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## At the boundaries of food and medicine: the genesis and transformation of the “functional food” markets in France and Europe

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## At the boundaries of food and medicine: the genesis and transformation of the “functional food” markets in France and Europe<sup>1</sup>

### Abstract

*Functional foods have swept across France and Europe since the late 1980s. Margarines enriched with omega 3 or phytosterols, yoghurts enriched with bifidus or vitamin-rich food supplements... these foods with health claims have reopened the boundary erected over the course of the twentieth century between the markets for medicines, whose primary function is to treat the sick, and those for foods, whose primary function is to meet the nutritional needs of healthy people. They thus raise many issues for regulators, producers, distributors and consumers. Are they health products that can usefully contribute to the prevention of chronic diseases or marketing manipulations that are not of any health interest? Should they be regulated and marketed as drugs, as food or as a separate category?*

*Drawing on significant contributions in economic history and sociology, this article analyzes the consequences of the classification of these products as medicines, foods or dietary supplements on their valuation and the structure of their markets. It also focuses on the boundary work in which industry and regulatory actors engage in order to “(re)classify” these products, and thereby “(re)structure” the markets in which they circulate.*

*The first part of the article describes the process that led France to establish a boundary between the previously intertwined markets for medicines and foods over the course of the twentieth century, which has been blurred by the appearance of functional foods since the beginning of the 1980s. The second part deals with the efforts of French and European regulatory authorities and industry actors to renegotiate these boundaries between the markets for medicines and foods bearing nutritional and health claims. We conclude this second part with a discussion of the consequences of this reframing for the reorganization of markets and the reevaluation of the health benefits and commercial advantages of these products.*

**Keywords:** Market Regulation; Classification and Valuation; Boundary; Health Claim; Functional Food; Medicine.

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## Introduction

In an article published in the journal of the European Society for Clinical Nutrition and Metabolism, Diana Cardenas (2013) examined the widespread quotation of a phrase falsely attributed to Hippocrates (or to what is known as the *Hippocratic Corpus*) – “let food be thy medicine and medicine be thy food” – in medical journal articles over the last thirty years.<sup>2</sup> For the author, use of this invented quotation leads to an essential misconception about Hippocratic medicine, which established a clear difference between food – which was to be assimilated by the body – and medicine – which was to change the body without being assimilated by it. However, as she underlines, these invocations of Hippocratic thought aim less at increasing our understanding of classical medicine than “at proving the role of nutrition in different fields such as cancer, epigenetics, immunology, disease prevention or chronic diseases [... or] validat[ing] and legitimat[ing] scientifically and ethically the current concepts of *nutraceuticals* or *functional foods* from Antiquity. However, by attributing pharmacological properties to foods, authors are confusing both food and medicine” (Cardenas, 2013, p.261; our italics).

This “confusion between food and medicine” is characteristic of the 1990s and 2000s, which saw a proliferation of products positioned explicitly at the intersection of medicine (in that they claim “health benefits”) and food (in terms of the industrial sector in which they are placed for regulatory purposes and from which their producers often come): the polyunsaturated fatty acids (omega-3 and 6) and phytosterols used in certain margarines and oils to reduce the risk of coronary heart disease; the probiotics and prebiotics<sup>3</sup> added to dairy products to facilitate digestion and protect against seasonal illnesses; or the vitamins and fiber contained in cereals and “energy” drinks to compensate for deficiencies due to unbalanced diets. The terms and definitions used for these products – “nutraceuticals” (portmanteau combining “nutrient” and “pharmaceuticals”), “functional foods”, “healthy foods”, or “*droids*” (portmanteau combining “drugs” and “food”) – proliferated at the beginning of the 1990s, signaling the diverse efforts and uncertainties on the part of producers and public regulators, as well as medical and scientific institutions, to place these products in a clear healthcare, regulatory and marketing category (Veyssière, 2007; Grossman, 2008). These initiatives continued to multiply until the adoption, in 2006, of a European regulation (CE 1924-2006) establishing norms for product labelling of nutritional and health claims, the implementation of which had significant consequences for the organization of these markets.

This study seeks precisely to analyze the dynamics of creation and institutionalization of these markets at the boundary of medicine and food, in France (and Europe) since the beginning of the 1990s. Drawing on significant contributions in economic history and sociology (Bowker

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<sup>2</sup> We also did a search for this phrase in the mainstream francophone press (using the Factiva search engine) and found roughly forty uses during the period from 1998 to 2016. As in the scientific articles studied by Diana Cardenas (2013), these press articles often discuss the links between food and health and many of them deal more specifically with “functional foods,” “healthy foods” or “nutraceuticals.”

<sup>3</sup> Probiotics were defined in 2001 as “a living micro-organism which, when introduced in sufficient quantity, produced beneficial health effects for the host.” The principal components of probiotics used in the industry are lactobacillus and bifidobacterium. Prebiotics are fiber compounds that serve as substrates for probiotic bacteria and thus promote their growth and development to the detriment of other bacteria.

and Star, 2000; Musselin and Paradeise, 2002; Stanziani, 2003; Beckert and Musselin, 2013), we aim to demonstrate the ways in which the classification of these products as medicines, foods, or dietary supplements, and the evaluation of their health benefits and risks, have major consequences for the organization of their markets and the value attributed to them. “Functional foods” constitute particularly interesting objects of study for exploring the links between processes of market *healthicization*<sup>4</sup>, which seek to turn markets into instruments for the promotion of public health, and the *marketization* of health, which aim to make public health into a means of organizing and developing markets. Indeed, these products have reopened the boundaries erected over the course of the twentieth century between the markets for medicines, whose primary function is to treat the sick, and those for foods, whose primary function is to meet the nutritional needs of healthy people. The present contribution aims to interrogate the *boundary work* (Gieryn, 1983) in which industry and regulatory actors engage in order to “(re)classify” these products, and thereby “(re)structure” the markets in which they circulate.

