Evidence for Markets, Markets for Evidence: Extending Evidence-Based Medicine to the Food Sector

A paper to be presented at the Rome IMP Conference 2012

Competitive paper

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Abstract:

This paper addresses the topic of standards and orders of worth and how they affect the relation between markets and firms. Our empirical setting is the emerging field of functional foods or foods which claim to have a health benefit. We follow how this market was formed and the critical role of standards in defining the product category and qualifying the evidence that could be used in claims about health benefits. These standards were largely based on those in use in the pharmaceutical industry which takes randomised clinical trials as the gold standard of evidence that has to be met before manufacturers are allowed to market their products.

In a second half of the paper, we shift our focus to how one large food multinational attempted to develop a market for functional foods, in parallel with more conventional foods and cognate areas such as medical nutrition. We show how this manufacturer addressed the development and marketing of functional foods and how it how it invested in creating an infrastructure to produce and use scientific evidence in its efforts to position itself in this market. We argue that these efforts produced a clash of different orders of worth within our focal company which eventually led to a significant decrease of its commitment to the functional foods market.

Key words: standardisation; evidence-based medicine; orders of worth; investments in form

INTRODUCTION

This paper addresses broadly the issue of standards and orders of worth and how they affect the relation between markets and firms. Our empirical setting is a traditional food company

and its attempts to move into the area of functional foods. Functional foods can be defined as foods which can claim a specified health benefit. The nature of these claims invoke a very different form of justification than that traditionally used in the food industry. Our focal company was unwittingly dragged into a world inhabited by the pharmaceutical industry where claims had to be justified on the basis of scientific evidence derived from randomised controlled trials and other standard protocols closely associated with evidence based medicine.

Our starting point is the notion of orders of worth first introduced by Boltanski and Thévenot (1991, 2006). Their key argument is that all forms of socio-economic ordering are permeated by multiple evaluative orders. These multiple evaluative orders are linked to particular forms of moral economy invoking different forms of justification. Boltanski and Thévenot (1991, 2006) invoke six different orders of worth (inspired, domestic, civic, opinion, market and industrial) featuring different modes of evaluation and relations.

In this framework, the firm is a particular institutional form which has been designed to compromise between the complexities created by multiple orders of worth (Thévenot, 2001). Other settings, such as markets, involve only one mode of coordination and as such, do not require the accommodation of multiple orders of worth. Whereas the framework proposed by Boltanski and Thévenot (1991, 2006) emphasises the working out of viable compromises, Stark (2009) proposes that multiple evaluative principles create uncertainties, and uncertainties create opportunities for entrepreneurships within organisations. Indeed, entrepreneurship is defined as the ability to keep multiple evaluative principles in play and exploit the resulting interplay (Stark 2009: 15).

Our purpose in this paper is to focus on how broader orders of worth are articulated and imported into the everyday practices of companies and what investments are required to subscribe to an order of worth. Thévenot (1984, 2001) introduces the notion of "investment in forms" to denote the generalisation of coordination that transcends idiosyncratic practices and local situations, and intends to support the standardisation of practices across contexts. An investment in form is thus costly in terms of socio-material infrastructures, but the return to this investment can be offset by the returns that can be obtained through the scope and temporal extension of the coordination regime it supports. If the notion of investment in form is directed at building these broader standards and regimes of coordination, it would be wrong to see these as public goods that can be accessed without further work or investment by those who access them. As the literature on standards illustrates (see e.g. Timmermans and Epstein, 2010), the implementation of standards is an active, time and resource-intensive process.

This paper examines how a particular set of standards, associated with evidence-based medicine (EBM) and randomised clinical trials (RCTs) [1]- progressively migrated from the pharmaceutical to the food industry and became a market device influencing how products are qualified and marketers frame their claims. In this paper, we focus on the migration of some of the principles associated with EBM migrate to functional foods. We show how the establishment of the functional foods is associated with standardisation efforts derived from the pharmaceutical industry and through our engagement with one major food producer, how the standards and orders of worth associated with EBM penetrate the world of food.

[1] The authors would like to thank Alain Desrosières and Fabrice Bardet for drawing our attention on the recent renewed interest for RCTs and the experimental society.

The structure of this paper is as follows: in the second section, we describe what we call the rise of evidence-based thinking. Our purpose is to paint a brief picture of the emergence of EBM, and how EBM became itself a template that other efforts at producing effort-based interventions tried to emulate. The standardisation efforts that consolidated the functional foods category owe a great deal to the principles of EBM. In the third section, we shift the focus to our case company and describe how this company approached the new world of functional foods and evidence-based claims on the qualities of functional foods. In the fourth section, we discuss the main findings from our empirical before offering some concluding comments on the final section.

THE INEXORABLE RISE OF EVIDENCE-BASED THINKING

The attempts to turn medicine into a science have been in evidence for a long while but are particularly noticeable after the Second World War (Timmermans and Berg, 2003). Medicine, like many other sciences, became the recipient of major investments leading to the creation of University medical schools and specialist institutes, the set up of considerable research infrastructures leading to an increasing specialisation of research areas, as well as the creation of specialised research journals and communities of research practitioners. Medical education evolved as a result and a particular form of research culture was wholeheartedly embraced.

Marks (2000) suggests that this evolution of medicine fits well with other stories about science, developed in the wake of the post-Second World War period with its emphasis on methodological positivism and the cult of objectivism. The evolution of medical sciences represents one more salient example of this trend. The insistence on the characterisation of phenomena through objective features and their measures; the reliance on standardisation including instruments and measures; the growth of knowledge through increasing specialisation; the emphasis on dispassionate and disinterested scientists; and the construction of objectivity as an impersonal standpoint, free from any bias or subjectivity, are all features of this movement.

The accumulation of medical knowledge based on extensive research created a significant gap between those who produced knowledge and those that were supposed to use that knowledge, namely clinical practitioners in the field. The training of clinical practitioners has always supplemented conventional education techniques with a significant socialisation aspect, with novices supposed to learn about institutionalised practices through their collaboration with established practitioners. In short, the building of clinical expertise had a solid scientific grounding but this knowledge needed to be filtered through contact with everyday clinical experience (Timmermans and Berg, 2003).

