

# BODIES OF EVIDENCE

## AN ANTHROPOLOGY OF THE HEALTH CLAIM

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En vue de l'obtention du titre de Docteur en sciences politiques et sociales

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# Introduction

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*Let food be your medicine and medicine your food.*

Hippocrates, 460-377 BC  
Thomas Hatzhold, Kraft Foods, 2008

*Just leave the debate to those who know what they are talking about.  
And not to unqualified researchers in the matter, even if they have a  
university diploma in sociology. Because they also will have to rely on  
science.*

Commentary on the website of *De Standaard*<sup>1</sup>

*Amid Europe's Food Fights, EFSA Keeps Its Eyes on the Evidence.  
Europe's food-safety watchdog, celebrating its 10<sup>th</sup> anniversary this  
month, wins praise for sticking to the science – even when European  
prefer not to hear it.*

Title of News Focus Article in *Science*<sup>2</sup>

Eating constitutes, along with breathing, one of the primary and most frequent interventions upon the body, linking it directly with its environment. Thinking about the applications of biotechnology in food, L. Dubois (1996: 46) emphasizes that knowledge and beliefs about food have always been invested with relations of power. Different groups and institutions have moralized food throughout the centuries, and have proclaimed the 'right' food and eating habits. Indeed different, often moral authorities have prescribed what one should (not) eat and continue to do so today. Apart from religious authorities and traditional healing systems we can, since the 19<sup>th</sup>-20<sup>th</sup> Century, count in state administrations and scientific institutes as producers of classifications of foodstuffs and prescriptions for healthy diets and ways of living (Foucault 2001; 2004; Nestlé, 2002), and their role today is of considerable importance (Demortain, 2007; Winickoff and Bushey, 2010).

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<sup>1</sup> Only available on the website to members subscribed to the newspaper. I translated from Dutch.

<sup>2</sup> See: Kupferschmidt (2012)

## Health Claims and Innovation in the Food Sector

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Today, food production has become largely industrialized, at least in the West. Our physical relation to food is mediated by a series of actors such as the food industry, transport companies, and supermarkets. Our cognitive rapport, and our emotional relation to food is in its turn mediated by advertisements, scientific information on food packages, doctors and occasionally dietary specialists. Mediation means that something changes along the chain of relationships (Latour, 2005; 2007). The food industry, for example, is not simply an intermediary in the food chain between raw material and the final consumer. It doesn't pass on this raw material without reworking and formulating it. The food industry delivers a particular *type* of food which is called 'processed food': raw material has gone through a mediation process involving physics and chemistry. Not only has the food industry changed the nature of many foods, or has it created entirely new foods, it has also changed the societies where these foods are available for sale. The availability of food products has become massive, although not equally distributed over the world's populations. Along with the multiplication of different products, but also more of the same, there emerged new spaces for the distribution of those products like convenient stores and supermarkets, where products are in direct competition to one another. This development has in turn changed or mediated our ways of calculating what we need, and how much we need of all the available products (Cochoy, 2008)<sup>3</sup>. If an international food market seems abstract, then the local supermarket is the place to go: there you can see how international forces fit into a building the size of a medium church. The strategies of international food players, but also of regulators come together on the food shelf. The European Commission defines consumers pushing their shopping carts as the *lifeblood* of the economy, representing 56% of GNP (European Commission, 2007). The EU, it is said, has the potential of becoming the world's biggest retail market (business-to-consumer) (*Ibid.*).

For Europe, the agro-food industry is the largest manufacturing sector (after metal) with 14.5% of total manufacturing turnover (€917bn for the EU-27)<sup>4</sup>. Employment in the food industry represents 14% of the entire manufacturing sector<sup>5</sup>. Europe is the world's largest

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<sup>3</sup> Franck Cochoy's analyses shopping carts, and how they mediate our decision-making, influence our shopping lists, and our calculations.

<sup>4</sup> Figures consulted at: [http://ec.europa.eu/enterprise/sectors/food/eu-market/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/food/eu-market/index_en.htm)

<sup>5</sup> *Ibid.*

food exporter and the second largest importer of food. However, the competitiveness of the European food industry has recently been questioned and assessed in a report made for the Commission (Wijnands et al., 2007). In the report, innovation is recommended as an important strategy to render the EU agro-food industry more competitive on the global market. The report mentions the following ‘external drivers’ of the food industry in Europe: population growth (*in casu* lower than in the benchmark countries); consumers’ preferences (for healthy food); technology development and innovation. The relatively low population growth (0.2% annually) is said to lower consumer demand and is considered a ‘major threat’ (p.9) to the food industry. So the food industry is in a battle over the consumers left. Marion Nestlé (2007) comes to the same conclusion concerning the fierce competitiveness on the U.S. food market, but through another argument: the battle is not going on because of low demands due to limited population growth, but because of oversupply from the industry side...

Back to the supermarket shelves. Since the 1990s, processed food is being put on the market which is alleged to support or even enhance human health: yoghurts that stimulate intestinal flora, or margarine that reduces cholesterol are among the best-known examples of products that make health claims. These products are placed in the supermarket among their conventional rivals without claims, but they are a lot more expensive. It is believed that people are willing to pay more if the product has health benefits. So health has become a theme for the innovation of food products. From the mid-1990s until about 2010, these products promised a bright future, not only for companies such as Danone and Unilever, but also for the European Commission that considers innovation a priority for becoming a knowledge-based economy. In the Commission’s Framework Programmes for example, funding research projects and encouraging collaborations amongst Member States, a total of (47) projects were funded that related food to health through science and technology<sup>6</sup>.

The 1970s and 1980s, just before health claims emerged in the late 1980s, were troubling times for industrial food products. Questions were being raised about the composition of such foodstuffs and their *negative* effects on human health. Sugar, for

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<sup>6</sup> The functional food related research projects are more or less equally distributed over FP5 and FP6. FP7 is still in course until 2013. The total (and provisional) number of 47 projects indicates that the scientific domain in question is acknowledged and in a sense ‘stabilized’ as a venture. The number cannot be taken as an indication of the relative importance that the Commission attaches to functional food research. In turn, this relative importance is hard to determine on the basis of fact sheets only, showing many and often overlapping subcategories within each research theme.

example, had already become suspect in the late 1970s (Brody, 1977). Until today, the debate on sugar's responsibility for chronic ailments such as diabetes and obesity continues (Taubes, 2011; Perreti, 2012)<sup>7</sup>. "Sugar is addictive and the most dangerous drug of the times," says a recent Telegraph headline (Westfield, 2013). Fat and transfatty acids (in margarine for example) and their effects on blood cholesterol and heart disease are another example (Scrinis, 2013; Schleifer, 2012), along with caffeine and its possible contribution to cancer, birth defects and heart disease (Troyer and Markle, 1984). The 1980s then saw the appearance of 'fat-free' and 'sugar-free' products, and just a little later, certain products were being marketed as having benefits for human health. Having been criticized for its trans-fat content, margarine appeared in a new guise in 1995: the Finnish product *Benecol* was a margarine that would *lower* your blood cholesterol levels (instead of raising them), and that would help to *prevent* cardiovascular disease (instead of causing it) (Lehenkari, 2003). Little later, the food giant Unilever marketed its own version of cholesterol-lowering margarine called *Becel ProActiv* or *Flora ProActiv* (in the UK). An oft-cited book about health claims and its related nutritional concept 'functional foods' calls the industry's move towards the marketing of health the 'functional foods revolution':

*During the late 1990s the food industry has enthusiastically, almost evangelically, come to embrace the whole new concept of functional foods – foods and beverages that may provide health benefits beyond basic nutrition, and which have been termed 'nutraceuticals' in the US.*

(Heasman and Mellentin 2001: xvi)

## Functional Foods and Science in Europe

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The concept of 'functional foods' provides the marketing of health claims with a nutritional concept, and the food industry embraced this concept. The concept makes an appeal to *science*. A landmark publication in the *British Journal of Nutrition*, which I will discuss in detail in Chapter 1, introduces a scientific consensus definition of the term 'functional food' for the first time:

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<sup>7</sup> "Is Sugar Toxic?" asks Gary Taubes in the *New York Times* (2011), while referring to the scientific work of Robert Lustig on the relation between sugar and chronic ailments such as obesity and diabetes. See also Perreti (2012).

*A food can be regarded as 'functional' if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being and/or reduction of risk of disease.*

(Diplock et al. 1999 : S6)

The authors of this article are enthusiastic about the possibility, contained in the definition of functional foods, for nutrition science to surpass and redefine its object of study: 'nutrition' science:

*We are at a new frontier in nutrition science because, at least in the industrialized world, concepts in nutrition are changing significantly. We are progressing from a concept of 'adequate nutrition' to one of 'optimal nutrition'.*

(Diplock et al. 1999 : S5)

Functional food was thus proposed as a scientific concept for nutrition scientists at the end of the 1990s, and the concept stood for a significant change in both science and society: the industrialized world was said to progress to 'optimal nutrition', leaving behind food as an basic need for hunger satisfaction and survival (Diplock et al. 1999: S5). I will show that the food industry did not simply 'embrace' the concept of functional foods as one of the quotes higher suggests, but that it also *forged* the concept (Chapter 1). But why would the food industry go through the trouble of making *scientific* claims? Isn't marketing and advertisement enough? It is relevant here to already note another trait of the concept 'functional foods' and the article that introduced it: the concept was presented as a *European* one. It was to render possible the creation of a European *market* for products with health claims. I will argue that the food industry anticipated new legislative and political developments in the EU when it introduced the concept of 'functional food' as a 'nutritional' or 'scientific' concept.

The concept was developed and introduced in scientific articles when the EU went through a political crisis in the wake of several food contamination scandals, such as the BSE crisis and the dioxin crisis. Food legislation was being redrawn and an independent food safety authority to scientifically assess food safety was proposed in this new legislation. I discuss this in more detail in chapter 4. What matters here is that Science became an important political operator for the EU in the years between 1999 and 2002, when a General Food Law was issued, establishing the European Food Safety Authority (European

Commission, 2002). I write Science with a capital letter to reflect its political role and how much was expected from it. Science was to answer questions about food toxicity on the one hand (contaminants, packaging, additives, GMOs) but also about food's *positive* impact on the body (health claims). The new legislation inserted Science as a *gatekeeper* between food ingredients and the market. A further step was the establishment of a premarket approval procedure, from 2007 onwards, to scientifically judge health claims before putting them on the market. The newly created European Food Safety Authority (EFSA) was charged with evaluating health claims. At the same time, food legislation (chapters 2,3 and 4) concerning health claims doesn't recognize the term 'functional food' but only health *claims* as a form of voluntary information given by food companies on food labels. So legislation considers health claims as a form of advertisement and information, but a premarket approval procedure was established at the same time to make sure that such information is Scientifically valid. There is a certain ambiguity about health claims, then, because they are considered as a form of advertisement on the one hand, but subjected to a scientific inquiry of the 'highest possible standard' on the other hand. Why must health claims, in an environment of seduction and allusions like advertising, be shown to be scientifically true? And what does it mean for a claim to be true? How can this be shown?

## The Politics of Definition

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Functional foods are a global phenomenon, and critiques have emerged as soon as the term 'functional foods' became diffused in the 1990s and 2000s, in the articles of scientific journals, industry and consumer organisation newsletters, and the media. While some scientists announced a revolution in nutrition science, where 'adequate' nutrition would give way to 'optimal' nutrition (Diplock et al., 1999), others insisted on the fact that it was above all a matter of marketing (Ostberg 2003; Nestlé, 2007). An editorial in the *British medical Journal* in 1999 had the title: "Functional foods: health boon or quackery?" (Jacobson and Silverglade, 1999) Another question, important to this thesis, is how functional foods can be distinguished from *drugs*. (*Ibid.*; Coppens et al., 2001; Katan and De Roos, 2004; Chadwick, 2010).



The debate continues today. Functional foods are seen by some as part of public health strategies (Stein and Rodríguez, 2008), while others place functional foods within the ‘ideology of nutritionism’ (Scrinis, 2008a). This ideology reduces and simplifies the relation between foodstuffs and human health to a matter of nutrients. Rather than public or personal health, functional foods are said to provide no more than a health simulacrum (Ostberg, 2003). Yet others place functional foods in a broader movement towards the medicalisation of food (Lawrence and Germov, 2004). The diagnosis that one makes about functional foods in society depends, of course on how functional foods are defined. Let me briefly look into this.

Different authors and organisations propose different definitions of what functional foods are. The International Food Information Council defines these foods as 'foods that provide health benefits beyond basic nutrition' (in Schneider, 2005: 1). This definition specifies an object with specific properties. The International Food Information Council, like its European variant the European Food Information Council, is officially a non-profit organisation, having food companies among its stakeholders. Watchdogs like the Center for Media and Democracy alert that this organisation actively defends the interests of the food industry<sup>8</sup>. This definition does not do away with the pleonastic character of the concept: doesn't food always have a function? And don't many foods provide some health benefit beyond basic nutrition? What does ‘beyond basic nutrition’ mean in the first place? Researchers Katan and De Roos, both critical of the concept of functional foods propose a different type of definition: 'a branded food which claims explicitly or implicitly to improve health or well-being' (Katan and De Roos, 2004). Here, emphasis is put on what is said about an object – a branded food – rather than on the object and its properties in itself. This definition defines a type of *claim*. This definition, however, doesn't specify the mode of production of functional foods, where nutritional elements can be removed, added or changed within a single product.

A report of the European Joint Research Centre, a part from the European Commission, states for example: “Functional food (FuFo) is defined as food that is taken as part of the usual diet and has beneficial effects that go beyond nutritional effects. They add: Currently functionality is created during the industrial processing of food through the addition

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<sup>8</sup> Source: [http://sourcewatch.org/index.php?title=International\\_Food\\_Information\\_Council](http://sourcewatch.org/index.php?title=International_Food_Information_Council). Last accessed on 1<sup>st</sup> May 2014.

of bioactive ingredients.”<sup>9</sup> The Directorate General for Research issued a brochure on the what, how and why of functional foods (European Commission, 2010). The brochure gives examples of what 'functionality' could mean:

- a natural food such as fruit or grain which may or may not be modified by plant breeding or other technologies (e.g. lycopene-enhanced tomatoes, vitamin E-enriched vegetable oils, vitamin A-enriched rice);
- a food to which a component has been added (e.g. a spread with added phytosterols);
- a food from which a component has been removed or reduced (e.g. a yogurt with reduced fat);
- a food in which one, or several components, have been modified, replaced or enhanced to improve its health properties (e.g. a juice drink with enhanced antioxidant content, a yogurt with added prebiotic or probiotic).

(Stein and Rodríguez, 2008)

Nutrition and Sociology Professor Marion Nestlé (2007) describes functional foods as a type of ‘technofoods’<sup>10</sup>. She explains that, in the US, a favourable regulatory environment for health claims on conventional foods, encouraged the food industry to design functional foods where ingredients are removed or added. In this context, functional foods appeared as a special version of foods for which health claims are made. Historian of science and social theorist Gyorgy Scrinis (2008b) critiques the category of ‘functional foods’, and proposes alternative ways of categorizing these foods<sup>11</sup>. He says: “I argue that there are no credible definitions of ‘functional foods’ that establish criteria for distinguishing between these and other foods (...) in terms of any intrinsic, health-enhancing characteristics. Instead, the main distinguishing features of foods defined as ‘functional foods’ appear to be either that they have been ‘nutritionally engineered’ and/or that they are promoted with nutrient-content or health claims.” (Scrinis 2008b: 541). He then proposes to distinguish nutritionally marketed foods (making a *claim* about the nutritional content of a food), functionally marketed foods (making a *health claim* about the functional properties or health benefits of a food), and nutritionally engineered foods (which have been nutritionally altered). A particular food product can be several of these at once. The main reason for Scrinis to propose these distinct categories is to question the relation between functional foods and health. Nutritional

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<sup>9</sup> Source: <http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=1719>

<sup>10</sup> See part 5 of her book ‘Food Politics’ (Nestlé 2002: 295-338). The author’s name is, as far as I know, unrelated to the Nestlé food company.

<sup>11</sup> His critique appears as an invited commentary in the journal *Public Health Nutrition*.

engineering in itself doesn't make a food necessarily healthier (for example: folic acid added to breakfast cereals high in sugar content). I agree with Scrinis that the definitions and concepts used (functional foods and health claims) need due attention, as they are not neutral. Defining functional food is indeed a stake in itself for both functional food promoters and critics. In chapter 1, I will discuss how a consensus definition was forged amongst European nutrition scientists and the food industry in order to promote functional foods. A health claim is indeed a *claim*, made in the context of the marketing of a product, whereas the concept of 'functional food' already presupposes its own functionality. Functional food, in that sense, is already a qualification: the food in question is functional (e.g. for health).

Given the different connotations of terms like functional foods, health claims, or functionally marketed foods, which one should I use? Generally, I have opted for 'health claim', but as I closely follow documents and discussions provided by different actors (the food industry, the European Food Safety Authority, European legislative documents, ...) I use the words that these documents provide, while at the same time trying to elucidate what they mean, or rather 'do' in these texts.

## The Reality of a New Market

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In this thesis, I will focus on concepts and strategies put forward, by different actors, to create a market for foods with health claims – to put health claims into circulation. As Michel Callon and his colleagues have shown, a 'thing' must be domesticated or pacified to become an economic good (Callon, Méadel and Rabearisoa, 2002; Callon and Muniesa, 2005; Caliskan and Callon, 2009; Caliskan and Callon, 2010). The thing, which can be a food product or something else, must be temporarily detached from its linkages to local situations and meanings, in order to become apprehensible and comparable to other goods. But can this operation of 'detachment' be performed with the same ease, no matter if the thing in question is a food product or, say, a tin opener or a car? In the chapters that follow, I will take the reader through different steps that have eventually led to the category of 'food bearing health claims', and a European Regulation for them that specifies an authorization procedure to place them on the market. So I propose an investigation into the conditions of possibility for a market where food is related to health claims. The relation between food and health is a very complicated one: if the EU has found ways to domesticate 'food' as such, and put it in

circulation in an international market, then food becomes extremely *recalcitrant* when it is put in relation to health. And it encourages humans (lobbyists, policymakers, scientists) to become recalcitrant as well. European legislation, as I will show in chapter 2, has pacified food (and European Member States) by making abstraction, to a large extent, of what individual products are actually composed of. There exist detailed regulations on the use of chemicals of all sorts in food products, but they apply to food in general, or to large categories of products. Relating food to health and the human body, poses the question of particular food products as a matrix of components that interact with one another within that product, and within the human body. This is a complicated legal, political and technical-scientific question. Within that context, what are the questions that science is allowed to ask?

