New novel food regulation and collaboration for innovation

Abstract

Purpose –The purpose of this paper was to study the novel food (NF) industry in Europe and how regulations have affected companies' collaboration and openness towards other actors during new product development. The research question, therefore, was "How do the European NF regulations affect radical innovation in the food industry?"

Design/methodology/approach – A multiphase mixed-methods design was used to combine three sets of data: the NF applications and copies of these from 1997 to 2018; the applications in the first 18 months of the revised NF regulation period after 2018 and interviews

Findings – Interactions with research and development (R&D) suppliers are common during development of NF products. Ownership and protection of knowledge are important for companies' openness during innovation and collaboration. The decentralised NF regulations from 1997–2017, with reduced possibilities for data protection, prevented innovation. However, both old and new NF regulations facilitates an easy route for a second-to-market approach. Companies of all sizes apply for NF-approved products under the new NF regulations, which ensure data protection.

Originality/value – The NF regulations and their effect on radical food innovation has not previously been studied according to innovation management theory. Understanding various forms of selective partnership and collaboration among actors in the food industry is valuable for future growth.

Keywords – Novel food, R&D, Open innovation, Food industry

1. Introduction

Throughout history new types of food have been added to our diets. Common food products like rice, potatoes, and coffee were considered novel when originally introduced from other parts of the world centuries ago. According to the European Commission (EC), foods that have not been consumed to a significant degree by humans in Europe before 15 May 1997 are defined as novel foods (NFs) and a pre-market authorisation for consumer safety is necessary before NFs can be put on the market. NF regulations in Europe (EC, 1997) only authorised 128 products in the first 20 years of the legislation. During the same period, 523 NF copies, coming from competing companies claiming to have comparable products, were approved. While a full application took two to four years, an approval for selling an NF copy only took a few months. The old NF regulation in Europe, in force from 1997 to 2017, included a number of elements that made it difficult for companies to form reliable plans for their route to market and the European Food Safety Authority (EFSA) and EC had to tackle these issues in the implementation of new regulations (Hermann, 2009).

NF regulations affect radical innovation speed and novelty through the publication of dossiers revealing ideas and technology. Costly scientific risk assessments involving a large number of unknown variables for pre-market approval, which are designed to protect consumers, have adversely affected radical innovation in food and nutraceuticals (Hyde *et al.*, 2017). The main reasons for food companies not applying for NF approval have been identified as the risk of delayed product introduction, approval

mechanisms encouraging companies to be followers rather than innovators, and the uncertainty about the timing of an approval or the legal status of a novel product, which increases risk and adds costs (Brookes, 2007).

In 2018 new centralised NF regulations were implemented to optimise the application and approval process and thus improve innovation conditions in the food industry (EC, 2015), assessing close to ten times as many dossiers per year compared to the earlier process. The new NF regulations are now simplified, and more transparent, and provide standardised generic authorisation as the default. The new regulations allow companies to protect their data for 5 years. However, scholars argue that the new regulations are particularly disadvantageous for small and medium-sized companies that rely on publicly funded R&D suppliers, which requires knowledge dissemination (Holle, 2018). Further, the introduction of data protection in the revised regulations has been argued to lead applicants towards more in-house R&D, secrecy, and closed innovation (Holle, 2018).

This paper asks what the innovation practices of NF companies are and how the new NF regulations have influenced them. The study consists of an analysis of an inter-country secondary dataset drawn from the EC's own records of NF applications, covering 22 years, combined with interviews discussing openness and transparency in food companies and their partners. Section 2 of the paper establishes the theoretical framework regarding open innovation and data protection mechanisms. Section 3 presents the context of NF regulations in Europe. Section 4 explains why multiphase mixed methods were used in order to facilitate understanding of the case. Section 5 presents the results and in section 6 policy implications of the findings are discussed in terms of OI and NF regulations.

2. The literature on NFs and innovation

Open innovation (OI) emphasises knowledge sharing in all stages of innovation processes. The concept is often explained by referring to its opposite. Closed innovation, which emphasises in-house R&D secrecy, is argued to have higher costs and extended time to market, thus hurting a company's competitiveness (Chesbrough and Crowther, 2006). Early conceptualisations of the OI paradigm assumed innovation to be closed and to be based on internal processes with little interaction with external entities before the entry of OI (Randhawa *et al.*, 2016, Mowery, 1983, Cainelli *et al.*, 2004). In this setting, organisations attained competitive advantage through exclusive ownership and control of intellectual property (Chesbrough, 2003).