The structure of this article is heavily inspired by the concept of “framing/overflowing” developed by Michel Callon (1998) to think about processes of innovation. Thus, the first part describes the process of “framing”, which led France to separate the markets for medicines and foods over the course of the twentieth century, before turning to the “overflowing” represented by the appearance of functional foods since the beginning of the 1980s. The second part deals with the efforts of French and European regulatory authorities and industry actors to “reframe” these overflowings through a “renegotiation” of the boundaries between the markets for medicines and foods (or dietary supplements) bearing nutritional and health claims. We conclude this second part with a discussion of the consequences of this reframing for the reorganization of markets and the reevaluation of the health benefits and commercial advantages of these products.<sup>5</sup>

## **I. A porous boundary between medicine and food: the creation of interstitial functional food markets**

The introduction of the first yogurts with “active bifidus” and the first “omega-3-enriched” margarines at the end of the 1980s set off intense media, but also legal, controversies between industry actors, consumer organizations and regulatory authorities. While industry actors drew on scientific research to claim health benefits for their products, and to thereby distinguish them from the competition, consumer organizations and regulatory authorities were highly skeptical of the scientific legitimacy and health advantages of these claims. Was health not the exclusive domain of the pharmaceutical field? To understand these controversies, it is necessary to return to the processes at work over the course of the twentieth century which gradually constructed an impermeable boundary between medicine, intended to heal or prevent illness, and food, whose health benefits were limited to providing for people’s nutritional needs. This boundary

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<sup>4</sup> The term “healthicization” is borrowed from Didier Fassin (1998), who defines it as a double process of medicalization (consisting in the framing of a social problem in the language of public health) and politicization (consisting in the placing of this social problem on the agenda as a problem of public health). For an argument similar to ours, see also Steiner and Trespeuch (2014).

<sup>5</sup> This study is based in part on a review of the francophone press over the period 1997-2016, conducted using the Factiva database, and in part on analyses of the legal norms and guidelines produced by French and European food regulatory agencies.

did not only separate categories of products but also ways of commercializing and promoting them. The proliferation of functional foods in the 1990s and 2000s had the effect of blurring this boundary, allowing for the creation of new interstitial markets, which belonged neither to the “pure” medicine market, nor to the market for “simple” foods, but which played precisely on the porosity of the boundary between the two.

### **1.1. From the insistence on a boundary between medicine and food...**

That hybrid “functional foods” proved problematic at the end of the twentieth century might seem odd, given the fact that the histories of medicine and food were very much entangled until the middle of the century. Indeed, numerous articles on the history of pharmacy highlight the therapeutic virtues that have long been projected onto many foodstuffs: bread, blessed or otherwise, was thought to combat the plague, eye disease and even rabies; chocolate was indicated for the treatment of “chest and stomach pain, fever, ‘fragile nerves’, biliary inflammation, colds, dysentery, diarrhea, cholera, etc., not to mention its reputation as a stimulant and aphrodisiac, blacklisted by the church but employed by royal mistresses” (Paternotte and Labrude, 2003). Certain staple foods were marketed from the outset as medicines. This was, for example, the case for the tomato, which was promoted at the beginning of the nineteenth century by European doctors in pill form for the treatment of diarrhea, gallbladder attacks, dyspepsia, etc., before becoming a popular vegetable known only for its richness in vitamins (Smith, 1991). This was also the case for Bulgarian yogurt, sold in France at the beginning of the twentieth century in pharmacies and creameries where its benefits for intestinal disorders and the immune system were celebrated, in keeping with the work of the Pasteurians, in particular Elie Metchnikoff. Aram yogurt was sold in the 1910s with the claim that it was “recommended by Prof. Metchnikoff of the Pasteur Institute for people with delicate constitutions and as a dessert” and was accompanied by a document in which the illustrious professor stated: “I have eaten and analyzed Aram yogurt. It is not harmful to health. On the contrary, it contains lactic bacteria which are useful for our bodies.”<sup>6</sup> The companies that market probiotics today make regular reference to “pioneering” scientists and producers in order to recall the historical pedigree of the knowledge on which their “innovations” are based and to underscore, by way of contrast, the “timorousness” of contemporary health regulators vis-à-vis their products. But this ellipsis also sheds light on the processes through which the twentieth century led to a separation of the regulatory, industrial and commercial spaces in which foods and medicines circulated.

These processes of separation impacted medicines first and foremost, steadily leading to the legal definition of these products around their therapeutic purposes (treating or preventing illness) and their pharmacological, immunological or metabolic properties (restoring, correcting or modifying bodily functions) (Chauveau, 2005). The definition of a medicine adopted in 1965 at the European level and transposed into French law by the administrative order of 23 September 1967 (reproduced in article L.5111-1 of the Public Health Code) read as follows: “Any substance or composition presented as possessing preventive or curative properties with regard to human or animal diseases, as well as all products that can be administered to humans with the aim of establishing a medical diagnosis or to restore, correct or modify their bodily

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<sup>6</sup> Source: <https://www.philippe-burlet.fr/famille/aram-deukmedjian/yaourt/>

functions.” This definition thus aims to establish a boundary between medicines – whose alleged function is to treat the sick or act on bodily functions, and for which a balance between health benefits and risks needs to be established – and other products, which might contribute to the “maintenance of health” in addition to their other functions but which must not represent any health risks.

Taking off from this definition, the regulatory boundary between medicines and other products (notably foods) was steadily extended to all dimensions of the market. At a primary level, the growth of regulatory pressure, in the wake of the health scandals that punctuated the century, thus led to the strict upstream control by public authorities of these products through procedures for market authorization delivered by a competent health authority (the pharmacy division of the ministry of health until 1993, the French Medicines Agency or the European Medicines Agency (EMA) after that date<sup>7</sup>) and based on an expert evaluation of benefits and risks (Chauveau, 1999). At a second level, doctors and pharmacists fought to obtain and retain an exclusive monopoly on the prescription and delivery of these products. They thus constitute essential intermediaries between supply and demand, and accordingly occupy a central position, as much for the regulation of competition as for the promotion of products, through their choice of prescriptions. At a third level, the industrialization of extraction and production techniques of active ingredients and the optimization of research and development, with the institutionalization of screening methods and randomized, double-blind clinical trials, encouraged the autonomy of the pharmaceuticals industry around a model of product promotion based on the demonstration of therapeutic added value (Marks, 1997; Chast, 2002; Timmermans and Berg, 2010). The translation of the latter into commercial added value relies on the mobilization of patents (enabling the “protection” of the original against the copy), on the one hand, and on the development of public healthcare insurance, on the other, which led to the adoption of lists of approved medicines, distinguishing those considered useful or indispensable for public health, and thus covered by the public healthcare insurance, from those judged unnecessary or superfluous and therefore not covered and left to the individual. The market for these medicines at the beginning of the 1990s was thus characterized by a mode of regulation, distribution, industrial development, and commercialization that constituted so many barriers to entry for products and firms that have not run this gauntlet.

