belgium.be/filestore/10136490/Information%20brochure%20on%20Novel%20Foods\\_10136490\\_en.pdf](http://www.health.belgium.be/filestore/10136490/Information%20brochure%20on%20Novel%20Foods_10136490_en.pdf) (last visited July 22, 2017).

<sup>92</sup> See Commission Regulation 1924/2006, 2006 O.J. (L 404) 13(5), 18. (There may also be associate health claims, which afford some level of propriety protection, as only the applicant will be aware of the scientific data necessary to utilize the health claim).

by the previous rejection that had conducted feeding studies.<sup>93</sup> In the initial application, the human feeding study was deemed too expensive, as competitors would be able to utilize the quicker and cheaper substantial equivalence provisions once the initial approval was granted.

### 3. *Narrow Range of Products Approved*

Applications have been submitted for all types of novel foods listed in the novel foods regulations. Graph 2 shows the food types for which applications were submitted for novel foods approval (submission up to June 25, 2012). Of the total 145 applications, the 15 applications which fall in classes (a) and (b) are no longer within the scope of the NFR (see Table 1.).



Classes (a) and (b) were removed from the scope of the regulations on April 18, 2004, with applications for GM food constituting 30 percent of applications in the period predating this analysis. Approval for food falling within Class (e) is by far the most common application, with 49.6 percent of all applications made falling within this category. This included foods such as chia seed, rooster comb extract, and coriander seed oil. It seems that the novel foods approval process is best suited to products within this class (although (e) is also the broadest of the four remaining classes).

### 4. *Simplified Procedure Utilized by Limited Product Types*

The Article 5 simplified procedure applies to two types of products that are substantially equivalent to foods that were on the market before 1997, and foods that

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<sup>93</sup> Letter from Julianne Lindemann, Ph.D., to Dr. Chris Jones (Jan. 14, 2009) (on file with Efficas) (Similarly, the letter of withdrawal of the application for approval of Kiwiberry Concentrate thanked the national body for “helpful . . . suggestions concerning the contents of the dossier.”).

are substantially equivalent to products that have received full approval under the Regulations. Between 1997 and June 2013, 296 applications were submitted under the simplified procedure. There were 217 applications that demonstrated substantial equivalence with a novel food approved under the full procedure, and 79 demonstrated substantial equivalence with a product on the market before the entry into force of the NFR.

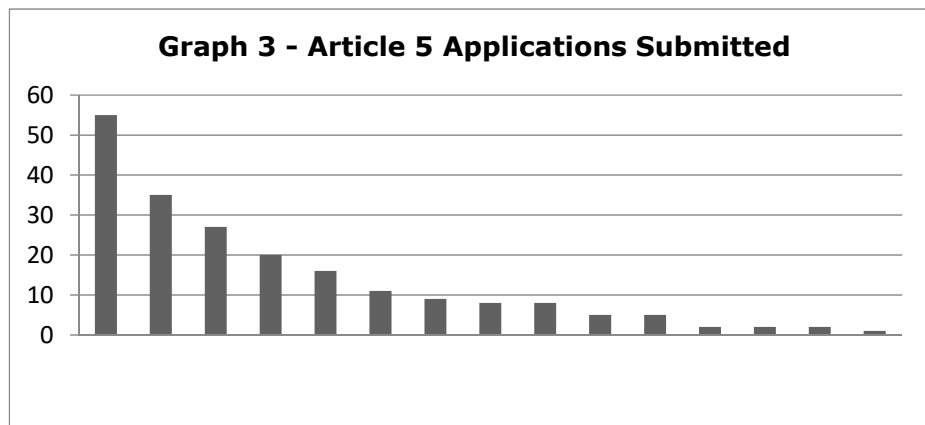
Applications for approval under Article 5 are dominated by 3 types of product. Over 75 percent (226 out of 296) of the Article 5 applications consisted of claims of substantial equivalence with three categories of food: argan oil (based on substantial equivalence with “other edible oils” that were on the market before 1997), Noni (based on substantial equivalence with Tahitian Noni juice and its purees and concentrates approved for the market by Commission Decisions 2003/426/EC and 2010/228/EU), and sterol esters (approved for use in different foods in a series of ten Commission decisions between 2000 and 2008). The use of the Article 5 procedure was much less common for other types of approved novel foods.

**Table 3: Use of the NFR Article 5 Procedure**

	Article 5 Approvals	Percentage of Article 5 Approvals
Sterol Esters	124	41.89%
Argan Oil	51	17.23%
Noni	51	17.23%
All Others	70	23.65%

The use of the Article 5 procedure is very uncommon where the application is based on novel food technology, as this technology is likely to be protected by intellectual property rights (particularly patents). Where such protection exists, it is difficult to show substantial equivalence as the technological specifications for the novel food will often not be available to an applicant under Article 5 as details will be confidential. Therefore, most applications are based on products which do not have proprietary protection.

The data available allowed the identification of the national bodies to which 206 of the applications were submitted.