OI is a solution to competitiveness problems and highlights collaboration, but it often entails challenges at early partnership stages , and these challenges have also been found within cases of NF (Holle, 2018, Hyde *et al.*, 2017). The NF pioneers might find themselves facing such challenges of early stage technology because they might require skills not held within the company itself.

OI is often associated with industries such as information technology and pharmaceuticals (Miglietta *et al.*, 2017). The food industry is mostly categorised as a mature and slow-growing low-tech sector with little R&D investment and conservative types of innovation (Costa and Jongen, 2006). However, NF pioneering companies differ from the average food industry actors and might have more in common with the pharmaceutical industry with end products being closer to nutraceuticals than to food. In the food domain, OI has been related to user innovation, networks, innovation systems, and R&D alliances (Saguy and Sirotinskaya, 2014). However, there is still a demand for deeper understanding of openness within the food industry on management, industry partnership, value chains and international collaboration.

2.1. Incremental versus radical innovation

Incremental innovations can be seen as improvements within a given frame of solutions, while radical innovation represents a change of frame. The major difference between incremental and radical innovation is whether the innovation is perceived as a continuous modification or whether it is new, unique, and discontinuous (Santoro *et al.*, 2017, Norman and Verganti, 2014). In this paper, NFs are considered radical innovations because they fulfil Dahlin's criteria for radical innovation (Dahlin and Behrens, 2005), including novelty, uniqueness, and adoption. The number of copied applications from 1997 to 2018 might be the equivalent of patent references and adoption (Dahlin and Behrens, 2005). NF copies, which are named notifications of substantial equivalence in the terms of the EC, can illustrate the influential role of NFs in Europe and the level of radicality. However, NF copies themselves represent incremental innovation.

Knowledge from R&D suppliers is important for developing radical innovation, while incremental innovation in food companies often results from market sources during OI processes (Santoro *et al.*, 2017). For knowledge sharing during radical innovation, R&D suppliers are involved and the depth of OI is important. The trade-off when companies open up to outsiders to generate knowledge might weaken their ability to capture knowledge, so if companies can open up and prevent spillover at the same time, we can find positive outcomes. However, we can also find negative relationships between protection and openness. Leading companies, often large enterprises, are more vulnerable to unintended spillover during collaboration compared to followers. Followers, with incremental innovations and with little proprietary technology and knowhow, might benefit less from protection mechanisms (Arora *et al.*, 2016).

2.2. Intellectual property rights and flag-planting

Being first to market as a source of strategic advantage is not always the best solution for companies; second or even third firms often outperform the innovator (Teece, 1986). How inventors often lose and imitators may benefit can be explained by the insufficiency of intellectual property rights (IPR) (Teece, 1986, Arora *et al.*, 2016). Access to complementary assets such as manufacturing facilities and related capacities is also coupled to this dilemma. IPR such as patents, copyrights, and trade secrets might not be as strong as intended, thus resulting in a weak protection regime (Cohen and Levinthal, 1990) and putting imitators and competitors in a better position (Brem, 2017).

Flag-planting refers to claiming ownership of no man's land, originating from early explorers laying claim to an area for their country. Flag-planting may also be used in IPR situations when claiming knowledge through scientific publication, patents, trademarks, and NF dossiers. There are strong indications of comprehensive IPR being put up for companies wanting to take leading roles in the functional food segment (Khan *et al.*, 2014). Further, more diverse external collaborations, with a broad aim to collaborate, are observed among companies developing functional foods. This is in contrast to food companies developing incremental products (Khan *et al.*, 2014). Functional foods may be categorised in the same segment as NFs and share the same patterns of collaboration and flag-planting during new product development.

It is therefore important to study knowledge sharing during radical innovation in combination with various protection regimes. For the current paper, this leads to important questions: What type of companies apply for NF authorisation, and has this mix of companies changed since 2018? What are the OI collaboration patterns of NF companies? How do NF pioneering companies use IPR instruments?

3. Context of the study – European NF regulations

Foods considered novel in the European Union (EU) include new ingredients, new food processes or food sources not traditionally eaten in EU. Examples can be new health ingredients like phytosterols, krill oil and vitamin K2; new food processes, often to create better food safety, as with UV treatment and high-pressure treatment; and food sources not traditionally eaten in the EU such as noni juice, baobab seeds and chia seeds. Crucial principles for the premarket authorisation procedure of any of these categories in the EU is safety, proper labelling and the food not being nutritionally disadvantageous for consumers.