Food products also became objects of regulation, in particular with the law of 1905 on fraud and counterfeit, which structured the regulation of this sector in France until the beginning of the 1990s. According to Alessandro Stanziani (2005), the primary objective of this regulation was not the protection of consumer safety but the regulation of competition among producers. The public health arguments were invoked to legitimate the prohibition of a production process. The use of a food or food additive was accepted or rejected based on their capacity to protect the interests of the French dominant producers from competition by foreign producers (Stanziani, 2005). This hypothesis emerges most strongly in the study he conducted with Laetitia Piet and Jérôme Bourdieu on the French meat market. From the trichinosis and bovine tuberculosis of the end of the nineteenth century to the mad cow crisis in the 1980s and 1990s, “questions of food safety in the meat industry reflect the hierarchy between the disciplining of

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<sup>7</sup> The French Medicines Agency (AFSSAPS or ANSM since 2012) was created in 1993. The French Food Safety Agency (AFSSA) was created in 1999 and then merged with the Environment and Labour Health Safety Agency (AFSSET) in 2010 to become the French Food, Environment and Labour Health Safety (ANSES).

competition and the protection of public health” (Bourdieu, Piet and Stanziani, 2004, p.155). But what is most interesting about this history of food safety is that it implicitly reveals a second hierarchy, one between security of supply (the objective being to increase the quantity of food produced to “meet the needs” of the population) and food safety (the objective being to ensure that the consumption of food does not present health risks). Thus, any possible health benefits from diet were conceived throughout the twentieth century in terms of the absolute quantity of “nutrients”, of carbohydrates and fats, supplied (underpinned by a caloric approach). While the regulation of medicine gradually stabilized around an assessment of the balance between health benefits and risks, the regulation of food sought to strike a balance between these health risks and other benefits not purely health-related. A second distinguishing element concerns the regulation of the market itself. While the market for medicines developed from the 1960s around the marketing authorization procedure, regulation of the food market rested more on the control of “claims,” with the law of 1905 introducing the notions of “fraud,” “counterfeit,” and “false advertising” (Frohlich, 2017).

Thus, at the end of the 1980s, medicine and food seemed to be separated by an impermeable boundary, bearing not only on the definition of their characteristics but also on modes of organization and commercialization. The development of functional foods fractured this boundary.

## **1.2. ... to its challenge by functional foods**

“Since the appearance of bifidus yogurt in the mid-1980s, ‘healthy’ foods have proliferated like biblical loaves in the large supermarkets. Fruit juices, yogurts and cereals rich in vitamins (A, E, calcium), ‘bifido-fiber’ sugar for intestinal regularity, milk pasta for child growth, eggs ‘enriched with omega-3 fatty acids’, etc. The list gets longer every day. According to the marketing consulting firm XTC, 19% of new food products launched each year in France, and 22% globally, display concepts related to health.”<sup>8</sup> This press article from 2001 highlights the magnitude of the wave that washed over France and European markets at the beginning of the 1990s. But we should also add to this already considerable list of “healthy foods” the dietary supplements (e.g. Oenobiol® and Bion3®), meal replacements (e.g. Slim Fast®) and dietetic products (e.g. products marketed by Bjorg), medicinal plants available outside pharmacies and phytotherapy (e.g. products marketed by Arkopharma and Fenioux laboratories), and finally oral care cosmetics (e.g. the Inneov line developed by L’Oréal), that fill the aisles of pharmacies and supermarkets, when they are not sold directly by mail order.

Bernhard Kitous (2003) has suggested the following definition for functional foods (inspired by the Canadian definition for health products): “all products, processed or raw, intended for human consumption, for which a claim of ‘health maintenance benefits’ is made. It might be a complete food, an ingredient (nutraceutical) or combination of ingredients integrated into a single food product, or a distinct product like a meal substitute, dietary supplement, or staple food supplement” (Kitous, 2003, p.20). These different products all share a common claim to “health maintenance benefits,” thus placing them outside the category of “staple foods,” which

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<sup>8</sup> Laurent Flallo, “Le potentiel de croissance du marché des aliments santé demeure incertain,” *Les Echos*, 12 December 2001.



do not offer any health “added value,” but also falling short of the category of medicine since they cannot claim therapeutic effects against illness or bodily dysfunction. Their claims rest most often on the presence of one or several “nutraceutical” ingredients whose health benefits have been long recognized by nutritionists or established by scientific studies: vitamins (A, B1, B2, B6, PP, C, D, E), mineral salts (folic acid, calcium, magnesium, iron, iodine, etc.), probiotics and prebiotics, poly-unsaturated fatty acids (omega-3 and 6), and plant sterols and stanols. The novelty lies in the capacity and intention of industry actors to incorporate them into food products (dairy products, cereals, fruit juices, mineral water, etc.) or dietary supplements, in which they are purified, concentrated and combined in capsule, pill or liquid form.

Due to their “hybrid” character, these products also occupy a position at the boundary of several industries and markets. Diverse actors positioned themselves in this sector in the 1990s: agro-food companies like Danone, Unilever and Nestlé, pharmaceutical companies like Novartis and Sanofi, and producers of nutrients and ingredients like Arkopharma and Fenioux, which signed numerous tie-ups and joint ventures, with the aim of knowledge sharing in manufacturing, research & development, and marketing (e.g. Coca Cola and Sanofi failed commercial alliance in 2012 to launch “health drinks”). Facing saturated and largely glutted markets<sup>9</sup>, agro-food companies saw in “health” claims a way of differentiating themselves from their competition and “enriching” their product lines with featured attributes (“health benefits” in addition to the taste or nutritional advantages of the product) and higher prices (functional foods sold at prices 2 to 7 times higher than comparable “traditional” food products). For their part, certain pharmaceutical companies invested in the dietary supplements sector in order to diversify their product lines in the context of declining innovation, major increases in the cost of research & development and intensifying regulatory burdens in the medicine sector.

To justify their health claims, agro-food companies multiplied scientific guarantees and certifications, adopting at their own cost (albeit lower) the strategies developed by the pharmaceutical industry to promote medicines. Certain companies thus invested heavily in research & development in order to demonstrate the legitimacy of their claims. Nestlé, for example, had a laboratory with 3,000 researchers and devoted 1.5 billion swiss francs (1.6% of its operating revenue) to research in 2006; Danone, for its part, invested 130 million euros in its research center. These companies conducted a range of clinical trials, resembling those undertaken by the pharmaceutical industry on medicines, but involving more limited populations (from several dozens to a maximum of a hundred, as opposed to several thousand for medicines) and rarely respecting the protocols of double-blind randomized controlled trials. They could thus for the most part not lay claim to the “gold standard” represented by “evidence-based medicine” in the world of pharmaceuticals (Timmermans and Berg, 2010; Bergeron, Castel and Hauray, 2015).