France received the most substantial equivalence applications (n=55), which contrasts with the findings in relation to the full application procedure (reported below at 4.3.2). The large number of applications is almost entirely attributable to applications for the substantial equivalence of argan oil products. Eighty percent of the applications received by the French national authority related to argan oil (n=44). Argan oil is viewed in most of Europe as a cosmetic product, but is used as a food ingredient in North Africa.<sup>94</sup> In France, with a large North African population, there is a market for argan oil for use in food. As France is the primary market, it is unsurprising that many of the substantial equivalence applications are submitted there.

The simplified procedure is intended to be quicker. As well as being quicker, the simplified procedure is also cheaper. In the UK, the fee is £1,725 (43.1 percent of the fee for the full application);<sup>95</sup> in the Netherlands, the fee is €2,086 (8.1 percent of the fee for the full application). If a business is able to use the simplified procedure, then there are clear benefits of doing so, but this may negatively affect businesses that wish to bring traditional foods to market using the full procedure. Businesses who elect to use the full procedure may be hampered by businesses who decide to immediately utilize the simplified procedure to become competitors, expending a much smaller amount of money. As the full procedure affords no market protection, the presence of a simplified procedure may be a deterrent to those producers who are not able to obtain intellectual property protection for their novel food, as their initial application, involving expensive scientific evidence, becomes public goods once approved and can be utilized by all those businesses claiming equivalence.

Further, the data suggests that the simplified procedure does not support market access for innovative products, as the vast majority of products that have gained access via the procedure are limited in scope. It appears to be far easier to show substantial equivalence where many products of a similar type have also demonstrated such equivalence compared to business who are attempting to demonstrate equivalence for the first time.

### *C. Data Supports Centralization*

As well as providing evidence that the NFR has failed to fulfil its goals, the data provides support for the centralization of the regulatory function within the EU laid out in the new regulation.

#### *1. Results of Applications*

Table 4 shows the results of the full applications submitted in the period between 1997 and 2012. It shows the outcome of the applications made. Where the applications were approved or refused, the Commission issued a formal decision addressed to the applicant.

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<sup>94</sup> Travis J. Lybbert et al, *Booming markets for Moroccan argan oil appear to benefit some rural households while threatening the endemic argan forest*, 108 PNAS 13907 (2011); Yves le Polain de Waroux, *The social and environmental context of Argan Oil Production*, 8 NATURAL PRODUCT COMMS. 1 (2013).

<sup>95</sup> Commission Regulation 1997/1336, art. 4.1, (1997), Novel Foods and Novel Food Ingredients (Fees) Regulations 1997.

**Table 4: Results of Applications**

	EU Applicants	Non-EU Applicants	Grand Total
Approved	37	30	67
Not Yet Determined	23	18	41
Withdrawn	14	9	23
Refused	5	1	6
Not with Scope of Regulations - Dealt with Under GMO Regulations	1	3	4
Not within Scope of Regulations - Not Novel Food		1	1

There is no significant difference in the results of applications made by entities based inside or outside the EU. 46 percent of applications made from within the EU and 48 percent of applications made by non-EU applicants were approved in the period between 1997 and 2012. What is notable is the small number of refusals in this period, with only six products being unable to be placed on the market as a result of a decision by the national or EU authorities. There is no pattern amongst the refusals, but in all cases the applicants were unable to satisfy the authorities that the food would not pose unacceptable risks to consumers. The scientific dossier submitted was insufficient to satisfy the consumer safety standards set by the regulators.

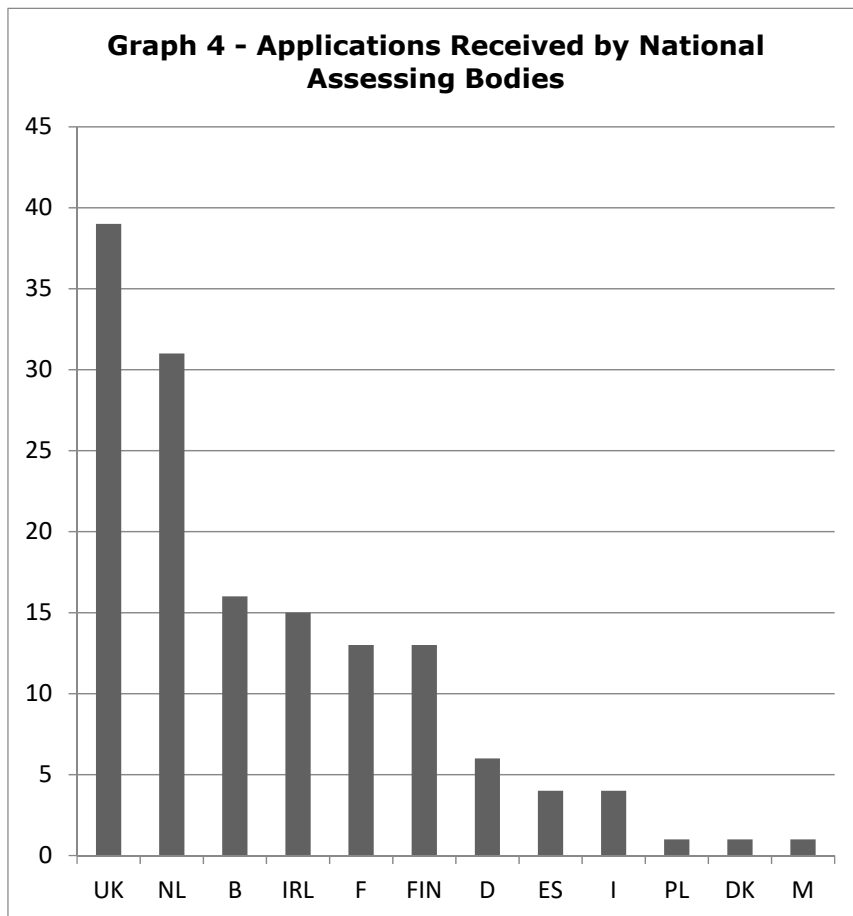
However, a large number of applications were withdrawn, and this can be seen as a preemptive step once it becomes clear that an approval will not be forthcoming. This step preserves the ability to apply for approval in the future if the submitted dossier can be improved in response to comments made by reviewers during the approval process.