The first EU regulation concerning NF was 258/97 of the European Parliament and the Council of January of 27 January 1997 (EC, 1997), commonly referred to as the Novel Food Regulation. It provided a framework for the entry of new NF products into the European market. On 1 January 2018, new NF regulation (EC, 2015) was implemented, replacing the first. Key differences in the legislations include changes in the evaluation process to reduce time of application and change in protection of property rights.

The requirements for preparation of scientific dossiers for the two regulations are similar: comprehensive scientific studies (de Boer and Bast, 2018). Preparation of dossiers for authorisation of NF, with comprehensive scientific studies, has been costly and time consuming for food companies. The total cost of bringing an NF to market varies enormously. The cost associated with regulatory requirements is claimed to be between €0.3m and €4m (Brookes, 2007). On a global level, when R&D costs are included, a range of €4m to €15m is suggested (Brookes, 2007).

3.1. NF regulations from 1997 to 2017

For the first 20 years dossiers were submitted to and assessed by one member state before passed over to the EC and the rest of the member states. If either of the member states had issues with the assessment they could question the applicants and if answers were found insufficient, a mandate was sent to EFSA for a full risk assessment. The process was at most times a long risk assessment procedure often including at least one request for additional information. The whole process took on average 3,8 years. For other producers to trade with already approved NF products, the regulation contained something in EU terms named substantial equivalence notification, where only a simpler dossier showing significant comparability to the authorised product was needed.

The EC did a critical impact assessment of the regulation of the first 20 years, finding that the regulation should aim at creating less bureaucracy, greater speed to market, and better protection for applicants (SANCO, 2008). Others have described the effect of NF policy as regulatory failure (de-Magistris *et al.*, 2015) or as blocking trade from developing countries (Hermann, 2009). NF analyses identifying trends and patterns in dossiers, notifications, and unapproved foods suggested that change was needed (Hyde *et al.*, 2017).

3.2. NF regulations from 2018

In the new authorisation process for NF, implemented from 1 January 2018, applicants submit directly to the EC and mandate the EFSA for a scientific assessment. The EC verifies its validity and may ask EFSA to provide input on the validity of the scientific dossier; after verification the EC sends EFSA a mandate for a scientific assessment. Risk assessments and the same loop with possible requests for

additional information, similar to the previous regulation are needed for approval. However, there are shorter deadlines given in the new regulation. The market authorisations granted by the EC is after 2018 generic, eradicating the need for notifications of substantially equivalent products in cases where data protection has not been granted in cases where the EC grants data protection applicants get 5 years of market exclusivity. Even though EFSA has a 9 month deadline, it often asks for more data extending the process to several years (Holle, 2018).

After 2018, approved NF products from 1997 to 2017 entered the Union list of NFs, which has replaced the need for notifications. The Union list includes NFs conditions of use, labelling requirements and their specifications. All new approvals without data protection will enter this list. This allows all food companies to use generic NF-approved products as long as they are labelled correctly.

4. Methods

In order to get a holistic view of NFs, R&D management, and collaboration among food industry actors, a multiphase mixed method design (Creswell, 2013) was chosen to interpret combinations of data extending over time. The mixed method moved from quantitative to qualitative data and back again to a second set of quantitative data representing a shift in regulations.

The study used data from the first 20 years of NF regulation in Europe and from the following 18 months of the new, centralised NF approval regulations. Public NF data were coded in Power BI to give visualisation of comparable data formats. NF applicants were further mapped in ATLAS.ti using social-network analysis to reveal patterns comparing old and new applicants with regards to repetitions, company size, and the use of data protection..

Access to the food industry and an understanding of the company's challenges were prerequisites for correct interpretation of the interview subjects in their settings. The author's background from food research, combined with extensive work experience in adjacent industries, was crucial to gaining access and checking validity of statements. Research in a field in which scientists have no experience will pose challenges such as lack of access, incorrect interpretations, and lack of trust (Rousseau *et al.*, 1998). Despite these benefits, cognitive blind spots and biased interpretation might result from being too close to the material. Whenever possible, a third-party adviser was consulted, and data were in most cases triangulated through the use of additional sources.

4.1. Quantitative data from NF applications and notifications 1997–2017

Public data from 20 years of NF applications and notification were coded to form comparable data formats and categories for analysis and visualisation. . These data were sent from the EC in various formats and converted into Excel spreadsheets before being uploaded into Power BI. Documents for applications and notifications contained the name of the applicant company, countries of origin, country of initial assessment, dates, decisions from the commission, descriptions of foods and ingredients, and scientific evidence. Findings from these 20 years of European NF data served as the background for the semi-structured interviews.