These companies also tried to buttress the credibility of their claims by drawing on leading figures in the medical profession and scientific institutions. Thus, in 2002, the company Cema negotiated a partnership with the Pasteur Institute of Lille allowing them to display the

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<sup>9</sup> Étienne Chantrel and Pierre-Emmanuel Lecocq, “Les marges dans la filière agro-alimentaire en France,” *Economie & Prévision*, 3, 2009, pp. 141-149.

institute's logo on the packaging of their omega 3-enriched margarine, in exchange for a financial contribution to the institute (which relies primarily on private-sector financing).<sup>10</sup> In a similar manner, Unilever mobilized the big names in cardiology to launch its Fruit d'Or Pro-Activ® margarine at the beginning of the 2000s.<sup>11</sup> In another example of imitation of the “promotion” techniques for medicines, Unilever entered into a partnership in 2005 with the insurance company MAAF, in which the latter committed to reimbursing its clients for products branded Fruit d'Or (up to 40 euros) in exchange for having its logo appeared on the packagings. A similar tie-up was signed in 2006 between Danone and AGF for the reimbursement of purchases of Danacol®, Danone's anti-cholesterol yogurt. Even though insurers are not scientific institutions, these tie-ups adopt the codes of the promotion of medicines. The reimbursement of products represents a kind of official recognition of evidence-based health benefits in European countries.

Finally, functional foods benefitted from their position straddling different distribution channels, from pharmacies to supermarkets, including mail-order sales. This multiplication of distribution channels was often linked to a multiplication of promotion channels, ranging from direct advertising to the public to mobilizing pharmacists and doctors as “prescribers” of these products. This strategy of enlisting prescribers, relatively classic among producers of medicines and dietary supplements, was also adopted by food companies, like Unilever, which systematically peddled its products to general practitioners and cardiologists to ensure the development of its “Fruit d'Or” product line, and especially its “Pro-Activ” margarine, recommended for the treatment of high cholesterol.

While the boom in functional foods resulted primarily in a transformation of commercial strategy, these products also benefitted from a favorable context for the “healthicization” of food in France, even if to a lesser extent than in other countries, like Japan, the United States and the countries of Northern Europe. The growing interest on the part of scientists and the media in chronic medical conditions – like cardiovascular disease, diabetes and cancer, presented as somehow representative of the late twentieth century – and the research of nutritionists like Serge Renaud and Michel de Lorgeril on the benefits of the “Cretan diet” and the “French paradox” contributed to putting front and center the links between food and cardiovascular risk. The creation of the French Food Health Safety Agency (AFSSA) in 1998, in the wake of the mad cow crisis (Besançon, 2010), and the implementation of the first National Nutrition-Health Plan in 2001, under the aegis of the ministry of health (Bossy, 2010), also created an institutional framework explicitly linking food and health, as much in the regulation of the agro-food sector as in the consumer information campaigns (e.g. the “Eat-Move” program) of the French Institute for the Promotion of Health (INPES)). This media and institutional context promoted and supported rising consumer interest in products that highlighted their benefits (healthy foods) or absence of risks (light or organic foods, for example) for health. Although the first “individual survey on food consumption” (INCA), published by AFSSA in 1999, did not include a section on “healthy foods” and dietary supplements, the second one, conducted from 2006 to 2007, showed that nearly 20% of surveyed adults (and 12% of children) had consumed at least one dietary supplement over the

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<sup>10</sup> Catherine Petitnicolas, “Le logo de Pasteur Lille apposé sur une margarine,” *Le Figaro*, 8 March 2002.

<sup>11</sup> Jean-François Arnaud, “Fruit d'Or invente la margarine qui se vend à prix d'or,” *Le Figaro*, 6 May 2002.

course of the previous year, and more than 11% (4% of children) over the course of the 7-day study.<sup>12</sup> Furthermore, 60% of surveyed households (15% “always”, 45% “sometimes”) said they favored foods that indicated nutritional or health benefits on their label.

At the end of the 1990s, these industrial strategies ran up against two kinds of uncertainties, which represented obstacles to the sustainability of the market. The first dealt with the regulatory status and the health advantages of functional foods. Should they be considered like medicines, like “enriched” foods, or as distinct products with their own classification? And how can one guarantee that these products indeed provide the health benefits they claim and, on the other hand, do not present risks that might be commensurate with these benefits? If this uncertainty about the regulatory status and health advantages of the products had enabled their development, in allowing industry actors to promote them “at the lowest cost,” they also represented a danger in exposing these same industry actors to regulatory interventions (from the French Administration of Consumption, Competition and Fraud Repression (DGCCRF), the Medicines and Food Agencies) or litigation by consumer organizations. Furthermore, industry actors experienced considerable difficulties in making their product lines sustainable and maintaining high prices based on claims that did not enjoy any official recognition.

A second uncertainty had to do with the commercial status and value of these products. An initial difficulty concerned their commercial positioning: Should they be distributed in pharmacies, parapharmacies, small or large supermarkets? Should they be placed in a specific “functional foods” section, or with other foods with no health benefits? Should they be promoted directly to the consumer through advertising, or via prescribers (doctors, pharmacists)? One may illustrate these issues with the commercial failure of certain products like the health drink Nesfluid®, because distributors and consumers failed to situate it between the “fruit juice”, “fresh snacks”, and “health and dietetic” sections and because it was priced well above other products in these sections.<sup>13</sup> Yet another difficulty involved competition between industry actors. As the claims born by these products did not benefit from any protections (in the form of a patent, certification, or exclusive claim) or market entry barrier (marketing authorization), they risked being copied at any time and low cost. Thus, throughout the 2000s, functional foods appeared as products under retailer's brand, making the same claims to health benefits but sold at lower price points<sup>14</sup>. Major agro-food companies became strong supporters of European regulation and evaluation of health benefits, because they saw it as a means of “disciplining the competition” (Stanziani, 2005). In obtaining certification of their claims by French and European health agencies, these companies hoped to thereby erect a barrier to market entry for their competitors, to justify their higher prices and thus finance their research efforts.

From the end of the 1990s to the middle of the 2000s, various initiatives were proposed by industry actors, consumer organizations, and regulatory authorities with the goal of clarifying

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<sup>12</sup> Agence française de sécurité sanitaire des aliments (AFSSA), *Etude individuelle nationale des consommations alimentaires 2* (INCA 2), September 2009. [<https://www.anses.fr/fr/system/files/PASER-Ra-INCA2.pdf>]

<sup>13</sup> <http://www.lsa-conso.fr/nesfluid-une-chute-annoncee.124599>

<sup>14</sup> Jean-François Arnaud, « Carrefour clone Actimel », *Le Figaro*, 7 octobre 2002.

the status of these boundary products in order to regulate the interstitial markets on which they circulated.