To resume, the market of health claims hinges upon ontological questions of what particular food products are, and what they do to human health. Investigating these questions seriously, means that caution must be taken with respect to the idea that health claims are but a promotional tool, or a piece of information ‘on top of’ what we already know about a product. This kind of appreciation – health claims as ‘pure marketing’ – is one I have come across in various situations where a sense of criticism is expressed with regards to health claims. This criticism can be rather spontaneous, like reactions I often get when I explain my research topic (“Oh, yes, those products... that’s all about marketing and making money isn’t it?”), or it can be informed, like in the examples I already hinted at higher, when the definition of ‘functional foods’ is at stake. This is problematic, because it trivializes health claims and what their ‘marketing’ involves, and it portrays these products as harmless. My intention is not to demonstrate that they can cause harm, but that the question merits as much attention as the question of their efficacy and possible beneficial effects on human health.

To give an example of the trivialization of functional foods, Ostberg (2003), the concept of functional foods from a Baudrillardian perspective: they are part of a semiotic system that places ‘magical’ power, as Ostberg has it, within the product. This system presents the product as having the inherent property to act upon the human body and it relates the body semiotically and symbolically to a healthier future. Ostberg calls this a ‘false ontology’, because the product does not necessarily have this power, let alone the power to solve the health problems of Western societies. I think Ostberg reasons too quickly, implicitly leaving the reader with the alternative between a product that works and one that only pretends to work; between reality and myth or ideology; between truth and lies; between

health and health simulacra (he calls functional food a ‘health simulacrum’). Such a vision makes it impossible to problematize the notion of a product that ‘works’.

As Latour (1999) has convincingly shown throughout the different chapters of his book *Pandora’s Hope*, a realist approach to science and its objects opens up very different questions than those approaches that separate scientific truth from opinions, representations, symbols, myths. In a similar vein, I want to keep open a passageway between health claims and functional foods, which means that foods could also be *dysfunctional* in certain circumstances or for certain people. At the same time, the passage between the two appears as a subject worthy of investigation: how are claims connected to real existing food products? Is this a scientific question?

As soon as a food ingredient has a real and considerable effect on the human body, then should we continue to call it a ‘food ingredient’? Where is the difference with drugs? If cholesterol-lowering margarine really acts upon the human body and lowers cholesterol, then what about the possibility of side effects? What else is this active agent capable of? Is the product suitable for everyone? And should it be sold in a pharmacy rather than in the supermarket? These questions have also been posed by consumer organisation Foodwatch, and the organisation’s persistence in posing this question very recently led the European Commission to oblige food company Unilever to mention on its product Becel ProActiv that it should not be consumed by people who have no cholesterol problems<sup>12</sup>.

Distinguishing, in a critical spirit, food from the claims made about it allows imagining the possibility of a claim proven to be true, but it implicitly suggests that food that works is still food. And what does it mean for a food to ‘work’? That it cures disease? Or only a risk factor of disease? That it has side-effects? And who decides upon these questions? These questions are related to questions about the difference between *markets*. According to consumer organisation Foodwatch, for example, cholesterol-lowering margarine should be sold in the pharmacy with an adequate information leaflet enclosed. One could reformulate this argument and say that, according to Foodwatch, this margarine is circulating in the wrong market.

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<sup>12</sup> [http://www.standaard.be/cnt/dmf20140216\\_002](http://www.standaard.be/cnt/dmf20140216_002)

The metaphors used by Callon and colleagues (mentioned higher) of taming, domesticating and pacifying objects in order to enable them to circulate in a market can be taken quite literally in a realist mode of inquiry. Throughout the chapters of this thesis, I will try to elucidate different attempts at domesticating food ingredients, and at framing their relationship with the human body. These attempts either fail, or are disputed, because, I will argue, we don't know all about real food and real human bodies. We are not familiar with everything they are capable of. I will try to show that the argument that functional food is about marketing and but a 'commercial' issue becomes true in a new way: markets involve real human bodies and real food ingredients. Commerce is bound up with ontology.

## Scientific Debate

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In the previous paragraphs, I have referred several times to the role of legislation to frame a market for health claims. Another, equally important dimension of health claims and functional foods is *science*. Food companies, lawyers, policymakers, and scientists themselves keep referring to science and the importance of *scientific evidence* for health claims. In order to understand and describe how the conditions of possibility of a health claims market are discussed and gradually established, it is important to question what is asked of science with terms like good science, sound science, science-base, scientific evidence, accepted scientific knowledge, scientific data, etc. Rather than entering into epistemological debates about what science is and what we can know about food and the human body, I will look, as far as possible, into what actors *do* when they refer to 'science' or one of its related concepts: what relations do they establish, for example between law and scientific experiment, or between data from experiments and market access?

Two actors, or organizations, are given special attention in the present thesis. The first is the International Life Sciences Institute (ILSI) that I discuss this at length in Chapter 1. I describe ILSI as an industry-funded think tank that proposes concepts and methods to be used in the scientific assessment of health claims. As I mentioned earlier, foods with health claims have led to the question of their market authorization. ILSI tried to anticipate this question in the late 1990s, and it proposed solutions that were expected to turn out favourable to the food companies that fund ILSI. Another actor that merits special attention is the European Food Safety Authority (EFSA). This is a European agency created in 2002 as a political answer to a number of European food crises in the late 1990s, as I will explain in more detail in chapter 4.

Europe's political answer to these crises, in one word, was: *science*. The threat that consumers and Member States would lose confidence in the European Single Market, where foodstuffs circulate without trade barriers, was to be countered with independent scientific advice on food safety matters. In 2006, EFSA was charged with the mission of evaluating health claims in a premarket authorisation procedure. So 'science' and related concepts will appear in different guises throughout the chapters, attached to different actors, organisations or institutions. What kind of science is being mobilized each and every time will also be part of my investigation.

The question of 'science' is very much bound up with the methodology and theoretical framework that informs this thesis. I will now turn more explicitly to my methods and theory, and I return to the question of science again in the last section of this Introduction.

## An Anthropology of the Health Claim

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The second quote at the beginning of this chapter was a clumsy assertion about sociologists having no competence on matters of food and health. It was a reader's comment on an opinion piece that a colleague and I had written for a Belgian newspaper (Van Oudheusden and Hendrickx, 2012). However, I am certain that the author of the commentary was trying to pose an intelligent and pertinent question: how can a sociologist make questions related to food and health matter with his own means? I take the formulation of this question from Isabelle Stengers, when she describes philosophy as a particular activity:

*Si la philosophie a quelque chose à voir avec une création, celle-ci ne transcende pas l'époque; elle fait importer les questions qui marquent une époque avec ses moyens (philosophiques) propres.*

Stengers (2006: 26)

The definitions promoting functional foods, and the denouncements, unveilings and reproaches of critics all have in common that they run ahead of the issue that I want to investigate. They run ahead because they make general statements about both functional foods and society. I argue that 1) the object and the type of claim that can be made about it are still in the course of being constituted and not predefined or given, and 2) that this constitution is specific to a political and regulatory environment and cannot be meaningfully analysed outside of that, 'in general'. It will become clear that food-related health claims and

their regulatory environment evolve together and mutually influence each other: they *co-produce* one another (Jasanoff, 2004). However, this coproduction in itself is not the main point I want to draw attention to. I want to investigate what is *at stake* in this process, and how food and the human body are *made to matter* in it. Asking how food and the human body are made to matter in this process will lead me to ask, in the same breath, which parts, or which versions of food and the body are put aside as ‘not being the matter’. Asking and investigating these questions is the mission that I set myself in this thesis. This mission goes on a par with the realist posture that I mentioned earlier: investigating the problem of health claims shouldn’t automatically mean that one is confronted only with *statements* and *representations* of food and human bodies or promotional tools that simply add information to already existing knowledge or an already existing object. I will try to show that preparing a market for health claims means that food – called ‘functional food’ by some, and ‘functionally marketed food’ by others – is *made to exist* in a specific manner, and that this generates consequences. At the same time, human bodies are not merely represented but made to exist, and required to act, in specific ways, like in clinical trials for example (Chapters 2 and 5), or through specific products and their advertisements, demanding cooperation from human bodies to make the product work (Chapter 6). Before I situate my work in a broader theoretical and bibliographical universe, let me first be delimit the scope of the research.

## Space of Mobilisation/ Problem Space

The research that I present in this thesis is a qualitative inquiry, based on interview material; attendance and participation to conferences on the topics of health claims, nutrition science, and food law; and written documentation of various sorts (legislative texts, scientific articles from nutrition journals, websites, newsletters, advertisements). A list of interviews and conference participations is provided in Appendix 1. The question of health claims is distributed over a wide range of actors, including scientists, policymakers, lawyers, specialized consultants. The composite nature of the subject, then, has led to a composite research and ‘fieldwork’. Trained in anthropology, I have not been able to do as much ‘field work’ as I would have liked to. The subject of health claims has brought me in contact with a lot of different people and institutions, but contacts were always fleeting, limited to the conditions and timeframe of a formal interview situation, a telephone call, or a quick chat over coffee at a conference. Texts have been my main interlocutors, because they are also a



place where actors meet and establish something. Interview situations, then, became moments to validate my interpretations of many texts like scientific publications or legislative texts. They were moments to validate whether the issues I retained as important, really mattered to those involved, and to ask additional questions. In the course of time, some interviews developed into conversations, where the interviewee asked *me* what an anthropologist makes of it all. I have had the occasion of presenting a keynote lecture where I tested my critical views about the notion of ‘consumer behaviour’ at the annual symposium of the Belgian Nutrition Society in 2012 (see Hendrickx 2012a). In 2013, I published an article in the journal *Food Science & Law*, in which I discuss the politics of ‘scientific evidence’ in the health claims debate (Hendrickx 2013, see also Hendrickx and Penders 2012). The editorial committee of the journal is composed of food scientists and lawyers, active in university and industry. Proposing the publication was also a way to try and validate my analyses, not in the sense of searching for agreement, but in the sense of having the pertinence of my questions confirmed.

Some remarks about this material and how I obtained it.

For the general overview that this introduction wants to give, I will give three demarcations, that were not settled when I started the research, but the pertinence of which confirmed itself during the course of investigation:

- A *thematic* demarcation: functional food/health claims is my central issue of focus.
- A *spatial* demarcation: I study functional food/health claims within the regulatory, economic and political environment of the European Union, or –more precisely – the European (Economic) Community or EC. It is here that a *market* for functional foods has been created, in line with Europe’s ambitions to create a Single Market where all foodstuffs (and other goods) can circulate without trade barriers imposed by Member States.
- A *historical* demarcation: My analysis concerns the emergence and evolution of an object/issue and its market from the mid-1990s till present.

These demarcations have to be taken for what they are: demarcations or delimitations and not more. They should not lead to the presupposition that everything within the frame is a

coherent whole. Rather, it is a *problem-space* for both the actors and myself as an anthropologist. Within this problem-space, I ask (along with many actors): what is a functional food? What is a health claim? However, the ‘what’ question is not a definitional question to the anthropologist, but an empirical one: *where* can we see functional foods? *What* are they doing (if we can see them)? *Who* is involved? Which traces does it leave? So the question ‘what is a functional food’ or ‘what is a health claim’ is reformulated as the question: ‘how are functional food and health claims made to exist’?

The above questions invite the researcher to take into account a wide range of sources and materials, while keeping the analysis centered on the main issue of functional foods and health claims. Placing an object or concept central makes the researcher work *outward* in various directions from the centre: into nutrition science, clinical trials, legislation and politics. The heterogeneity of the subjects that I will treat is in no way related to the ambition of proposing an interdisciplinary approach, nor a hawk’s eye view on the matter – a ‘complete picture’. The heterogeneity of the material is the consequence of another ambition: to ‘stay with the trouble’, as Haraway (2010) puts it. The problem space of health claims is composed of technical, scientific, legal, economical and political elements. Taking the problem seriously requires to follow the problem where it leads. The methodology of actor-network theory (ANT) allows for ethnographic research that takes into account such heterogeneity. Next to my focus on a specific problem or problem space, *time* is a second ordering principle in this thesis. I look at how health claims were gradually made to exist on the European market. Law and legislation play a fundamental role here, not in the sense that they are sufficient to fix the problem, but they give it new directions through time. Even while my research was in due course, debates about health claims changed and evolved significantly from 2010-2014. The European Food Safety Authority (EFSA), for example, started publishing, with regular intervals, scientific opinions on the validity of health claims on food products before they could enter the market. This spurred reactions from the food industry, and of certain scientists. It called into existence specific groups of scientists around ‘their’ functional food. Ongoing discussions took new directions and new themes were brought in, and problematic issues continue to be discussed today. This thesis, then, is not a casestudy but more something of a monograph. Speaking in terms of a casestudy implies that your object is a particular ‘case’ or ‘example’ of something else – something more general. I will show that determining such a general frame, is precisely one of the issues at stake with functional foods and health

claims. As we will see, promoting functional food as a special category of *food*, and not of *medicine*, for example, is an economic and political stake for the food industry.

Where appropriate, I will continue to make use, for the sake of clarity, of the terms ‘functional food’ and ‘health claim’, even though these terms already make assumptions about the nature of the issue at stake: they assume that one is dealing with *objects* or *statements* about these objects; that these objects are in fact *foodstuffs*, etc. Analytically, however, I consider functional food and health claims as a *problem space* or a *space of mobilisation*. I take the latter term from Nicolas Dodier and Janine Barbot’s research on controversies about AIDS treatments in France (Dodier and Barbot 2008). They propose this term to identify an “overall dynamic that links a series of controversies together” (2008: 3). In the historical and spatial demarcation that I propose, a number of debates and small controversies will become visible as well. These debates anticipate political and legislative developments as much as they follow from them. The notion of the ‘health claim’, as we will see, develops in tandem with these discussions, legislative proposals and scientific assessments. Along the way, and in response to the developments that I will describe, new interest groups mobilize, and existing ones redefine their object of focus. So both the terms ‘space of mobilisation’ and ‘problem space’ are suitable characterizations of the ‘issues’ that functional foods and health claims pose<sup>13</sup>. While the term ‘space of mobilisation’ emphasizes the dynamics and the action of actors involved, the term ‘problem space’ highlights the contours of a *problem*, both for the actors involved as for the researcher. The sense in which I try to problematize ‘functional food’ or ‘health claims’ (and calling them a ‘problem space’ helps) is very much akin to what Michel Foucault called ‘eventalization’:

*I am trying to work in the direction of what one might call ‘eventalization’. (...) What do I mean by this term? First of all, a breach of self-evidence. It means making visible a singularity, at places where there is temptation to invoke a historical constant, an immediate anthropological trait, or an obviousness which imposes itself uniformly on all. (...) Secondly, it means rediscovering the connections, encounters, supports, blockages, plays of forces, strategies and so on which at a given moment establish*

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<sup>13</sup>The debated issues that I will discuss throughout the thesis, for example the design of clinical trials for food (chapter 5), could be called *matters of concern*, following Latour. Latour proposed this term in contrast to *matters of fact* to avoid the perspectivalism that ‘matters of fact’ imply: there may exist different interpretations or perspectives, but in the end they are but perspectives on an essential fact or single reality. With ‘matters of concern’ Latour allows a different kind of world to exist: actors gather around an issue that affects all of them differently, without privileging one reality above another. There are worlds (in the plural) of matters of concern in contrast to a single world of matters of fact (Latour 2005: 116).

*what subsequently counts as being self-evident, universal and necessary. (...) As a way of lightening the weight of causality, 'eventalization' thus works by constructing around the singular event analyzed as a process a 'polygon' or rather a 'polyhedron' of intelligibility, the number of whose faces is not given in advance and can never properly be taken as finite. (...) The internal analysis of processes goes hand in hand with a multiplication of analytical 'salients'.*

(Foucault in: Burchell, Gordon and Miller (1991: 76-77). Original emphasis)

I consider this a very powerful quote, which densely contracts 3 issues that are important to this thesis. Firstly, the quote evokes a method of inquiry that is rooted in *resistance* to what appears as self-evident or obvious. Secondly, this resistance makes it possible to rediscover a certain *indeterminacy* about those elements which compose events, objects, institutions. Evidence and necessity are replaced by a fresh appreciation of things in terms of connections, encounters, plays of forces, ... Thirdly, this indeterminacy of affairs 'in the world' is *allowed to affect* the research process of the analyst, who engages in the creation of intelligibility while accepting that the result of his research will not be the truth, nor a complete picture of the issues analyzed. This thesis does not start from a hypothesis, but it initiates a problematisation and works through it iteratively.

I said that indeterminacy is 'allowed' to affect the researcher, because indeterminacy, in this approach, is not considered as a *problem* to get rid of. Foucault formulates this as: "lightening the weight of causality". This wonderful formulation can be read as an invitation into pragmatist thinking: there is no sense in accepting, elucidating or criticizing 'the way things are' (as determined by inescapable factors and determinants), because that is precisely what keeps these things in place. The only thing we cannot escape from is performativity itself (Law, 2009)<sup>14</sup>. Thinking differently, and multiplying the "analytical salients", creates a different *grip* on problems and makes new possibilities thinkable and realisable. This also means that research and analysis become forms of *engagement* (Law, 2004; 2009; Law and Hassard, 1999; Mol, 2008; Gad and Jensen, 2010). In philosophy, this sort of thinking and engagement can be found in the works of Michel Foucault, Gilles Deleuze, and, today, in Isabelle Stengers' work. In the province of the social sciences that lies adjacent to pragmatist philosophy, and where the 'social' has taken new meanings with actor-network theory and its

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<sup>14</sup> In Law's words: "There is nowhere to hide beyond the performativity of the webs." He then goes on: "But since our own stories weave further webs, it is never the case that they simply describe. They too enact realities and version of the better or the worse, the right and the wrong, the appealing and the unappealing. There is no innocence. The good is being done as well as the epistemological and the ontological." See: Law (2009: 154).

ramifications, the works of Bruno Latour, John Law, Michel Callon and Annemarie Mol have particularly informed the research process of this thesis. I briefly turn to these works now, and how I relate to them in this thesis<sup>15</sup>.

## Anthropology, ANT and Resistance

I have placed Foucault's earlier citation under the sign of *resistance*. But why 'resistance'? Resistance seems to suggest that there is a force, or a temptation perhaps, that, if left alone, would arrange things all by itself. Is this the case? If so, then *what* is there to resist?