4.2. Qualitative data from interviews

Between late 2018 and mid-2019, 13 interviews were conducted. Six Norwegian companies that have succeeded with NF approvals over the past 22 years were interviewed, followed by seven interviews

with experts. The experts interviewed represented NF associations, NF distributors, NF producers, NF R&D suppliers, NF consultants and government actors managing NF policy instruments.

Most interviews lasted from 1 to 1.5 hours. They were transcribed and coded using ATLAS.ti. Findings from the interviews were coded into groups of OI patterns, closed innovation patterns, and other issues like IPR and regulatory challenges. A semi-structured interview guide with background details from the OI literature in the theory section was developed. Experiences during radical new product development under the European NF regulations were encoded according to the OI framework in the theory section. In order to get optimal feedback from the actors, six of the interviews were face to face, while seven of the interviews were conducted as Skype and telephone meetings, sharing screens online or offline for visualisation purposes. Qualitative research should not be used to develop generalisations but rather theoretical ideas (Strauss and Corbin, 1994).

4.3. Quantitative data collected from 90 NF approvals 2018–2019

Public data from the first 90 NF applications from 2018 to July 2019 were downloaded from the EC database and coded in Excel spreadsheets in order to create comparable data in the same way as the first 20 years of NF data. Documents from the new NF applications are more uniform and application summaries are more transparent regardless of country of origin. These documents were sorted by applicant company, countries of origin, food source, food ingredient, usage of food, data protection, and extended use from the EU's list. Data from both regulation periods were compared and made recognisable. Under the new regulations, five applications were withdrawn, and data from these applications were not included in the analysis. Importing traditional foods from non-European countries is not considered radical food innovation in this setting, and the nine traditional food notifications and their data were not included in the analysis.

5. Findings

This study clarifies innovation practices for NF pioneering firms under both the old and new NF regulations in Europe. The mix of NF companies in terms of sizes was mapped together with collaboration patterns and the use of IPR instruments.

5.1. Mix of NF pioneers

There were no systematic differences in the sizes of the companies applying in both regulation periods. Figure 1 illustrates how nearly half of all companies, marked with red circles, applied for data protection after this option was provided in 2018. The companies applying for data protection were a mix of new and old NF pioneers as well as a mix of company sizes. In addition, figure 1 illustrates how a third of all applicant companies, marked in yellow boxes, had applied under both the old and new regulations. Equal numbers of micro sized companies (Micro) with fewer than 10 employees, small and medium-sized companies (SME) with fewer than 250 employees, and large enterprises with 250 or more employees are represented with blue and orange lines, respectively. Numbers of applications per company is illustrated in figure 1. In figure 1 the square boxes in either orange, green or yellow are made larger as companies have more than one application.