## **II. Boundary work: the frustrated institutionalization of the functional foods market**

The appearance of functional foods in the middle of the 1990s greatly contributed to a blurring of the boundary between the markets for medicine and for food, chipping away at it from both sides. The ambiguity surrounding the regulatory status and health merits of these products undoubtedly contributed to their success in the 1990s. But it was also the cause of numerous controversies between industry actors, consumer organizations and regulatory authorities, which greatly complicated their establishing a sustainable position on the market. From the mid-1990s, these various actors engaged in considerable “boundary work” to redraw the boundaries between medicine and food. The concept of “boundary-work” has been developed by Thomas Gieryn to think about the ways in which scientists attempt to attribute “selected characteristics to the institution of science (i.e. to its practitioners, methods, stock of knowledge, values and work organization) for purposes of constructing a social boundary that distinguishes some intellectual activities as ‘non-science’” (Gieryn, 1983, p.782). As with the scientists Gieryn studied, regulatory authorities and industry actors undertook a project of codification and evaluation so as to be able to distinguish medicines, intended to treat and prevent illness, from food products (and supplements), intended to maintain good health and to act against the risk of illness. This work of setting boundaries was the source of intense controversy. It created new “territorial divisions” and new interstitial zones straddling these different domains. On the other hand, one also witnessed a convergence of modes of evaluation and thus of demonstration of health benefits and risks associated with medicines and food, leading industry actors to reconsider their research & development and marketing strategies. In what follows, we will therefore first present an analysis of this boundary work, with an initial focus on the new modes of regulation of functional foods put in place over the period from 2000 to 2006. We will then turn to the modes of evaluation of product health benefits by the AFSSA and the EFSA, before concluding with a discussion of the strategies developed by companies for responding to this new regulation.

### **2.1. A (re)composition of regulatory boundaries**

Regulation of functional foods stirred considerable controversy among public authorities and industry actors. The issue was whether to maintain (even if it meant altering) the regulatory boundary between the two and situate these products on one side or the other, or to erect new boundaries and construct an *ad hoc* commercial space by defining new categories for these products. There were thus multiple initiatives in the 1990s and 2000s coming from both public and private actors, both French and European, seeking to redefine product categories and regulatory modes.

The first option envisaged by public authorities consisted in simply applying existing regulation. According to the provisions of the Public Health Code, all products other than medicines claiming “preventative or curative properties in relation to illness” or “to restore, correct or modify bodily functions,” must submit an application to the Medicines Agency

(AFSSAPS) for a “product advertising” visa (PP visa), describing the proposed advertising campaign as well as the grounds for the properties being claimed (Veyssière, 2007). A commission of the AFSSAPS would then rule within 30 days on the merits of the claims with regard to the law and their scientific basis, after possibly consulting with the Food Agency (AFSSA). Food products also fall within the Consumption Code, article L.121-1 of which prohibits all false advertising to the consumer. Oversight of claims was thus entrusted to the French Administration for Consumption, Competition and Fraud Repression (DGCCRF), who could then solicit a scientific opinion from the AFSSA and, in the event of an infringement, prohibit the advertising campaign or impose a fine on the company. In addition, consumer organizations could refer a case to the DGCCRF or bring a legal action against the company for false advertising (Veyssière, 2007). In cases of “boundary products,” where there was a doubt as to whether to classify the product as food or medicine, the product in question had to be submitted to the regulatory procedure for medicines, in line with the European Directive 2001/83/CE of 6 November 2001.

Although the boundary between medicine and food was clearly delineated by the law, it did not resolve the uncertainty surrounding the status of functional foods in the 1990s. As Laurence Veyssière (2007) has observed, there were very few applications for PP visas submitted by companies selling supplements or food products with health claims. But consumer organizations, and in particular the UFC-Que Choisir, brought several law suits against these companies for “false advertising.” Indeed, these companies used vague terms to suggest benefits for well-being or prevention without explicitly falling within the legal definition of medicines. In spite of this strategy, numerous judgments led to the reclassification of these products as medicines by presentation (and more rarely by function) and convicted their producers of illegal pharmacy practices, selling of medicines without marketing authorization (AMM), and illegal advertising for medicines (Sevaux, 2014). Clearly, the uncertainty surrounding the regulatory status of functional foods offered companies a useful framework for innovation in advertising but also exposed them to considerable legal risk. However, this uncertainty surrounding the legal and regulatory classification of functional foods also constituted a major difficulty for regulatory authorities, whose mandate to control and sanction did not rest on precise categories for classifying these boundary products, at the very moment of their proliferation.

The solution adopted by French, and later European, regulatory authorities consisted in reconstructing the boundary between claims made by two types of products, medicines and foods. As seen above, all products that claim “preventative or curative properties in relation to illness” or “to restore, correct or modify bodily functions” are considered medicines. Throughout the 1990s, commissions of experts, representatives of public authorities and industry actors tried to specify precisely what claims could be made by foods without falling under this definition of a medicine. The first of these to be subject to attempts at definition in France and Europe were nutritional claims. They were defined by the decree of 27 September 1993 as “all representations and advertisements that state, suggest or imply that a food product possesses particular nutritional properties, either by virtue of the energy (caloric value) that it provides or does not provide, or that it provides at a reduced or elevated level, or by virtue of

the nutrients it contains or does not contain, or contains in reduced or elevated amounts.”<sup>15</sup> Based on this decree, the Inter-ministerial Committee for studying foods with specific diet purposes (CEDAP) proposed, in a notice issued on 18 December 1996, a list of nutrients and labelling that could be used by companies in their advertisements without requiring a PP visa.<sup>16</sup> This list was primarily comprised of vitamins and mineral salts whose effects on the normal functioning of the body had long been established by nutritionists.

Based on this determination, industry actors and scientists tried to erode the boundary established with medicines and extend as much as possible the spectrum of possible claims that could be made for foods. At the end of the 1990s, the European projects FUFOSE (Functional Food Science in Europe)<sup>17</sup> and then PASSCLAIM (Process for the Assessment of Scientific Support for Claims on Foods) – coordinated by the International Life Sciences Institute (ILSI), a consortium of scientists and industry actors, and financed by the European Commission – generated the following definition of a functional food: “Similar in appearance to a conventional food, a functional food is demonstrated to have physiological benefits and/or to reduce the risk of chronic disease beyond basic nutritional functions.” Two different claims – “improving function” and “reducing risk of illness” – were suggested. The first challenged the monopoly of medicines in the maintenance, restoration and improvement of bodily functions. The second aimed to establish a new boundary between curative claims (acting on illness), falling within the exclusive domain of medicine, and preventive claims (acting on the risk of illness), which might also be made by food products or supplements.

