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Institutional Barriers for Food Innovation: A Study of the Brazilian Functional Food Industry

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ABSTRACT: The regulation of functional food (FF) is essential to develop innovation in food industry and to ensure consumers' health. This study aims to identify if and how the institutional environment affects the FF R&D initiatives in Brazil. Data were collected through personal in-depth interviews with FF chain members (experts; industries; regulatory agency) and analyzed through content analysis. Three main agents were identified in the FF R&D initiatives: food manufacturer, functional component suppliers and universities. Results show a negative impact of resolutions proposed by the regulatory agency in these initiatives, but also highlight the importance of institutional factors as drivers to the innovation process. A clearer legislation is needed in order to facilitate innovations in the food sector. Moreover, the selection of the most promising partnerships can help to minimize uncertainties involved in those initiatives. Further researches on measuring the regulation impact on the innovation initiatives are suggested.

Keywords: *Functional Food, New Institutional theory, Regulation, Food Supply Chain.*

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1. INTRODUCTION

Health is the most significant trend and innovation driver in the global food and beverage market. The definition of health is no longer restricted to the absence of disease; it also includes physical, mental and psychological well-being. The term "functional food" (FF) refers to a food that provides health benefits besides the conventional nutrition value.

The concept was first introduced in Japan in the 1980s and further developed in the United States and in Europe, although nowadays there is a global (and growing) market for FF (De Barcellos & Lionello, 2011; Euromonitor International, 2012). It can be a natural, whole, fortified, enriched or enhanced food. In sum, FF includes all those food products that have the potential to improve mental and physical well-being and reduce the risk of diseases. The ingredients responsible for these benefits can be naturally present or may have been added during food processing. It is important to highlight that eating FF is not sufficient in itself to make us healthier, but FF products are an important part of a sustainable and healthy diet. Nowadays, food is not only required for body development, growth and maintenance, but it is also recognized to play a key role in quality of life (Ashwell, 2002).

FF represents one of the most interesting areas of research and innovation in the food industry (Annunziata and Vecchio, 2011; Betoret, Betoret, Vidal, & Fito, 2011; Bigliardia & Galati, 2013; Khan, Grigor, Winger, & Win, 2013). Particularly for this industry, innovation is an important source of differentiation, as well as a value-adding opportunity for managers to develop new products. Hence, innovation constitutes a competitive advantage in the globalized agri-food scenario (De Barcellos, Aguiar, Ferreira, & Vieira, 2009).

FF global sales reached the amount of US$ 150 billion in 2011. The top five markets are United States (21.82%), China (13.59%), Japan (8.45%), Mexico (6.85%) and Brazil (5.65%). It means that Brazil was in 2011 the fifth largest FF market in the world, with sales' amount of US$ 7 billion (Euromonitor International, 2012).

A market forecast for 2015 indicates the Brazilian FF market as the third largest market in the world. It will represent 7% (US$ 14 billion) of the market share worldwide, just behind the market shares of China (20.46%) and the United States (17.66%) (Euromonitor International, 2012). These numbers suggest a positive scenario for investments in FF in Brazil. The Brazilian dairy sector represents one of the most innovative.

Conversely, as consumers have become increasingly concerned about what they eat and how it affects their health, the food industry has responded by providing more detailed nutrition labeling and often making claims about the beneficial effects of certain foods (Lalor et al., 2011). Despite the positive FF market overview, there were only eight products with functional and/or health claims registered under the Brazilian Regulatory Agency (ANVISA, National Sanitary Surveillance Agency) in November 2012.

There has been evidence that the regulation and claim process may affect research and development (R&D) initiatives on this sector in Canada (Herath, Cranfield, Henson, & Sparling, 2008) . Kaushik and Kaushik, (2010) declare that a proper regulation is a key factor to the success of FF globally. Bigliardi and Galadia (2013) and Khan et al. (2013) highlight the importance of identifying the barriers for development of FF.

Supply chains are embedded in an institutional environment. Some previous studies have highlighted that national regulation impact on FF supply chain configuration. Therefore, the aim of this paper is to understand the influence of regulation on the FF supply chain configuration and R&D strategies. Our assumption is that the regulation in the incipient Brazilian FF market can be perceived as a driver or a barrier to product development as well as it shapes the inter-firm relationships between agents in order to develop new products. This paper is organized as follows. Section 2 reviews the theoretical background and the context of this research. Section 3 presents the method carried out in this study and section 4 summarizes the main findings. Finally, section 5 draws the conclusions and suggests a research agenda for future studies.

2. LITERATURE REVIEW

2.1 New Institutional Theory

New Institutional theory pays attention on how relationships are shaped by the socioeconomic institutions. Institutions are a human creation, a system that establishes rules and durable structures for an orderly social interaction (economic transactions) be-

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tween "organizations" (Hodgson, 2001, 2006; North, 1990; Nye, 2008; Rubin, 2008). For North (2008), organizations can divide into: (1) economic: firms, cooperatives, associations, among others; (2) educational organizations such as: universities, schools, research laboratories and development. and (3) political organizations such as the state and regulatory agents. The latter two are constituted for exercising special powers and prerogatives. They are not just another actor in the environment of organizations, but their ability to rely on legitimate coercion makes it a rather distinguished actor. All organizations are rightly seen as governance structures, but the state is separated (Scott, 1995).

In a social context of broad diversification, institutional theory is the emergence of order, stability, socially integrated patterns out of unstable, loosely organized, or the narrowly technical activities. They determinate processes that are dynamic, it means, patterns. Patterns set by an institution can reduce uncertainty in an environment of economic interactions (North, 1990).