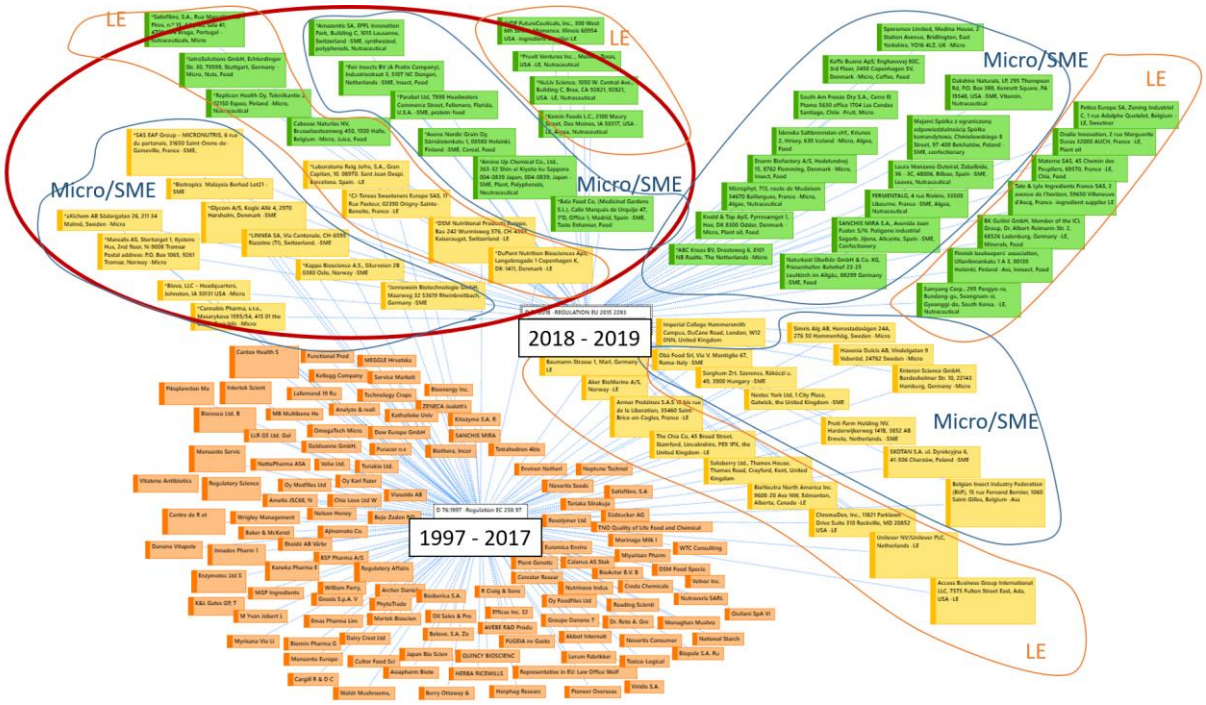

Figure 1: Social network of companies that have applied during the old and new NF regulations up to October 2019. 1997 to 2018 are shown in orange boxes. Companies in yellow boxes applied under both the old and new NF regulations, and the companies in green only applied under regulations from 2018. Companies who sought data protection are marked with the red circle. Micro companies and SMEs are marked with blue lines, and the large enterprises (LEs) are marked with orange lines.

In terms of ingredients, proteins are by far the most popular NF source followed by chia seeds, sweeteners, and marine oils. In terms of sources insects, algae and bacteria are getting popular. Findings from these applications are pointing in directions of healthy dietary trends from sustainable food systems in a similar manner as international sustainable development goals, the Paris agreement, and the EAT–Lancet commission report (UN, 2016, UN, 2015, Willett *et al.*, 2019). Monitoring NF dossiers in terms of food sources, ingredients, and nutrients gives an updated view on dietary trends and points out the directions the food industry is heading.

5.2. Transition and collaboration among smaller actors

There is a new wave of edible-insect applications coming up, which was not previously viable (Marberg *et al.*, 2017). Under the old NF regulations (EC, 1997), whole insects were not considered as falling under the scope of NFs by the UK, Austria, the Netherlands, Belgium, Denmark, and Finland. Therefore, insects were subject to national safety and consumer protection legislation and to the general internal market rules on free movement and import of goods in the EU. Protein production through insects is a potential new industry that has been heavily affected by transitional regulations regarding NFs. Edible insects made up 20% of the NF applications during the first 18 months of the new regulations. This insect component of NF ingredients was put into special transition regulations, whereby proven marketed ingredients, commercialised before the start of 2018, were given a further 2–3 years of pre-approval sales before the products may be finally approved.

"Fortunately, there is an association called IPIFF (The International Platform of Insects for Food and Feed). They have been helpful. I feel that this has been key, that we can talk a lot with the other smaller actors in other countries and can collaborate closely" (Micro industry NF actor producing and selling insects as human food ingredients in the transition of regulations). This quote illustrates how small actors

collaborate with both competitors and associations. Collectively, collaborations between groups with non-governmental association are taking place in the edible insect sector. Inter-firm collaboration with distributers and retailers is also occurring in this young industry. Information sharing in order to develop collective governance policies takes place, but in line with findings from Marberg (Marberg *et al.*, 2017) a lack of collaboration between SMEs and large enterprises might be hindering the sector's development. Enterprises in this low technology part of NFs close their facilities towards other actors, probably due to their production not being advanced and being easily copied.

5.3. R&D collaboration patterns

Suppliers, users, and associations were mentioned as partners for new product development, and the transition towards the new NF regulations has initiated new forms of collaboration among traditionally strong competitors. *"Finally, it was the work on the EU's list. We went in with all the others because… it was in a way … the problem was that there were a number of different approvals, so we set up a group harmonising this as much as possible*" (Experienced NF applicant).

OI patterns towards R&D suppliers in combination with internal R&D competence were found among the research-heavy NF pioneers. *"We have something we call open innovation where we go out and offer different products to those who want to do research on them. It's a great way to get collaboration started. Then we propose to engage us a little more and help out and provide guidance if desired. Thus, we have quite a few collaborative projects going on around the world"* (NF pioneer enterprise). Companies find collaboration with academia fruitful, and they benefit from publications and new information. In the interviews, original product ideas could be traced back to R&D partners such as universities and research institutes.