This work culminated in the European Regulation 1924/2006 of 20 December 2006 “on nutritional and health claims made on foods.”<sup>18</sup> Justified in terms of the need to harmonize the functioning of the internal market, to promote innovation and protect consumers, this regulation defines acceptable claims and their mode of regulation at the European level. It defines three types of claims:

1. Nutritional claims, which are defined in the same terms as the French decree of 1993: “any message that states, suggests or implies that a food has particular beneficial nutritional properties”;
2. Health claims: “any message that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health”. Health claims are themselves divided into two groups:
  - 2.1 Reduction of risk of illness claims: “any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease”;
  - 2.2 Functional claims: “the role of a nutrient or other substance in the growth, development and functions of the body; or psychological and behavioral functions; or [...] slimming or weight-control or a reduction in the sense of hunger or an

<sup>15</sup> <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000006082742>

<sup>16</sup> “Avis du 18 décembre 1996 sur les recommandations relatives au caractère non trompeur des allégations nutritionnelles fonctionnelles”, *Bulletin officiel de la concurrence, de la consommation et de la répression des fraudes*, n° 97/17, p. 730.

<sup>17</sup> <http://www.ilsilife.com/Europe/Pages/FUFOSE.aspx>

<sup>18</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1924&from=en>

increase in the sense of satiety or to the reduction of the available energy from the diet”.

Thus, the regulation created a new boundary between foods and medicines, having essentially to do with the kinds of claims made by the products: with medicines comprising any product claiming a curative effect on illness or on bodily dysfunction; and healthy foods and dietary supplements including any product claiming a preventive effect (on the risk of illness) or an effect on the maintenance or development of bodily functions.

The regulation also initiated a procedure for evaluating these health benefits. It assigned to the European Food Safety Authority (EFSA) the role of studying and issuing opinions on the scientific bases for all claims submitted by member states. Based on these opinions, the European Parliament was to adopt, by 2010, a positive list of all the nutritional and health claims that could be used by industry actors in the advertising and packaging of their products. Any claim not appearing on this list would be prohibited.

Even while creating a boundary between the claims made by medicines and those made by foods, the regulation established a procedure that tended to cause the modes of evaluation of both products to converge. From this point on, the claims made for products by industry actors would be made to conform, in advance, by scientific assessments conducted by a health authority: the EMA (or the AFSSAPS in France) for medicines, the EFSA (or the AFSSA in France) for foods.

## **2.2. A (re)evaluation of health benefits and risks**

The uncertainties raised by the appearance of functional foods did not only have to do with their regulatory status but also more generally with their health benefits. As the markets developed, it appeared increasingly necessary in the eyes of various actors to evaluate the legitimacy of these claims. For French and European public authorities, it was about protecting the health of consumers who might be encouraged to consume these products in excessive quantities or instead of medicines, but also a matter of promoting innovation and regulating competition while avoiding the “inflation” of “fantastic” and “unfounded” claims. For industry actors, it was an issue of protecting themselves from legal action for false advertising, making credible their health claims to consumers, and justifying considerably higher prices for these products. Thus, Unilever used the European procedure for “novel foods” – which submits market authorization for new food ingredients to clinical testing to assess any possible health risks<sup>19</sup> – as a way of establishing recognition of the significant benefits of plant sterols in the reduction of “bad” cholesterol. Requests for the evaluation of health benefits on the part of agro-food companies also served as a means of protecting themselves from the risk of lawsuits brought by consumer organizations. This was for example the case with Danone, who responded to the threat of legal action for “false advertising” made by the French Confederation of Housing and Living Conditions (CLCV), a consumer group, by submitting a request to the DGCCRF in 2002 to verify the ten claims made on the label of its yogurt drink, Actimel®, which was ultimately done by the AFSSA in 2004. Conversely, a lawsuit filed by the UFC-Que Choisir organization

<sup>19</sup> [https://ec.europa.eu/food/safety/novel\\_food/authorisations\\_en](https://ec.europa.eu/food/safety/novel_food/authorisations_en)

(another consumer group) against MAAF (an insurance company), challenging the advertising campaign announcing the partnership between the insurer and Unilever for the reimbursement of the latter's Fruit d'Or Pro-activ® margarine, was rejected by the Court on the grounds that the campaign "clearly specified that the product line enriched with plant sterols markedly reduced bad cholesterol when consumed as part of an appropriate, fruit-rich diet."<sup>20</sup> More broadly, some large agro-food companies were strong supporters of the implementation of European regulation and evaluation procedures for health claims, seeing it as a means of eliminating products and companies whose claims were not based on scientific evidence and considerable investment in clinical research. Main French retailers developed throughout the 2000s their own functional foods labeled under their retailer brand, making the same claims to health benefits but sold at lower prices.<sup>21</sup> By obtaining validation for their claims from French and European health agencies, these companies hoped to thus erect a barrier to entry for their competitors.

These private interests converged in part with the desire of health authorities and consumer organizations to control a nascent market whose effects on public health appeared mixed. Since its creation in 1999, the AFSSA has been charged with evaluating both the nutritional and toxicity risks as well as nutritional, functional and health claims of functional foods. This mission was undertaken internally by a "nutrition" committee of specialized experts (CES), which itself combined committees that had previously been located within the French Higher Council for Public Hygiene (CSHPF) and the CEDAP. The agency conducted individual analyses of products at the request of the DGCCRF or the company concerned. More broadly, it sought to establish guidelines for industry actors to assist them in preparing applications in anticipation of the implementation of a European evaluation procedure by the EFSA. Between 2000 and 2008, 590 claims were evaluated, with 20% receiving a favorable opinion from the AFSSA. And in 2006, the experts of the "Human Nutrition" CES relied on these evaluations to formulate guidelines for industry actors for the constitution and evaluation of their applications dealing with nutritional and health claims for their food products.

An analysis of AFSSA opinions on product health claims as well as the guidelines published in 2006 sheds light on the challenges of this evaluation. The first challenge concerned demonstration of the benefits of the food or nutrient. Numerous claims were rejected by the AFSSA due to an insufficient characterization or demonstration of the causal link between the nutrient and the claimed health effect. Taking the example of probiotics, the committee repeatedly questioned the concept of "good" and "bad" intestinal flora as well as the links between the properties (live or dead bacteria, family or specific strain of bacteria), the amount of bacteria and their effects on intestinal flora. The AFSSA rejected the claim "probiotic good for the intestine" made for a dietetic food product containing a probiotic, intended for infants and young children with risk of lactose allergies. If the first opinion (2004) had insisted on the absence of a demonstrated clinical effect, the second one (2007) underscored again the lack of comparative clinical studies (with the same product, but without the probiotic) and the claim was thus rejected as "imprecise" and scientifically "not proven." When the Afssa evaluated the

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<sup>20</sup> "Feu vert du TGI pour la pub anticholestérol," *Ouest France*, 14 June 2006, *Factiva Stérols*, p. 96.