Shirley and Menard (2008) assume that organizations have "incomplete information and limited mental capacity", suggesting that they are inserted in a world of uncertainties. Meyer (1977) declares that institutional patterns collaborate to provide improvement of competitiveness for less efficient organizations. Dimaggio & Powell (1983) propose that organizations tend to became more similar in institutionalized environment as result of institutional isomorphism. Institutional isomorphism is a homogenization process of organization motivated by political and legitimacy purposes. The authors identified three kinds of mechanisms that isomorphism happen: a) coercive, where formal and informal organizations pressure on other organizations which they are dependent. According to the authors, the existence of a common legal environment affects many aspects of an organization's behavior and structure; b) mimetic is when uncertainty lead organizations to model according other organizations. This has been used as an explanation for the homogenization of innovation models. Finally, normative isomorphism is a result of professionalization, meaning, and the role of universities, professional training institutions and trade associations for the definition and promulgation of normative rules about organizational and professional behavior. (Rubin (2008) declares that unsuccessful economic experiences, with the removal of restrictions on international barriers, reinforce the creation of a legal system to promote development. A legal system consists of several institutions that are able to ensure the proper operation of economics transaction among agents through norms or standards (Rubin, 2008; Nye, 2008). However, Nye (2008) points: "any group or organization or individual with the power to make laws and guarantee the functioning of market institutions is also powerful enough to abuse those who need such protection". Although the institutionalized environment can ensure order and development for a market, it cannot ensure efficiency and reduce risk in every instance (Benham, 2008). The challenge for the institutions is creating a balanced environment that provides more benefits than barriers for market development.

Institutions are an important factor in the process of innovation as can they can promote a stimulating environment or may barrier companies´ willingness to develop new products or processes (Coriat; Weinstein, 2002; Edquist, Bjorn, 1997; Zawislak et al., 2008). Suchman et al. (2001) exemplifies the role of institutional environment and isomorphism in the innovative Silicon Valley.

2.2 Supply Chain and Functional Food Innovation

In an institutional environment, "firm" is the transforming agent capable of generate innovation (Schumpeter, 1942). Complexity and uncertainty are some of the aspects that a firm must deal in innovation of products or processes (Dosi, 1988). To achieve this goal, a consistent organizational structure is needed, in order to support the firm to manage resources, focusing on maximize gains in an environment of scarce resources.

However, as Williamson (1973, 1985, 1998) said there is a cost for governing activities. Innovation involves a wide amount of capabilities, in many functions of an organization. Thus, it is costly to keep it internalized and to compete in the sector.

The modern paradigm of business is moving from the competition between companies to competition between supply chains. According to Beamon (1998), the supply chain is an integrated production process in which raw materials are converted into a final product, and then delivered to the final customer.

The supply chain is more than a union of fragmented businesses: it is a single body that manages the

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relationships, information and materials flow. The final objective is to create or delivery a product or service to the final customer with higher competitive advantage than other supply chain. In this paper, the process of managing interorganizational relationships in response to product regulation is the focus and is aligned to the view that SCM is a set of management processes (Mentzer et al. 2001). Besides, Charvet et al (2008) identify interorganizational relationships as one important domain of the supply chain management literature. Governance is an important component in the supply chain that ensures its effective operation, ensuring the interaction between firms. Supply chain governance exists when the parameters of products, those required for process, logistics and qualification, are defined by a focal company/organization and have consequences upstream or downstream (Humphrey & Schmitz, 2001; Kaplinsky & Morris, 2001).

A focal company takes responsibility for structuring the division of activities between companies, using power to create desired rules which helps activities to flow neatly. In a supply chain, power can be understood in at least two ways, (a) ensuring standards along the chain, and (b) actively managing or coordinating the operations of the chain members, to ensure that those standards are met (Henson & Humphrey, 2010).

According to Hobbs (2001), FF supply chain has adjacent activities, previously to production and distribution: R&D, technology development, technology transfer and commercialization. The development of new products commonly includes alliances with different sectors such as universities, specialized laboratories and suppliers, among others. Each one contributes with technical competences and/or specific components that add the functionality to the food product. This is a way of reducing R&D costs. Only large companies have their own R&D department, but usually work with input suppliers and universities.

The specific asset and the necessity of a wide variety of firms in chain in innovation process are factors that improve the uncertainty for companies. A coordinator is requested to join the competences of each firm to create an innovative product and reduce risk and losses. For the functional food chain two capabilities are needed: (1) technological knowledge – normally located in the pharmaceutical and chemical industry – which includes the knowledge of the state of the art technologies in any particular sector, and (2) marketing knowledge – the understanding of the market dynamics, knowledge of the marketing process, management, business licenses (Mark-Herbert, 2004; Broring, 2010; Brannback & Wiklund, 2001) and knowledge of the competitors' actions (Tidd, Bessant, & Pavitt, 2005).

For a purpose of this paper, we adopted the Schumpeterian definition of innovation as a new product (1942). Additionally, innovation in products may have different forms and types. For Tigre (2006), it can be incremental, when improvements are made to the product or service (whether in quality, designed and/or process), and new logistical and organizational arrangements. Or it may be radical when there is a disruption of the market trend, ie a technological leap. FF is an example of incremental innovation as the introduction of a new input/component provides functionality to the food product.

The real challenge for FF companies is not the generation of innovative ideas for R&D, but to deliver to the market a product which, besides being innovative, also fills consumers' needs and desires (Thamhain, 2003; Bigliardi & Galati, 2013).

2.3 Regulatory Agency

According to Sabatier (1975), the regulatory agency was a mechanism developed in North America between 1887 and 1917 to deal with the low quality of many consumer items and social cost of economic activities. This involved the formation of government agencies to regulate specific aspects of industrial and commercial activities.

Many states, mainly concerning with consumer protection, create agencies for dissolving socioeconomics differences. These agencies may be classified according to policy outputs: intersecting nature of the results (i.e., whether they allocate goods and services or regulate behavior), and the intended and/or unauthorized distribution of costs and benefits. Based upon these policy outputs, Sabatier, (1975) proposes a typology: (1) Regulatory Policy: demand change in the behavior of some agents in other benefits (balance of power between economic agent); (2) Distributive Politics: allocates goods and services among agents in order of distribute proportional benefits; (3) Policy re-distributive: allocates goods and services among actors. Winners and losers are defined in situation which resources are reallocated causing loss; and, (4) Self-regulatory policy: impose restrictions on members of a group to collectively benefit.