5.4. The old regulations prevented NF applications

The old, decentralised regulatory system for NFs dating from 1997 seems to have prevented innovation. Over this 20-year period, only 163 dossiers were submitted for the whole of Europe, and of these 125 applications were authorised, 33 applications were withdrawn, and 8 applications were rejected. The number of applications has exploded from an average of 8 dossiers per year (1997–2017) to 90 approved applications during the first 18 months of the new NF regulations. In this context, the quote from the NF applicant below illustrates how the old decentralised NF approval system involving food authorities all cross Europe was causing delays. "*Just to say how unprofessional it was. It was supposed to go through Germany, and we had this Danish company to help us out, and the guy who was going to consider it in Germany, he got sick, and left it to someone who didn't take any responsibility. It was absolutely crazy…"* (Experienced NF applicant talking about the first NF approval regulatory policy).

However, there are indications of applications being held back during the transition period between the old and new regulations, resulting in a large number of applications once the new regulations were in place. *"When I started in 2016, the plan was to make a substantially equivalent (application), but we did not get enough documentation until they closed the door. Then they closed the door, I think it was a year where they did not accept applications, and we just had to wait"* (Experienced NF applicant). How great this holding back effect has been is difficult to determine. However, there was no obvious drop in the number of NF applications in the years before the new regulations were implemented.

Companies have a positive view of the new regulations after 2018, with the possibility of data protection. Such data are often costly toxicological data. *"When companies put so much research and documentation behind this, then it should not just be there for the next company that comes along the*

next day, reads that documentation, and says, yes, we can do it in exactly the same way. Okay, then you are also approved. Five years, it is really just the least amount of time they should give us" (Experienced NF applicant talking about the new NF regulatory policy).

5.5. Second-to-market approach

During the first 20 years of NF regulation in Europe, the UK and Belgium were the two nations in Europe that had the most NF applications approved. Companies from the US came second in this ranking. The reason why food industry actors from Belgium were most often the first movers is not clear, but for the UK the already well-developed system for assessing the safety of NFs dating back to an approval system from 1983 (Tomlinson, 1998) might have been positive for actors because the EU regulations did not appear as totally new and companies were used to the process. The European NF regulations were partly built on the regulations from the UK developed a decade earlier (Tomlinson, 1998). Further, the open public policy in the UK with publication of NF dossiers through official websites stands out from the rest of the EU and has surprisingly not prevented the large number of NF applications filed. 523 notifications of second-to-market approaches was approved. Germany and France are the two nations that have had the most notifications. See figure 2

Patterns described in the early literature (Teece, 1986) on why innovating companies fail to obtain returns, while imitators benefit, might also be the case for several NF pioneers. When imitation is this easy, markets do not work well and profits from innovation might not benefit developers of intellectual property (Teece, 1986, Arora *et al.*, 2016). Looking at notifications regarding substantially equivalent products from Germany and France, noni juice, phytosterols, chia seeds, marine oils, and vitamin K2 are the most-copied products. These products are also the ones with the biggest adoption impacts on future innovation (Dahlin and Behrens, 2005). These original approved NF products can be seen as the most radical NF products when measured by adoption. Two of the top ten copied NF products are originating from Norwegian NF pioneers.