There is no statistically significant difference in the results of applications submitted before the removal of GM foods from the regulation into the independent GM governance framework on April 18, 2004. Of the applications submitted prior to the removal of GM foods, 54 percent have been approved compared to 46 percent of applications submitted after the removal of GM foods. Just over a quarter (26 percent) of pre-removal applications were withdrawn (with five withdrawn applications relating to GM foods) whereas only 10.5 percent of applications have been withdrawn in the period following April 18, 2004. The lower approvals and withdrawals post-GM foods removal can be explained as many more applications (n=38) were submitted following the removal of GM foods that remain to be determined when compared to applications submitted prior to the GM foods removal (where only one remains outstanding).

### 2. Inequitable Regulatory Burdens

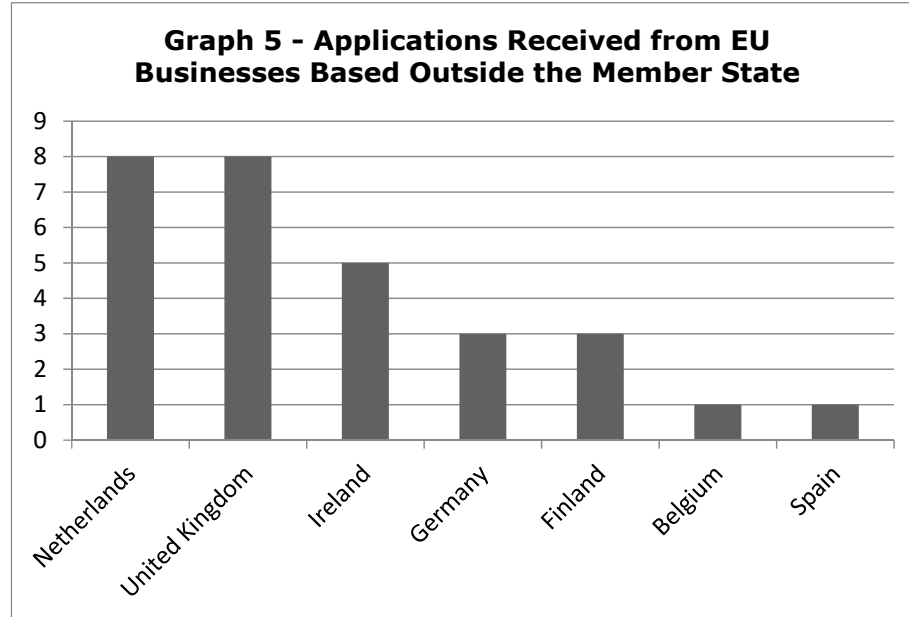
Inequitable regulatory burdens arise in two ways: pre-market and post-market regulatory burdens. Pre-market burdens arise from applications for approval submitted to national bodies. Post-market burdens arise when regulators take action in response to unapproved novel food present on the market.

Applications for approval must be submitted to competent national authorities. Graph 4 shows the countries that received the applications contained in the dataset. As mentioned previously, these national authorities are then responsible for the evaluation of the submission before it is submitted to the Commission and circulated.



The first thing to note is that the competent authorities of only 12 Member States out of 28 received full applications for novel foods approval. These are disproportionately weighted towards pre-2004 Member States, with only two applications made to Member States that acceded after the NFR was adopted (one application each received by Poland and Malta). The lack of applications to the new Member States is unsurprising given the perceived or actual regulatory, scientific, and administrative capacities of these States compared to the pre-expansion States.<sup>96</sup> In a complex regulatory network such as that governing food, these capacities can lead to particular national regulatory agencies assuming central roles in achieving the goals of the network, in this case the governance of novel foods.<sup>97</sup>

It is notable that the UK receives the highest number of novel food applications (n=39). This might be expected given the size of the UK's agri-business sector compared to other Member States. However, this presumes that the food businesses making the submissions are based within the Member State, and thus submitting applications to the national novel foods authority for that state. This is not demonstrated by the data. Only 35 percent (n=52) of the applications are made by a food business based within an EU state to that national body. Graph 5 shows which countries are being selected by EU food businesses when they make an application to a national body outside the Member State where they have their center of operations. A total of 29 applications were made by EU food businesses to national bodies other than the national body of the state in which they are based, with UK based food businesses most regularly submitting a novel foods application to a competent authority in a different EU Member State (n=9).