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The Brazilian regulatory for food (ANVISA) seeks to balance the power between consumer and food manufacturer and reduce information asymmetry. There is no allocation from on agent to other. Generally, public regulatory agents are the ones that can create and imposes rules, norms and standards, based on the intended outcomes. In the last 20 years, this reality has changed and private standards have arisen.

Mayer and Gereffi (2010) argue that public standards are more legitimate than private. They are democratic, transparent and likely to make decisions in the public interest. In Brazil, functional and health claim for foods can only be provided by the public regulatory agency ANVISA.

2.4 Functional Food Regulation in Brazil

FF has not a universal definition. They began as a concept in the 1980s in Japan, where the Japanese Ministry of Health and Welfare officially defined these kinds of products as "Foods for Specified Health Use" (FOSHU) (Roberfroid, 2000). Since then, FF has become a diet and nutrition trend worldwide.

Functional foods may do more than simply supply the macro and micronutrients that the human body needs for normal biochemical reactions. They contain compounds or ingredients that may help reduce your risk for certain health conditions or promote better health, reducing the risk of chronic diseases. These compounds can either occur naturally in the food product/ingredient or they can be added by fortification or enrichment. FF should be consumed as part of the usual diet to produce physiological or metabolic effects. To be named as a FF, a product must have a functional and/or health claim recognized by ANVISA. It means that even without official claim registered by the Brazilian regulatory agency; the producer may use and inform in the product's package that it contains a functional ingredient. However, he cannot claim their benefits. For example, a company can sell a bread with collagen, informing in the package "with collagen", but cannot report the collagen health benefits, such as "it helps you to reduce wrinkles and fine lines".

According to the Brazilians' laws, ANVISA statutory responsibilities to the federal government include food safety and food standards. The agency aims to promote the protection of society's health, by means of sanitary control throughout all the production and distribution process of products and services subjected to sanitary surveillance. It includes the environments, processes, materials and technologies related to them, as well as control of ports, airports and country borders. That is, everything that involves risk to public health is considered products and services subjected to health inspection and enforcement by ANVISA (Souza, 2008).

These risks may be result of the incorporation of either unknown components or one that cannot be scientifically proved to bring health benefits. The institutional structure is built as an independent regulatory agency: it has administrative and financial independence. The control management is responsibility of a committee, composed of five members. The committee leader has stability during the mandate period (Souza, 2008).

In sum, the regulation is an attempt to control and minimize risks. It is the result of the process of governance which, in turn, relates to the negotiation of the necessary measures to avoid risks throughout the process.

The Brazilian regulation for functional and health claims, both for ingredients or final food product, has been developed based on safety, efficacy and specific laws, being guided by the idea that FF are food products, not medicines. The main goal of the Brazilian Food Regulation are the protection of society' health by reducing the risks associated with the consumption of food, as well as to contribute to economic development and fair trade practices and to achieve consumers' reliability (ANVISA, 1999). The challenges are related to changes in consumption patterns, health food production increment, and development of new technologies in food engineering, reduction of risks in new food products, agricultural practices' switches and globalization.

It means that FF has not been officially defined as a food classification in Brazil. The legislation basically asks for demonstration of products' safety and claims' efficacy (see Figure 1) (Lajolo & Miyazaki, 2007). There are three different resolutions in Brazil. The three regulations were first introduced in 1999 and refer to risk assessments, registering of novel products and for proof of efficacy.

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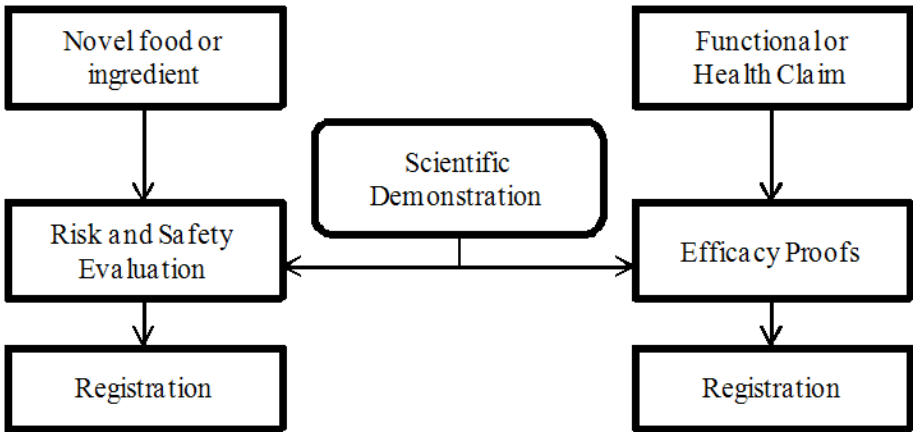
Figure 1: FF product or a health claim register process in Brazil.



Source: Adapted from Lajolo and Miyazaki (2007)
Note: All regulations are available on the website: http://anvisa.gov.br/ing/legis/index.htm.

More recently, in 2002, another regulation was created. This document introduced a list of bioactive and probiotics substances with functional or health claims, aiming to distinguish FF products from nutraceuticals. Nutraceutical is the combination of the words nutrition and pharmaceutical and they are defined as dietary supplements (capsules, tablets, powders) that provide health benefits (Lajolo & Miyazaki, 2007).

Globally, regulatory issues with respect to FF are quite distinct. Brazil was the first Latin American country to have a specific legislation for FF. While Brazil has its own regulatory procedure, almost all countries follow the guidelines of *Codex Alimentarius* (the universal food code, authored by U.S.A.). In that sense, some regulatory particularities may be a barrier to export this type of product. Therefore, proper regulation, in consonance with health benefits, is key factor to the success of FF globally (Kaushik & Kaushik, 2010).