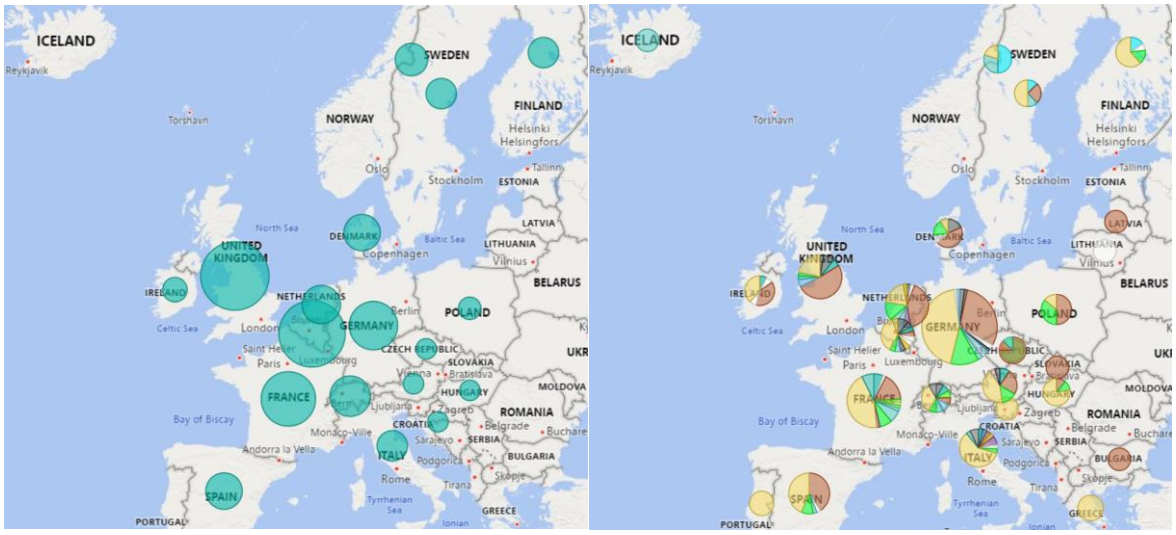

Figure 2: The first 20 years of NF approval in the EU, with turquoise-green circles illustrating the number of new applications per country to the right and the notification applications to the left. Noni juice in light-green, phytosterols in yellow, chia seeds in brown and marine oils in light blue.

Under the old NF regulations, each country interpreted the regulations somewhat differently. The consulting companies on NFs knew about this and advised food companies to file NF applications towards the easiest pathway.

5.6. Protection mechanisms

Patterns of OI for the NF applicants usually appeared among government actors and R&D suppliers, followed by consultants and distributors. *"Then, we have tox (toxicological data), which is the foundation of the novel food application. The tox data we have are from rat studies. That, if I remember correctly, was a consultant company in Canada or the US who did all the studies. But, then we are the client, we are the sponsor, we pay for everything, but it's still an independent company that conducts the studies and writes the report. So, it becomes an attachment to the application. You could say that we finance, we pay for it, but it's still an independent R&D provider that draws the conclusions"* (Experienced NF applicant).

Other patterns of openness and sharing came up during this study regarding competitors, associations and official instruments. Scientific publications backing up NF approvals and hopefully EFSA health claims, are tools for the NF applicant companies. *"It's a very competitive industry and we have to …keep our secrets when it comes to how we produce it. When we do our research, we want to publish and then it becomes public and there it goes two ways. I mentioned… yes, eh … a competitor of ours who used our tox data in his application… But, then there can also be competitors of ours who do research that we also can use as documentation"* (Experienced NF applicant). How some competitors manage situations like this without conflicts, while others have years of lawsuits, is not clear.

6. Discussion and conclusions

The OI paradigm, used in this specific context, has contributed to a better understanding of the new product development process within both old and new NF regulations. Innovation practices of companies with NF approvals can be untangled in terms of openness, secrecy and co-creation among actors in the food industry, R&D suppliers, suppliers, and governmental institutions. How companies involuntarily open up their new product development process during NF development, with the risk of external actors capturing value from the innovation, should be of interest for further development of OI theory. Patterns of OI during NF development are not the same as the OI paradigm, which originally focused on R&D mechanisms that manage spillovers with formalised plans of action. In this section types of companies applying for NF, OI collaboration patterns and IPR use by NF pioneers will be clarified.

6.1. Mix of NF pioneers

High R&D commitment and radical product development, where food products are approaching nutraceuticals, are qualities these companies have in common. There are so far no indications of the new regulations favouring larger enterprises. In contrast, there is a combination of all company sizes among new NF pioneers. The mix of companies applying for NF approval during the first 18 months under the new regulations in terms of size is the same as under the old regulations.

NF followers are having an easy route to the market in line with earlier conclusions where companies entering the market second could get a free ride and avoid the costs associated with seeking authorisation (Brookes, 2007). Adjustments to earlier approvals can explain why one out of three applicants in the new regulations also applied under the old NF regulations. The pre-selection of NF pioneers, specialisation, and companies' knowledge of the policy instruments might be explanations for why the same companies apply more than once.

6.2. OI and NF

There seems to be a paradox whereby regulatory openness leads to fewer OI processes. However, the fear of regulatory centralisation leading to fewer opportunities for dialogue and improved regulatory capacity between food businesses and regulators (Hyde *et al.*, 2017) has been exaggerated. There are no indications in this case study of the new NF regulations backing up this fear of lost dialogue. The assumptions of lost dialogue under the new NF regulation from Holle (Holle, 2018) concerning the new regulations with data protection favouring larger enterprises with in-house R&D closing up all innovation processes have not come to pass. This might be due to apparently successful collaboration among food companies of all sizes and R&D suppliers managing IPR challenges.