The rise of evidence-based medicine (EBM) – starting in the early 1970s – came to question these assumptions and propose an alternative model for clinical practice, based on entirely different assumptions. EBM is defined as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett et al, 1996: 71). As Timmermans and Mauck (2005: 18) remark, EBM is an umbrella term that includes anything from conducting a statistical meta-analysis of accumulated research, to promoting RCTs, to supporting standard reporting styles for research findings or even a personal orientation toward critical self-evaluation.

As Timmermans and Berg (2003: 88-89) explain, EBM set itself up against a conventional view of medicine characterised by these attributes:

1) The clinical experience of individual practitioners provides the foundation for diagnosis, treatment and prognosis;
2) Diagnostic and therapeutic reasoning relates observable symptoms and proposed interventions relate to the underlying pathophysiological processes taking place inside the patient's bodies.
3) Conventional medical education and training provide a good enough grounding for practitioners to assess novel medical knowledge.
4) Clinical guidelines may be of help to novices but constitute an unnecessary distraction for experienced practitioners.

The alternative proposed by EBM relied on a different set of principles:

1) Practitioners should use information derived from systematic, validated and unbiased medical research to support their judgments regarding diagnosis, interventions or tests. Clinical guidelines are an essential mediator between up to date scientific findings and the places where clinical knowledge is applies, namely medical practices and hospital wards.
2) Pathophysiology is a necessary but insufficient component for successful clinical practice. All inferences derived from pathophysiological knowledge should be benchmarked against diagnostic and therapeutic knowledge derived from methodologically sound empirical studies.
3) The evaluation of the medical literature should be grounded in a clear understanding of what counts as sound scientific evidence.

In summary, the ostensible aim of EBM is to produce a strong scientific foundation to eliminate variations in clinical practice, by promoting standards for effectiveness, efficiency and quality in medical care (Timmermans and Mauck, 2005). EBM has, according to some, been elevated to a new international standard of health care as attested by the growth of institutions and research programmes associated with the topic as well as the surge of methods such as RCTs in medical research.

The growth of EBM has had a profound but not entirely univocal impact on the profession. Supporters see EBM as the means to address the rising costs of healthcare, inequity and variability in the provision of health care (Timmermans and Mauck, 2005). By contrast, detractors see EBM as embodying all the limitations of standardised practices, including disincentives to innovation, as well as deskilling practitioners by encouraging "cookbook medicine" (see Isaacs and Fitzgerald, 1999 for a humorous commentary on EBM).

At the heart of EBM, lies the notion of standardising medical practice. Timmermans and Epstein (2010) define standardisation as a process of constructing uniformities across time and space through the generation of consensually agreed rules. Standards tend to span activity sites, coordinate activities over distance and heterogeneous metrics and are usually supported by a range of actors, going from professional or industry associations to states or international bodies. In healthcare initiatives like the Cochrane Collaboration (www.cochrane.org), established in 1993, provides a summary of the best available research evidence based on an international network of collaborators spanning over 100 countries.

In medicine, the term "gold standard" is used to describe the most decisive of compelling standard of evidence available. EBM and RCTs have become the gold standard in the health care field. As Timmermans and Berg (2003: 27) note, what counts as good practice and

increasingly, what meets the approval of those who finance health care, is inextricably linked to clinical guidelines derived from RCTs. The gold standard represents an epistemic shift in medicine, namely the move towards the outcomes of RCTs and population thinking at the expense of physiopathology and individual outcomes (Timmermans, 2008).

The rise of EBM also marks a shift towards what Daston and Galison (2007: 121) call mechanical objectivity – the drive to suppress traces of human intervention in the construction of knowledge and move it instead to a set of aperspectival procedures and protocols. Porter (1995) associated the rise of many forms of quantification (e.g. cost-benefit analysis) with the flight towards objectivity, not because these forms of quantification are necessarily better mirrors of nature, but because they best serve the ideals of standardisation, namely the ability to bridge variations in practice across barriers and distance and distrust.

Marks (2000) associates the history of RCTs with a drive to overcome mistrust in health care research. And in the 1950s, when the some of the practices that are an integral part of RCTs started in earnest, the objects of mistrust in clinical research included patients, general practitioners, clinical researchers, nurses and above all, drug manufacturers. In pushing the need for change, including randomisation, blinding and objective outcome measures, reformers pointed to the need to remove any vestige of bias and subjectivity from clinical research. In particular, as Marks (2000: 351), the image of medical profession in danger of being systematically misled by the pharmaceutical industry proved to be a potent argument in favour of RCTs.

Evidence-based approaches and the increasing reliance on RCTs as producers of reliable evidence has spread to a number of fields, including the social sciences, and crucially, public policy. In the US, the Coalition for Evidence-based Policy (www.coalition4evidence.org) portrays itself as a non-profit, nonpartisan organization, seeking to increase policy effectiveness through the use of rigorous evidence about what works. The hope is that the use of appropriate evidence could spur progress in public policy similar to that which transformed medicine. In the UK, the open endorsement of evidence-based policy by the incoming Labour administration in the late 1990s led to a boom in contract research and a newfound thirst for knowledge but all sorts of public bodies seeking answers to the question: what works?

At the end of the 1980s, after two decades of social experimentations in the USA designed to scientifically test the efficacy and the side effects of public programs, experts in public policy evaluation reached the conclusion that the model of an experimentation society should be rejected (Monnier, 1987). The experimentations at stake had at first generated a great interest, leading to protocols that involved cohort of several thousands of subjects, over several years and estimated at a cost of several million dollars (Bardet and Desrosières, 2011). They were deployed to study unemployment and the policies to get unemployed people back to work (Allègre, 2008), the reinsertion of prisoners in civil society, and the effect of educational programs on success or failure of school children.