3. METHOD

To achieve the purpose of the paper and supported by literature review, an exploratory-descriptive study was carried out. Authors have applied three methods of data collection (Silverman, 2009): (1) observation, (2) interviews and (3) texts' analysis.

First, direct observations were performed at the two largest international food fairs in Latin America in 2012, all of them based in São Paulo – Brazil (Vitafoods South America 2014 and SIAL Brazil – The Latin American Food Marketplace) Moreover, data were collected in retail stores during May 2012 and July 2012, aiming to identify and characterize the Brazilian' FF market and the main food processors. This approach was used to better understand the context (Silverman, 2009) and to reveal the key agents which were interviewed in sequence. The direct observation during the food fairs intended to identify the launching of new FF products, their promotion and health claims, the main FF manufacturers, food components industry and FF trends. The participation in the food fairs also provided technical background about the product and access to main agents (companies and experts). Besides, the direct observation in the retail stores followed a guideline regarding: number and variety of FF products, their positioning on the shelves, main brands, use of labels promoting health benefits, availability of leaflets about FF, among others.

Thus, the next step was performing the interviews. A well-conducted interview provides a range of information that cannot be compared with other methods (Byrne, 2004). On this research, all the interviews involved a semi-structured questionnaire. In the first stage of primary data collection, authors have interviewed: (a) two food consultants; (b) two FF researchers; and (c) the manager of an Institute of Food Research. These interviewees are here denominated as 'experts'.

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The results of this first stage of interviews helped the authors to identify and describe the Brazilian FF supply chain structure and to understand how the Brazilian regulation influences the FF R&D initiatives. As well, the preliminary results of this first stage of interviews have driven authors to segment the second group of interviewees. Thus, the second stage of interviews was compound by six food processing companies (from now on called 'food processors'), which included: (d) the president of a food company; (e) three marketing department managers; (f) and other three R&D managers.

Finally, as part as the data triangulation process, a representative of the Brazilian regulatory agency (ANVISA), responsible for the Special Products sector was also interviewed. ANVISA aims to control all supply chain agents, ensuring a balanced environment, but the FF regulation was primary develop to provide guidelines for the food processor. Secondary data (laws) obtained with ANVISA were included in the analysis.

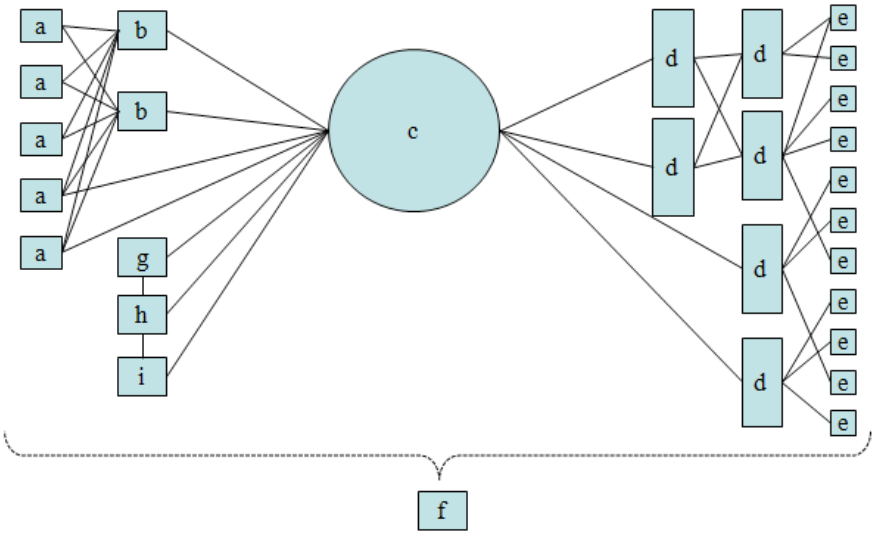
In the last stage, the data were categorized and analyzed using a qualitative data analysis program (NVivo 10©). A content analysis was carried out, which allows the researcher to establish a set of categories and subsequently analyze their frequency (Silverman, 2009). Initially the content analysis was made separating the interviews according to the interviewees' profile – experts, food processors and the regulatory agency. Next, some categories of analysis were created based on literature review (innovation process, regulation and supply chain).

4. RESULTS

4.1 FF Supply chain

In order to better understand the institutional environment behind the FF market, authors have identified the structure of the Brazilian FF supply chain (see Figure 2). It is embodied of (a) basic inputs producer, (b) inputs processor, (c) food processor, (d) distributors/ wholesaler and, finally, (e) final customer. Other agents have emerged as essential to make possible to develop an innovative food product: (g) Technological components producer, (h) University and research centers and (i) Consulting companies. Finally, (f) the Regulatory Agency aims to control and regulate the relationships among all agents.

Figure 2. Functional Food Supply Chain in Brazil



Notes:(a) Basic inputs Producer; (b) Inputs Processor; (c) Food processor; (d) Distributors/Wholesaler; (e) Final Customer; (f) Regulatory Agency; (g) Technological Components Producer; (h) University and research centers; (i) Consulting companies.

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Figure 2 stresses the importance of the food processor in the innovation process and the interaction of regulatory agency with all other actor in supply chain. The same importance was found in the content analysis results, as shown below.

4.2 Content analysis: Strengths and Weaknesses

In order to understand the regulatory aspect of FF institutional environment, this study identified qualitatively the strengths and weaknesses of the regulatory agency as well as the FF regulation, according to the interviewees' perceptions (see Table 1).

Table 1. A synthesis of the positives and negatives aspects related to the Brazilian FF regulation

Strengths	Weaknesses
Strict	Lack of clarity in the registration process
Well-structured	Lack of standardization in decision making
Pioneering	Slowness of the registration process
Modern	Hard to comply

Table 1 summarizes both interviewees' responses (experts and food processors). Some of these aspects were found in both respondents' groups.