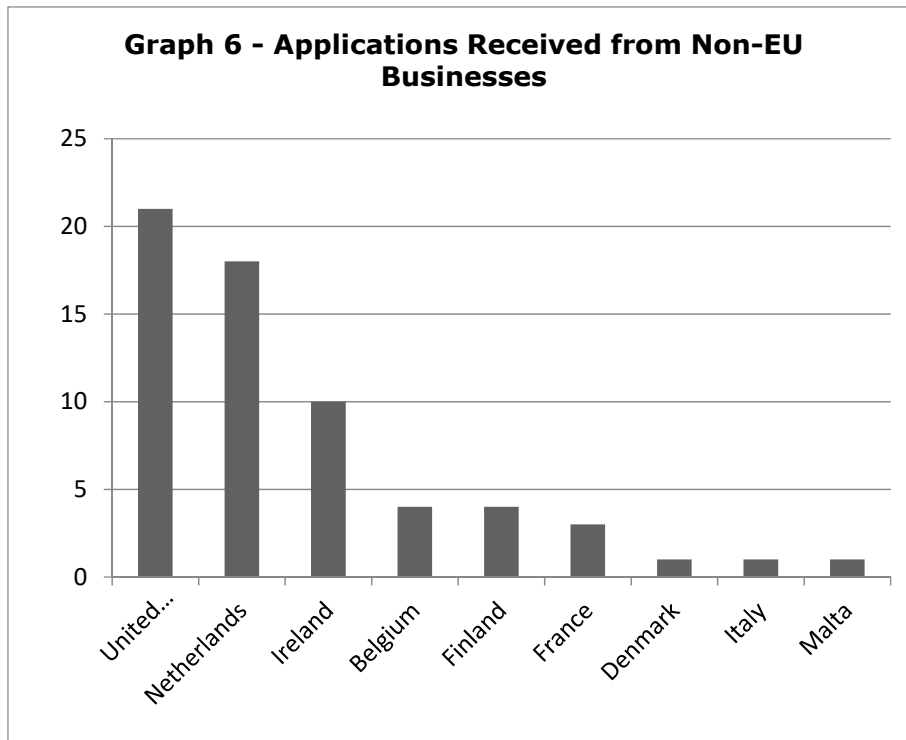


<sup>96</sup> Antoaneta Dimitrova, *Enlargement, Institution-Building and the EU's Administrative Capacity Requirement*, 25 WEST EUR. POLITICS 171 (2002).

<sup>97</sup> Julia Black, *The Decentred Regulatory State?*, in CRI REGULATORY REVIEW 2006/2007, 249–90 (Peter Vass ed., 2007).



The data shows that applicants favor the UK and the Netherlands and this trend is replicated within the dataset of 63 applications received from food businesses based outside the EU. The most prominent nationality of non-EU business was USA (n=30). Graph 6 sets out the number of non-EU applications received by each national authority.



The UK received the most applications from a business outside of their national jurisdiction (n=29) and the Netherlands received the second most with 26 applications. All other States received 38 non-State applications combined. Given the clear preference of non-national businesses for submission of novel food applications in the UK or the Netherlands, it is important to explore why this might have occurred. Specifically, why do non-EU applicants and intra-EU applicants who choose to submit outside their jurisdiction favor the UK and the Netherlands as the point of submission for novel foods applications? Why do the Member States bear inequitable regulatory burdens?

The first reason that can be proposed is language. First, English is the international language of science, and agri-food applicants may be choosing to submit applications to the UK as they work in this language when publishing their own research and preparing the scientific evidence base underpinning a novel foods application. Second, English may be the working language of the business.<sup>98</sup> When examining the applications, 60 percent (n=38) of the non-EU submissions came from

<sup>98</sup> The importance of this may be demonstrated by the Deer Horn Powder application, which was made by a Québécois company to the French national authority. Two leaf extracts from Lecurine, *supra* note 87.

applicants based in countries where English was an official language. This could explain the number of applications to the responsible bodies in the UK, and also the relative popularity of Ireland for non-EU applicants (n=15). Further, it is possible to submit an application to the responsible body in the Netherlands in English whereas, in contrast, it is not possible to make a submission in English to other countries, such as France.

The second reason that food businesses may be choosing to submit their application to the UK and the Netherlands could be that more favorable results are achieved in those jurisdictions compared to the rest of the EU. Table 5 examines the results of all applications submitted compared to applications submitted to the Netherlands and the UK. Applications made to both the UK and the Netherlands are more likely to succeed when compared to the European average, however neither variation is statistically significant ( $P > 0.90$ ;  $\Phi$ -test).