Twenty five years later, we can observe the rebirth of an approach to public policy that is not unlike the one abandoned a decade or so ago. An editorial in the medical journal *The Lancet* (Vol. 364, August 28, 2004) stated: “As the Poverty Action Lab’s Esther Duflo, a professor of economics at MIT, has written, “Creating a culture in which rigorous randomised evaluations are promoted, encouraged, and financed has the potential to revolutionise social policy during the 21st century, just as randomised trials revolutionised medicine during the 20th””. This experimental approach, best exemplified by the work of Banerjee and Duflo

(2011), has attracted both interest and criticism in development economics (Rodrik, 2008; Deaton, 2009). Some of these arguments revolve around the refusal to accept RCTs as a gold standard of evidence, rather than a straightforward refusal to accept RCTs as a form of evidence.

Walshe and Rundall (2001) wondered whether the problems of managing health care organisations could be compared to the challenges faced by medicine in the pre-EBM era, and if decisions on how to organise, structure, deliver or finance health care should be helped by a form of evidence-based management. Rousseau (2005) looks forward to an evidence-based management characterised by Big E evidence – systematic, generalisable knowledge derived from scientific methods – as opposed to little e evidence, characterised by local, organisation specific, problem-solving knowledge. Pfeffer and Sutton (2006) follow in the same vein, even if they recognise – as does Rousseau – that a move to evidence-based management shifts power away from leaders, often venerated for their intuition and experience, towards impersonal judgments based on widely available data.

In short, the rise of evidence-based thinking has been fairly relentless largely based on the purported success of evidence-based medicine, even if this success is not as decisive as many followers would like us to believe. Clinical practice guidelines are often just that – guidelines rather than strictly enforceable standards (Timmermans, 2008). And the type of standards that can be applied to different areas is different, embodying a variety of types of investments in standardisation processes.

Thévenot (2009) regards standards as conventional forms of coordination, joining information and conformity. Standards require what Thévenot (1984) has called investments in form, which support generic forms of coordination. The returns on these investments vary according to three dimensions: the spatial and temporal validity of particular forms as well as their solidity. The last dimension is of special interest. Solidity refers to the weight of the material infrastructure that supports the implementation of standards. The gold standard of RCTs, for example, rely on significant investments in the solidity of protocols and statistical techniques, and these can be contrasted with less solid standards such as opinions of communities of experts. Thévenot (2009) emphasises the costs of setting up standards and participation in the processes that lead to the formulation of standards. A somewhat overlooked aspect is the costs incurred by adherent to standards in maintaining the necessary infrastructure required to comply with standards – these include the costs of acquiring certification of people and procedures, running laboratories and testing equipment and so on.

As Thévenot (2009) highlights, the adoption of standards in health care implies a variety of tensions and compromises between different orders of worth. Manufacturers of drugs, for example, make use of standards to get their products approved by regulatory authorities before they are allowed to sell them, and users of those products can access reimbursement schemes, either public or private. These processes invoke a variety of orders of worth, from the industrial (related to productivity and efficiency) to market (related to exchanges via sales or reimbursements) and civic (related to formal collective interests). And EBM could be regarded as combining a similar set of compromises, embodying the virtues of collective solidarity (civic), technical efficiency (industrial) and the economisation of scarce resources (market).

The rise of evidence-based thinking has thus many consequences beyond medicine and healthcare. It represents above all an epistemic shift in the types of arguments and statements that can legitimately be deployed in a variety of arenas – namely within markets and

organisations. Good practices and credible rhetoric need to be based on sound evidence, and what counts as sound evidence needs to firmly anchored in the dispassionate, unbiased protocols of credible science. Evidence-based approaches provide a sort of safety net, eschewing controversies fuelled by idiosyncratic judgments and biases, and promoting an impersonal, aperspectival brand of objectivity. It is, in a nutshell, the attempt to trump ideology through particular brands of pragmatism. EBM proved to be a beacon of excellence for all aspiring evidence-based approaches from evidence-based policy by government and public bodies, to evidence-based management in private firms. The fact that the standards demanded by medicine could not be attained, or what counted as evidence could not be restricted to hard-won, uncontested facts backed up by extensive protocols, did not seem to have dampened the enthusiasm of evidence-based advocates.

As Marks (2000) argued, EBM and associated protocols based on RCTs, was targeted at overcoming mistrust in the healthcare system, and fundamentally the mistrust engendered by the exaggerated and unproven claims of drugs manufacturers. As Timmermans and Berg (2003) show, it was the worldwide thalidomide disaster in the 1950s that triggered the now familiar system of regulation required drug manufacturers to prove the efficacy and safety of their products before bringing them to market. These regulations institutionalised RCTs as the gold standard in healthcare, a standard later explored in EBM evaluations.

The introduction of RCTs for the pharmaceutical industry has had a widespread effect on markets, beyond the testing of efficacy and safety of products prior to regulatory approval. As we will attempt to show in the empirical sections of this paper, the spread of an evidence-based logic based on RCTs to other markets, namely food markets, redefined what counted as evidence and what claims legitimately be made about products and their benefits. This is an area of obvious interest for all forms of market practices, and above all those related to marketing. The disciplining effects of evidence-based standards, backed up by sound scientific protocols, had a profound impact on how markets worked and how companies could relate to markets. In the next section, we will briefly describe the methodology of our study before introducing our empirical material in detail.

METHODOLOGY

The focus of our study is functional foods, broadly defined as foods that have proven health benefits. The collection and analysis of empirical data comprised two phases. The focus of the first phase was the history of functional foods. This phase of the study involved mainly desk research and involved the consultation of numerous books, articles, websites and publicly available policy documents. The history of functional foods can be traced back to a number of different countries and to particular government priorities, long before major corporations became involved. In particular, we tried to trace this history back to time periods of food shortages around the Second World War and how nutrition became a salient public health issue.

At the same time, the history of functional foods is tied up with concerns of defining the category and regulating what can be counted as a functional food. This phase of the desk research focused on the processes that led to the promulgation of standards at national and international levels, namely at the European Union level. To track the controversies and the progressive stabilisation of the vocabulary that defines the key food categories and in particular functional foods, our study has focused on the projects run by DG Health and Consumers (SANCO) of the European Commission that is in charge of food and safety.

Minutes of the task force created to reach a consensus on what is evidence and what is not were also consulted through the website of the DG SANCO.

The second phase of our study comprised field work in one major food producer, a multinational company with a strong presence in many European markets, the geographic focus of our study. This part of the study built on a significant degree of collaboration with the company over a long period of time, involving the first author.