6.3. NF and IPR

Patents, trademarks, EFSA approved health-claims, scientific publications, and NF approvals are being combined to form complementary flag-planting strategies during radical innovation in the food industry. This is consistent with earlier studies of innovation, IPR, and protection regimes (Santoro *et al.*, 2017, Teece, 1986, Arora *et al.*, 2016, Khan *et al.*, 2014). Spillover prevention strategies are followed in the same way as described by Arora (Arora *et al.*, 2016), where IPR measures are combined with openness. However, in this case the openness may be involuntary due to the open governance of the NF regime. Radical innovation, R&D collaboration, and OI are in this case consistent with the findings from Santoro (Santoro *et al.*, 2017). However, the cost for a company to sustain a high protection regime can also be seen as the cost related to OI and to the flag-planting strategies. Due to weak protection regimes and easy free riding with notifications, and access to the EU's NF union list, NF have affected radical innovation through the publication of dossiers revealing ideas and technology. In addition, the costly scientific dossiers with risk assessment required from the EFSA has affected innovation speed and novelty. However, if this is due to safety of NF products being hard to prove, or companies not willing to invest in risk assessments is not clear.

6.4. Implication for theory

OI research within the food sector primarily concentrates on the role of clusters, networks, and innovation brokers as enablers of innovation activity (Procopio Schoen, 2017). In general, OI research has had a company-centric aspect, and the role of OI networks is relatively under-researched (Randhawa *et al.*, 2016). Similar to the results of Procopio (Procopio Schoen, 2017) and Arora (Arora *et al.*, 2016), IPR policy instruments were found to be important for balancing collaboration among the NF applicants, R&D suppliers, and government actors. The interview findings from these NF cases illustrate how collaboration between food companies and R&D actors have been important for radical product development. This was also suggested by Santoro (Santoro *et al.*, 2017).

Open governance makes mutual trust and secrecy during collaboration among actors important factors in radical new product development processes for these food companies in the same way as for the earlier OI researchers (Chesbrough and Crowther, 2006). The NF applicant companies differ from the traditional food industry in many ways, being more of a nutraceutical industry with leanings towards medicine, and this may be why open collaboration towards R&D suppliers are of the same importance as for more typical high-tech industries. Furthermore, informal collaboration such as participation in associations was found to be important in the same way as described previously (Chesbrough and Crowther, 2006).

6.5. Implications for practice

The old regulations involved few possibilities for data protection, and was criticised by many scholars on practical implications (SANCO, 2008, Hermann, 2009, de-Magistris *et al.*, 2015). This was acted upon by policy makers. Ten years before the new NF regulations (EC, 2015) were implemented, a briefing paper with impact assessments was published, suggesting an exclusive access right to the market in order to provide better incentives for NF pioneers (Brookes, 2007). The new NF regulation has also been criticized for hindering innovation (Holle, 2018). However, criticism of the new regulations has been too brutal according to feedback from interviews and the mix of applicant companies of all sizes among NF food pioneers. Although, entering the marked second and not first is still a cost-efficient strategy under the new NF regulations.

This study supports policymakers with more insights regarding radical food innovation for Europe. This study will also aid policymakers in providing better organisation in regards to new radical food products and safety for future consumers. The food industry and its suppliers will benefit from holistic insights regarding collaboration in networks as a way to guide their innovation initiatives. The food industry will gain more accessible knowledge of NF regulations and the way they affect OI and forms of collaboration. The study illustrates which regions of Europe can be seen as being the most innovative and the drivers of radical new product development in the food sector.

6.6. Limitations and future research

This contribution to OI research and radical product innovation, using the European NF regulations as a case, will help future researchers to better understand how a regulation of openness impacts companies' protection regimes. IPR measures in this NF case have been combined in various blends and used for preventing knowledge spillover, for justification of novelty, and for marketing purposes. Opportunities to create ground-breaking radical food innovations are dependent on regulations and policies. Regulations are rarely positive for innovation, but when it comes to food and the possibility of unintended side-effect for consumers, the EC and EFSA are not willing to compromise. Further studies of NF and OI would benefit from a more systematic patent search and studies of cases involving litigation and lawsuits.

This exploratory work has several limitations. The NF case might be an instance of the phenomenon of radical food innovation, and these NF pioneers can be seen as a subgroup of the food industry with the products leaning more towards nutraceuticals than foods. Another limitation might be the reflective perspective in the study. The author has reduced his bias by collecting and integrating data from interviews with secondary data. However, there will still be limitations linked to the subjectivity of informants in recalling the processes of their NF dossiers from many years earlier. However, the results obtained should provide a foundation for further studies both for innovation and for food.

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