**Table 5: Application outcome for The Netherlands, UK and across the EU**

Result of Application	NL	UK	Pan-EU
Approved	51.61%	61.53%	49.31%
Not with Scope of Regulations - Dealt with Under GMO Regulations	9.68%		2.78%
Not Yet Determined	12.9%	23.08%	27.08%
Refused	0%	5.13%	4.86%
Withdrawn	25.8%	10.26%	15.28%

Third, the length of the review process may be a factor. This can be examined through consideration of the average lengths of time between submission and determination. Once applications that have missing data are removed, the length of time for determination can be calculated in 75 cases. In the Netherlands, the average length of time between submission and determination is 1,500 days (306 days more than the pan-European average) and in the UK the average is 986 days (208 days less than the pan-European average). Therefore, whilst the period between submission and determination may be a factor in the decision to choose the UK as the point of submission of a novel foods application, this factor cannot be an explanation for the high level of submissions to the Netherlands.

The fourth reason may be scientific expertise, particularly in biotechnology, which may be supported by the history of biotechnical innovations in a particular country. The UK has a large science base and, in the Advisory Committee on Novel Foods and Processes (ACNFP), an acknowledged expertise in the biosciences.<sup>99</sup> However, the preference for the UK and the Netherlands persists after the removal of GM from the scope of the regulations, meaning that the removal of these biotechnological products does not appear to affect the choice of State, and therefore suggesting that this is not a key factor.

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<sup>99</sup> Derek Burke, *Novel Foods: The Changing Regulatory Response*, in FOOD, SCIENCE AND SOCIETY: EXPLORING THE GAP BETWEEN EXPERT ADVICE AND INDIVIDUAL BEHAVIOUR, 127–42 (Peter S. Belton & Teresa Belton eds., 2003).

Other factors can also be suggested. Perhaps technology transfer partners who will use the novel food in other products are based in the chosen jurisdiction, meaning that the application is part of the process of commercializing an innovation. This may account for the choice of another jurisdiction by businesses based within the EU. Another factor may be the advisors (either food consultants or law firms) used by the business who may be based in a particular jurisdiction, and choose to submit an application to the competent authority within that jurisdiction. This may be particularly the case with businesses from outside the EU, particularly the US. Perhaps public attitudes towards novel foods are taken into account, with countries more willing to embrace a particular novel food chosen to submit the application.

Drawing on the case of Oca (*Oxalis tuberosa*) in the UK, Hermann suggests that Member States implement the NFR in different ways and may have different standards of evidence.<sup>100</sup> Hermann points out that relying on “somewhat anecdotal” evidence, the UK authority took a “relaxed” view and agreed with the applicant that Oca fell outside the remit of the NFR.<sup>101</sup>

The choice of jurisdiction for submission will be taken away from the applicant in the proposed new regulations. A centralized process for the assessment and approval of novel foods will replace the current Member State-centric system. This may have the effect of equalizing and centralizing regulatory burdens.

If an unapproved novel food is placed on the market, a Member State regulator may take enforcement action to ensure the product is withdrawn. This is a post-market regulatory burden. The Member States that have taken unapproved products off the market are shown in Table 6.

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<sup>100</sup>Hermann, *supra* note 38, at 38.

<sup>101</sup>*Id.* at 505.

**Table 6: Number of Unapproved Products Taken off the Market by Member States**

Member State	Total Products Taken off the Market
Finland	51
Malta	29
Germany	28
Italy	15
Denmark	10
France	9
Portugal	7
Czech Republic	7
Slovenia	6
Norway	6
Lithuania	6
United Kingdom	6
Austria	6
Netherlands	5
Slovakia	5
Cyprus	4
Belgium	3
Ireland	3
Estonia	2
Poland	2
Greece	2
Hungary	1
Romania	1
Sweden	1
Grand Total	215

The regulatory burden could be said to be inequitably distributed. There is a wide variation between the Member State that has taken the most unapproved products off the market (Finland) and the Member State which has taken the least (Hungary,

Romania, and Sweden). Whilst some of the variation may be due to geographical variations, and the possibility that unapproved products are coming into Finland from outside the EU via its borders with non-Member States, this is unlikely to be sufficient to explain the variation, particularly given the presence of Germany as the Member State with the third most food products taken off the market. Instead, it is likely that different Member States have different approaches to enforcement of the NFR, with some Member States being more willing to take a product off the market in circumstances where there is a dispute surrounding its novelty or approved status. However, whilst pre-market regulatory burden is to be centralized, the post-market regulation of novel foods will remain the responsibility of the individual Member States.

## VI. DISCUSSION

Reflecting on the data presented in this paper and the recent changes to novel foods policy raises three important questions. First, did the NFR achieve its policy goals and if not, are changes to novel foods policy empirically supported? Second, what does the data analysis tell us about the ability of the new regulatory framework to fulfil its objectives? Finally, are there any remaining unknowns that may impact the ability of the new novel foods policy to achieve its goals? These three questions are examined in more detail to inform the management of the new novel food governance regime at this critical juncture.

### *A. Novel Food Regulations 258/97 Was Not Fit for Purpose*

The stakeholder consultation conducted in 2006 suggested that amendments to the novel foods regime were supported, at least by those who took part in the consultation.<sup>102</sup> Therefore, within the limits of the consultation, the regulatory changes appear to have democratic legitimacy. However, do the changes have empirical legitimacy?