We conducted a total of 15 semi-structured interviews in 2010-2011 with a range of managers across three food-related business units gaining rich data on how the company approached markets for different food categories and the infrastructures it built to address the requirements of those markets. The selected interviewees comprised the head of the medical department as well as the heads of 4 sections of the medical department, namely medical marketing, sales force, regulatory and science & trial sections. The emphasis on this phase of data collection was to understand how the company attempted to comply with evolving requirements in the functional food area and how it built a scientific and marketing organisation to cope with these new challenges. The interviews last in average 1,5 hour. They were held at the head office of the company, before and after department meetings.

During this period of the study, we collected a fair amount of archival materials namely training manuals, PowerPoint presentations and other forms of documentary evidence with the objective of understanding which tools and type of analysis were conducted to evidence the superiority of one type of functional foods over competitors'one. These materials were used to confirm the main events in the market, to provide details not available via interviews and also to provide textual accounts of debates and discussions.

THE EMERGENCE OF FUNCTIONAL FOODS: A CASE STUDY

The food industry has long been concerned with proposing foods with organoleptic benefits to consumers. In other words, producers have long since tried to differentiate their products through claims about taste. In Europe, at the start of the 21st century, a new trend emerged when food producers started to promote aggressively the functional qualities of the ingredients present in their products. The emergence of this trend and the mechanism through which these claims have been pursued is interesting because it represents a major shift in terms of how these claims are justified. This shift involves the use of a particular technique, RCTs more commonly associated with evidence-based medicine.

A short history of functional foods

The key milestones of a history of functional foods have been exposed by the International Life Sciences Institute (ILSI), a nonprofit, worldwide foundation established in 1978 to advance the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment. This institution is affiliated with the World Health Organization. By bringing together scientists from academia, government, industry, and the public sector, ILSI seeks a balanced approach to solving problems of common concern for the well being of the general public and tracks the emergence of new phenomena that can possibly have an effect on human being's health, including food trends.

The emergence of the term “functional foods” is located in Japan (Ashwell, 2002). But the famous Greek physician, Hippocrates understood this concept well, when he claimed: “Let food be thy medicine and medicine be thy food”. As early as in the 1980s, the Japanese government financed research programs on food with the aim of analysing their health benefits. In 1991, Japan produced legislation on food for Specified Health Uses (FOSHU). The objective of the legislation was to slow down the raising health costs and encourage the Japanese to consume more fibres and calcium. In fact, this trend was also to be observed in many other locations in the world soon after the end of the Second World War. The contemporary emergence of functional foods is the result of a combination of several factors, such as the ageing population in developed countries, the increasing autonomy and willingness of people to take initiatives regarding their own health, as well as the opportunities generated for food producers to sell value added products by claiming particular health benefits (Ashwell, 2002).

But before specialist would speak of functional foods, the initial official food regulations can be traced back to 1942 in Canada (Ashwell, 2002). They were part of a nutrition program during war time and aimed at improving Canadians’ health despite restricted food availability. The prevention of nutritional deficiencies was the main objective of the guidelines that followed. It was only in 1982 that the Canadian nutritional guidelines integrated the concept of functional foods, defined as a type of nutrition designed to reduce the incidence of chronic diseases.

Between the 1950s and the 1980s, the link between foods and chronic disease was systematically explored by researchers. In the 1970s, authorities in North America and Europe started to set up nutritional guidelines with specific targets such as the reduction of cardiovascular diseases and cancer. In France, for instance, the national plans for health nutrition (PNNS I et II) are examples of this type of guidelines, with a strong focus on over nutrition rather than under or malnutrition. These programs emerged at the beginning of the 2000s (WHO, 2008).

In the last 20 years, researchers have established that foods contain much more than calories, proteins, carbohydrates, vitamins or minerals as frequently reminded to us by health magazines and websites (Ruby, 2006). Ingredients such as omega 3 in linen seeds or fish, or foods rich in polyphenols are examples of specific ingredients studied by researchers to investigate their health benefits. Research centres on functional foods popped up all over the world. Numerous countries have initiated innovation programs to develop foods with functional benefits. Europe, in particular, seems open to functional claims about foods, resulting in public administration’s efforts to define what functional foods are.

Qualifying functional foods

At first, functional foods developed without any official definition. The wish to stress the functional benefits of particular substances led to various denominations and concepts: nutritional health, designer food, pharmafood, medifood, vitafood and so on. Progressively, a stabilised term became accepted, functional foods. To qualify as functional, food must contain a substance with proven positive effects on health. A further qualification was added: functional foods are conventional foods that deliver physiological benefits beyond the basic nutritional functions, such as a benefit related to the reduction of chronic diseases. These benefits have to be demonstrated and documented scientifically (Diplock et al, 1999 ; Ashwell, 2002). This precise qualification of functional foods made them more visible, more

unified as a category, and thus contributed to accelerate the positioning and development of new food products with health benefit claims. In the dairy industry, for example, Danone promoted the favourable benefits of bifidus on intestinal transit. Unilever companies promoted the benefits of vegetal sterols contained in margarine to reduce cholesterol. Numerous players in the fish industry have stressed the benefits of omega 3 in improving metabolism.

Consequently, a second type of discrimination appeared (Diplock, 1999). Brocoli, onion, olive oil and some types of fish are functional foods as they contain several components with health benefits, such as sulforafanes, flavonoïdes or omega-3. They can be labelled intrinsic functional foods in contrast to other type of foods whose benefits are derived from industrial processes. These are called functional foods by addition, or extrinsic functional foods. Some foods have also been systematically enriched, such as flour or pasta, to prevent potential deficiencies in specific nutrients. Various types of justification are used to support enrichment processes such as the weakening of certain foods through industrial processes that need to be rebalanced. In other cases, such as in Canada, public health policies require common foods such as white flour, corn semolina or pasta, to be enriched with folic acid. This practice is aimed at improving the intake of foliates by pregnant women and reduce disorders of the neural tube for new born babies (Ruby, 2006).