4.3 Strength: well-structured, pioneering and strict

Findings showed that a strength is that the FF regulation is considered well-structured. The respondents declares that the regulations adopts an easily and understandable writing. But only for those professionals who are involved in the R&D of food products. Some difficulties could be found for some managers that does not have technical knowledge, especially for entrepreneurs in small companies.

The Brazilian FF regulation established by ANVISA is seen as pioneer and modern in the Latin America context. According to experts, the regulation has arisen during the 90's due to numerous requests of food registers. These products had no identity and quality standards, and, at that time, it was also identified that they could not be classified as conventional foods. Therefore, in 1998, a group of experts was assembled to work on a new set of food regulations. The FF regulation was the first in Latin America.

Yet, according to the experts, the regulation is extremely strict and this is considered as a positive aspect. In their point of view, the strictness helps to avoid the registration of products that could possibly put consumers' health under risk, since it is necessary to provide evidence-based guidance on consumer health to claiming functional/health benefits.

4.4 Weaknesses: lacks, slowness and hard to comply

On the other hand, food processors emphasize that the regulation is extremely rigid (strict). Other negative aspect is that the regulatory agency has no standardization of decision-making regarding to the registration processes. Although FF regulation bears a guide for the registration process, they argue that it is not clearly specified whereby scientific essays and documents are most appropriate to scientifically prove the claimed benefits. Eventually, the regulatory agency requests additional documents, which implies in higher expenses (with food testing labs) and delay in the process result. Such cases, often lead companies to just give up of the claim for functional and/or health claim registration process. Notwithstanding, it is important to say that all respondents (experts and food processors) agree that the FF registration process at ANVISA is slow and hard to comply with.

For the regulatory agency, the advantage is to ensure a healthy relationship between food companies and consumers, i.e. a balance of power between both agents. The regulatory agency seeks to assure that consumer will have access to reliable FF products; and for food companies, to provide a favorable economic environment. The ANVISA's representative informed that the agency is improving and complementing the current guidance on FF registration.

Summarizing, the weaknesses addressed by the interviewees related to regulation aspects are: the lack of clarity in the guidelines of the registration process, the absence of standardization in the decisions

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about the tests and documents, delays in registration processes and strictness of the regulation. The strictness of the health/functional claims, however, is a precautionary action of the regulatory agency, in order to avoid the consumer the feeling of being cheated. Considering consumers' legal rights, this is a positive restrain.

4.4 Functional and Health: Claiming it

ANVISA (2012a)'s Special Products Committee provides the list of products registers and processes currently status. According to ANVISA's database (in Nov. 2012), there are only nine registered FF products, and these are associated to seven different companies. Figure 3 shows the ongoing processes. It is worth to notice that most of the requesting of FF registers are "Waiting for selection and distribution", i.e., documents have already submitted for ANVISA and waiting to designate an inspector for each specific case. Only 4 cases are been analyzed. There is no additional information available for these cases.

Figure 3. Ongoing processes

Description	Situation	Number
Register of Food with Functional Properties and/or Health Claims	Waiting analysis	4
	Waiting for selection and distribution	45

Source: ANVISA (2012b)

According to the ANVISA's representative, FF regulation is a guideline for innovation processes. The 18th and 19th ANVISA's Resolutions (ANVISA, 1999a, 1999b) has allowed food industry to scientifically prove functional and health claims of their products and to communicate it as front-package label. ANVISA states that "*claims are not approved for ingredients or components of food, but for the final food product that contains these functional ingredients or component*s".

ANVISA provide information in its website, about all functional and health claims that are approved. They have become regulated to avoid the use of unjustified and potentially misleading claims and to enhance healthy-food choices (van Trijp & van der Lans, 2007).

However, some of them are still restricted. Functional claim are allowed since on label mention only the content/function. Health claims are allowed in products for purpose of health maintenance; with objective of "disease risk reduction", it has some limitation; but, claim of prevention or cure is still forbidden. These labels are seen as tools to allow consumers to be aware of the benefits a specific food product should have (Lajolo and Miyazaki, 2007).

4.5 FF Regulation influence

As can be seen, the food processors are the main agent in the FF supply chain in Brazilian context. It is the manufacture who should provide the necessary documents for evidencing functional and health claims. Also, the interviewees stress the importance of the food processor on the coordination of activities along the supply chain to develop and produce the FF product. Therefore, in Brazil, the food processor is directly affected by the FF regulation.

Despite of not been directly affected by the same regulations, the technological components producers, Universities and research centers are important partners in the supply chain. They own technological capabilities that may give assistance (sometimes even crucial) to the innovation process and claim approvals. However, FF regulation might influence on increasing or decreasing the demand for their products and/or services by food processors, it can be considered an indirectly effect in the supply chain. Food processors declare that knowing the Brazilian FF regulation is key for partnership establishment.

But how exactly the FF regulation influence? The negative factor stands in communicating the product innovation. Claiming health or functional in food is still a challenge (Lähteenmäki, 2013), i.e., to define the company's marketing strategies for FF. The innovation needs to be understood by the consumer to become, indeed, an innovative product. For the experts and food processors interviewed, the regulation strongly restricts the way to communicate the claim to consumers. The allowed information

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on label is insufficient or too technical to consumer understanding, since the claims contain a varying amount of information.

As Lähteenmäki (2013) shows, there are three typical elements that built these claims: (1) the compound or component that triggers the function, (2) their function as such, and (3) the benefit that may be derived from the physiological or psychological function. For example, if the functional ingredient is beta-glucan, the food processor may claim that "Beta-glucan (dietary fiber) helps to reduce blood cholesterol absorption. Consumption must be associated with a balanced diet and a healthy lifestyle" (ANVISA, 2013).

In that sense, the application of the approved claims comes out as a negative aspect. Only a few terms are able to be printed on the products' packages. Some descriptions are extremely specific, raising the difficulty of consumer's comprehension. Due to these restrictions in communicating, the food processing company fails to clearly inform their consumers the real benefits, enabling the contrary effect: the "do not buy".