The data gathered here suggests they do, and that change was needed. The regime as it operated under Regulation 258/97 was not fit for purpose. The process neither protected consumer safety nor facilitated novel foods entering the market, and the inequitable distribution of regulatory burdens appears to support the need for a pan-European regulatory process.

One of the goals of Regulation 258/97 was the protection of public health, as set out in recital 2 to the Regulation, yet the large numbers of unapproved products placed on the market suggests that it failed to do so.<sup>103</sup> A further goal of Regulation 258/97 was to provide a unified and clear pathway to allow new products onto the market, as set out in recital 1, harmonizing the internal market. However, the time, the cost, the narrow range of products approved, and a limited substantial equivalence procedure suggests it failed to meet this goal.<sup>104</sup> The lack of market protection following a successful full application may have dissuaded businesses from incurring the cost of making the full application (for example, echium oil). The

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<sup>102</sup>Directorate-General for Health and Consumers, *supra* note 34.

<sup>103</sup>See above section E(I).

<sup>104</sup>See above section E(II)(4).

apparent differences in enforcement behavior in respect to unapproved foods suggest that the internal market has not been successfully harmonized.<sup>105</sup>

Therefore, data presented here supports the proposed changes to novel food policy, and suggests that the policy reforms are empirically legitimate. The NFR was designed principally to address GM foods and reflects the prevailing policy of the EU towards GM foods, putting in place strong controls on market access. The barriers to market access remain despite the removal of GM foods from the scope of the regulation. The purpose that the NFR is fulfilling is no longer the purpose for which it was designed. This analysis supports the view that the policy needs redesigning to rebalance the consumer safety and market access goals. Centralizing the process reduces the potential for differences in regulatory practice to impact food businesses and consumers, preventing the clear choice-making behaviors of food businesses shown in 5.3. However, it is important to note that this analysis suggests that change was needed but it does not prescribe what form this change should have taken. What then can this data say about the changes to be made to the process of novel foods approval?

### *B. The Risks in the New Regime*

The data suggests that substantial equivalence has been underused in the current regime, focusing on a small number of products.<sup>106</sup> As an open textured term, substantial equivalence has been subject to unclear interpretation by businesses and regulators.<sup>107</sup> With the move of substantial equivalence from a formal process of notification and approval to a question of business judgment, the first risk identified relates to the regulatory capacities of food businesses. The handing of regulatory responsibility to businesses to determine whether food falls within the boundaries of substantial equivalence may lead to a more confrontational relationship between regulators and regulated, and potentially to more unapproved novel foods entering the market and the associated risks to consumer protection. The requirements for substantial equivalence approval provided a space for consultation and communication prior to the placing of food on the market, which may have supported a dialogue process that lead to a mutually acceptable outcome for regulator and applicant. With the shift from a pre-market to a post-market control of substantial equivalence, this opportunity has been lost.<sup>108</sup>

The five reasons that businesses may be failing to comply with the NFR, discussed above in section E(I), apply equally here. The uncertainty is likely to lead to disputes between regulators and food businesses regarding the status of the food as substantially equivalent or otherwise. Businesses, in particularly SMEs, may not have the capacity, both scientific and legal, to perform their regulatory responsibility for determining whether the food is substantially equivalent. Indeed, one of the reasons for unapproved foods appearing on the market may be that such businesses do not have the capacity to exercise their current regulatory responsibility of determining whether food is novel.

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<sup>105</sup>See Table 6.

<sup>106</sup>See above section E(II)(4).

<sup>107</sup>See Jones, *supra* note 32.

<sup>108</sup>See Commission Regulation, 2015/2283, 2015 O.J. (L 327) 4(1). Instead the business is required to determine whether their food should be placed on the market.

The facts of *M-K Europa GmbH v Stadt Regensburg* illustrate the difficulties that businesses have experienced determining whether a food is a novel food within the regulations.<sup>109</sup> M-K Europa GmbH placed a product made up of fermented plant ingredients on the market believing it was not novel as the plants that were fermented had previously appeared on the European market, the product had a history of safe use in Japan, and the product had been sold in San Marino prior to 1997. However, the regulator and the Court of Justice disagreed. The product therefore had to be removed from the market following contentious proceedings between the regulator and the regulated. This indicates that M-K Europa GmbH did not have the capacity (or at least did not utilize the capacity) to determine whether the product was a novel food within the regulation. With the expansion of the regulatory responsibility of food businesses to determine substantial equivalence, such disputes may be more likely to arise.

The space for discussion allowed by 258/97 had the potential to cooperatively enhance the capacity of the business and the regulator through an expert dialogue.<sup>110</sup> Whilst the regulatory responsibility for determining novelty fell on food businesses, determination of substantial equivalence was a matter for regulators. With the regulator responsibility for determining substantial equivalence now transferred to food businesses, this discursive space has been reduced, and the future cooperative capacity of the network appears limited.