<sup>21</sup> Jean-François Arnaud, « Carrefour clone Actimel », *Le Figaro*, 7 octobre 2002.



ten claims proposed by Danone for its Actimel® product in 2004, it recognized that the strain might have beneficial health effects, but that the scientific evidence adduced was insufficient to demonstrate all the claimed effects (insufficient number of subjects in the clinical trials, study subjects who did not correspond to targeted population, ill adapted product dose, etc.).

The second issue concerned the articulation between the benefits and risks of the products. Unlike medicines, whose risks are acceptable as long as they are counterbalanced by significant therapeutic benefits against serious illness, foods are defined, first and foremost, by their absence of risk, with any consideration of health benefits being secondary. It was for this reason that the European regulation of 2006 subjected the acceptance of these claims to an evaluation of the nutritional profile of the products. In the same way, the AFSSA proceeded to the systematic evaluation of health and nutritional risks of food products. At a basic level, the committee ensured that the nutrient or food bearing the claim did not constitute any risk to health or of interaction with other foods. In the case of probiotics, companies were systematically asked to demonstrate, based on the literature or preclinical or clinical trials, the absence of any danger from the strains. At a second level, the product itself – in terms of dosage – must integrate into a normal daily diet and its components must respect the nutritional profile of products of the same type. Any health benefits depend, of course, on the quantity of the substance said to be beneficial, but also on the recommended amount of this substance and of the food product in the recommended dietary allowances. The AFSSA and the AFSSAPS also established maximum doses of nutrients above which the product passes from the domain of food to that of medicine. Thus, in a 2008 opinion on the evaluation of the scientific basis for claims related to cerebral functioning, memory and vision for an omega-3-enriched dietetic margarine, used for spreading or cooking, the agency issued a favorable response for the claim “omega-3s contribute to the sound functioning of the cardiovascular system,” on the condition that the applicant respect “a quantity of omega-3 fatty acids for 100g of product greater than or equal to 15% of the Recommended Dietary Allowance (RDA) for an adult man; a ratio of alpha-linolenic acid (ALA) below or equal to 5; and a total lipid composition in accordance with recommendations for the prevention of heart disease.” Finally, at yet another level, the AFSSA incorporated consideration of the population targeted by the claims. Same claims made for biscuits received a negative opinion for children, because they could contribute to childhood obesity, and a positive one for seniors.

A third issue, directly linked to the second, concerns the formulation of the claim by the company. Once information became the central element of the regulation (Frohlich, 2017), the conflict around the boundary between medicine and food was in effect largely displaced onto the choice of terms likely to be endorsed by both industry actors and regulatory authorities. For the Food Agency, a product claim should not lead to unbalanced dietary behavior (overconsumption of the product, underconsumption of others) and the company should take care to indicate that the food should be consumed as part of a balanced diet. Likewise, the claim should not promote “unsuitable” behavior on the part of individuals who consume a food (or dietary supplement) instead of a medicine to treat their illness, putting at risk their chances of recovery. This was the reason for the rejection in 2001 of a claim – “part of a diet for elevated cholesterol” – for an oil with a certified quantity of vitamin E and rich in omega-3 fatty acids aimed at people with hypercholesterolemia or risk of heart disease. In the case of Actimel®,

the AFSSA rejected nine of the ten claims submitted by Danone<sup>22</sup> and proposed “participates in the strengthening of natural bodily defenses” instead of “helps to strengthen natural defenses,” even while requiring that the label specified that “the expected beneficial effects are only scientifically proven while the product is being consumed and cease very quickly after stopping.” Behind these modifications, which may seem minor at first, we see precisely the boundary work being carried out by the AFSSA. In substituting the term “participates” for the term “helps,” the agency wanted to insist not only on the limited effect of the product in the prevention of illness but also to neutralize any risk that this product might be substituted for a balanced diet (when maintaining “normal bodily function”), or for a medicinal treatment (when treating an illness that has already taken hold).

From 2006, the EFSA commission responsible for the evaluation of nutritional and health claims recruited a number of experts from the AFSSA and was to a large extent inspired by the criteria developed by that agency for evaluating claims. Like its French counterpart, the EFSA revealed itself to be particularly demanding, since only 510 claims out of 2,758 (created through the consolidation of nearly 40,000 applications submitted by member states) received positive opinions at the end of the evaluation process in 2010. As for probiotics, the EFSA rejected all 39 applications. Danone decided to withdraw its application in the middle of the EFSA procedure rather than risk a negative response.

These decisions slammed the brakes on the development of functional foods in Europe, to the astonishment of the companies that had invested in the sector. As the EFSA adopted methods and criteria of evaluation for functional foods that were as demanding as those adopted by its counterpart in charge of medicines (EMA) for their market authorization, was it still worth proposing claims for food products?

### **2.3. A (re)organization of markets and commercial strategies**

While many industry actors had been in favor of a European evaluation procedure for health benefits, the EFSA’s very severe responses to the vast majority of applications constituted a veritable bolt from the blue. This was particularly the case for probiotic companies who saw all of their claims rejected. We will now conclude our analysis by exploring the influence of these evaluations on the reorganization of the commercial strategies and markets for functional foods since the implementation of the European Regulation of 2006.

The case of dairy products enriched with probiotics – Danone’s Activia® and Actimel® – illustrates the strong links between the possibility for a company to make claims for its products and its ability to thereby promote these products. Whereas an article in the newspaper *Libération*, on 24 March 2004, considered that the opinion of AFSSA rejecting nine of ten claims constituted a humiliation for Danone, the company’s spokesperson, Corinne Robin, declared the opposite: “The claim of natural defenses, the one we have used since the beginning,

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<sup>22</sup> The nine rejected claims were as follows: “helps to strengthen your intestinal barrier”, “helps to regulate the immune system”, “contributes to the proper functioning of the immune system”, “helps to strengthen the intestinal immune system”, “helps the body to defend itself effectively”, “contributes to making the body more resistant”, “helps to protect your body”, “helps your intestines reject certain undesirable bacteria”, “helps your body fight against daily attacks”.

was accepted as the most pertinent. This decision grants for the first time the status of probiotic for a mass consumption product.”<sup>23</sup> Indeed, the company turned this claim into the basis for the promotion of Actimel®. And the AFSSA’s positive opinion, even if it came with numerous reservations, greatly contributed to legitimating this claim. Danone’s 2004 sales of Actimel® in France were 111 million euros (a 50% increase) and 285 million euros (+14%) for Bio®/Activia®. Sales for these two products saw considerable growth in France, and even more so globally, with Actimel® going from 890 million euros globally in 2006 to 1.2 billion in 2009, and Activia® going from 1.3 billion euros in 2006 to 2.6 billion in 2009 (with annual growth for the two products ranging from 10% to 20%). However, after withdrawing its applications to the EFSA for claim recognition for both products in 2010, Danone was no longer in a position to make any health claims. Even though the company tried to preserve the association of these products with health benefits, playing on certain elements of their marketing (the downward arrow on the packaging for Activia® suggesting effects for digestion, and the advertising associating the consumption of Actimel® with the arrival of winter), the brands registered a steady decline in sales, with the figures for Activia® declining from 2.9 billion in 2012 to 2.4 billion in 2014, and those for Actimel® dropping by 17% in France between 2013 and 2014.<sup>24</sup>