Van de Ven (1981) discusses the products that are originally supposed to be known in the market as innovative and fail in transmitting their purposes and, therefore, are not consumed. The product may be called a 'mistake' and is fated to forgetfulness. Besides that, consumers also show resistance to the adoption of new food products that are introduced into the market (De Barcellos et al., 2009). It is known that consumer choices for FF depend on how consumers perceive and understand the claims (van Trijp & van der Lans, 2007; Lähteenmäki, 2013). Thus, it is also relevant to advance our understanding of consumer claims, in order to improve the message content and the right way to communicate it. Research with focus on consumer comprehension could be help to divulge the concept and benefits of this emerging market. However, ANVISA states other priorities as more important.

Moreover, it was observed that some food companies avoid claiming the functionality of their products. Instead, they prefer to produce a food product with a functional ingredient but not communicate the benefits – it is sold as a conventional food products (regarding to regulation aspects). It means that there are food companies that invest and sell a FF product, but they are aware to submit their products under the rigorous registration process from ANVISA. Unfortunately there are evidences that these products' launch fails due to the lack in the communication process. Thus, food processors and experts state that the ANVISA action might inhibits the innovation process and induces them to imitate those products which are already consolidated on the market (follower strategy).

5. CONCLUSIONS

This study aims to clarify the effects of institutional environment on FF R&D initiatives of Brazilian companies. It helps to understand the main role of the regulatory authority. The increased health concerns offer possibilities but also create challenges for the food sector (Lähteenmäki, 2013). Content analysis results have shown that the weaknesses are stronger than the strengths. These negative aspects have a direct impact on the FF R&D initiatives. This may be evidenced by the low amount of FF products registered in Brazil.

The need for structured social systems to coexistence among agents (Selznick, 1992) is a factor that favored the emergence of institutional entities – as regulatory agencies – stated to bring balance for the environment (Rubin, 2008). It means that the ANVISA's required norms are supposed to reduce economic uncertainty (North, 1990, 2008; Shirley & Menard, 2008) and/or control the environment of economic interactions for companies' strategies. Institutional isomorphism also affects the willingness for companies to innovate, adopting a mimetic behaviour and focusing only in incremental food innovation.

Brazil is pioneer in Latin America in the development of a FF regulation. Nonetheless, the introduction of innovation in the market might promote changes in the institutional environment. These changes can affect the configuration of supply chain and/or patterns previously established by institutions.

The responsibility of requesting the functional and/or health claim is from the food company (manufacturer). The food company is also responsible for ensuring the functionality of the final product. Periodically, proofs of the claimed benefits are requested by the regulatory agency. This is the way used to avoid opportunism in this market and to assure consumers' health and rights. Indeed, the R&D of FF appears to be a long-term trend with important market potential, where information flows generated by research are needed to support government regulations, private investments and consumption decisions (Bigliardi & Galati, 2013).

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The FF regulation also influences the marketing related to the innovation process of the food sector. Although it is allowed to claim the functionality, there is a specific way to communicate it to consumers. Either health or functional claims must be approved beforehand and only pre-approved claims can be used on food products labels or in any related material used in marketing (Lähteemäki, 2013).

It was identified that institutional factors may influence the organizational environment, i.e. mandatory norms (patterns) established by governmental regulation agency affect the FF innovation process in Brazilian food sector and the development of a national market. Summarizing respondents' points of view, it was found that the regulatory aspects (both the agency and FF regulation) influence either positively or negatively in the innovation process.

Positively, the regulation provides a modern and a pioneering guideline for analysis, verification and procedures of FF register in the Brazilian context. Throughout the regulation, food processors are allowed to communicate consumers about the functional benefits of their products. So the regulatory agency does not impose procedures for FF R&D, but aims to control how to communicate the innovation (claims) to the consumer.

It must also be mentioned that the innovation also is a driver for institutional changes. The regulatory agency is not a static agent of the FF supply chain; it seeks to interact with the environment to reduce uncertainty. This issue could be further studied The research also contributes for the comprehension of the institutional environment on supply chain management. Institutional factors must be considered by food companies' managers on product innovation planning for the Brazilian market, since it may affect financial gains and cause reduction of the market share.

In Brazilian context, the food processor is the main agent of innovation and responsible for regulatory aspects, differently from other studies (Boring; Leker, 2007; Broring, 2010; Hobbs, 2001, 2002) in developed countries where there is a more integrated view of the supply chain.. The authors suggest that all FF supply chain agents, such as the basic inputs producers; distributors/wholesaler and final customer have to discuss the current regulation. The combination of capabilities by different agents is essential for the development of innovative products and particularly for the FF R&D (Bigliardi & Galati, 2013). Public agencies, such as SENAI (the National Service of Industrial Learning), could provide assistance for SMEs food companies that have interest to get into this specific market.

This research has used qualitative method seeking to describe a social fact. A further way to expand this topic is to measure the impact of institutional factors, surveying a significant sample of food companies. Another suggestion is to verify, in both qualitative and quantitative ways, the impact of institutional factors in others companies along the FF supply chain, such as components producer's companies.