Succinctly put, what needs to be resisted are representations of states of affairs 'as they are', or of the world 'as it is', because *representation is a political question*, as Bruno Latour (1999) has argued, for example, and also Callon, Lascoumes and Barthe (2009). What needs to be resisted is not politics, but *naturalisation*: the idea that things are natural and necessary, and that it is possible for knowledge to faithfully represent the 'natural order'. This natural order can refer to both a naturalized nature 'out there' (Law 2004), or to 'society', which, by its very 'nature' is claimed to be no part of nature. The question of representation is not a philosophical problem only – it has major repercussions for the daily work and method of social scientists<sup>16</sup>: if sociology and anthropology have as their main mission to describe and

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<sup>15</sup> The question of how one relates to other authors is an important one: what does one *do* when referring to an author? Putting an author's name between brackets after a statement doesn't always do justice to the work of the author cited (and I claim no innocence for myself here). Is it always possible to do justice to an author's work, which usually spans several publications? Doesn't one always bend an author to one's own purposes? If so, is that 'bad'? Aren't connections with other ideas always *partial*? These questions have been wonderfully put to work in the subtext of Annemarie Mol's book *The Body Multiple* (2002). In their book *La sorcellerie capitaliste* (2007, English translation 2011), Philippe Pignarre and Isabelle Stengers formulate their 'relating to' Marx as 'inheriting from' Marx. This pragmatist approach avoids the problem of the 'right' or 'faithful' interpretation of Marx, which, according to the authors, is an uninteresting problem. Their challenge is to reinvigorate Marx' thinking and make it matter for their purposes.

<sup>16</sup> Numerous references could be made here to thinkers within the tradition of ANT. A very clear example that deals with the question of method in the social sciences *head on* is John Law's book *After Method. Mess in social science research* (Law 2004). Perhaps the word 'mess' is a bit unfortunate, as it functions as the antonym of necessity and order, whereas Law's message implies that there exist other versions of order ('modes of ordering'), which are contingent and not necessary, but rather compositional. Perhaps 'composition' is a better, and more positive term than 'mess', reflecting both how humans and non-humans compose a common world (e.g. Despret, 2012), and the social scientist composes along with that (Law, 2004). It gives social science a positive mission, without relegating it, as the word 'mess' seems to imply, to another realm than the disciplined and methodological realm of the 'hard sciences'. Mess, in short, risks resuscitating the modern division

analyse ‘society’, then the question of what is to be included in the notion of ‘society’ is of major importance: do we count in objects and animals as well? And if we do so, do we grant them agency and allow them to interfere with the human actions we describe? Or are objects and animals more of a backdrop or a way to enrich accounts of interactions that remain essentially human? Actor-network theory (ANT) holds that non-humans must be accounted for symmetrically to humans. ANT takes note of how non-humans contribute to human action and vice versa. In the 1980s and early 1990s, various scholars took an interest in technology and technical objects, and looked at what these objects do: the concept of ‘script’ was useful here to make ‘de-descriptions’ of what objects expect or require from humans in order to work (Akrich, 1994). Noteworthy is also the question that Langdon Winner posed in 1986: “do artefacts have politics”? This question is still of relevance today. Rip (2009), for example, speaks of artefacts as ‘material stories’ that create agenda’s for both humans and non-humans to engage in configurations that must be made to ‘work’. Rip emphasizes that technology is always a form of prospection, and that this prospection is ontological. So technologies can only work and exist if they are *made to*, and if they are supported by the right configurations. At the same time, technologies make a certain type of society exist as a configuration of humans and non-humans. Nuclear power, only works in certain conditions, and it can, in turn, reshape society (Hecht, 2009). Van Zwanenberg and Arza (2013) describe how genetically modified cotton seeds in Argentina only do their work on large-scale, capital-intensive farms. For small farmers, lacking the technical, financial and infrastructural support to make the seeds work, the modified seeds are a catastrophe and a technology (in combination with pesticides) they cannot control. The role of objects and their relations with humans came to be studied in a variety of settings: I already referred to the study of markets and economisation, but there is also medical practice and life sciences (e.g. Clarke and Fujimura, 1992; Mol, 2008; Michael and Rosengarten 2013). The latter also renewed interest in the human body (Mol, 2002; Berg and Akrich, 2004). An important insight that came from these different studies, was that what we tend to call ‘the social’ is heterogeneous indeed, composed of humans, non-humans, devices, buildings and cooking pots, but also the way things are made to hold together makes an essential difference. Asserting heterogeneous connections is one thing, but differentiating *types* of connections, and making these matter, is yet another. The latter implicates a turn to *practices* (e.g. Stengers, 2006; Mol 2002) or - in Latour’s latest work – ‘modes of existence’ (2012). The difference between ANT in its earliest forms and the

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between society (passions, irrationality, opinions, ...) and nature (to be analysed by scientists). But perhaps Law just wanted to catch attention with the title of his book. In that case, he has succeeded.

type of philosophical anthropology it has rendered possible today is that a certain notion of ‘delimitation’ is reintroduced:

*Il existe une définition de la limite qui ne dépend ni de la notion du domaine ni de celle de réseau*

(Latour 2012: 50)

ANT resisted the grand modern division of nature and society, but also smaller divisions between for example science, law and economy. The question then arose how the difference between these domains could be accounted for and respected. The solution of everything being a heterogeneous ‘heap’ seemed as strange as the modern divisions ANT rejected to account for things that matter in the world and our worldmaking.

Of particular relevance to this thesis, where different actors speak in the name of ‘science’, is the characterisation of science as a particular practice. Science is not like other practices, in the sense that there isn’t any practice that is like other practices (Stengers 2006). It is politically important to distinguish the particularities of science from other practices that are presented as ‘science’. Stengers (2006; 2013) calls this, with a chemical metaphor, *dissolving the amalgams* of science.

The political importance to dissolve the amalgams of science has to do with the capability to characterize claims to truth and authority, either from the industry-side or the government side. In the third citation that I placed at the beginning of this chapter, the prestigious journal *Science* endorses the authority of a particular agency in the EU – the European Food Safety Authority – while putting aside ‘Europeans’ who do not want to hear the truth. Dissolving the amalgam here means to make visible the political content of this statement and its truth-claim. This is an *engagement* that informs this thesis. But it begs the question of the demarcation principle that one would apply to distinguish science from other practices. Is that not a very old question that has led to an epistemological deadlock? And hasn’t ANT shown that science is bound up with society and politics? There is, however, a demarcation principle that is not epistemological, and that embraces ANT’s focus on hybridity. The principle is driven by the pragmatic question: how are things made to relate? In a way that makes the world and its possibilities *richer* or *poorer*?

## Normative Conception of Science

In the second edition of *Laboratory Life*, Latour and Woolgar (1986) dropped the word ‘social’ in their subtitle *The social construction of facts*. They thought that it presupposed too much initiative on the part of humans alone, while molecules are social as well, and science really engages with nature. In short, the word ‘social’ doesn’t add anything a part from a meaningless division between society and nature<sup>17</sup>. Later, in *Politiques de la nature* (1999) and *L’espoir de Pandore* (2007) for example, Latour also replaced the notion of ‘construction’ by that of ‘articulation’, as ‘construction’ seems to presuppose a zero-sum game: a number of things are put together, like so many bricks, and then there is a scientific result, a wall of bricks, which can be deconstructed again easily. ‘Construction’ makes it difficult to think of an *event* that makes a significant *change*<sup>18</sup>. The idea of science that Latour develops gradually, in dialogue with Isabelle Stengers, is that science is practiced differently than it is explained or accounted for in schoolbooks, or even in certain philosophical strands. This message is rooted in the observation that scientific facts are not discoveries about the ‘laws of nature’, but very delicate constructions *with nature*, comprised of objects, measuring equipment, graphs, publications and so forth. Talking science is about discoveries; *doing* science is about negotiating with the environment and trying to find arrangements wherein nature will respond in the same manner to the same manipulation by scientists. Both nature and scientific manipulations have to be attuned until a situation is reached that *holds together* – a situation that is repeatable, and transportable, but not without care. A scientific fact, in brief, is an *achievement*. And this achievement is an *event* that, once it has taken place, will have transformed both the object under investigation and the concepts to grasp it. Indeed Latour (2007) describes how Louis Pasteur subjects a substance which he will come to call lactic ferment to different kinds of operations, soliciting reactions from it which in turn lead Pasteur to change his experimental setup. In this new setup the substance is made to react with other reagents. Bit by bit, both the experiment and the substance are being articulated together until the point that Pasteur has found a mode of interaction with a stable entity that he calls lactic ferment. The bottom line of this story about Pasteur is that the substance Pasteur calls lactic ferment is no longer the same substance he started experimenting with. Both the substance and the experimental setup have changed along the way, until an

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<sup>17</sup> The authors give a brief comment on this in the postscript to the second addition of their book, on page 281.

<sup>18</sup> And the notion of ‘event’ comes from Whitehead’s process philosophy (Whitehead, 1995)



articulation that holds together is reached. This process of articulation is conceived by Isabelle Stengers and Vinciane Despret as a situation wherein the experimenter allows the object to reformulate the experimenter's questions (with the risk that the object really 'objects' and dismisses the experimenter's questions as irrelevant). Both Stengers (e.g. 2006; 2013) and Despret (e.g. 2009) define science, and its difference with non-science, in the light of this *risk*: allowing the object - or *animal* in Despret's casestudies on ethology - to object to the researcher's questions; to reformulate it; to testify to how the experiment affects it or leaves it indifferent. Latour expresses his indebtedness to both Stengers and Despret in several texts, and reformulates these thinkers' definition of science as a *shibboleth* to distinguish science from non-science, or good experiments from bad experiments (Latour, 1997). Latour, inspired by Whitehead, talks of the difference between well-articulated propositions and badly articulated propositions.

In another text, Latour names the principle of demarcation the 'Stengers-Despret falsification principle' (Latour, 2004a) – a normative principle that displaces epistemological discussions of what science is, in favour of a pragmatic take on science and experiment: does the experiment allow the object, animal, and the experimenter to articulate a richer and more intelligent situation? Is there room for surprises? Can the object, animal, and experimenter explore new capabilities? Is the world richer after the experiment than it was before? The consequence of applying this principle of distinction or shibboleth between good and bad experiments, is that an experiment is not necessarily scientific because it is run by natural scientists. The shibboleth doesn't follow the contours of disciplines or specialisations. An ethologist can perfectly be scientific if he allows an animal to invalidate and transform his questions. On the other hand, a social psychologist, for example, has no guarantee of becoming scientific by simply following a rigid methodology, covered by statistical data that have been validly obtained and calculated. If subjects are forced to respond (sub-jected to the experiment), and the possible categories of response are pre-coded, then, according to the shibboleth, it is a bad experiment that teaches nothing about the behaviour of people (or animals), and their creativity and capabilities. What it teaches is how *subjects* respond to a situation wherein they are forced to answer in terms of the categories preconceived by the experimenter. Rather than a scientific experiment, such experiments are a form of violence.

The question of expertise and the authority of science is an important stake in discussions about food and health. Both the second and third quote at the beginning of this chapter, establish a division between those authorized to meddle in the debate, and those who are not.

The question of expertise was taken up by Callon, Lascoumes and Barthe in their book *Acting in an Uncertain World* (2009), a political essay on technical democracy, and, according to the authors, a constructive response or prolongation to Latour's *Politiques de la nature* (1999).

So the ethnography of science, putting humans and non-humans on a same analytical plane, has not only led to the development of actor-network theory, but it has also led to new definitions of 'politics' and what pertains to the political. In parallel, it has redrawn social theory and defined new challenges for it.

## Overview of the Chapters

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The chapters follow a chronological order of events (although some overlap) since 1999 until present. The period since 1999 has been a tumultuous one for European food policy, and a lot of overlapping events and changes have contributed to how health claims are regulated by the European Commission and the European Food Safety Authority (EFSA) today.

The sequence of chapters is iterative and they all add a part to the puzzle. The concluding chapter is where I draw together the material.

Chapter 1 looks at two much-cited publications that made *functional foods* a European concept. The first publication dates from 1999. Why would this concept need to be European? I also describe ILSI Europe, an industry-funded think tank, that coordinated these publications by gathering scientists in consensus meetings. I ask why the food industry is interested in science and health, and what kind of 'science' they are advancing.

Chapter 2 gives a brief overview of a number of issues in European food law that are of relevance for the following chapters. Then I turn to a Court case in 2002 that has been

important to the further development of *health claims* as a legal category. Some of the laws introduced in this chapter are important to follow the developments in the following chapters.

Chapter 3 discusses a legislative initiative from the Commission in 2003, in the wake of the Court case in Chapter 2, that proposes a separate regulation for nutrition and health claims on food products. I focus on three issues, two of which are polemic. The first is the proposal to allow indirect references to the prevention of disease on foods; the second, very polemic proposal is to evaluate foods, by establishing nutrient profiles, in order to decide which foods are *eligible* to bear a health claim and which are not. This poses the question whether certain industrial food products have a less favourable nutrient composition than others. The contours of a moral economy in which “there is no such thing as good or bad foods” become visible. The third proposal is that of a premarket approval procedure for health claims by the EFSA. This also spurs reactions from various ‘stakeholders’ involved in the decision-making procedure. A final Regulation is voted in 2006, and it enters into application in 2007.

Chapter 4 is a shorter chapter that situates EFSA and its experts historically and anthropologically. Chronologically, this chapter discusses a period that overlaps with the former chapters: between the late 1990s and 2010. I briefly look at the institutional reforms on the EU level in the wake of several food crises, and how the concept of ‘independent science’ has become a political operator. I also characterize the work of EFSA’s experts and the constraints they have to respect when making scientific judgements. These constraints are both legal and economic.

Chapter 5 discusses a number of debates that follow EFSA’s first evaluations from 2008 onwards. EFSA’s evaluations spurred the reactions of food companies and scientists with an interest in making health claims. They accused the EFSA of applying pharmaceutical standards for evaluating food products. A space of mobilisation emerges with the difference between food and drugs, and health and disease as the main stake. I identify two political operators that in combination have a normative or moral character: ‘scientific evidence’ on the one hand, and the ‘provenance of science’ or its ‘affiliation’ on the other hand. New groups with specific knowledge claims appear within this space of mobilisation, such as ‘gut health scientists’ and adherents of ‘evidence-based nutrition’. In this space of mobilisation the difference between food and drugs is fought over by mobilizing the human body in different

ways, along with different conceptions of health and disease, and what they *should* be; what evidence *should* be; and what public health *should* be.

In chapter 6, I look into a product that has passed all its tests and that is available ‘on the market’: cholesterol-lowering margarine. What interests me here is the products’ articulation with science, and cholesterol as a biomarker. I briefly and speculatively analyse an advertising campaign and its conjugation of images and text. I argue that references to science and cholesterol turn the margarine into a moral agent.

Chapter 7 is the final chapter and concludes the thesis. Here, I draw together all observations from the previous chapters to ask *why* health claims are such a troublesome issue. I open a number of questions and further reflections with respect to food, drugs, science and therapeutics in the *modern* industrialized world.

# Chapter 1 The Stratagem of Functional Food Science

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In this first chapter I will discuss the activities of an international organisation – the International Life Sciences Institute (ILSI) and how this Institute coordinated scientists and data to publish a consensus definition of the term ‘functional foods’ in 1999, in the *British Journal of Nutrition*. The analysis I present draws on *in situ* observations, interviews, and document analysis. I grant equal importance to all of these sources, at least a priori, because I look for how each object *enables* ILSI to further its mission. This chapter can be read as a separate ethnography, but it is also of central importance to the overall story on health claims that I present in this thesis.

ILSI is an industry-funded think tank that presented the concept of *functional food* as a ‘scientific’ concept. My question in this chapter is what sort of ‘science’ this is: what research is it based on? What is its purpose? I start with a general description of ILSI itself, and then analyse in some detail two of their publications. These peer-reviewed publications have become ‘classics’ in the literature on functional foods and health claims, and they have also provided input into policymaking and the preparation of a European Regulation for nutrition and health claims in 2006 – the NHCR (discussed in chapter 3). These publications provide a working definition for functional foods and ways of assessing their efficacy respectively. The articles want to propose a science-base for the development and evaluation of health claims on food products. This science-base, I argue, is a strategic move away from clinical endpoints in therapeutic research. ILSI and its industry members are not interested in making medicinal claims and selling their products in pharmacies. They want the best of both worlds and combine the value of a supposed active agent, like drugs, with the advantages of the food market in which they already occupy strong positions.

The articles that I will discuss were published between 1998 and 2005, at a time when health claims were proliferating without any overarching regulation on the European level. Member States were dealing differently with these claims, and attitudes varied from tolerance in some countries, to prior approval procedures and market restrictions in other countries. My main argument in this chapter is that ILSI proposed biomarkers in the human

body as the main *point of articulation* between the ‘therapeutic’ agents of food companies and a European market for functional foods.

## ILSI Europe: Setting problems and diffusing solutions

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### Connecting science and health

*Founded in 1978, the International Life Sciences Institute (ILSI) is a nonprofit, worldwide foundation that seeks to improve the well-being of the general public through the advancement of science. Its goal is to further the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment. ILSI is recognised around the world for the quality of the research it supports, the global conferences and workshops it sponsors, the educational projects it initiates, and the publications it produces. ILSI is headquartered in Washington, DC. It is affiliated with the World Health Organization (WHO) as a non-governmental organisation and has special consultative status with the Food and Agriculture Organization (FAO) of the United Nations.*

(ILSI website)

This is how ILSI presents itself on its website<sup>19</sup>. The organisation also refers to itself as a ‘neutral platform’<sup>20</sup>. The question I will ask here is not whether what they say (e.g. about well-being or science) is true or not, but how it makes ILSI exist and how it attaches ILSI to other organisations, concepts and practices. The status of a nonprofit organisation suggests a certain distance from lucrative activities, and this distance again suggests a proximity to more philanthropic motives such as improving the well-being of the general public (like the word ‘foundation’). The word ‘well-being’ is interesting, especially with respect to ILSI’s affiliation to the World Health Organisation (WHO) as a nongovernmental organisation (NGO). Well-being is hard, if not impossible, to define. The WHO defined the concept of health in terms of ‘well-being’ in 1948, and this definition has remained unchanged since: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”<sup>21</sup> If health is more than the absence of disease and infirmity, then there is room for improvement. If health is a state of *complete* physical, mental and social well-being, then it becomes permanently out of reach. The WHO definition in terms of well-being puts the human body and mind in a permanent state of deficit. Health, in other

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<sup>19</sup> <http://www.ilsil.org/Europe/Pages/Who-We-Are.aspx> (Consulted on the 15th January 2014)

<sup>20</sup> see e.g. Diplock (1999)

<sup>21</sup> Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948. For more information, see: <http://www.who.int/about/definition/en/print.html>

words, becomes a *promise*, and ILSI proposes to bring the promise closer for the *general public*, through the advancement of *science*. What sort of ‘science’ is capable of this?

And why would an organisation like ILSI, funded by food companies and a number of chemical companies, be interested in the health and well-being of the general public, and act as a spokesperson of health – something that usually falls within the remit of public authorities?