The situation was markedly different for dietary supplements. If many failed to receive approval from the European authority for their health claims, their sales were not as strongly affected by these decisions as were those for food products. If we are to believe the figures reported by the association of dietary supplement producers (Synadiet), sales slid between 2008 and 2010, but then returned to growth from 2011, with average annual increases of 3% to 4% between 2011 and 2016. The Synadiet reports sales figures for each market segment (from diet pills to immune defenses, including beauty products, constipation, respiratory tract and pregnancy). It is thus not possible to precisely measure the effect of the (non-) recognition of claims on sales based on this data. It is worth noting, however, that the two segments – “constipation/digestion” and “immune defenses” – in which some products contain probiotics and prebiotics (whose claims were all rejected by the EFSA) experienced divergent trajectories, with the sales for the former showing considerable growth and those for the latter collapsing.

The market for supplements would thus seem to have been less affected by regulation than that for food products. Indeed, the industry actors in this sector deployed a series of strategies to counterbalance the potentially harmful effects of EFSA regulation on the marketing of their products. A first strategy consisted in associating the “nutrients” whose claims were rejected by the EFSA with others (e.g. vitamins), which bore claims recognized by the EFSA and close to those promoted by the producers (e.g. muscle tone or protection against winter illnesses). A second strategy, which complemented the first, entailed promoting the “health benefits” of their products with doctors and pharmacists rather than directly to consumers. Indeed, the European Regulation of 2006 applied only to claims made directly to consumers and thus left outside its purview the interactions between industry actors and healthcare professionals, as well as those between healthcare professionals and patients/consumers.

<sup>23</sup> <http://www.lsa-conso.fr/actimel-ne-convainc-pas-l-AFSSA.78167>

<sup>24</sup> <http://www.capital.fr/entreprises-marches/danone-ses-yaourts-sante-n-ont-plus-la-forme-967287>

More generally, however, the companies that had invested in the functional foods sector were made to rethink their research & development and marketing strategies. The regulatory division of labor between the European Medicines Agency and the EFSA was mirrored in the division of labor of certain companies (primarily from the agro-food industry), between those which continued to hope to be able to modify the evaluation criteria and the opinions of the EFSA on health claims, and others that considered the EFSA opinions to have definitively blocked the institutionalization of a healthy foods market and decided to turn to the European Medicines Agency. Producers of supplements and ingredients seemed to still hesitate between the two strategies and thus participated in meetings and conferences organized by these two groups of producers. Far from completed, the boundary work of regulatory authorities and industry actors seems to have only just begun.

## Conclusion

Two major conclusions emerge from this study of the formation of a market for functional foods in France and Europe at the end of the twentieth century.

The first brings us to a reconsideration of the now classic works in the sociology and history of quality that we presented in the introduction. We rediscover a certain number of conclusions from these works concerning the importance of processes of classification in the reduction of commercial uncertainty and the disciplining of competition. Thus, the rise and fall of the functional foods markets is explained in large part by the high degree of uncertainty on the part of consumers, industry actors and regulatory authorities with regard to the health qualities of these products, and the incapacity of these different actors to distinguish “good” from “bad” functional foods. In rejecting the overwhelming majority of claims presented by companies, the French and European regulatory authorities not only brought “discredit” upon the health virtues of these products, but they also modified the terms of the competition between companies by greatly increasing the cost of market entry. However, our research brings to light a second level of uncertainty presented by the functional foods themselves, concerning their own status. The challenge for public authorities, industry actors and consumers was, in effect, to rethink the established boundary between medicine and food, and more generally between sickness and health, treatment and prevention. Drawing on the typology established by Armand Hatchuel (1995), the challenge for these actors was not only to sort good from bad functional foods (factual uncertainty) but to rethink this category of products and, through this process, redefine the boundary between medicine and food, sickness and health, treatment and prevention (notional uncertainty). Accordingly, our research constitutes a contribution to a sociology of commercial innovation, by showing the importance of boundary work in the classification of products and the structuration of the market.

A second major conclusion of this research involves the dynamic articulation between two processes: the *commoditization* of health and the *healthicization* of commerce. At first pass, the history of functional foods can be read as a process of commoditization of health, leading companies to instrumentalize the value accorded by our societies to health in order to “enrich” their food products by highlighting a distinctive quality (“health benefits”), thereby justifying higher prices and distinguishing them from their competition. According to this approach, the highlighting of the health virtues of products by companies is the extension (and flipside) of the

processes which, throughout the twentieth century, had led to the increasingly robust regulation of health risks linked to food and to the recent discovery of the influence of food on the most emblematic chronic illnesses of the late twentieth century (cardiovascular diseases, obesity, cancer, etc.). Another reading, complementary to the first, consists in seeing the formation of this market as the consequence of a strengthening of the regulation of the medicine market around a curative logic and evidence-based medicine. According to this logic, the functional foods market would constitute a space of “reclassification” for products not situated in the curative field or not satisfying the criteria of evidence-based medicine. This approach in terms of *commoditization* of health clearly illuminates the importance of the commercial *marketing* strategies that presided over the genesis of the functional foods market through the 1990s. However, in order to grasp the second part of this history, centered around the regulation of nutritional and health claims by food safety authorities from the 2000s, it seems to us crucial to invert the perspective and instead explore the process of *healthicization* of the market, along two interrelated lines. First, in regulating nutritional and health claims indicated on package labels or in advertising to consumers, this policy made the market into a mechanism for the promotion and extension of public health (Frohlich, 2017). Second, in applying to food (and dietary supplements) the evaluation framework developed for medicines (and based essentially on the evidence-based evaluation of a balance between health benefits and risks), this policy extended regulation from a curative approach to a public health approach, conceived by the World Health Organization as “a state of complete physical, mental and social well-being.” Even though they correspond to different moments in the history of the functional foods market, these two processes are intertwined in a dialectic, the endpoint of which, still uncertain, is central to the institutionalization of the functional foods market.<sup>25</sup>

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<sup>25</sup> Our current research seeks to examine this dialectical process at work on the European probiotics market since the implementation of the European Regulation of 2006. For another analysis of these intersecting dynamics, see Greene (2006) and Bergeron and Nouguez (2014).

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