Within the European Union, a large project called FUFOSE (Functional Food Science in Europe) was initiated to promote scientific research on functional foods. This project, led by ILSI was started in the early 2000s, with a broader scope than the ones in North America. Further to the idea of reducing the risk of diseases, the European project includes the notion of improving health and well-being.

For FUFOSE, a functional food can be:

- A natural type of food whereby one component has been naturally raised through techniques of culture. For example, a variety of strawberry, rich in anti-oxydant, could be created. Omega 3 eggs also fall into this category, when the content in omega 3 is improved through poultry feeds.

- A type of food that has been enriched through addition with one beneficial component. Fruit juices can be enriched in calcium, or milk can be enriched by adding omega 3.

- A type of food whereby one ingredient has been withdrawn to reduce the negative effect on health. Biscuits without trans fats are an example of this kind.

- A type of foods in which one component has been modified chemically to improve its positive effects on health. The hydrolisation of proteins in formula milk for babies, for example, reduces the risk of allergies.

- A type of foods where the bioavailability of one or several ingredients has been increased to allow a better absorption of a beneficial component.

- Any combination of the above.

This project has allowed a convergence of interests between food producers, scientific bodies and consumers concerned with the relation between the consumption of food and its impact on health. The question of how to prove health benefit claims became a central issue (ILSI,

2002). Functional claims require the ability to demonstrate the effects of functional foods on health. Biomarkers have to be defined as indicators of real or potentials modifications within functional systems (organs, cellular and sub-cellular tissues), that can be used alone or in combination to trace the evolution of health and the exposure of populations to certain ingredients. These markers should allow the observation of effects, including in those situations where the time lag between the consumption of one ingredient and its effects would be long. A classification of markers soon emerged: markers of an exposition, markers of the target function and its biological response, markers of intermediary reactions (linked to the reduction of the key driver of a particular risk). In the case where the allegation would support the reduction of a disease risk, the proof should be based on validated markers of the disease itself (ILSI, 2002).

If the work to establish the denomination functional foods was a somewhat chaotic process, the one used to identify markers was a complex one. Still, this did not stand in the way of food producers communicating through TV commercials the health benefits effect of their products, raising a legitimate question on the part of consumer associations: what is the legal framework that regulates such claims? Indeed, the claim that chewing gum benefits breath freshness is one thing, but the use of gum to claim a reduction on tooth cavities is quite another. In many countries, consumer associations, but also public bodies such as health ministries and drug and food administrations, were calling in the early 2000s, for a legal framework against which these claims could be checked and validated.

At first, producers suggested that the presence of one ingredient that can promise to deliver a health benefit would suffice. In the case of chewing gum, for example, the presence of xilitol or any other polyalcool would be enough to explain why this product would have an impact on cavity prevention. The impact of polyalcool on the prevention of tooth cavities has been established scientifically (Ruby, 2006). But what are the quantities of a substance required to observe particular effects? Indeed, the presence of one ingredient says nothing about the quantities needed to reach a desired effect. Thoughts about the definition of functional foods led public bodies to progressively request greater rigour in demonstrating health claims before using them, in advertising for example.

The emergence of a legislation and a process to evidence claims

In the context described above, the role of regulators has been crucial for consumers or any competitor within the sector to protest against unproven claims. The proposed implementation of legislation that would force producers to prove their claims led logically to a debate on how to establish the scientific basis of claims. Establishing a scientific frame would help define the validity of claims and consequently help consumers to make valid choices and reduce market confusion. In June 2002, the General Directorate for Consumer Health (DG SANCO) at the European Commission published a draft proposal about functional claims in nutrition and foods. This proposal served as a basis for negotiations between EU member states in the second half of 2003. The tools involved to establish scientific claims emerged and were further defined in a second project called PASSCLAIM (Process for the Assessment of Scientific Support for Claims on Foods) also coordinated by ILSI Europe. This second project built upon the principles defined within the publications arising out of the FUFOSE project. PASSCLAIM aims at creating a consensus document containing criteria to assess the scientific basis for claims on foods, and disseminating it amongst scientists, producers, consumer groups and regulators.

It is only in December 2006 that regulators at the European Union reached a consensus and voted a law that grounds the foundations of a European harmonisation regarding the rules to follow in terms of health and nutritional claims. Through this legislation, the EU wishes to ensure that all claims are substantive and justified scientifically. They stress that "applications for the authorisation of health claims should adequately demonstrate that the health claim is based on and substantiated by generally accepted scientific evidence, by taking into account the totality of the available scientific data and by weighing the evidence". They define that "well-designed randomised controlled trials (RCT) provide the most persuasive evidence of efficacy, allowing strong inferences" (Gallager et al. 2011: 19). Three set of laws are issues under the articles 13.1, 13.5 and 14. The EFSA (European Food and Safety Administration) received the mandate to check the claims' validity of already launched products, as well as receiving and validating all filed requests for the launch of new products in European markets.

Benefits of a legislation about health and food claims for all stakeholders

Consumers have an interest in this type of device, in particular with the ageing population that wishes to stay healthy for longer. This interest has been largely triggered within a context where chronic diseases increase dramatically, together with the social trend of taking care of one's health (self-care).

The food industry has often been blamed for serving consumers with too fatty, too sweet or too salty types of foods. This industry regards functional foods as a strategy to improve its image and also to generate further profits. In the early 2000s, the market for functional food was said to represent nearly one hundred billion Euros of sales, following a steep growth curve, expecting to reach € 150 Billions by 2010 and represent nearly 5% of total food expenditures in the developed world. (Aroq, 2004)

For public bodies, this legislation proved to be a helpful device as well. It allowed health authorities to promote the benefits of particular types of foods to prevent the onset of costly chronic diseases, such as cardiovascular ailments, cancer, diabetes or obesity. Countries such as Japan have invested into the promotion of functional foods with the objective of improving the general health of the population and thus slow down the cost of treating disease. It appears from this short history that traces the emergence of functional foods that the universe of the food industry has started to resemble more and more the world of medicine and pharmaceuticals. Claims have to be substantiated scientifically. They have to be approved by an official organization (the EFSA, in the case of Europe) before some marketing activities such as advertising can use them.

How did a food company adjust to these developments ?