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REFERENCES

AGENCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA (1999a). *Resolução nº 18, 30 de abril de 1999. Regulamento técnico que estabelece as diretrizes básicas para análise e comprovação de propriedades funcionais e ou de saúde alegadas em rotulagem de alimentos***. Retrieved December 06, 2012, from** http://www.anvisa.gov.br/legis/resol/18_99.htm

AGENCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA (1999b). *Resolução nº 19, 30 de abril de 1999. Regulamento técnico sobre procedimentos para registro de alimento com alegação de propriedades funcionais e ou de saúde em sua rotulagem* **Retrieved December 06, 2012, from** http://www.anvisa.gov.br/legis/resol/19_99.htm

AGENCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA (2012). *Análise de perigos e pontos críticos de controle – APPCC*. Retrieved November 21, 2012, from http://www.anvisa.gov.br/alimentos/appcc.htm

AGENCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA (2012a). *Consulta à Situação de Documentos*. Retrieved November 21, 2012, from http://www.anvisa.gov.br/servicos/consulta_documentos.htm

AGENCIA NACIONAL DE VIGILÂNCIA SANITÁRIA – ANVISA (2012b). *Produtos com Registro das Empresas de Alimentos*. Retrieved November 21, 2012, from http://www7.anvisa.gov.br/datavisa/Consulta_Produto/consulta_alimento.asp

Agencia Nacional de Vigilância Sanitária – ANVISA (2013). *Alegações de propriedade funcional aprovadas*. Retrieved

October 02, 2013, from http://portal.anvisa.gov.br/wps/content/Anvisa+Portal/Anvisa/Inicio/Alimentos/Assuntos+de+Interesse/Alimentos+Com+Alegacoes+de+Propriedades+Funcionais+e+ou+de+Saude/Alegacoes+de+propriedade+funcional+aprovadas

Annunziata, A., & Vecchio, R. (2011). Functional foods development in the European market: A consumer perspective. *Journal of Functional Foods*, *3*(3), 223–228.

Ashwell, M (2002). *Concepts of Functional Foods*. Europe Concise Monographs Series.

Beamon, B.M. (1998). Supply chain design and analysis:Models and methods. *International Journal of Production Economics*, *55*(3), 281–294.

Benham, L. (2008). Licit and Illicit Responses to Regulation. In C. Menard & M. M. Shirley (Eds.), *Handbook of New Institutional Economics* (pp. 591–608). Berlin:Springer.

Betoret, E., Betoret, N., Vidal, D., & Fito, P. (2011). Functional foods development : Trends and technologies. *Trends in Food Science & Technology*, *22*(9), 498–508.

Brannback, M., & Wiklund, P. (2001). A new dominant logic and its implications for knowledge management: a study of the Finnish food industry. *Knowledge and Process Management*, *8*(4), 197–206.

Bigliardi, B., & Galati, F. (2013). Innovation trends in the food industry: The case of functional foods. *Trends in Food Science & Technology*, *31*(2), 118–129.

Broring, S. (2010). Innovation strategies for functional foods and supplements. Challenges of the positioning between foods and drugs. *Food Science and Technology (IFST)*, *7*(8), 111–123.

Bröring, S., & Leker, J. (2007). Industry Convergence and Its Implications for the Front End of Innovation: A Problem of Absorptive Capacity. *Creativity and Innovation Management*, *16*(2), 165–175.

Cabral, J. E. de O. (2007). Determinantes da propensão para inovar e da intensidade inovativa em empresas da indústria de alimentos do Brasil. *Revista de Administração Contemporânea*, *11*(4), 87–108.

Charvet, F. F., Cooper, M.C. & Gardner, J.T. (2008). The intellectual structure of supply chain management: a bibliometric approach. *Journal of Business Logistics*, 29 (1), 47-73, 2008.

Coriat, B., & Weinstein, O. (2002). Organizations, firms and institutions in the generation of innovation. *Research Policy*, *31*(2), 273–290.

De Barcellos, M.D., Aguiar, L.K., Ferreira, G.C., & Vieira, L.M. (2009). Willingness to try innovative food products: a comparison between British and Brazilian consumers. *BAR. Brazilian Administration Review*, *6*(1), 50–61.

De Barcellos, M.D., & Lionello, R.L. (2011). Consumer Market for Functional Foods in South Brazil. *International Journal on Food System Dynamics*, *2*(2), 126–144.

Dimaggio, P.J., & Powell, W.W. (1983). The iron cage revisited: Institutional isomorphism and collective rationality in organizational fields. *American Sociological Review*, *48*(2), 147–160.

Dosi, G. (1988). The nature of innovative process. In G. Dosi, C. Freeman, R. Nelson, G. Silverberg, & L. L. Soete (Eds.), *Technical Change and Economic Theory* (pp. 221–238). Pisa: Laboratory of Economics and Management (LEM), Sant'Anna School of Advanced Studies.

Edquist, C., & Johnson, B. (1997). Institutions and Organizations in Systems of Innovation. In: Edquist, C. (ed), Systems of Innovation: Technologies, Institutions and Organizations. London: Pinter, 41-63.

Euromonitor International (2012). Health and Wellness: trade sources/national statistics Brazil (August, 2012).

Eussen, S. R. B. M., Verhagen, H., Klungel, O. H., Garssen, J., van Loveren, H., van Kranen, H. J., & Rompelberg, C. J. M. (2011). Functional foods and dietary supplements: products at the interface between pharma and nutrition. *European journal of pharmacology*, *668 Suppl* , S2–9.

Gay, B., & Dousset, B. (2005). Innovation and network structural dynamics: Study of the alliance network of a major sector of the biotechnology industry. *Research Policy*, *34*(10), 1457–1475.

Hailu, G., Boecker, A., Henson, S., & Cranfield, J. (2009). Consumer valuation of functional foods and nutraceuticals in Canada. A conjoint study using probiotics. *Appetite*, *52*(2), 257–65.

Henson, S., & Humphrey, J. (2010). Understanding the complexities of private standards in global agri-food chains as they impact developing countries. *The journal of development studies*, *46*(9), 1628–646.

Herath, D., Cranfield, J., Henson, S., & Sparling, D. (2008). Firm, market, and regulatory factors influencing innovation and commercialization in Canada's functional food and nutraceutical sector. *Agribusiness*, *24*(2), 207–230.

Humphrey, J., & Schmitz, H. (2001). Governance in Global Value Chains. *IDS Bulletin*, *32*(3), 19–29.

Kaplinsky, R, & Morris, M. (2001). *The handbook for value chain reserach*. London.