ILSI’s 1978 founding father was Alex Malaspina, then vice-director of the Coca-Cola Company in the US. He is said to be a ‘real visionnaire’<sup>22</sup>. He had created ILSI because Coca-Cola had a caffeine problem. Rumours abounded that caffeine has toxic effects (see e.g. Troyer and Markle, 1984). Malaspina would counter such rumours with scientific evidence. It *had to be* shown, with scientific arguments, that caffeine was not toxic. Eight years later, in 1986, ILSI created its European branch ‘ILSI Europe’, in Brussels. In total, the organization counts fifteen regional branches all over the world<sup>23</sup>. Today, ILSI also has an environmental branch (ILSI Health and Environmental Sciences Institute - HESI); an International Food and Biotechnology Committee (IFBiC); and a philanthropic, science-based branch (ILSI Research Foundation). ‘Science’ and ‘science-base’ are keywords in ILSI’s communications. In politically charged conflicts, ‘science’ is often called upon to provide a ‘neutral’ perspective on the matter. The effect of this is a *depoliticization* of political issues (Maesele et al. 2013). ILSI, as I will discuss below, presents itself as a ‘neutral platform’.

ILSI is entirely funded by food, chemical and biotech companies that pay for ILSI membership. Only the larger companies can afford to pay the membership fees, and therefore very few small or medium enterprises are part of the ILSI network<sup>24</sup>. ILSI Europe (henceforth: “ILSI”), gathers scientists from all over Europe into thematic task forces. Currently, there are 21 task forces<sup>25</sup>, covering themes like: ‘dietary carbohydrates’, ‘threshold

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<sup>22</sup> Personal interview with ILSI’s deputy director in Brussels, (date)

<sup>23</sup> Argentina; Brasil; Europe; China (ILSI ‘focal point’); India; Japan; Korea; Mexico; North Africa and Gulf Region; North America; North Andean; South Africa; South Andean; Southwest Asia Region; Taiwan. For more info and a hyperlink to each branch, see: <http://www.ilsa.org/Pages/GlobalNetwork.aspx>

<sup>24</sup> Interview at ILSI, Brussels, 26/11/10 with FM and FR.

<sup>25</sup> As counted on the ILSI Europe website on the 15th January 2014: <http://www.ilsa.org/Europe/Pages/Task-Force-List.aspx>

of toxicological concern’, ‘addition of nutrients’, ‘consumer science’, ‘probiotics’, ‘prebiotics’, ‘novel foods and nanotechnology’, ‘packaging materials’, and ‘functional foods’.

The leading branch working on functional foods within ILSI’s global network is the European one. As paying members, food and chemical companies like Danone, Nestlé, Unilever, Kellogg’s, Cargill, BASF, and many others have the initiative of proposing a new task force<sup>26</sup>. The agenda of the task forces – the topics and problems that they address – is also set by the paying members. The task force is comprised of representatives of member companies, and “non-industry experts whenever required”<sup>27</sup>.

Finally, the three main organs are the General Assembly, the Board of Directors, and the Scientific Advisory Committee. The General Assembly is the main decision-making body wherein all member companies are represented: 62 in total in January 2014. The General Assembly elects the Board of Directors – ILSI’s managing body. The Board is composed of an equal number of member company representatives on the one hand, and academic scientists on the other, to “ensure a balanced input”<sup>28</sup>. The Scientific Advisory Committee is composed in the same way, balancing industry and non-industry scientists, to provide scientific guidance.

## The neutral platform as a mediator

I visited ILSI Europe, at its headquarters in Brussels on several occasions, and I start this section with field notes from my first visit<sup>29</sup>.

*I have arranged my first interview with one of ILSI’s project leaders in 2010, and I am preparing to visit a big building in Brussels, equipped with offices and laboratories: ILSI Europe has its base on the Brussels university campus of the UCL (Université Catholique de Louvain), along the main axis, the Avenue E. Mounier, that separates the campus in two halves. The campus is*

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<sup>26</sup> The procedure is briefly explained on the website (see footnote 37).

<sup>27</sup> *Ibid.*

<sup>28</sup> <http://www.ilsa.org/Europe/Pages/Board-of-Directors.aspx>

<sup>29</sup> Making field notes is not only an integral part of ethnographic work, they also have a public function that enables an author to communicate non-verbal information concerning material settings, landscapes, bodily gestures, etc. See e.g. Emerson, Fretz and Shaw (2011).



*only a few metro stops away from Brussels' European district, where the "European Commission", as an institution is distributed over a number of buildings, and a staff of roughly 25,000 people<sup>30</sup>. The UCL campus in Brussels is entirely devoted to 'sciences de la santé'<sup>31</sup>.*

*ILSI doesn't occupy an entire building, but only part of it. The building is not impressively tall, and my first surprise is the entry: a small vestibule with mail boxes and a vertical row of buttons – one button or buzzer for each floor. It was like visiting someone's private apartment: you look for the name, press the buzzer and wait for someone to answer. In fact, the vestibule didn't have much more appeal or space than those of the student residences that dot the campus. Each buzzer had the name of an organisation and one of them was ILSI Europe. Indeed ILSI only needed one floor, and there were no laboratories. When I stepped out of the elevator, I walked into an open, luminous space with small, tidy offices on both sides, most of the doors invitingly opened. One of the doors was closed – I would learn later on that the probiotics task force was having a meeting there. The atmosphere was rather quiet and relaxed, with people walking in and out of their offices, stopping for a chat with the receptionist who I only noticed when I was already well-advanced in this central space, on my way to have a look at the shelves with brochures and printed ILSI publications on display. The receptionist told me that the man who I came to see had cancelled the appointment. The receptionist was kind enough to see if anyone was available to answer my questions, and found two colleagues who invited me in their shared office "for the presentation". "What do you already know about ILSI?" asked the senior scientist, an engineer in food processing then heading the 'consumer science' task force. She launches a Power Point Presentation. I notice that both women had a francophone touch to their English, so I ask which language they prefer for the interview. They opt for English, as they are used to talking their specific jargon in English, and as it is compatible with the Power Point. Before explaining the first slide, involving three intersecting circles representing 'academia', 'industry', and 'government', the senior scientist asks me who I am, and what I want to know. I explain that I am an anthropologist, preparing a PhD on the history of*

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<sup>30</sup> [http://ec.europa.eu/civil\\_service/about/figures/index\\_en.htm](http://ec.europa.eu/civil_service/about/figures/index_en.htm)

<sup>31</sup> <https://www.uclouvain.be/woluwe.html>

*functional foods. She thinks “this is funny”, because in her consumer science task force, she had already worked with an anthropologist. The aim of the project with the anthropologist had been to investigate how consumers understand health claims. Then the presentation starts<sup>32</sup>:*

FM: So our Mission. So our mission is to improve public health and safety through the advancement of science. So we are a scientific organization, and what we want is to advance the scientific knowledge in nutrition and food safety, in order to make sure that policy decision-making is based on science. So that the people that have to take political decisions related to nutrition (...) have all the scientific backgrounds. So we're *not* here to provide any recommendation, or position or opinion. We're here to provide scientific... ehm, *facts*.

Kim Hendrickx (KH): Ok.

FR (complements M's explanation): - and not to...not to...*create* any science. We are not a research institute. (5:57)

FM (confirms): No.

FR: - in the sense that there is no lab, as you can see.

KH: Oh yes, I was wondering about that, I imagined ILSI ... I imagined labs and all that.

FR: No.

FM: No actually we work, well that's later in the presentation but I can explain it now, we work with *experts*. (...) So on specific topics we invite experts and they produce review papers. So they take what is available in the scientific literature, and they apply it to a specific topic. So they take scientific basic information and put it together on a specific question that is raised by our members.

KH: Ah, all right.

FM: See? So it's not creating new data, it's taking the scientific data available and ... put them together in a way that answers a specific issue.

The explanation of the two scientists is quite clear: they are not doing science. They say so themselves, and their approach to 'science' – or rather: scientific *data* – is indeed very different from what can be read in ethnographies of scientific work (e.g. Knorr-Cetina, 1983; Latour and Woolgar, 1986): they are not involved in a process of testing and hesitating, eventually leading to the qualification of data, but they *start* from data. They have an 'issue',

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<sup>32</sup> Transcription Interview 26/11/10 at ILSI, Bussels. I anonymize with initials.

proposed by *someone else* (food companies), and they compile existing data while that issue remains fixed, and an answer must be formulated with the data available.

As the above description from my field notes shows, I only saw a very small part of ILSI: the office that makes ILSI ‘happen’. No research is done in the office. Rather, it is a small coordination centre, where some 20 people make phone calls, organize events and workshops, prepare publication layouts, maintain the website, and host small meetings<sup>33</sup>. The aim is to bring together scientists from industry and universities in thematic task forces one the one hand, and bigger events or symposia on the other. ILSI also submits research proposals to the European Commission, and has obtained several budgets under the European Framework Programmes.

The experts that ILSI gathers are not in-house experts, but task force members that meet at specific times and places, often outside the ILSI office. ILSI coordinates experts who do a specific kind of work. As my interlocutors say: this work consists of gathering existing data, and ‘put them together in a way that answers a specific issue’. So ILSI is a translator (Callon, 1986) driven by the question: how can existing research and data be translated in a way that is of interest to the member companies (who set the agenda)? I argue that ILSI doesn’t gather ‘existing data’ but that the category of ‘existing data’ is precisely what they call into existence. They gather publications, and create an entirely new context for them. ILSI is not a neutral platform, but a *mediating* platform<sup>34</sup>. ILSI is not an intermediary point, but a *mediator* that transforms what passes through it (see e.g. Latour 2005). ILSI a launching platform for ideas; and a landing platform for travelling scientists.

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<sup>33</sup> Many of them are early-career researchers. Although I did not investigate this more closely, there seems to be a regular turnover, and my guess is that many of these individuals get recruited by food companies. This was the case of MS, for example, a young woman I interviewed in 2010 and who went back to her home country to work for a food supplement and pharmaceuticals producer. The former executive director, Nico van Belzen, left ILSI in 2012 to become the Director general of the International Dairy Federation, which represents the dairy sector worldwide. Looking back at the staff structure on the ILSI website now, quite a number of faces changed since I started my research in 2010.

<sup>34</sup> As a mediating and active configuration, this ‘platform’ has common traits with what Keating and Cambrosio (2000) have called ‘biomedical platforms’ as Foucaultian ‘dispositifs’ (Keating and Cambrosio 2000: 361). I come back to the question whether this notion is appropriate to characterize ILSI’s activities at the end of this chapter.

## From Experts as Individuals to Expertise as a Practice

A characteristic of the experts that move in and out of ILSI's expert groups, is that they move in and out of *many groups*. They travel between all kinds of national and international organisations, advisory bodies and technical committees. In his book *Scientists and the Regulation of Risk*, David Demortain (2011) characterizes these scientists, travelling between the FAO, WHO, the European Commission, ILSI, national institutes and advisory bodies of all sorts. They are 'experts', for sure, but how to characterize these experts as a collective, asks Demortain, many of whom personally know each other? He goes through a number of concepts in the social and political sciences that designate interdisciplinary groups and transnational scientific collectives such as 'epistemic community', 'policy network' and 'transepistemic arena'. He opts for another term – 'invisible college' – that emphasizes the *elite status* of the individuals involved; their *circulation* (not belonging to one specific 'community'); and their *interstitiality*. These three characteristics, and especially the interstitiality explain better how these experts can exert influence on EU policy-making, because they are constantly on the verge of it.

The term 'invisible college' is somewhat unfortunate in the sense that it has an occult ring to it and suggests more unity amongst the experts (the 'college') than there actually is. Nonetheless, the three characteristics given by Demortain accurately describe the profile of the individuals that ILSI brings together: circulating and interstitial elite experts. This description, however, doesn't specify the nature of their work when they are in an *ILSI meeting*, rather than in another meeting. And it doesn't help me to characterize how they handle, create, translate the specific concept of 'functional foods'.

The invisible college is a term that distinguishes a community of *individuals*: they are part of the 'college' precisely because, as an individual, they occupy so many different positions, and because they are trained in different types of practices: scientific work at the university, policy advice, the coordination of projects, discussing regulations, etc. ILSI meetings are full of people holding degrees in the life sciences. But what does an individual become in an ILSI meeting? What is the type of practice that ILSI generates?

In a broad sense, this type of practice corresponds to what Alvin Weinberg (1972) termed ‘Trans-Science’. Weinberg says that the relation between science and politics or decision-making is often divided into two neat compartments: scientists answer a question, and this serves the decision-maker as a means to political ends. Weinberg argues that political and societal questions – concerning public health for example - can indeed be formulated in scientific language, but that science cannot answer them. Managing a mixture of political considerations and scientific data is what Weinberg calls trans-science. It has also been called ‘regulatory science’ (Irwin et al., 1997) and recently ‘cameral science’ (Stengers, 2013). The difference is, perhaps, that ILSI doesn’t officially act on behalf of any government. A more appropriate term would perhaps be ‘lobbying science’, but I will call it ‘stratagemic science’ or simply a ‘stratagem’ for reasons that I will explain later, after further analysis. It seems as though ILSI answers questions of interest to policymakers “to make sure that policy decision-making is based on science”, as my interlocutor said in the interview extract above. ILSI, then, would seem to act as a transmitter or intermediary between industry and policy. But in fact they are a *mediator* making a twist along the way: they send answers to policymakers to questions posed by food and chemical companies. This means that ILSI doesn’t simply prepare, and then ‘pass on’ information to policymakers. There is more than one ‘pass’ in the game, neatly expressed in French as a *tour de passe-passe*. In English that is called a *conjuring trick*. The trick is, I argue, that ILSI doesn’t respond to questions and then transmit answers, but that, with its industry members, it already has a number of answers for which appropriate questions must be formulated. In their publications, the questions and answers are invented at the same time, making the concepts ILSI proposes potentially appropriate for political agenda setting<sup>35</sup>.

In the following section, I illustrate this argument with two of ILSI’s publications that are of special interest with respect to functional foods and health claims. They are relevant, because in 2003 their concepts were taken up in the European Commission’s legislative proposal for a European Nutrition and Health Claims Regulation (the NHCR), as I will show in Chapter 3.

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<sup>35</sup> Demortain (2008) shows how ILSI succeeded in creating a safety norm and practice for the European regulation on novel foods called ‘post-marketing monitoring’.

## Functional Food Science for Europe

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Functional Food Science for Europe (hereafter: FUFOSE)<sup>36</sup> was a 4-year project (1995-1998) to create a community of scientists around a concept: functional foods. The project resulted in a publication in the *British Journal of Nutrition* in 1999 (Diplock et al., 1999. Hereafter: ‘Consensus Document’). In this publication, the concept of functional food is proposed along with a working definition *and* the methods to validate that definition. This definition and the FUFOSE project are cited internationally in every review and manual on the subject of functional foods or health claims, published after 1999.

The FUFOSE project was larger in subject scope and human resources than ILSI’s punctual meetings and conferences. To realize it, ILSI had applied for European funding within the European Commission’s 4<sup>th</sup> Framework Programme. The aim of the FUFOSE project was to “establish a science-based approach for concepts in functional food science.”<sup>37</sup> In fact, as I show below, what is established is functional food science *itself*. This was to be done by setting up an international and multidisciplinary European network of researchers in the life sciences. More specifically, the objectives of the project were:

1. to assess critically the science base required to provide evidence that specific nutrients and food components positively affect target functions in the body;
2. to examine the available science from a function-driven perspective rather than a product-driven one; and
3. to reach consensus on targeted modifications of food and food constituents, and options for their application.

(Diplock et al., 1999: 1)

The first point already illustrates ILSI’s conjuring trick: the *answer* is that ‘specific’ nutrients and food components positively affect the human body. They speak of ‘target functions in the human body’ and I will give due consideration to ILSI’s terminology in the next section below. Here I focus on the FUFOSE’s aim. The aim then, is to provide the right question or problem to the answer they already have: a science is needed to support the answer that specific foods are good for you. Science is to be subjected to the requirements of the provision of evidence. This requirement is confirmed in the third point: a consensus must

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<sup>36</sup> The full name of the project: *European Concerted Action on Functional Food Science in Europe*. FUFOSE is the abbreviation used in publications of the Commission and of the project members.

<sup>37</sup> Consensus Document, preface

be reached to align all researchers in the project on the problem that will accommodate the proposed solutions. The second point of the quote above deserves special attention: a ‘function-driven perspective’ is preferred over a ‘product-driven’ approach. By this, ILSI means that *specific foods and their nutritional composition* will *not* be investigated, but only the function of isolated nutrients in relation to functions of the body (hence ‘functional’ food). To understand this, it must be reminded that ILSI has 62 different food and chemical companies in its General Assembly. Amongst the food companies alone, there are several competitors with similar products. Next to similarity, difference can also cause trouble because certain products, like yoghurts, may be easier to promote as beneficial than snacks, rich in sugars and fat, or soda drinks: yoghurts have a more favourable ‘nutritional profile’ and are, potentially, more credible bearers of health claims. Of course, companies like Nestlé and Unilever have various product categories on the market. A second and related reason for eschewing a ‘product-driven’ approach is Europe’s market itself. The composition of food products is a very sensitive issue, and the opinions amongst Member States of the European Community constantly risk obstructing the free movement of foodstuffs within the Community. I discuss this in detail in the next chapter. For now, it is important to note that what ILSI calls ‘science’, a ‘science-base’, or ‘functional food science’ is a strategic move to encourage and anticipate a Community legislation for health claims as a promotional tool. In Europe and worldwide, health claims became very much in vogue during the 1990s. However, there were no common rules to deal with them. Each Member State had its own policy<sup>38</sup>. Aware that certain countries were sceptical about this health niche, ILSI wanted to turn its initiative into an advantage by proposing a science to evaluate health claims in terms that were favourable for the food industry at large. The core of the strategy is to *detach* ‘functional components’ from actual products and their complex and ambivalent nutritional composition, and to *detach* ‘target body functions’ from an individual’s complex clinical experience. Although this ‘function-driven approach’ is the core of functional food science, the landmark article in the *British Journal of Nutrition*, called the Consensus Document, is rather short about it:

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<sup>38</sup> See for example: Heasman and Mellentin (2001) and the next chapter.

*Up to now, the approaches used for functional food science, both in Japan and to a lesser extent in the USA (...) have mostly been 'product or food component-driven', and they are likely to be very much influenced by local, traditional or cultural characteristics. A science-based, 'function-driven' approach is preferable, because the functions and their modulation are **universal**. Functional food science, therefore, refers to the new concepts in the science of nutrition that lead to the stimulation of research and to the development of functional foods.*

(consensus document, p. 6, my emphasis)

The universality of science is opposed to culture, which is a theme that is, paradoxically, *part of the culture* of modern Western societies since at least the 17<sup>th</sup> century (Latour 1999, Stengers 1993, Bensaude –Vincent 2003). In the citation, the word 'influence' is used, and it gives the impression that culture *contaminates* food products, whereas functional food science can purify them, by detaching them from their particularities. This detachment is also a general operation to transform products with particular histories into goods that can circulate in the calculable space of markets, before attaching themselves again to particular people who buy them (Callon *et al.*, 2002). The detachment that ILSI proposes, however, is paradoxical: to value and qualify food products, food products must become invisible. As this particular detachment is driven by economic and political motives, *nutrients*, with their specific functions, can be said to become the political representatives of the 'general population' of foodstuffs. Historian and philosopher of science Gyorgy Scrinis has coined the strategic focus on separate nutrients 'nutritionism', and he qualifies it as an ideology<sup>39</sup>.