The second risk results from the regulatory capacity of EFSA. As noted above, Regulation 258/97 appears to have operated as a governance network with detailed discussions between regulators and regulator businesses regarding applications. An examination of the application documents confirms that conversations between businesses and regulators were taking place, molding the application into one likely to receive approval.<sup>111</sup> Businesses could choose to approach the regulator with the greatest capacity to assist placement of a novel food on the market. It is clear that choices were being made about this from the data presented in 5.3.2. Now there will be no choice, which eliminates the potential for market distortion, but may also eliminate choices based on the regulatory capacity of particular regulators. Ensuring that EFSA has the capacity to engage in productive and cooperative conversations with the applicants is likely to be a challenge. EFSA's regulatory capacity has usually been seen as scientific, rather than fostering relationships with regulated bodies.<sup>112</sup> Due to the changes in institutional responsibility, a capacity to build cooperative relationships with businesses may not be harnessed under the new regime, which may lead to both the submission of more incomplete dossiers and a greater number of rejections. In order to prevent any potential problem, EFSA may need to build regulatory capacity in order to achieve cooperative working relationships with food businesses.

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<sup>109</sup>C-383/07 *M-K Europa GmbH & Co. KG v. Stadt Regensburg*, *supra* note 74.

<sup>110</sup>Commission Regulation 2015/2283, 2015 O.J. (L 327) 4(2). It may be argued that Regulation 2015/2283 article 4(2) is meant to provide this space, but the shift in emphasis in the decision-maker of regulation compliance from state to business makes it less likely that the consultation will take place.

<sup>111</sup>*See e.g.* Letter from Julianne Lindemann, Ph.D., to Dr. Chris Jones (Jan. 14, 2009) (on file with Efficas) (in the Kiwiberry files thanking the FSA and the ACNFP for "helpful reviews and suggestions") [http://acnfp.food.gov.uk/sites/default/files/mnt/drupal\\_data/sources/files/multimedia/pdfs/kiwiberrywithdawalletter.pdf](http://acnfp.food.gov.uk/sites/default/files/mnt/drupal_data/sources/files/multimedia/pdfs/kiwiberrywithdawalletter.pdf).

<sup>112</sup>Fran Wickson & Brian Wynne, *The Anglerfish Deception*, 13 EMBO REPORT 100 (2012).

### *C. Unknowns in the New Regime*

First, as is usual in EU food law, the enforcement of the new regulations has been left to the Member States. They determine their processes for taking unapproved food off the market. Our data showed that some Member States were more active than others in taking action against unapproved novel foods. As Hermann suggests in relation to the process for determining whether food is novel,<sup>113</sup> Member States may vary in their approach when interpreting the regulation. Regulators may take different approaches to the determination of whether a food is novel, whether a food is substantially equivalent, and whether a food should be taken off the market. Differential interpretations and levels of enforcement by regulators have the potential to lead to disparity within the European market, with food products subject to different actions depending on the Member State involved. Such differences are already apparent in the data concerning unapproved foods, where some Member States have been much more active than others in taking novel foods off the market and notifying EU bodies of this formal action via RASFF. A differential regulatory approach by Member States, both in relation to advice under the article, may undermine the aim of the new regime by leading to unequal burdens continuing to exist, thus distorting the single market.

Second, the approach to determine the history of safe food use outside of the EU for the purposes of the fast-track procedure in Regulation 2015/2283 Chapter III Section II is unknown. As an open textured term, the history of substantial equivalence applications (5.2.4) suggests that there is a risk that the requirement will be interpreted narrowly. The addition of Chapter III Section II is meant to address some of the longstanding criticisms.<sup>114</sup> In the current process, traditional foods, which have tended to fall within class (e) of the regulation, have been successfully negotiated through the challenges of obtaining novel foods approval, through the full application process (e.g. Noni and boabab) or through the substantial equivalence procedure (argan oil). However, such negotiation has been described as a substantial challenge with high costs, as noted in the case of the Boabab application that was estimated to cost £15,000.00 to demonstrate safety.<sup>115</sup>

In many cases, the applications relating to traditional foods, particularly the substantial equivalence applications relating to Noni, have tended to be made by SMEs. It may be questioned whether such applicants have the financial or regulatory capacity to make a full application for approval, meaning that a larger firm may make such an application and have market priority for five years. This may function to therefore exclude SMEs who produce traditional foods in third countries from the EU market in favor of large companies.

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<sup>113</sup>Hermann, *supra* note 38.

<sup>114</sup>*Id.*

<sup>115</sup>*Id.*



#### *D. The Risks of “Brexit”<sup>116</sup>*

The data analysis illustrates the importance of the UK in the current novel foods regime. The UK is the most frequent recipient of applications for authorization, reflecting the preference of food businesses for the linguistic, regulatory, scientific, and administrative capacity of the UK.<sup>117</sup> Following the UK vote to leave the EU in the referendum on June 23, 2016, there may be accompanying risks to the novel foods approval process. The new regulatory framework set out in regulation 2015/2283 reduces the role of Member States in the approval of novel foods, and therefore the reduction in technical knowledge represented by a UK departure presents fewer challenges than it might otherwise have done.<sup>118</sup> However, linguistic challenges may arise. If English is not an official language of the EU following the departure of the UK,<sup>119</sup> this may dissuade businesses from launching applications to place the novel food on the list, or at least increase the regulatory burdens in doing so, because, as argued above, being able to submit an application in English is something that businesses value in submitting an application for novel foods approval.