Beyond these developments within the food industry, a look at individual companies will show how these trends are rooted in specific practices. The second part of our study consists in identifying how a large corporation takes into account the scientific dimension to promote its functional food products. Healthy Foods (a pseudonym), our focal organization, is a corporation that operates in the nutrition sector with three business units. First, it produces and sells foods for consumers; secondly, it offers baby nutrition to mums through health care professionals (HCPs) such a paediatricians, general practitioners and pharmacists. And lastly, it offers advanced medical nutrition, aiming at complementing medical treatments for diseases such as cancer, for example.

A particular department dealing with health issues

Within the last two divisions, Healthy Foods structured its sales activities around three major departments : marketing whose role consists in studying markets, developing adapted offers, and promoting them towards HCPs; the medical sales force, whose mission is to present the company's offerings to doctors through face to face interactions; and lastly, medical affairs is the department in charge of running the ad-hoc scientific research to justify the functional claims made by the company's brands. It is also important because this is the one department that checks if marketing messages comply with legislation.

Studies about the perception of science among HCPs

Healthy Foods addresses health care professionals (HCPs) such as paediatricians, neonatology specialists, midwives, GPs and nutritionists. Market specialists in this company describe their targets with in-depth studies. The large population of HCPs shows various attitudes and behaviours towards the prescription products. Typologies are thus built to create clusters of homogeneous HCPs and qualify their propensity to recommend a specific brand of baby milk. In one given country such as the UK, one can register up to 58,000 HCPS that can be grouped around the following criteria: a) HCPs totally opposed to prescription, b) HCPs who are partly open to prescription based on pragmatic considerations (e.g. the product helps the patients even if it only has a placebo effect), c) HCPs who based their prescriptions on what they consider very strict scientific criteria, and lastly, d) those HCPs who accept to prescribe the product of one specific supplier, Healthy Foods or any other competitor.

These clusters predict the type of information that an HCP will expect to receive from producers, either through specialist magazines, or sales reps, before engaging in a conversation with the parents of a child. They impact the type of evidence requested by these professionals before they accept to prescribe one particular product or brand. These clusters characterize the type of sales devices that medical visitors should be equipped with, when meeting doctors, for example.

Some HCPs have great empathy towards mums and feel comfortable to prescribe milk whose scientific claims are very limited, provided the baby and the mum feel relieved. Other HCPs, on the other hand, will only propose products that have been studied scientifically with what they perceive are very strict protocols. But even in this case, studies carried out by Healthy Foods show differences across HCPs: immunologists would accept protocols that include *in vitro* experimentation, while paediatricians only accept studies carried out on human beings. The studies produced by the company also rank the prestige and authority of scientific journals according to the various types of HCPs.

These observations based on behaviours and attitudes of HCPs have an impact on the ways research programs are developed and implemented at Healthy Foods. Most research programs are costly, and often lead to uncertain results in terms of commercial exploitation. Scientific results are to be achieved in long term horizon whereas Healthy Foods traditionally expects short term results. With similar constraints, competitors of Healthy Foods have made a strategic choice to use generic claims, based on less specific research programs with weaker scientific basis, but delivering a better return on investment, aligned with the company's traditional expectations. The engagement of a firm in a scientific program is subject to a risk analysis that oscillates between managing financial return expectations and the scientific

expectations of the medical community. The choice of Healthy Foods was, over the last decade, to invest in credible scientific research in the medical nutrition and baby nutrition departments.

How to assess the strength of claims?

In an industry where producers talk to HCPs, the competition to demonstrate the scientific relevance of products is fierce. Marketing and sales people spend a significant amount of their time and effort to prove why their products are better than those of their competitors. Scientific argumentation is at the root of the rhetoric used by these market professionals.

Over the years, specialists within the medical affairs department have built a method that allows them to qualify the claims issued by competitors to HCPs. This scale, as the director of medical affairs explained, is freely inspired by the work of Guyatt & Rennie (2002) who argue that expert opinions without explicit critical evaluation, based on physiology or on studies carried out on animals lead to weak statements. Building progressively stronger argument takes place through a series of case studies, studies with a control case, cohort studies, RCT studies, and ultimately, meta analysis. It is helpful to sensitize the marketing and sales teams to this variety of scientific studies, says the director of medical affairs, to show that science feeds on controversies and requires the progressive settlement of controversies through different forms of empirical studies. Thanks to this method, marketers and salesmen are trained to build strong statements and argue them in front of doctors who would contest them with ideas learned at university or promoted by competitors of Healthy Foods. Of course, because they develop this new critical expertise, marketers and salesmen turn this process to challenge the benefits of their own products as well.

This easy to use method is based on an ordinal scale designed to score the strength of a scientific argument. The first level of this scale qualifies “weak” an argument that says that an ingredient, known for producing a positive effect is present in the product, even if the benefit has not been proven in a real usage situation with the product. Level 2 is used when a product contains an ingredient present say in mother’s milk, and when it is claimed that if the product has the ingredients profile of mother’s milk, it is then close to the ideal standard. At level 3, the metabolic function of the ingredient is documented. At level 4, clinical trials based on RCTs are carried out, leading to claims such as “we could record a higher level of Zinc in the plasma after a Zinc supplementation”. At level 5, the link between a health benefit and a cause has to be investigated and established through an RCT. For instance, a statement such as “we could record significantly less atopic dermatitis in a population supplemented with prebiotics” should be demonstrated through the use of a RCT. And finally, at level 6, the results of studies carried out at level 5 have to be published in reference peer reviewed journals. The quality of the journal, based on a citation index and its impact, allows a claim to reach the top, 7 score. The scale, as enacted by Healthy Foods, helps the company to argue against competitors’ claims by proving that their evidencing protocol is inadequate.

An example of argument assessment

Beyond the use of the scale just exposed, a more sophisticated analysis is carried out to make a judgement about competitors’ claims. An example will help understand the process.

Company A, a competitor of Healthy Foods, communicated in brochures given to doctors the following argument : “Product X contains a unique mix of fatty acids (without palm-olein) which allows the absorption of calcium, and thus allowing bones growth among kids, faster than any other product on the market.”