I am inclined to agree with Scrinis, although the word 'ideology' gives the impression that nutritionism is but a set of ideas, or even a superstructure that mystifies an underlying material and economic infrastructure. However, it is as much an 'infrastructure' as a 'superstructure' as it informs politics with scientific concepts while also providing the means and language to market products (as Scrinis shows himself too).

A final aspect that I would like to highlight before looking into the contents of functional food science and the Consensus Document, is ILSI's *claim* – in the sense of claiming a right – to talk in the name of public health. ILSI wants to contribute to the

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<sup>39</sup> See his book Scrinis (2013). For his characterisation of nutritionism as an ideology: see Scrinis (2008). Michael Pollan (2008) has introduced the term 'nutritionism' to a wider audience in his best-selling book *In Defense of Food. An Eater's Manifesto*.



improvement of public health through the advancement of science. I have already indicated that ILSI works on several topics, ranging from food benefits and safety to environmental safety and sustainability. Here I focus on functional food science:

*We are at a new frontier in nutrition science because, at least in the industrialized world, concepts in nutrition are changing significantly. We are progressing from a concept of 'adequate nutrition' to one of 'optimal nutrition'. We have moved from a former emphasis on survival, through one of hunger satisfaction and of food safety, to our present emphasis on the potential for foods to promote health, in terms of both improving well-being (mental and physical conditioning) and reducing the risk of diseases.*

(Consensus Document, p.5)

What this excerpt shows is that science is expected to be able to help 'us', in the industrialized world, to eat better. ILSI, speaking in the name of public health, defends nutritionism as a timely solution, as Western societies face the problems of ageing, chronic and non-communicable diseases like diabetes, obesity, cancer, and cardiovascular diseases (e.g. Howlett, 2008; Chadwick, 2010; Roberfroid, 2008).

In the history of medicine, connecting public health to science has been a complicated historical process<sup>40</sup>. Historian Harry Marks (1999) gives a detailed account of how medicine has become 'scientific' – that is: how clinical trials became a way of discriminating between effective and non-effective or even dangerous forms of therapy. In the United States, this was the project of a heterogeneous community, spanning several generations throughout the 20<sup>th</sup> century, that Marks calls the 'therapeutic reformers':

*Les réformateurs thérapeutiques (...) constituent plutôt une communauté politique, un groupe soudé par sa croyance dans le pouvoir de la science pour unir les chercheurs et les praticiens de la médecine **malgré** d'évidentes différences de formation et de pratique. (...) (C)e qui lie les réformateurs est la croyance partagée qu'une meilleure connaissance des effets et des usages des médicaments entraînera directement une meilleure pratique médicale."*

(Marks, p.17, original emphasis)

This was a powerful movement, rooted in a growing mistrust of the clinical judgement of individual practitioners, and the putting on the market of drugs that have had dangerous and sometimes lethal side-effects. So it was a movement critical of private judgement and

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<sup>40</sup> Foucault, for example, (2003) discusses the 19th Century origins of the medical 'gaze' in relation to a new geography and ontology of diseases in his famous *The birth of the Clinic*. He also discusses the birth of 'social medicine' in a conference lecture, published in *Dits et Ecrits* II, see Foucault (2001).

clinical experience, but also wary of the private interests of the pharmaceutical sector. Already in the early 20<sup>th</sup> century, the American Medical Association (AMA) “put their faith”, as Marks (2009) says, “in laboratory experiment to counter drug promotions in the marketplace.”<sup>41</sup> Like in the previous quote, Marks insists on a shared faith or belief, and he considers this constellation of beliefs and research practices as a *moral economy*, as it is used by Lorraine Daston (1995) to historically characterize scientific practices<sup>42</sup>. The AMA believed in the moral authority of evidence, and there was a distinctive anti-commercialism in its work. In more general terms, in the US and in Europe, the professionalization of the medical discipline from the 19<sup>th</sup> Century onwards, developed in close relation to the State, the latter setting the mission of protecting public health<sup>43</sup>.

In its mission and faith to connect science and public health, ILSI and its nutrition community bears some resemblance to this movement of therapeutic reformers. The community is also multidisciplinary, although it does seem to aspire to a certain specialization, or perhaps even professionalism, formed around the object of functional foods: “Functional food science is a new discipline that is part of the science of nutrition and is aimed at stimulating research and development of these foods by using a function-driven approach” writes the scientific coordinator of the FUFOSSE project (Roberfroid, 2000, p.1661).

However, the community that the FUFOSSE project created is not anti-commercial. Its boundary is not between private and public, but *sectorial*: between the agri-food sector and the pharmaceutical sector and their respective markets. “In no case must functional foods be considered drugs,” write the authors of an article in the *Scandinavian Journal of Nutrition* (Coppens et al., 2001)! The authors, at that time, were all members of the Health Claims Expert Group of the European Confederation of Food and Drink Industries (CIAA)<sup>44</sup>. If Marks’ therapeutic reformers operated according to a certain moral economy with the

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<sup>41</sup> Marks (2009): 83

<sup>42</sup> See Daston (1995). For her, ‘moral’ refers to both the psychological and the normative. And ‘economy’ means, in this context, a “balanced system of emotional forces, with equilibrium points and constraints” in which “(n)ot all conceivable combinations of affects and values are possible.” (p.4) A moral economy is rooted in activities or practices, and derives its stability from it. As such, it is also a *collective* phenomenon.

<sup>43</sup> See Marks (1999, 2009); Adam and Herzlich (2010). See also: Freidson (1984).

<sup>44</sup> This is mentioned in the form of a disclaimer underneath the article. The disclaimer further states that: “This article expresses the views of the authors and does not necessarily represent the policies of their employers.”

authority of evidence as its point of gravity, then, I argue, the functional foods community is trying to establish point of gravity and a form of evidence of its own, in a moral economy where industry, government and academia sit together peacefully, agree on the problems of a given, common world, and forge consensus on the solutions under the sign of science.

## Qualifying Nutrients and Body Functions

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The FUFOSE project ended in 1998, and in 1999 the results of the consensus meeting in Barcelona were published in the British Journal of Nutrition (Diplock et al., 1999), along with the following working definition for functional foods:

*No universally accepted definition of functional foods exists. In fact, because functional foods are more of concept than a well-defined group of food products, a working definition is preferred for the purposes of this Consensus Document.*

*A food can be regarded as 'functional' if it is satisfactorily demonstrated to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being, and/or reduction of risk of disease. Functional foods must remain foods and they must demonstrate their effects in amounts that can normally be expected in the diet: they are not pills or capsules, but part of a normal food pattern.*

(Diplock et al., 1999: 6)

Let us consider the definition in separate parts. Here is the first part:

*A **food** can be regarded as 'functional' if it is **satisfactorily demonstrated** to affect beneficially one or more target functions in the body, beyond adequate nutritional effects, in a way that is relevant to either an improved state of health and well-being, and/or reduction of risk of disease.*

(my emphasis)

The starting base is 'food' but the most important word in the citation is 'demonstrated'. Functional food is a concept for *food that has passed a test* of some sort. The kind of test remains unspecified in this definition. Functional food is not an object or a predefined group of food products, as the authors argue, but it is a *qualification* of food ("*a food can be regarded as 'functional' if...*")

The authors then repeat that only foods can be qualified as functional:

*Functional foods **must remain foods** and they must demonstrate their effects in amounts that can normally be expected in the diet: they are not pills or capsules, but part of a normal food pattern.*

(my emphasis)

Pills or capsules cannot participate in the kind of test that attributes effects ‘beyond nutrition’ to foods. The question then becomes: what are food’s effects beyond nutrition, and how do you demonstrate it? The main issue in the Consensus Document is to make a number of proposals to answer that double question. The Document in fact proposes the term functional food and its definition as a working programme. To better characterize this programme, let me reformulate the definition of functional food in terms of the *genus-differentia* definition it implies<sup>45</sup>.

The definition specifies a *genus* (functional food belongs to the category of food), and a *differentia* (it affects functions in the body beyond nutritional effects). The *differentia* is hypothetical in nature and refers to other concepts that need to be defined (‘target functions in the body’, ‘beyond adequate nutritional effects’, ‘improved state of health’). Now, one could argue that this *differentia* does not really distinguish functional food from other food: all foods are likely to have effects beyond mere nutrition, it is just that we are not aware of it. But this is exactly the point: the Consensus Document is not about a new category of food, but about what I would call a methodology of *demonstration*. Both the genus and differentia, if we follow the logic of the Consensus Document definition, refer to the effects of food and not the essence of it. The aim of the Document is to propose a method, or rather a series of methods, to demonstrate these effects. What complicates things is that these methods are proposed together with new concepts: effects, qualified as ‘beyond basic nutrition’ have to be made visible in ‘target body functions’, indicating ‘an improved state of health’. So the Document’s working definition does not qualify as a referential definition since the description does not refer to known terms. Rather, it is an operational definition or a working programme for *functional food science*, which I describe as *a science that is capable of demonstrating what food is capable of in human bodies*. The structure of the article gives a hint of what this programme looks like. Here are titles of the most important subsections in

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<sup>45</sup> The genus-differentia definition goes back to Aristotle, and a discussion of it can be found in: Granger, E.H. (1984). Granger argues that Aristotle defines the relation between genus and differentia in three different manners, and that this represents three stages in Aristotles thought. My use of the two terms is less nuanced and serves only as a first clarification of the term ‘functional food’.

the introductory part of the article: “From traditional to new concepts in nutrition. From new concepts in nutrition to functional foods. From functional foods to functional food science” (pp.5-6).

If it seems a bit awkward to have a science *following from* the functional foods concept, and not the other way round, it must be remembered that the ‘science’ described in the Document is in fact a method of demonstration, subject to specific constraints. ‘Functional food’, as a concept, is defined, I argue, *according to the requirements of the type of human intervention trials that are likely to make effects of certain nutrients in the human body visible*.

The Consensus Document introduces a definition of functional foods that is dependent on methodologies yet to be developed. Only these methodologies can call functional foods into *existence*.

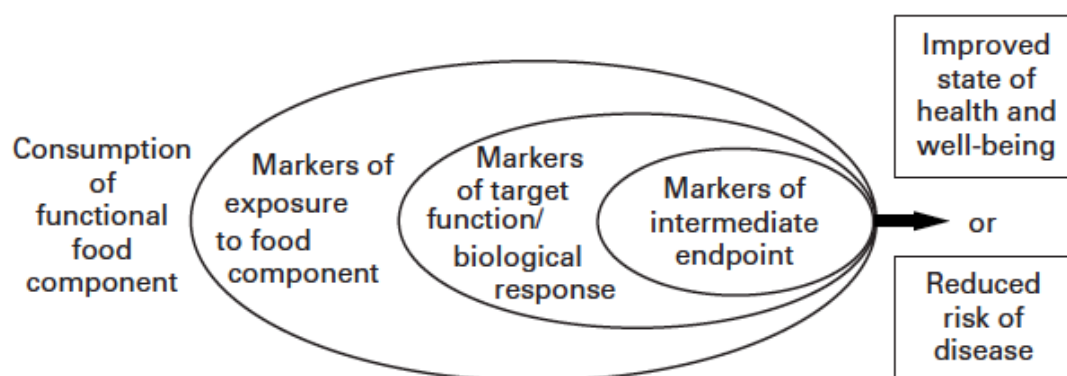


Figure 1: Classification of markers relevant to the effects of functional foods

(Reproduced from Diplock et al. 1999: 7)

Figure 1 helps us to understand what the methodologies that define and qualify functional foods consist of. A functional food component is anything that can be formulated into a food matrix and that is safe for consumption. The food component can be a nutrient, like a vitamin or a mineral, but also a non-nutritive component like a bacterial strain, certain fibres, or plant sterols (e.g. in cholesterol-lowering margarine). The authors propose themselves to investigate the ‘black box’ between a food component and a health-related outcome. The idea is that there is a chain of markers that mechanistically lead to an outcome.

The original explanation with figure x is: “This is a diagrammatic representation to show how different types of markers would be expected to lie within a logical progression from the food component to the health outcome. The types of markers are completely independent of each other. Markers can either be indicators or, if they can be proven to be causal, factors (p.7)”

The first type of marker is the marker of *exposure* like for example a serum, faecal, urinary or tissue marker. These are ‘available’ and ‘feasible’ markers, as the Document indicates. The increased level of red-blood-cell folate is a marker of the exposure to folate in food, for example. The second type of marker is a marker of *target function* or biological response. The example given is the reduction of plasma homocysteine as a possible response to dietary folate. The third type of marker is the marker of *intermediate endpoint*. This concerns, again, the measurement of a biological process that is somehow related to a clinical outcome (improved state of health and/or reduced risk of disease). The example given is the extent of narrowing of the carotid artery as evidence for cardiovascular disease. Another example would be the lowering of cholesterol which is also considered to be related with cardiovascular disease.

I will now explain two key issues about this classification of markers that are of importance for my characterization of functional food science. Firstly, the word ‘clinical’ has no significant role in this Document. The word occurs 4 times over the 27-page article, but in three of the four cases it has no significant relation to the methodologies of functional food science. Only one of these four mentions is interesting. In a paragraph on ‘safety considerations’ the following is said: “Protocols for human nutrition studies need to be developed including, in some cases, post-marketing surveillance. Even though the design of *clinical studies as used in drug development* can serve as a reference point, specific protocols and specific criteria relevant to functional foods might be needed.” (p.8) I have emphasized in which context the word ‘clinical’ occurs: in relation to drugs. Drug testing, both with regards to safety and efficacy, involves the evaluation of clinical outcomes or ‘endpoints’. A clinical outcome is a therapeutic or toxic effect that is clinically observable: a human being recovers, gets better, heals or, on the contrary, gets sick or worse. For the development and putting on the market of drugs, it is crucial to know the effect they have on human beings, even if the exact mechanisms of the molecule’s action in the human body are not always known (Pignarre, 1997; Dagognet and Pignarre, 2005). It is the clinical outcome that counts. With functional food science, we are in a different situation, where it is – almost - the exact

opposite: functional food science *is not concerned with clinical outcomes, but with mechanisms*. Functional food scientists want to stop right ‘before’ the clinical outcome, at the ‘intermediate endpoint’: a marker that stands in a hypothetical relation to the clinical outcome because there is evidence for the relation in *other studies*. In fact, presenting intermediate outcomes as ‘right before’ a clinical outcome is part of the argument in functional food science: it suggests a straight *causal* pathway of bodily responses that has predictive value. One of the main authors of the Consensus Document has developed this idea further and calls it ‘evidence-based mechanistic reasoning’ (Aggett, 2011). The reason to encourage this type of ‘reasoning’ and to focus on markers is to avoid any confusion with drugs and the costly business of large-scale clinical trials.

This brings me to the second point that characterizes functional food science as a specific practice. When I said that functional food science is concerned with mechanisms (rather than clinical outcomes), the understanding of mechanisms is not a goal in itself. Functional food science is a science that demands *leeway*, and looks for associations rather than strong causality. If causality can be established, *then all the better*. If it cannot be established, then this is no reason to say that a claim about nutrient’s health benefits cannot be formulated:

*The differential classification (of markers) is considered to be of real importance in the development of new markers for use in human studies. The result from such studies can also form a scientific basis for formulating and controlling claims.*

(Diplock, 1999: 8)

The term ‘indicator’ is used for markers that are not causally related to the health outcome, and ‘factor’ is used for those that are causally related, although it is not specified what causality exactly means<sup>46</sup>.

Criteria for markers are proposed in bullet points such as:

- Markers should represent relatively immediate outcomes, which can be used to assess interventions in a reasonable timescale; they could, therefore, wherever possible, *replace later and more remote outcomes as have been used in some epidemiological studies*.
- Markers must be rigorously validated and amenable to standard quality-control procedures.

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<sup>46</sup> I refer again to cholesterol as one of many risk factors. Causality is mentioned three times in the entire Document, without it being the main issue in the section where it occurs.

- Markers must be clearly linked to the phenomena involved in the biological process being studied. (...).
- (...)
- Markers must be measurable in easily accessible material, or obtainable using methodology that must be both ethical and minimally invasive.

(Diplock, 1999: 8, my emphasis)

These criteria constrain the possibilities of scientific research, while insisting on the fact that it must be rigorous and quality assured. Functional food scientists, then, appear as a type of *technician* constrained to avoid too difficult (and time-consuming) questions and focus on *solutions*.

A final remark about the concept of ‘markers’ in the Consensus Document, and their classification in ‘indicators’ and ‘factors’. This terminology is used in the Consensus Document to avoid the term ‘biomarker’. As a later publication (Biesalski, 2011) of ILSI Europe-affiliates explains:

*The FUFOSSE consensus eschewed the term biomarker, which has biochemical connotations. It preferred markers because this acknowledged the broad range of available and applicable markers. Thus, apart from biochemical markers, study outcomes can quite feasibly be derived from, among others, behavioral or psychometric outcomes, physiologic performance, adaptive phenomena, and metabolic clearance studies; (...) In fact, any marker that can be quality assured and validated should be appropriate for establishing causality. Often, it is likely that a “battery” of markers might be needed to address the perspectives of evidence appraisal (...) for multiple and variable sources of data. In fact, given the quality of data available for health claims, these considerations about markers should inform “new human intervention studies using appropriate markers to generate readily interpretable, valid and reliable data”.*

(Biesalski, 2011: 4)

The quote in the above excerpt is a citation from the FUFOSSE Consensus Document. To resume: the category of ‘markers’ must be broader than the biochemical ‘biomarkers’. This diversity of markers must also be combinable (it is not clear how) to generate ‘batteries’ of markers. These terminological and conceptual choices are all related to the fact that functional food science is not a fundamental science, but a strategic programme to generate evidence for health claims. FUFOSSE was written and published before a European regulation on health claims existed, at a time when food companies and national authorities were pushing for a regulation of claims on food products. Food companies were pushing to have access to a European market with a clear and light approval procedure on the European level. National authorities were pushing because some of them were put under pressure by



industry<sup>47</sup>. When the Consensus Document was written, there were at least three reasons to propose ‘markers’, subdivided into indicators (correlation) and factors (causality). The first is to *avoid being limited to biochemistry*; the second (related to the first) is to *broaden the scope* of marker-oriented research to cognition, psychology and performance; the third is to *broaden the evidence-base* for functional food by including weak causality or correlation.