Kaushik, D., & Kaushik, N. (2009). Functional Food/Nutraceuticals Regulation In India. *Pharmaceutical Reviews*, *7*.

Khan, R. S., Grigor, J., Winger, R., & Win, A. (2013). Functional food product development – Opportunities and challenges for food manufacturers. *Trends in Food Science & Technology*, *30*(1), 27–37.

Lajolo, F. M., & Miyazaki, E. (2007). Functional Foods Legislation in Brazil. In J. N. Losso, F. Shahidi, & D. Bagchi (Eds.), *Anti-Angiogenic Functional and Medicinal Foods* (1st ed., pp. 275–189). Atlanta: Taylor & Francis.

Lalor, F., Madden, C., McKenzie, K., & Wall, P.G. (2011). Health claims on foodstuffs: A focus group study of consumer attitudes. *Journal of Functional Foods*, *3*(1), 56–59.

Lähteenmäki, L. (2013). Claiming health in food products. *Food Quality and Preference*, *27*(2), 196–201.

Mark-Herbert, C. (2004). Innovation of a new product category — functional foods. *Technovation*, *24*(9), 713–719.

Mayer, F., & Gereffi, G. (2010). Regulation and Economic Globalization: Prospects and Limits of Private Governance. *Business and Politics*, *12*(3), 11.

Maynard, L. J., & Franklin, S. T. (2003). Functional Foods as a Value-Added Strategy: The Commercial Potential of "Cancer-Fighting" Dairy Products. *Review of Agricultural Economics*, *25*(2), 316–331.

Menrad, K. (2003). Market and marketing of functional food in Europe. *Journal of Food Engineering*, *56*(2-3), 181–188

Mentzer, J.T., Dewitt, W., Keebler, J.S., Min, S., Nix, N.W., Smith, C.D. & Zacharia, Z. (2001). Defining supply chain management. *Journal of Business Logistics*, *22*(2), 1–25.

Ménard, C., & Shirley, M.M. (2008). *Handbook of new institutional economics*. Berlin:Springer.

Meyer, J., & Rowan, B. (1977). Institutionalized organizations: Formal structure as myth and ceremony. *American journal of sociology*, *83*(2), 340–363.

North, D. (1990). *Institutions, institutional change and economic performance*. Cambridge: Cambridge University Press.

North, D. (2008). Institutions and the Performance of Economies Over Time. In C. Menard & M. M. Shirley (Eds.), *Handbook of New Institutional Economics* (pp. 21–30). Berlin: Springer.

Raud, C. (2008). Os alimentos funcionais: a nova fronteira da indústria alimentar análise das estratégias da Danone e da Nestlé no mercado brasileiro de iogurtes. *Revista de Sociologia e Política*, *16*(31), 85–100.

Rubin, P. H. (2008). Legal Systems as Frameworks for Market Exchanges. In C. Menard & M. M. Shirley (Eds.), *Handbook of New Institutional Economics* (pp. 205–228). Berlin: Springer.

Sabatier, P. (1975). Social movements and regulatory agencies: Toward a more adequate - and less pessimistic - Theory of "clientele capture". *Policy Sciences*, *6*(3), 301–342.

Selznick, P. (1992). *The Moral Commonwealth: Social Theory and the Promise of Community*. University of California Press.

Schumpeter, J. (1942). *Socialism, capitalism and democracy*. New York: Harper and Brothers

Silverman, D. (2011). *Interpreting qualitative data*. London: Sage Publications Limited.

Scott, W. R. (1995). *Institutions and organizations: Foundations for organizational science*. Thousand Oaks, CA: Sage Publications Limited

Souza, M. A., F. DE. (2008). *Dos Laboratórios Aos Pontos de Venda: Uma Análise Da Trajetória Dos Alimentos Funcionais e Nutracêuticos e sua Repercussão sobre a Questão Agroalimentar* (Doctoral dissertation). –Available from Domínio Público.

Suchman, Mark C., Daniel Steward and Clifford Westfall (2001), "*The Legal Environment of Entrepreneurship: Observations on the Legitimation of Venture Finance in Silicon Valley*," in C. Schoonhoven & E. Romanelli (eds.), The Entrepreneurship Dynamic: The Origins of Entrepreneurship and Its Role in Industry Evolution. Palo Alto, CA: Stanford University Press

Tigre, P. B. (2006). *Gestão da Inovação: a economia da tecnologia no Brasil*. Rio de Janeiro: Elsevier.

Thamhain, H.J. (2003). Managing innovative R&D teams. *R and D Management*, *33*(3), 297–311.

Toledo, M. C. de F., & Lajolo, F. M. (2008). Supplements and Functional Foods Legislation in Brazil. In *Nutraceutical and Functional Food Regulations in the United States and Around the World* (pp. 349–365).

Tidd, J., Bessant, J. R., & Pavitt, K. (2005). *Managing innovation: integrating technological, market and organizational change. Research-Technology Management* (Vol. 47). John Wiley & Sons Inc. Williamson, O. E. (1985). *The economic institutions of capitalism*. *Social Sciences*. Free press New York.

Van Trijp, H. C. M., & van der Lans, I. a. (2007). Consumer perceptions of nutrition and health claims. *Appetite*, *48*(3), 305–24.

Zawislak, P. A., Alves, A. C., Tello-Gamarra, J., Barbieux, D., & Reichert, F. M. (2012). Innovation Capability: From Technology Development to Transaction Capability. *Journal of technology Management & Innovation*, *7*(2), 14–27.

Zucker, L.G. (1987). Institutional theories of organization. *Annual review of sociology*, *13*, 443–464.

Williamson, O. E. (1973). Markets and hierarchies: some elementary considerations. *The American Economic Review*, *46*(2), 316–325.

Williamson, O. E. (1985) The economic institutions of capitalism. New York: The New York.

Williamson, O. (1998). Transaction cost economics: how it works; where it is headed. *De Economist*, *146*(1), 23–58.

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