This claim is based on a series of studies run through RCTs, by testing product X against mother’s milk, against competitors’ milks, including the one of Healthy Foods. Apparently, the research has a strong scientific basis, as a RCT procedure was involved. It leads to the claim for the superiority of this product against others. Confronted by this claim, the medical affairs department of Heathy Foods was asked to assess its legitimacy so that salesmen and marketers can contest the argument of company A. Here is the logic put in place after a bibliographic review of the research carried out by company A:

“In human milk palmitic acid represents 20-25% of fatty acids. The substance Palm oil / olein (PO) is a traditional substitute to palmitic acid present in mother’s milk. It is used in maternities as the primary source of palmitic acid. PO has proven over the years to be a safe substance so that the ingredient has never been restricted or banned for its use among children”.

Studies carried out and validated by Koo et al. (2006) have proven the effect of Ca and absorption of fatty acids on the mineralization of bones. In comparison to the infant formula produced by competitors, the proportion of PO in the tested formulas was higher (15-30% vs. 45-53% of total fatty acids), which suggests that product X could deliver a better mineralization than other products on the market, including those of Healthy Foods. However, the mineralization values published by other formulas present on the market evidence a level certainly lower than the one of X, but totally included in the normative values accepted at age of 3 and 6 months (Clandinin et al. 2004). Furthermore, all studies produced by company A refer to short term effects. To discuss the effect over time, Young et al (2005) could prove that observed mineralization differences, resulting from variation of PO (so long this proportion remains in the normative values) given to kids before age 6 months, had no significant impact on calcification in the long term (4 years).”

As a conclusion, company A made a robust statement using good science when the analysis only reaches level 5 in the ordinal scale developed by Healthy Foods. However, when a further judgement is involved including a more complex bibliographic analysis, company A was only able to establish a well known generic result that so far, it could not demonstrate to apply to its own fatty acid. The claimed superiority on mineralization, suggested by a higher proportion of PO, is a claim that cannot hold. The results of the study generated by company A do not produce sufficiently strong evidence to sustain its targeted claim.

Training managers on the principles of EBM

Marketers and sales people are commonly not trained to carry out the type of analysis described above. One could argue that this is not their job either. But still, they have been able to engage in a conversation at this level in front of HCPs. It took Healthy Foods a significant amount of effort to make these market professionals familiar with research methods and the processes involved in assessing the validity of a statement. Healthy Foods put in place training actions to help these populations understand that the statement “scientifically proven”, frequently used in advertising communication, does not mean anything by itself. The quality of a research, it is said at Healthy Foods, lays first in the

quality of the statement put to the test. One can indeed prove scientifically a statement with weak relevance. The quality of a research lies in the quality of the experimental protocol and ultimately, in the reliability of the experimentation.

Because nutrition is a discipline that mirrors medicine and because HCP are involved in the prescription of infant milk formulas, scientific experts at Healthy Foods promoted what they considered to be the gold standard of evidence based medicine (EBM). Training sessions were further organized for marketers and sales people to learn the appropriate scientific language. It was expected that they would be able to engage in conversations with doctors, not so much on the physiological processes involved when using baby milk, but on the experimental processes involved in research about infant formulas. The RCT protocol in general, and in particular the 4 major types of bias (selection, performance, attrition and detection) became core concepts selected to be central to these training sessions.

The EFSA trial

Our case has so far described how Healthy Foods progressively promoted a careful and detailed education about the production of scientific knowledge and associated research processes. Whereas this is the domain of R&D and health affairs managers, the education of marketing and sales population within the baby nutrition and the medical nutrition divisions became a top priority. In the consumer goods division, it was of a very different kind of game: products are sold to consumers in supermarkets, with the support of intensive TV advertising. The buying process is based on other considerations and HCPs are not part of it, or play only a very marginal role, such as in the case of products with anti-cholesterol benefits or those promising a faster bowel transit. But still, TV ads largely refer to health claims and the statements made by Healthy Foods were at times couched in a very loose scientific language. It is true that consumers are frequently not competent to appreciate the scope or the validity of a statement, provided they are at all interested in being addressed on such terms. Globally, the consumer goods divisions could face the criticisms commonly levelled at functional foods in past public debates, as we have reported in the first section of this paper.

As all players within the food industry, Healthy Foods has been exposed to the regulatory constraint of having to prove its claims, using a protocol that resembles to the one widely adopted within the pharmaceutical industry. When filing its case, the company was exposed to a variety of situations. In two of its divisions, the teams were prepared for this confrontation. Numerous studies had been conducted, leading to claims about what constitutes good scientific evidence. A few cases with a fair chance of success were filed at EFSA. Most of them were approved by this institution.

In contrast, within the consumer goods division, several cases were put forward, with some of them had to be withdrawn before the EFSA validation. Many of them were rejected because they were based on substandard science. The consequences of rejection by the EFSA had dire consequences. Healthy Foods had to withdraw all communication materials that referred directly or indirectly to health benefits, and it was widely believed that the negative reputational effects extended well beyond the consumer goods division.

A year after the rejections by the EFSA, Healthy Foods estimated that the investments required to establish the health benefits of functional foods were too costly and demanding.

This marketing option was partly divested and investment proposals to exploit this type of claims were carefully scrutinized.

DISCUSSION

The evolution of functional foods shows how its establishment as a recognised and distinctive category relied on its progressive hybridisation through the importing of standards that are generally associated with the pharmaceuticals. The move to define functional foods as types of foods with proven health benefits brought into play the standards of evidence required to prove these benefits.

The standards of evidence that the EU regulators settled on in 2006, established the gold standard of evidence-based medicine namely RCTs as the benchmark for functional foods. The establishment and enforcement of standards, through the European Food Standards Agency, had a powerful impact on the establishment of a market for functional foods. It provided an arena through which health benefits could be established and marketed to HCPs. The convergence of standards between the food and pharmaceutical industries, namely the reliance on RCTs as the gold standard, made it easier for manufacturers of functional foods to align their scientific and market practices with the pharmaceutical industries.