Let me resume the characteristics of functional food science, as a specific practice, that we have explored up to now. I will call the first characteristic ‘the externalization of the clinical’: the clinical is suggested but kept at bay at the same time. Instead of ‘clinical studies’, the terms ‘human studies’ or ‘human intervention studies’ are used. The clinical is situated outside the box of markers and mechanisms that functional food scientists would ideally like to investigate. *Investigating* is perhaps not the right word. *Operationalizing* is probably better, in view of the definition that I have proposed for ‘functional foods’ or ‘functional food science’: a technology of demonstration, established *according to the requirements of the type of human intervention studies that are likely to make effects of certain nutrients in the human body visible*. The human intervention studies, as we have seen, are in fact marker-oriented studies, with leeway for associations or ‘batteries’ of markers to approximate causality. The idea is defended that association *as such* has a cumulative effect and increases evidence for a relationship with the clinical. This is the second characteristic of functional food science: it excludes the risk that in theoretical-experimental sciences is *constitutive* of association or ‘articulation’ (Latour, 2007). The risk taken in scientific practice is that the object under study is *given the power to redefine the questions addressed to it* (Stengers, 2006). To be sure, my argument does not concern the competence of nutritionists or life scientists here. Competence is not the matter. What I am concerned with here is what Stengers (2006) calls the *milieu* or environment that FUFOSE and ILSI create for scientific research. This environment doesn’t allow researcher to pose their own questions, and take the risk of granting objects the power to redefine those questions. The Consensus Document formulates a series of concepts and constraints that do away with this risk, because the final aim is not to gain fundamental knowledge on a food ingredient or body function, but to *pass through the human body as a site of demonstration of the ingredient’s market value*. If this resembles the way drug molecules are socialized and put on the market (Pignarre 1997), functional food science turns the body into a site to differentiate food from drugs, and health

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<sup>47</sup> Interview at the European Commission, DG Sanco, Brussels, 23/04/13.

from disease, by externalizing the clinical from its ‘box’ of mechanisms. Functional foods have no patients, but consumers (cfr. Mol 2008). Consumer’s experience of well-being are irrelevant to the market test that functional food science proposes. With regards to ‘science’, the question that is asked in the Document is: ‘how much science is enough?’ (Heasman and Mellentin, 2001). The figure below is also reproduced from the Document and I propose to read it as follows: this figure visualizes the body, detached from clinical experience, as a point of articulation between a component and a *claim* with market value.

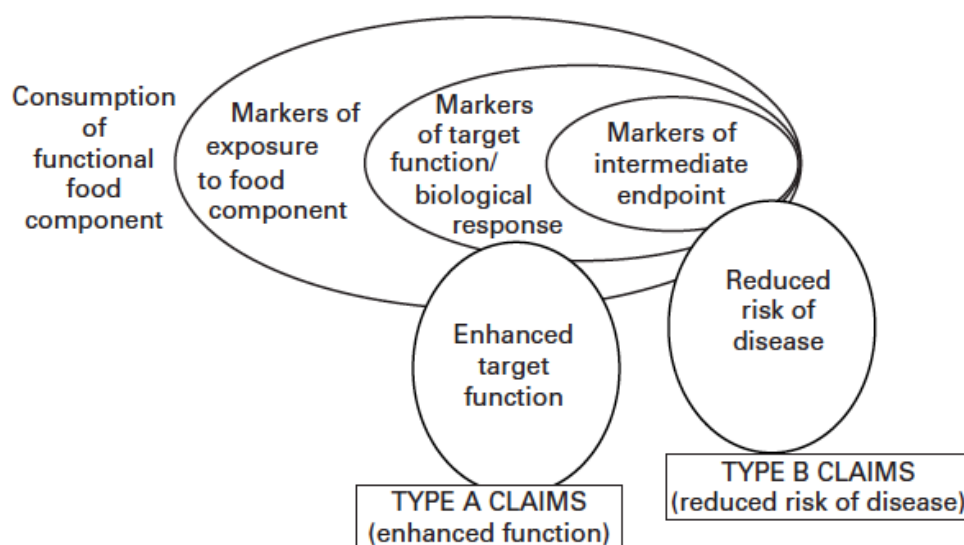


Figure 2: the human body as a point of articulation between components and claims

(Reproduced from Diplock et al., 1999: 25)

Again, the difference with scientific practice as a mode of taking risks with objects is salient. Making a scientific claim means taking a risk: the claim will be examined by colleagues, and also the object itself can at a certain point contradict a claim or hypothesis. In *Laboratory Life*, Bruno Latour (1986) shows that claims or statements go through a spectrum of modalities, and that these modalities are also a resource for other scientists to make the statements of their colleagues more or less credible. Some claims will eventually ‘descend down the ladder’ and laid to rest as claims. Other statements, however, will become more and more solid. A scientific object is a solidified claim: science creates its own objects and this represents a considerable investment and the taking of risks. Functional food (science) uses the risks taken by other researchers, start from recognized objects and make them subordinate to a claim. The object comes to *carry* a claim, and this claim is the final result and benchmark

of excellence. The logic with respect to *Laboratory Life* is turned on its head: instead of making risky claims to articulate (or not) objects, the question becomes what kind of fixed procedure can deliver good claims, without them mattering for the object. In that sense, and to avoid any further confusion with science, I propose to call functional food scientists *claim technicians* from here on. This name enables me to distinguish the ‘technical’ from the scientific in the way that Isabelle Stengers proposed:

*Faire exister les techniques comme distinctes est (...) crucial s'il s'agit de résister aux effets de fascination associés aux discours sur l'inexorable redéfinition technoscientifique du monde.*

(Stengers 1997: 57)

As I have discussed earlier on, the Consensus Document announces a new frontier in nutrition science that would help us to eat better. This is the ‘inexorable technoscientific redefinition of the world’ in the quote, the fascination of which must be resisted, because it is not a new frontier in science but in food technology, which is confirmed by some of the authors of the Consensus Document themselves<sup>48</sup>.

Functional food science is designed to craft a territory for therapeutic claims outside of the scientific and regulatory regime of pharmaceuticals, but it actually has a lot in common with ‘rational pharmacology’ or ‘drug design’. Rational pharmacology emerged in a context of crisis: a lot of patents expired in the 1980s-90s and innovation became difficult and costly, because the production of drugs had, until then, followed a model that generated ‘more of the same’ during several years (Pignarre, 2004). Rational pharmacology promised a scientific approach that would focus on the elucidation of biological mechanisms between a biological ‘target’ or ‘lock’ and a molecule or ‘key’ to open the lock. A lot was expected from molecular biology on the one hand, and computer simulation to match the properties of molecules with those of biological targets. The model of drug design would ideally be able to create such perfect matches, without side effects, and at a much lower production cost than through screening methods and clinical trials. In the words of historian Philippe Pignarre:

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<sup>48</sup> Personal interview at ILSI’s Annual Symposium. Brussels, 24th March 2011.

*Cette pharmacologie rationnelle laissait discrètement transparaître le rêve d'une recherche thérapeutique qui, dans sa phase ultime, permettrait de se passer des essais cliniques eux-mêmes. Elle permettrait d'aller directement de l'identification d'un mécanisme biologique et des moyens rationnels de son blocage ou de son activation, à un médicament efficace parfait.*

(Pignarre, 2004: 103)

The Consensus Document presents a nutritionists' variation on the project of rational pharmacology or drug design. It is not called 'rational nutritionism' but 'evidence-based nutrition' or 'evidence-based mechanistic reasoning'. Through the notion of 'evidence-based', however, it acknowledges the missing links in the chain of markers, and therefore proposes, in the same run, a scheme to assess evidence. In other words it proposes how regulators should deal with the incompleteness of claim substantiation: different kinds of studies, indications, markers should all be recognized to contribute to the strength of a health claims dossier, and *should be taken into account*. Scientific proof should not be dependent on one specific demonstration, and certainly not on the strong causality of clinical trials. A certain amount of science should be enough, and that amount, preferably, shouldn't involve anything clinical, *especially* not the randomized controlled trial (RCT). By eschewing the term 'biomarker', functional food science, like rational pharmacology, places its hopes on molecular biology as an approach that will lead to the understanding of biological mechanisms, which is something that chemistry is less equipped for<sup>49</sup>. Next to molecular biology, the Consensus Document mentions immunology as a promising field for their purposes, as it offers dynamic concepts of immunity that are interesting for functional food science. It opens the door to new markers, not indicating a *state* of the organism, but its ability to *adapt*.

Functional food science, then, as 'evidence-based nutrition' is a project similar to that of drug design, and it comes with its own policy:

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<sup>49</sup> See Pignarre *op. Cit.*, p.96 for the inversion of the traditional roles of chemists and biologists in rational pharmacology. The Consensus Document, next to molecular biology, mentions immunology as promising field, as it offers dynamic concepts of immunity that are interesting for functional food science. It opens the door to new markers, not indicating a state of the organism, but its ability to *adapt*.

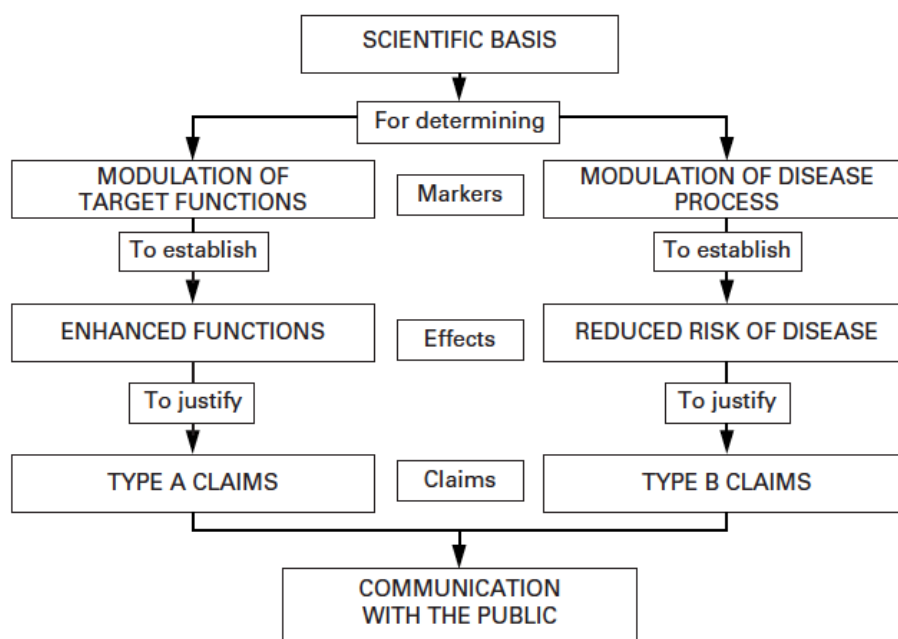


Fig. 3 (Reproduced from Diplock et al., 1999: 25)

The scheme above again indicates the special nature of functional food technology, as a form of regulatory science (Irwin et al., 1997). In fact, the need for a ‘scientific basis’ is stipulated as a starting point. Such an assertion is absurd within scientific practice, but it makes sense within product development. Type A claims are *enhanced function claims* and Type B claims are *reduction of disease risk claims*. As we will see in chapter 3, the Commission’s proposal for a health claims regulation in 2003 (4 years after the publication of the Consensus Document in 1999), took up these categories and cites FUFOSE as ‘valuable work’ (European Commission, 2003: 9). In that same proposal, the Commission interpreted the legal prohibition on medicinal (or ‘disease-related’) claims on food as going too far, and not in keeping with new technological developments (2003: 2). This made disease *risk reduction* claims possible. That way, connecting a food ingredient to disease as a clinical outcome is avoided, while making a therapeutic claim anyhow. Avoiding that confusion also fits the food industry’s agenda to invest ‘health’ as a market niche.

FUFOSE's follow-on project, conveniently called PASSCLAIM, which was also funded by the European Commission and coordinated by ILSI Europe (2001-2005), proposes criteria to assess health claims made on food products, thereby providing a source of inspiration for the European Regulation on Nutrition and Health Claims (NHCR) that was

under discussion when the PASSCLAIM results were published in the European Journal of Nutrition in 2005 (Aggett et al., 2005). The project ran from 2001 to 2005 and was already mentioned in 2003 for its ‘considerable work’ in the Commission’s first proposal for a NHCR (European Commission, 2003), and it is still recognized as an important work for policymakers today<sup>50</sup>. PASSCLAIM is the acronym of: ***P**rocess for the **A**ssessment of **S**cientific **S**upport for **C**laims* on foods, and it is one step closer to policymaking –or rather: pre-market approval of functional food – than FUFOSE. FUFOSE, as we have seen, introduced the concept of functional foods with a specific terminology (functional components; target functions; health benefit; marker; etc.) and a classification of markers. But it didn’t address the question of how different types of studies should be *assessed* by any competent authority and what their respective importance is. I will turn to this project now.

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<sup>50</sup> Interviews at the Belgian Federal Ministry of Health, Brussels, 12/03/2012, and at the Commission’s DG Sanco, Brussels, 23/04/13.

## PASSCLAIM: Calibrating the Balance before Weighing

Like FUFUSE, PASSCLAIM is based on a strategic programme that is directed (with an arrow) and establishing scientific consensus about the criteria of ‘sound science’. The structure of the project is visualized in the project’s final article, published in the *European Journal of Nutrition* (Aggett et al., 2005):

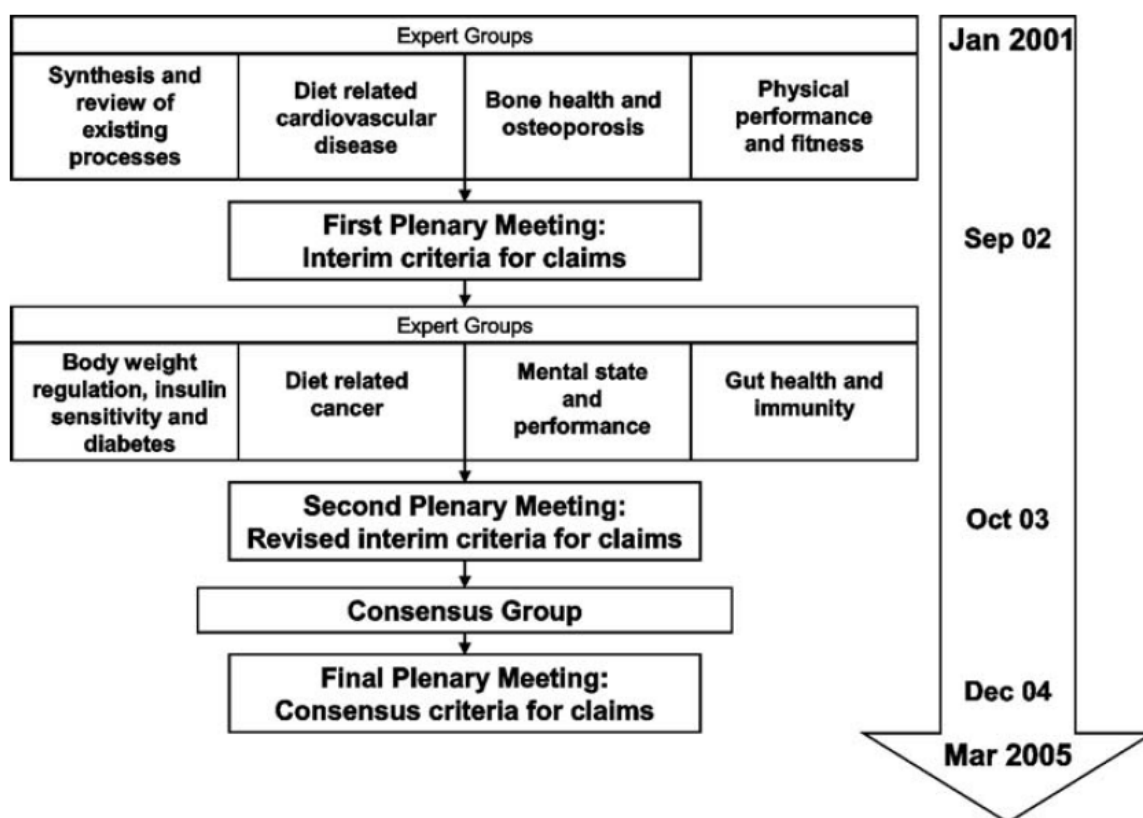


Fig. 4: Structure of the PASSCLAIM project.

(Reproduced from Aggett et al., 2005: 10)

As the figure shows, expert groups gather around pre-established body functions<sup>51</sup>. Indeed, ILSI itself, as we have seen above, has been subdivided into thematic ‘task forces’. The themes are set by food companies that are member of the organization<sup>52</sup>. Even more explicitly than in FUFUSE, the PASSCLAIM project, as the acronym indicates, is a strategic programme to deliver a science-base to policymakers when a European regulation was under

<sup>51</sup> These have been chosen according to promising food ingredients or molecules (e.g. inulin extracted from chicory root) and/or existing markers (e.g. cholesterol), see Diplock et al. (1999).

<sup>52</sup> Interviews at ILSI Europe, Brussels 16/11/10, 26/11/10, 26/08/11.

way. More precisely, PASSCLAIM wants to set the terms of such a science-base. The Commission, not sufficiently staffed to deal with the increasing number of technical issues that the EU decided to regulate<sup>53</sup>, welcomed such input, and the framework programmes were there to generate policy-relevant inputs<sup>54</sup>. A total of 6 criteria for the scientific substantiation of claims are proposed, with a number of subdivisions. I will restrict myself to a number of issues concerning 'human data', to be generated from 'intervention studies'.

First of all, in contrast to FUFOSE, more attention is given here to the importance and strength of the randomized clinical trial (RCT). However, the main argument is consistent with the line of thinking that FUFOSE initiated: *all* available data should be taken into consideration, without granting absolute privilege to one type of study (e.g. RCTs). In the words of the authors: "For all studies and methodologies, quality and power may take precedence over the type of study in weighing evidence for the substantiation process" (p.14). This statement, resembling a principle, is complementary to the content of criterion n°6 that says: "A claim should be scientifically substantiated by taking into account the totality of the available data and by weighing of the evidence". A similar reflection is made with respect to the elucidation of biological mechanisms, which is the ambitious ideal of functional food science, but not for health claims: "For substantiation of a claim, it is (...) more important to demonstrate a consistent effect of a food or food component on health across a range of studies than to have a scientifically substantiated mechanism" (p.15). In other words: health claims *cannot wait* until science advances. In fact, the elucidation of mechanisms on the one hand, and RCTs on the other, seem to represent two extremes in terms of requirements, none of which functional food scientists wish to privilege when it comes to substantiating health claims. PASSCLAIM encourages the mixture, association and accumulation of different studies, depending on what is available. I already pointed to this in FUFOSE: the *risk* that scientists usually take when associating and articulating their experiments with the objects of investigation, is reduced in advance, as much as possible. Such scientific and financial risk is at a minimum when computer models can be used: "Many laboratory or computer based models are now used in nutrition to circumvent the long and costly procedure of human

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<sup>53</sup> Barry (2001). During the 1980s, the EU went through a reform and expanded its areas of regulation. See e.g. Young (2005: 105), and the work of lobbyists Guéguen (2007) and Guéguen and Rosberg (2004).