Outside the EU, the UK would need to put in place its own novel foods approval process.<sup>120</sup> This would require legislative time and capacity to operate such a process. It is perhaps fortunate that the UK has the experience of operating the regime under 258/97, and the capacity built under this regulation could form the basis for a national novel foods regime. For the UK, the risk is that agri-businesses are unwilling to launch novel food products in the UK if they require separate approval. The regulatory costs, compared to the size of the UK market, may dissuade food businesses from launching novel food products in the UK. However, the UK could opt for a national novel foods regime that seeks to respond to the perceived weakness of the EU novel foods regulation regime, taking advantage of the high regard for UK food regulation demonstrated in E(III)(2) above. This could lead to greater availability of novel foods on the UK market. If this is the case, the UK must be careful to ensure that any domestic provision retains the careful balance struck in

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<sup>116</sup>See Lang & Schoen, *supra* note 10; Brian Kelly, *The Impact of Brexit on Food and Drink Regulations*, 26 WORLD FOOD REG. REV. 28 (2016). For a broader examination of Brexit see Russell A. Miller, *Brexit: An End to the End of History*, 17 GERM. L.J. (2016), <http://www.germanlawjournal.com/brexit-supplement>.

<sup>117</sup>See above section E(III).

<sup>118</sup>Although the UK might usefully have been used as an initial market for novel foods in order to take advantage of expertise when asked for advice under Commission Regulation 2015/2283, 2015 O.J. (L 327) 4(2).

<sup>119</sup>See Commission Regulation 1/1958 (1958) determining the languages to be used by the European Economic Community article 1. Currently only the UK notified English as an official language (although it is likely that another Member State, such as the Republic of Ireland or an independent Scotland, would put forward English as an official language in the event of withdrawal, although other Member States would have to agree).

<sup>120</sup>The premise of the so-called Great Repeal Bill, promised by the UK Prime Minister in autumn 2016, is that all EU law becomes part of UK national law. However, it is difficult to see how this would be adequate for new novel foods approvals, as the EU is unlikely to allow regulatory free-riding, and similarly new EU approvals would not become directly effective EU law. *See also Legislating for the United Kingdom's withdrawal from the European Union*, Dep't for Exiting the E.U., 113-14, [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/604514/Great\\_repeal\\_bill\\_white\\_paper\\_print.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/604514/Great_repeal_bill_white_paper_print.pdf).

the new proposal between encouraging innovation and ensuring safety, and ensure provisions do not lean too far in either direction. However, it may be the case that there is scope to pursue a freer approach toward food with a history of safe use outside the EU. On the one hand, if one is to take certain pro-Brexit campaigners at their word, this would certainly be a mechanism for stimulating trade beyond Europe. On the other hand, if the UK remains in the European Economic Area (EEA)<sup>121</sup> the approval process under 2015/2283 will remain operative. The UK will not have any scope to deviate from the process agreed upon in the regulation, and the challenges identified in 6.2 and 6.3 will remain operative.

## CONCLUSIONS

The data presented in this paper represents a timely analyze of the empirical legitimacy of the recent amendments to EU novel food policy. By considering how novel foods have fared on the EU market under the NFR, and by examining the nature of full and substantial equivalence applications as well as the identification of unapproved novel foods, this analysis strongly suggests that the decision to replace the regime of Regulation 258/97 is empirically well-founded. Hence, this paper supports the centralizing approach taken by the Commission. In particular, this policy analysis supports a number of the longstanding criticisms of Regulation 258/97, including that it failed to achieve consumer safety and market access goals, and, as such, the regime was not fit for purpose.

Regulation 2015/2283 has not yet come into force, but should address some of the central problems of cost, delay, and the perverse incentive not to be the first entity to market a novel food in the EU. However, the examined data identifies some issues that should be further considered in the new novel food policy approach, particularly in terms of the regulatory capacity of EFSA. A number of these potential risks and uncertainties need to be considered and managed during the implementation phase. In particular, centralization may lead to a loss of opportunities for dialogue and improved regulatory capacity between food businesses and regulators. The responsibility for post-market enforcement will still remain with Member States and may lead to a lack of uniformity, which would at least require guidance and support, and may still result in market inequalities. The use of highly interpretive concepts, such as “substantial equivalence” and “history of safe food use,” may be challenging for both food businesses and regulators, which could threaten the policy goals of an equitable market and consumer protection.

Alongside the challenges of the new regulatory regime, the challenges of Brexit are likely to render novel foods policy difficult for both the UK and the EU. The UK expertise has made a substantial contribution to novel foods regulation, and its loss will be felt. Similarly, without the scale offered by a novel foods process at an EU level, foods may not appear on the UK market, necessitating a less restrictive approach to avoid the sclerotic foodscape discussed in section 4.

In light of these insights and the recognition that European Novel Foods Policy is at a critical juncture, it is important that the various EU institutions responsible for equitable market access and public health protection conscientiously and proactively manage the implementation of the new regulation. The retrospective examination of Regulation 258/97 presented here is intended to support this important policy work.

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<sup>121</sup> See Agreement on the European Economic Area, March 17, 1993, O.J. (L 1, 3).