Manufacturers such as Healthy Foods embraced the challenge of meeting the evidence-based challenge with important investments in both R&D as well as marketing. These investments would allow the company to produce statements about their products that were backed up by appropriate scientific evidence and complied with the rules set up by the regulator. As Callon (2009) argued, the meaning and impact of scientific statements are tied up with the socio technical *agencements* involved in the production of the facts that these statements uphold. Statements are thus entangled with the technical devices, procedures and protocols, embodied skills and so on. In the functional foods case, as we have highlighted, statements about the qualities of these foods are entangled with the bricolage of practices that are associated with RCTs, namely the double blinding of researchers and research subjects, the monitoring of an untreated control group, the random assignment of patients to control and treatment groups, the statistical treatment of results and the reliance on the objective measurement of outcomes (Marks, 2000).

As the Healthy Foods has shown, the adoption of standards and the capabilities required to comply with standards requires major upfront investments in external as well as internal infrastructures, as well as continuous investments in maintaining and upgrading those capabilities. To produce scientific statements about one's own products and to assess statements about competitor's products requires that those statements are anchored in appropriate scientific evidence, complying with the cannons of RCT studies. This required Healthy Foods to acquire and maintain a scientific infrastructure, including the ability to produce and use scientific knowledge in a variety of ways. HCPs were classified and ranked in terms of their interests, level of susceptibility to different forms of argumentation, scientific journals they would read and types of evidence they would be willing to listen to. Sales and marketing personnel were trained to deploy arguments based on the logic and standards of evidence-based medicine, including the sources of bias in RCTs, and to use these arguments in their contacts with different categories of HCPs.

Whereas the first part of our empirical story regarding the set-up of a standards infrastructure illustrates Thévenot's (1984) notion of investments in form, the costs of setting up standards

and participation in the processes leading to the formulation of standards, the example of Healthy Foods brings to the fore another aspect of standardisation. The recurrent costs incurred by complying with standards requires the maintenance of an extensive infrastructure required to comply with standards – in our example, these include the costs of keeping up to date with the scientific literature, teaching non-experts to recognise different standards of evidence, tailoring different types of argumentation to different types of HCPs and so on.

The example of Healthy Foods also illustrates the problems of reconciling different orders of worth within the same company. The company's business across nutrition areas involved baby, medical and consumer-based businesses. Whereas baby and medical nutrition followed the path of hybridisation, bringing the company closer to the standards expected from drug manufacturers, the more consumer side of the business operated in a looser regulatory environment, where claims to health benefits were more diffuse and subject to less rigorous standards of evidence. When it came to submitting claims to the EFSA, two of the teams were well-versed in the types of arguments and evidence expected to obtain regulatory approval. The same could not be said about the consumer side of the business and some of its attempts to obtain regulatory approval for functional food products fell by the wayside, with the company having to write off significant investments in promotional materials. These failures led the company to become wary of further investments to sustain what it perceived as risky claims regarding functional foods, scaling back its ambitions in this area. In short, whereas two of the three nutrition areas seemed well-equipped to deal with the compromises and tensions of adopting health care standards (Thévenot, 2009), the foray into functional foods laid bare the strains of trying to operate within a consumer market environment whilst trying to abide by the rules of healthcare markets.

CONCLUSIONS

The history of functional foods and the case of one major food multinational's foray into the world of functional foods, illustrates a number of issues with theoretical and methodological implications for our understanding of markets. First, we can mention the issue of standards and its impact on markets. Timmermans and Epstein (2010) regard the creation of standards as the meeting of numerous parties with the intent of promoting coordination, comparability and compatibility across multiple contexts. To build up standards requires significant investments in form as Thévenot (1984) has mentioned, and some of these investments display considerable solidity – i.e. in terms of the material infrastructure that supports their establishment and maintenance.

The case of functional foods illustrates how standards were instrumental in defining and qualifying this new product category. The emergence of a market for functional foods preceded standardisation efforts, but the emergence of standards has greatly contributed to the expansion of the market. As Callon et al (2001) remark, markets can be efficient when they are able to frame problems simply and not entangled in all the overflows that framing can produce. Markets abhor deep uncertainty and develop when stable frameworks for action can be provided. The standardisation efforts at the turn of the century have certainly provided a degree of stability.

As we have seen, if the setting up and maintenance of standards involve significant investments by public agencies and bodies, their adoption by private firms requires important investments in infrastructures to ensure compliance with standards. The case of Healthy

Foods exemplifies the nature and scope of these investments in a scientific and marketing infrastructure to address the effects of standards on the marketplace.

Secondly, the example of functional foods illustrates how new standards are deeply influenced by existing standards and existing philosophies underpinning standardisation. At first sight, functional foods have little to do with pharmaceuticals. Market structures for functional foods and drugs are highly differentiated, the structures for accessing each product category are totally different, and so on. But, the emergence of nutrition as a health care specialism and as a public health objective, have brought the two domains closer together. If functional foods could be characterised in terms of producing demonstrable health benefits, then the standards of evidence demanded of drug manufacturers could be easily transposed into the newly-defined product category. Claims about health benefits could thus be judged using the same type of evidence regardless of whether the product in question was food or drugs, and this evidence should meet the gold standard of EBM, namely RCTs.

Finally, our case brings forward a number of issues related to orders of worth. Markets are taken to embody one order of worth, concerned with the reduction of all matters to economic value, the calculation of revenue, profits, return on investment and so on. Organisations, on the other hand, are compromising devices between different orders of worth, involving at least an accommodation between the market and industrial modes of worth with their different approaches to temporality (Thévenot, 2001). The case of functional foods and Healthy Foods illustrates that orders of worth are more variegated and less easily containable that this account suggests. The infrastructure of calculation that sustains functional foods markets relied on the prior establishment of standards, as we have mentioned. The qualification of products in terms of health benefits – a key market activity – rested on the ability to back up claims with evidence derived from scientific research. Similarly, the activities of Healthy Foods in functional foods relied on its ability to accommodate the order of worth produced by standards derived from EBM (what counts as a legitimate claim about health benefits?), and find ways to accommodate this order within its three business units devoted to food. As the history of Healthy Foods illustrates, this did not prove easy or durable. Organisations may be indeed compromising devices by nature, but there are serious limits on how much controversy can be accommodated within any one complex structure.

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