<sup>54</sup> In the preface to the PASSCLAIM published article, European Commissioner Jürgen Lucas states: "*The results of PASSCLAIM have been and will be an important input into the regulation on nutrition and health claims made on foods, which is under discussion at the moment.*" Agget et al (2005: 3)



studies, to dissect out mechanisms and predict behaviour in biological systems. Such models can provide additional evidence for the substantiation process” (p.14).

For nutritionists, computer simulations are indeed of some interest, as they address behaviour in biological systems, rather than behaviour in *humans*. Functional food scientists know that conducting RCTs, the gold standard for the testing of drugs, are not always easy to design for food components. The authors discuss these difficulties, while at the same time giving some recommendations on how to conduct RCTs, or other human studies, as good as possible.

A first concern is the selection of ‘subjects’ to participate in a study: “Subjects should be selected on the basis that the appropriate control group is one with a typical diet, and not a special diet that might interfere with the intended benefit. For example, it might not be appropriate to use vegetarians to test the effect of an added fibre” (p.16). More generally, the study group’s background diet and lifestyle must be characterized to exclude confounding factors. Put differently: beneficial nutrients, in order to be nutrients and not drugs, must be demonstrated to have an effect in dosages that can be expected in human diet. At the same time human diet is where nearly all confounding variables stem from. Humans, as the authors concede, are exposed to many active substances in their diet. So which of the tested active substances is *already present* in the diet and how can we know about it? And what about interactions of nutrients in the diet with the tested substance? Diet must then be normalized through the selection of subjects (and the exclusion of vegetarians), and by the invention of devices to ensure the subject’s compliance, especially where markers of intake or exposure do not exist. A questionnaire or logbook can be used as a device to check what people eat, and if there are changes in the ‘baseline diet’, characterized at the beginning of the study. However, the authors go on, *misreporting* is a well-known problem, especially in ‘obese subjects’, who tend to underreport what they eat (p.17). In addition, the act of recording is thought to influence food choices and intake (p.17).

These examples show that ‘taming’ food through clinical trials, in order to obtain clear responses from it, implies that human beings must be tamed to a large degree as well, without any certainty as to the final results. One could conclude that there is not much sense in doing such trials, given the many confounding factors of substances that are already present in the normal diet of many people. But ILSI draws another conclusion: if such trials are

complicated, then the clinical body must be detached from a body of markers. Markers, they assert, can be handled. Markers can act as a reliable witness to exposure on the one hand, and as a site of inscription for predictive therapeutic scenarios on the other.

## Discussion: Functional Food Science as a Stratagem\_\_\_\_\_

### The Stratagem

In this chapter, I have discussed ILSI Europe as an organisation, and I have described the organisation in terms of what they do: if ‘science’ is the keyword in their self-presentation, then what sort of science are they advancing? For this, I have chosen not to focus on epistemology, but on the practitioners and what they do. However, for me, there was no laboratory to study, and my ‘participant observation’ was limited to a number of interviews at ILSI Europe’s headquarters in Brussels. But an important part of ILSI’s strategic work is textual: diffusing concepts through publications. The concept that I investigated was that of ‘functional food’, and ‘functional food science’.

The meanders of FUFOSE and PASSCLAIM tried to tackle what is at once an economic, political and ontological problem: the human body as a reliable testifier/witness for both the truth-claims and the marketability of a product. The fact that the human body is also a testifier for drugs is relevant. If functional food must pass through the human body before being put on the market, *just like drugs*, then the human body becomes the site to create a difference with drugs. For ILSI’s nutrition scientists, academic and industrial, functional foods must become agents *in their own right*: agents of *health*. The food industry wants to address health *on its own terms*, with its own agents, and these agents require a new nutrition science – functional food science - with its own methodologies, addressing objects worthy of specialized, autonomous *professional* judgement. The Consensus Document is a conceptual apparatus to invent both a new type of product and an expert to evaluate it.

ILSI refers to itself as a (neutral) ‘platform’, and at this point it can be asserted that functional food science is indeed a platform, not in the sense intended by ILSI, but in the sense elaborated by Peter Keating and Alberto Cambrosio (2000). In their work on ‘biomedical platforms’, they describe a platform as a heterogeneous dynamics involving

humans, objects, techniques, and political referents. A platform is above all a “way of arranging things in both a material and a discursive sense.” (Keating and Cambrosio, 2000: 346) A platform is not passive, but it does something, it transforms what passes through its meanders. As such, the notion bears resemblance to what Foucault termed a *dispositif* (Foucault, 2001b), although the equation between the two has been criticized as well (Murray 2013). Both the notions of the platform and the *dispositif* are very rich and complex. At this point, I have two reservations about their use. Firstly, as for the ‘platform’, this notion has been developed with respect to *biomedical* platforms and my chapter here indicates that the comparison between biomedical, clinical practice and ‘functional food science’ must be treated with some caution. In addition, ILSI operates through meeting rooms and texts: functional food science as a new sort of nutrition science is, anno 1999 (and even with PASSCLAIM in 2005), a *proposal* for a “way of arranging things”.

As for the ‘dispositif’, the many applications and meanings that have been given to it, will not allow me here, in the first chapter of this book, to advance with it analytically<sup>55</sup>. The concept that I would like to propose to characterize functional food science, is ‘stratagem’.

I propose the term stratagem, because it denotes both a strategy and a form of deception, and of *ruse*<sup>56</sup>. In a book on Sun Tzu, a Chinese military general and strategist, Pierre Fayard (2011) described it as: « L’art stratagémique dans sa version chinoise ne s’impose pas en s’opposant mais en épousant pour conduire ». Rather than opposing (an enemy in the case of warfare), Chinese stratagemic art is about guiding. ILSI guides with the aid of concepts. It insists on science and neutrality, and, paradoxically, this *enables* ILSI to do something completely different.

Interestingly, this principle of guiding is explained by Jean-Pierre Mourey (1994) in another context: labyrinths in 20<sup>th</sup> century art. Drawing on Deleuze, he distinguishes what he calls the ‘labyrinthe-stragème’, which has a clear objective and traces a way to it, from the rhizome, which, as a ‘line’ is erratic and undetermined. ILSI has a clear objective, but it needs to trace a way to this objective through detours, meanders, mediations. This is reminiscent of Latour’s chapter “la dédale de la médiation technique” in *L’espoir de Pandore* (Latour, 2007).

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<sup>55</sup> For general reviews on the notion of ‘dispositif’, see e.g.: Buescart and Peerbaye (2006); Peeters and Charlier (1999).

<sup>56</sup> Definition of ‘stratagème’ in the online dictionary of *Larousse*. See : <http://www.larousse.fr/dictionnaires/francais/stratag%C3%A8me/74814>

For this reason, and to avoid further confusion with the singularity of science as a practice, I have proposed to call functional food scientists ‘claim technicians’, to indicate a *cross-over* and *twist* or *torsion* between the particularity of the scientific claim and its development (Latour and Woolgar 1986) on the one hand, and the ‘technical mode’ which is about delegation, detours, folds (Latour, 2007). Pragmatically, then, the word ‘stratagem’ calls for attention (*mise en garde*). The former and new logos of ILSI become interesting in this light<sup>57</sup>.

*ILSI logo until 2011*



*New ILSI logo, autumn 2011*



The first logo is a microscope as big as the Earth itself; the world would seem, in a sense, *subjected* to science. The second logo was adopted in 2011, on the occasion of ILSI Europe’s 25<sup>th</sup> anniversary (founded in 1986 in Brussels). ILSI Europe’s autumn newsletter of that year stated: “It is a pleasure to announce that ILSI has a new visual identity. Our new logo represents “the whole is greater than the sum of its parts” and we feel that it captures and conveys the strength as well as the dynamism of our global organisation.” (ILSI Europe, 2011: 3). The logo now appears on publications, on slides during conference talks and on the website. It establishes a relation between the beholder and the organisation, communicating a ‘visual identity’ as in the quote above. Arguably, the logo also looks like a *labyrinth*, and like mazes and spirals, labyrinths *do* something: they have power over their beholders, who get captured by the inward movement of the design (Gell 1998: 95-90). Rather than representing ‘the whole is greater than the sum of its parts’, the design performs precisely what ILSI performs when it constructs new concepts in its publications.

<sup>57</sup> As a reminder, within actor-network theory (ANT), as a form of anthropology, non-humans act, in the sense that they contribute to action. The anthropology of Alfred Gell, although not strictly ‘ANT’, gives special attention to the agency of art and designs. See: Gell 1998.

## Excluding the Clinical

The functional food stratagem seems to have a lot in common with drug testing, as it revolves about procedures to test therapeutic efficacy – an obligatory test to put a product on the market. The risk, as Pignarre (1997; 2004) explains, that the clinical trial represents, is above all a financial risk, as nothing new will be learned about the nature of the molecule or the mechanisms of its action. What the clinical trial shows is whether the molecule works or not: does it relieve disease symptoms in human bodies? Will all the previous work to develop and test the molecule be rewarded or not? Food companies are not interested in making *medicinal claims*, and in performing the clinical trials required to put products with medicinal claims, or drugs, on the market. These are costly, and the food sector has no expertise in the matter. This is why functional food scientists propose a new science that comes with its experts. From a legal point of view, a food that relieves disease symptoms would be a drug, and it would have to pass the same test as drugs. For this reason, food companies and nutrition scientists focus on ‘health’ and ‘reduction of disease risk’. As a consequence, the ‘clinical’ must be *introjected* into the body itself. Indications and markers are searched for that do no longer relate to observable well-being or disease. As such the human body becomes a site of difference between two kinds of therapeutics: drugs and food, but also between two markets. ILSI and the two projects I have discussed are stratagems to develop biomarkers as a point of articulation between functional components and a market for functional foods. ILSI doesn’t take the same kind of risk as for example natural scientists, and they try to avoid the financial risk represented by clinical trials of the pharmaceutical kind, involving lots of human bodies and rigorous testing for safety. Rather than putting claims at risk, a procedure for making safe claims is the strategy of functional food science. And those claims come with their specialists: functional food scientists.

However, ILSI’s stratagem is not a guarantee in itself to realize or perform the functional foods market. The following chapters show that there are many other passage points to create this market for health claims.



## Chapter 2 Food and Health Claims in a Juridical Europe

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ILSI launched two research projects, funded by the Commission's Directorate General for Research, that represent a convergence between the food industry's interests and that of the Commission: the possibility of innovation through functional foods; thereby strengthening the European food and drink industry's position in the global market. But to strengthen that position, Europe had to create its own market for such innovative products. The Single Market programme is an ongoing effort of the European Commission since the Treaty of Rome in 1958.

The first 'Europe' was a common market of coal and steel. Making rivalling nations dependent on the same strategic resource and obliging them to collaborate was a strategy to create a Europe of peace, after decades (and even centuries) of war (Hobsbawm, 1995; Devuyst, 2006). Creating a common market was a priority to stabilize Europe as a region of peace, but also as a consuming market for products, many of which were imported from the US. This single market is not a given but has to be created over and over again for different products. In a sense, products push humans to create a market for them. The conditions of the functioning of a market are decided politically and are laid down in European legislation and the Treaties.

I will briefly look at European legislation for food, before I turn to an important juridical event for health claims in 2000. This event is of relevance for my overall story of health claims, because it puts a national law (of the Republic of Austria) to the test with respect to existing legislation on labelling and information on food. I will follow the reasoning of the advocate-general in this court case on the European level, in order to 'think with the Single Market' with respect to health claims. Many aspects of this court case, and the relevant legislation it refers to, will continue to play a role in the chapters that follow this one.

*No such unified and authoritative text has been available to date and that must be the reason why instructors have shied away from teaching such a course to undergraduate and/or graduate students. I can think of only 3 other individuals who have taught Food Laws and Regulations in their food science curricula.*

(Kroger, 2009)

These are the comments of an enthusiastic editor in his review of the then freshly published *European Food Law Handbook* (van der Meulen and van der Velde, 2008)<sup>58</sup>. Such a comment evokes something about ‘food law’ and how it is perceived. It is something instructors ‘shy away from’ in science curricula, but it is important at the same time, as the editor adds: “Such a course ought to coexist alongside those of chemistry and microbiology”. But the editor also says, more or less implicitly, that food law is not *unified* by and through itself, and that it may be difficult to give it unity.

In an article published in a law review, one of the authors of the 2008 *European Food Law Handbook*, Bernd van der Meulen, Professor of Law and Governance at Wageningen University, reflects upon his own approach to food law and the fact that a ‘system’ in food law is not necessarily a given:

*(M)aybe my quest for a system is a typical civil law approach to law. In this contribution I will show how our system can be applied. I will leave it to the readers to judge if this approach is too complicated or boring, or if it helps in understanding European food law.*

(van der Meulen, 2009: 307)

By ‘civil law’, van der Meulen means the conception of law as a codified system as we find it in the EU for example, represented as a tree branching out in subsections of law, in contrast to the anglo-saxon tradition of ‘common law’ where the focus lies on Court cases and precedents<sup>59</sup>. In the EU, legislative documents drafted by policymakers are an important *source* of law, and the European Court of Justice (ECJ) protects the uniform interpretation of

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<sup>58</sup> Contrary to what the editor says, these authors are not the only ones, nor the first to have produced a comprehensive account of EU food law. Caoimhín Macmaoláin, Lecturer in Law at Trinity College, Dublin, published his critical book *EU food law* in 2007. See Macmaoláin (2007).

<sup>59</sup> For an accessible explanation and historical overview of the two traditions, see: <http://www.law.berkeley.edu/library/robbins/CommonLawCivilLawTraditions.html>



these documents. There is an ongoing effort to systematize, create subcategories, or merge existing provisions into a single legislation (for example the General Food Law, see below). This is why van der Meulen makes a ‘disclaimer’ before presenting his approach of EU food law as a ‘system’:

*The structure of European food law presented in this contribution does not – at least not entirely – relate to a blueprint that has been applied in creating legislation, but is superimposed on a situation that has grown organically.*

(van der Meulen, 2009: 307, my emphasis)

What has ‘grown organically’ is a body of legislation drafted by policymakers and lawyers; European case-law and the creation of precedents and principles; a constitutional framework (the EU Treaties); and an institutional framework (roles of the Member States; the Commission; regulatory agencies like EFSA; the Court of Justice). Two concepts are important for my research on health claims and the important Court case that I will discuss in some detail. The first is the distinction between law as a mode of enunciation on the one hand, and its sources on the other. The second concept, which we will better understand through the distinction between law and its sources, is the European Single Market.

## Law and its Sources

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The problem I investigate in this chapter is how the health claim becomes a stabilized legal category as related to a food product. The chapter is crucial because we will discover through a court case how health-related statements become separated from disease-related statements. And yet I will argue that the advocate-general who operates this distinction is not performing a normative act *per se*. This doesn’t mean that the distinction cannot have normative *consequences*. A distinction must be made between law on the one hand, and legislation on the other.

Opening a book on EU Food Law (e.g. Macmaoláin 2007), one finds a table of contents at the beginning of the book, but also a table of *court cases*, and a table of *legislation*. Both are incredibly important for EU food law, but the single noun ‘law’ doesn’t help us to characterize their respective roles, functioning, and – consequently – the *articulation* between the two. This problem of articulation is not conceivable if one continues to use the word ‘law’ for what happens in the court room *and* for what happens in Brussels in

the offices of the Commission, and the arena of the EU Parliament for example. Serge Gutwirth (2013) has clearly diagnosed this problem and provided a solution that I will follow in this chapter. Gutwirth identifies a paradox in the way we talk about law: the *practice* of law is made to coincide with its formal *sources*, as if the two were the same thing. By formal sources he means legislation, jurisprudence, legal doctrine, legal custom, general principles, equity:

*Ces “sources formelles” ont un double caractère: d’une part elles indiquent les référents qui permettent de faire émerger ou de fabriquer du droit, et de l’autre, assez paradoxalement d’ailleurs, les lieux où le droit en vigueur s’exprime et serait lisible.*  
(Gutwirth 2013: 1)

Professor of law and legal theory himself, Gutwirth notes that virtually all introductory manuals for students define law as a set of norms and constraints imposed within a society and sanctioned by that society. It is difficult, then, to distinguish law from morality; from religious prescriptions; from professional codes; from conventions.

*(T)ant chez les profanes que chez les juristes, l’évocation du droit réveille avant tout l’idée de la norme, de la règle, et donc, plus concrètement, de la loi, de la législation (...). Droit et normes semblent coïncider. Mais la législation, somme toute, n’est-elle pas l’aboutissement par excellence du politique – du processus législatif – et donc de toute autre chose que du droit?*  
(*Ibid.* :2, original emphasis)

It helps there are two words in French where there’s only one in English: *le droit* and *la loi*, which I will translate as ‘law’ and ‘legislation’ respectively, rather than using ‘law’ for the two. Legislation, as Gutwirth notes, is thoroughly political, and it is a *source* of law, but not the *practice* of law.

What law has in common with politics is that it is a *practice*. But, as practices, law, politics, and also science are very different. This has been argued and ethnographically investigated by Bruno Latour in his book *The Making of Law (Hereafter: ML)*<sup>60</sup>. Latour’s ethnography of the French Conseil d’Etat was an inquiry in what characterizes law as a particular mode of enunciation. This project was similar to his former investigations into science (e.g. Latour and Woolgar, 1986; Latour, 2007). The most important characteristic of

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<sup>60</sup> Originally published in French as *La fabrique du droit* (2002) and published in English in 2010. See: Latour (2002).

law-in-action is that it is a *way of tying together* heterogeneous elements: particular facts, dates, names, and all sorts of things that one could call ‘scientific’, ‘economic’, ‘political’, etc. as long as law hasn’t start operating yet, and hasn’t imposed its *own* qualifications, according to its own rules. Law is *superficial*:

*There is no point in studying law in depth! The relationship between appearances and reality, which is so important in science, politics, religion and even art, is meaningless here: appearances are everything, the content is nothing.*

(ML: 267)

In contrast to science, law doesn’t transport any information. In contrast to scientists, jurists want to get rid of the facts as quickly as possible by qualifying them and move on to what is legally interesting (ML: 215): this legal provision with respect to another, for example, and the testing of connections between them (ML: 218). And law isn’t like politics either:

*For law to be a force, to have teeth, the entire circle of representation and obedience constantly has to be covered; this is statesmen’s job. If there is one thing law doesn’t know how to replace, it is the gradual composition of sovereignty that is achieved by politics (...)*

(ML: 270).

Gutwirth (2013) acknowledges Latour’s characterization of law as a specific mode of making connections between heterogeneous elements, and pays more particular attention to why we keep confounding law as a specific practice with normativity or politics. This happens because jurists and non-jurists alike, helped by introductory handbooks on law, confound law with its formal sources: legislation, legal doctrine, legal principles etc. For this chapter, the difference between food-related legislation as a political *source* of law, and how this legislation is *treated* by the advocate-general we will meet shortly, is important. It will also allow me to characterize in the next chapter what happens *after* and outside of the courtroom: a thoroughly political process that takes the court case as its starting point in the making of legislation, while at the same time immediately deviating from it and bending it to its own purposes. The importance of the EU’s Single Market project traverses both legislation and law, and I will propose some questions about its political-juridical articulation at the end of the chapter.

Before I delve into a court case that is of interest because it deals with health-related statements on food products, I need one more item to take on board: some basic background knowledge on food *legislation* through a brief discussion of selected events.

## Food legislation and the Single Market in the EU

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The most important element of the European Union is the European Economic Community (now called to European Community – EC), founded by the Treaty of Rome in 1957<sup>61</sup>. The most important goal of this Treaty is the creation of an internal market or single market within the EU. Before the 2002 General Food Law, there existed no separate branch of legislation called ‘food law’:

*Interestingly, the EC Treaty does not in itself provide a basis for food law. In consequence, legislation giving effect to EU food policy has been based on a combination of Treaty provisions, such as the provisions on agriculture, and on the internal market, in combination with the obligation to ensure in its policies a high level of protection of public health, and to contribute to a high level of consumer protection.*

(van der Meulen, 2009: 310)

Food legislation, as a form of policymaking, takes the Treaty as its starting basis<sup>62</sup>. The Treaty is considered the legal or constitutional basis of the EC, but it must be kept in mind that it is a legal *source*, and a thoroughly political one establishing the foundations of the EU *polity*<sup>63</sup>. The Treaty, as ‘Community Law’, has primacy over secondary legislation and national legislation. Concretely, this means that food legislation is placed under the sign of the internal market and the free movement of goods. Food was considered a commodity in its own right from the beginning of the EC, but the origin or initiative of legislation shifted quickly from the Commission’s Directorate General (DG) for agriculture to that of the DGs

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<sup>61</sup> Except for citations or specific analyses, I will not always cite separate authors or works in this paragraph, as I am resuming general knowledge about the EU from different sources, the most important of which are: Macmaoláin, 2007; van der Meulen and van de Velde, 2008; van der Meulen, 2009. As for EU policy in general: Wallace et al., 2005; Devuyst, 2006.

<sup>62</sup> The ‘Treaty’ is in fact a range updates that started with the first Treaty establishing the European Coal and Steel Community (signed in 1951); the Treaties of Rome (1957); The Brussels Treaty (1965); the Single European Act (1986) ; the Maastricht Treaty (1992); the Treaty of Amsterdam (1997); the Treaty of Nice (2001); and the Treaty of Lisbon (2007) where the Treaty came to be named the Treaty of the Functioning of the European Union (TFEU). The content of all separate Treaties is accessible at: [http://europa.eu/about-eu/basic-information/decision-making/treaties/index\\_en.htm](http://europa.eu/about-eu/basic-information/decision-making/treaties/index_en.htm)

<sup>63</sup> See Devuyst, 2006, p.35-40 for a discussion on the Treaty as a ‘constitution’.

responsible for industry, enterprises and the internal market, as van der Meulen (2009) notes. Under the Treaty as the basis for the EC, food legislation is drafted within a particular version of ‘Europe’: an economic one. This becomes clear when van der Meulen (*Ibid.*) notes the following:

*All EU Member States are also among the members of the Council of Europe and, as such, are state parties to the European Convention on Human Rights and Fundamental Freedoms and to the European Social Charter. They are also state parties to the UN human rights treaties: the International Convention on Civil and Political Rights and – from a food perspective most important – the International Covenant on Economic, Social and Cultural Rights. The European Union has its own Charter of Fundamental Rights. Despite the emphasis that the European Union lays on respect for human rights by its Member States, in EU food law human rights consciousness is almost totally absent. Nowhere does the EU legislature express the opinion that, in ensuring the safety of food, it is living up to human rights obligations.*  
(van der Meulen, 2009: 312)

The internal market ‘drive’ of food legislation led to what is generally acknowledged as a landmark event in food law: the *Cassis de Dijon* (*Cassis*) case, judged in 1979<sup>64</sup>. What led to *Cassis*, was a German prohibition on the importation of a French fruit liquor (after which the court case has been named). The reason for this import restriction was that the liquor had an alcohol content which was *lower* than what the German Authorities had fixed for ‘liquor’ (between 15 and 20%, instead of the required 25% in Germany). Germany reasoned that this is deceiving and that their measure was justified on the grounds of consumer and health protection. According to Germany, the French *Cassis* may more easily induce a tolerance towards alcohol than more highly alcoholic beverages<sup>65</sup>. The European Court of Justice (ECJ) considered that Germany infringed upon the Treaty provisions concerning the free movement of goods. The Court’s interpretation of the Treaty created a new principle: the principle of *mutual recognition*. This general rule states that products that have been lawfully produced and marketed in one of the Member States may not be prohibited in other Member States (on the grounds that they do not comply with the national rules). Van der Meulen (2009: 316) summarizes the importance of this case as the shift in emphasis from vertical (product-specific) to horizontal legislation where rules address common aspects of a broad range of foodstuffs, and he adds:

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<sup>64</sup> Rewa-Zentral AG v Bundesmonopolverwaltung für Branntwein (C-120/78) [1979] I-649.

<sup>65</sup> For a summary of the case and the arguments, see: [http://eur-lex.europa.eu/smartapi/cgi/sga\\_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=61978CJ0120](http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=61978CJ0120) (consulted on the 19th december, 2013).

*Several commentators expressed concern that the principle of mutual recognition would lead to product standards based on the lowest common denominator. It is clear that manufacturers established in Member States with the most lenient safety or technical requirements or legal procedures do gain a competitive advantage.*

(van der Meulen, 2009: 316)

Jurist Macmaoláin (2007) comments on this historic shift away from the product-specific ‘recipe laws’, which concern a food’s production and what it is made of. *Cassis* has consequences for the *rules of production* of foodstuffs:

*The ‘recipe laws’ set common compositional and production method requirements for, amongst others, chocolate, honey, and jams and marmalades. (...) Cases such as Cassis (...) were to lead to an alteration in domestic customary practices and rules for the production and marketing of food and drinks. It was also clear, from subsequent decisions of the European Court of Justice, that the legal principles developed from these initial judgments would extend to all national rules relating to food and drink that were deemed to be a restriction on trade within the Community in any way, subject to some, albeit very limited, exceptions. The manner in which the Court began to interpret the EC Treaty (...) removed much of the need to introduce further harmonizing measures, such as those set out in the earlier recipe laws.*

(Macmaoláin, 2007: 4-5).

The author further expresses explicit concern about the consequences of *Cassis* and subsequent judgements and legislation on the *quality* of food within the EU (*Ibid.*).

*Cassis* was judged in 1979. This was also the year that European Directive 79/112/EEC on food labels entered into force<sup>66</sup> (hereafter: ‘Labelling Directive’). Although there are no cross-references between *Cassis* and the Labelling Directive, it seems that 1979 was a pivotal year, in pivotal times for food legislation *and* the production, marketing and material composition of food in the EU (European Commission, 1979)<sup>67</sup>.

The Labelling Directive was one of the earliest pieces of Community horizontal legislation, meaning, as we have seen, that it applies to all foodstuffs across the board (2007: 78). It is not entirely a coincidence that one of the earliest pieces of horizontal legislation is on food *labelling*. According to Macmaoláin, food labels and the compulsory information that must appear on them can be formulated in a relatively straightforward manner in legislative

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<sup>66</sup> Now replaced by food information regulation EC n°1169/2011.

<sup>67</sup> One lawyer I spoke to called 1979 the ‘beginning of the modern food era’ (personal note, 16/12/2013).

texts, compared to efforts at harmonization of specific products or vertical legislation<sup>68</sup>. In the latter, it is very hard and contentious to align all Member States, each with their own tastes, preferences and interests to protect. For example, a debate on which foodstuffs may legitimately be called ‘chocolate’ (in function of their composition) has divided Member States for almost 30 years<sup>69</sup>. So when the composition of food is addressed, Member States become alarmed and defensive. Their interests, production methods and traditions are bound up with the nature of the foodstuff: one version of chocolate is made with vegetable fats, and the other with cocoa butter. Are both of them ‘chocolate’? At first sight, this may look like a bureaucratic and political quarrel about *name-giving*. But it is more than that: the political decision to be made articulates terminology and ontology: it *performs* ‘chocolate’. Those who want to sell a product that can be legitimately called ‘chocolate’ will have to respect the legislation that specifies the ontological ‘envelope’ (Latour, 2007) of chocolate where ‘chocolate’:

*... designates the product obtained from cocoa products and sugars which (...) contains not less than 35 % total dry cocoa solids, including not less than 18 % cocoa butter and not less than 14 % of dry non-fat cocoa solids.*

(Directive 2000/36/EC)

The *Cassis* Court case made it easier to avoid such recipe laws for all foodstuffs with the principle of mutual recognition and adequate labelling.

## The Commission v Austria

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In the EU, Regulations and Directives are rarely unambiguous. In addition, it is not always clear which article, principle or provision ‘applies’ and puts more weight into the scale of a final Court decision. Some court cases, dealing with a new problem, become references or sources of law themselves, as with *Cassis*. They constitute legal ‘events’ as they reinterpret the past and generate consequences for the future. This is why moving through the intertextuality of legislative *sources* alone is insufficient to understand where certain regulations come from, like the 2006 Regulation on health claims (NHCR) that I will discuss in the next chapter. We will see that regulations and directives are hybrids of political

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<sup>68</sup> *Ibid.*, for example on page 131.

<sup>69</sup> The ‘chocolate debate’ ended in 2000 and had opposed Ireland, the UK on the one hand, to eight other Member States (Belgium, Luxemburg, France, Germany, The Netherlands, Spain, Italy, Greece) on the other. See Macmaoláin (2007) for a discussion.

discussions and case law. They are temporary stabilizations until they are challenged and put to the test. They become the object of reinterpretation and in that sense the Court has its role in advancing legal frameworks, sometimes with new additional principles.

The 1980s and especially the 1990s have seen a proliferation of health claims throughout Europe (and the world). Opinions on the usefulness or ethics of such claims to consumers diverged, depending on different policies, guidelines and practices until the NHCR was drafted between 2003 and 2006 (chapter 3). A first proposal by the Commission (who always has the initiative in drafting legislations) for the NHCR was published in 2003 (European Commission, 2003), right after the final decision in a Court case brought by the Commission against the Republic of Austria<sup>70</sup>.

The European Commission had received numerous complaints that foodstuffs lawfully marketed in other Member States were not allowed on the market in Austria, which would mean that Austria was not respecting the principle of mutual recognition and forming an obstacle to the free movement of goods. The reason for the ‘obstruction’ however, was new: the products were carrying health claims, or –in the language of the court case – ‘health-related statements’. Among these claims, featured the following: ‘for a cholesterol-conscious diet’ on salmon-oil capsules; ‘a contribution to healthy intestinal bacteria and healthy cells’ on bread; ‘dietary fibre and bulking agent for sufferers of constipation caused by diet’ on the labelling of linseed<sup>71</sup>. A number of Austrian courts had sent prejudicial questions to the ECJ about the compatibility of their national legislation with Community law.

More precisely, Austria had a national law on foodstuffs – the *Lebensmittelgesetz* – that made such health claims subject to a premarket approval procedure. In other Member States, food companies had to be able to justify any voluntary ‘information’ that appeared on their labels and that seemed to infringe upon provisions laid down in legislation concerning misleading advertising. But Austria had established a *premarket* approval (to be granted by ‘the competent Minister’) meaning that all health-related statements were *a priori forbidden*.

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<sup>70</sup> C-221/2000 *Commission vs Austria* ECR I-1007.

<sup>71</sup> These examples are presented in the introductory paragraphs of the opinion of advocate-general Geelhoed. See Geelhoed (2002).



To understand how and why a conclusion is reached, there is no choice but to follow every step of the construction of the argument, though qualifications and delimitations. In fact, the entire 35 -page opinion should be reproduced, but that is not possible within the scope of this thesis. It is not a thesis in law. I have looked for a compromise: in what follows, I follow the Advocate-General, focusing on the most important steps and resuming the intermediate ones. I provide a summary of the case, after the analysis.

## Main arguments of the parties

The Commission, challenging the Republic of Austria, uses both the Labelling Directive (European Commission, 1979) and the EC Treaty (of Amsterdam at that time) as means to support its arguments. Concerning the Treaty, the Commission refers to two articles in particular: Art. 28 and 30<sup>72</sup>. Article 28 concerns the prohibition on quantitative or equivalent restrictions on trade within the Community. Article 30 mentions possible grounds for derogation from Art 28. Austria appeals to those grounds, including protection of public health and consumer protection, but the Commission thinks that measures *less restrictive of free trade* than Austria's premarket procedure can be used to those ends. As for the Labelling Directive, The Commission refers to specific parts of two articles in particular: articles 2 and 15. Article 15 (1) essentially states that Member States are not allowed to forbid trade in foodstuffs that comply to the Labelling Directive. 15 (2) then mentions a number of grounds for exception, including consumer protection and public health. The reader will notice that these two parts of article 15 are much akin to articles 28 and 30 of the Treaty. For that reason, the Advocate-general of this case argues that he will not directly take into account the Treaty, as the Directive concerns labelling more specifically, and is conclusive as a system (I-1024). So the Labelling Directive will be the main touchstone to test Austria's *Lebensmittelgesetz* and its procedure of premarket approval for health claims.

Article 2 of the Labelling Directive, and more precisely article 2 (1) (b) states the following:

*The labelling and methods used must not (...) attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties.*

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<sup>72</sup> Articles 28 and 30 of the Treaty of Amsterdam have become articles 34 and 36 respectively in the Treaty on the Functioning of the European Union (TFEU).

The Commission argues that the article only prohibits information on food labels relating to *disease*, and that Austria stretches the interpretation too far by also forbidding claims related to *health*.

Austria recognizes that it transgresses the span of article 2, but defends that their policy is justified on the basis of the possible grounds for derogation provided in article 15, especially consumer protection and public health. It argues that misleading health messages may give the impression that the foodstuff will cure, and this, in turn, could lead patients to wrong and dangerous expectations and the neglect of a truly efficacious treatment. This is why Austria deems that prior approval is necessary and Austria also refers to its right to take all necessary action to counter misleading *advertisement*, as mentioned in article 7 of Directive 84/450 (replaced by 97/55) concerning misleading advertisement (not limited to foodstuffs).

The president of the Court has allowed the Kingdom of Denmark to intervene and support the arguments of the Republic of Austria.

## Assessment by advocate-general Geelhoed

Advocate-general Geelhoed summarizes the issue to be dealt with as follows<sup>73</sup>:

34. The point at issue is **the extent to which Community law permits** a national prohibition on health-related information appearing on foodstuffs, subject to the possibility of prior authorisation. Basically, the questions which arise in particular are the extent to which health-related claims are in fact likely to **mislead consumers and endanger their health** and whether the national system in question is **consistent with the principle of proportionality**. Before those questions can be answered, it is necessary to examine how labelling with **'health-related information'** is

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<sup>73</sup> When citing Geelhoed, I keep the original layout in columns, which I feel facilitates lecture and follows the 'thread' of reasoning. I have also kept the numbering of the original columns.

**positioned within the scheme** of Directive 79/112. That analysis is **technical and legal** in nature. Nevertheless, a number of **questions of principle** arise in this regard, which are **relevant to the further development of law** in the field of information about, and labelling of, foodstuffs.

I've highlighted several parts of the quotation. First of all, the point at issue is 'the extent to which the Community law permits' Austria's policy. This is a question of the compatibility of the legislation of a Member-State with a more binding legislation for all Member-States – the Labelling Directive. This Directive stipulates a number of requirements and compulsory indications concerning food labels, with the aim of facilitating the free movement of foodstuffs. As we have seen, the Directive prohibits Member States to deny access to foodstuffs that comply with the Directive and that have been lawfully produced and put on the market in other Member States. Exceptions are possible on a number of grounds such as consumer and public health protection, but any trade barrier must be justified – the burden of proof lying with the Member State. *Austria must convincingly argue that consumer's health is at stake.* Is this possible? Furthermore, the measures that the country takes must be proportional, meaning that it must not restrict trade more than necessary. The first issue to investigate, as Geelhoed indicates, is how health-related information is *positioned* within the Directive. We will see what this means, and how this is both 'technical and legal' with consequences for the further development of a legal framework for health claims in the EU.

## Delimitations

Before dealing with the question of health-related information, Geelhoed clarifies the relevant legal framework, as both the Commission and Austria invoke other legislative documents than just the Labelling Directive to support their arguments. The Commission refers to articles 28 and 30 of the Treaty. I have already mentioned that Geelhoed finds this unnecessary, as the Labelling Directive is, according to him, precise and conclusive enough. However, he makes two interesting remarks that give us more insight into the working of case

law and this case particularly. Firstly, he says that the Commission may have chosen to found its arguments not only on the Directive, but also on the Treaty, as jurisprudence shows that the Court has taken into account primary Community law (the Treaty) on the circulation of goods in other similar cases where there was an alleged infringement of a specific Directive. However, in yet other comparable cases, the Court did *not* refer to the Treaty. In fact, the Court has not been very consistent, and it is not clear altogether why the Treaty is used in some cases and others not. It is up to Geelhoed, then, to provide an opinion on the matter and for him the Labelling Directive is sufficient. This brings us to Geelhoed's second remark where he says that:

46. However, that does not alter the fact that the provisions of Directive 79/112 (the Labelling Directive, KH) must, as must any provisions of secondary law, be interpreted in the light of the provisions of the Treaty relating to the free movement of goods.

Indirectly, the Treaty and its provisions on the free movement of goods *do* matter, and Geelhoed refers in a footnote to another case to support this argument. It matters all the more for Geelhoed ('a fortiori': p. 1027) as the scope of the grounds for derogation in the Directive has common characteristics with the grounds mentioned in article 30 of the Treaty, *and* with the 'Cassis de Dijon' case law.

Geelhoed is still delimiting the field within which he is going to examine the case. He notes that Austria refers in its arguments to Directive 84/450 concerning misleading advertising. He says in point 48 that the Labelling Directive is more specific on the topic of misleading the consumer with regards to the *labelling* of *foodstuffs*, whereas the Directive 84/450 applies to *advertisement* in general and not only to labelling, nor only to foodstuffs. Here the principle *lex specialis derogat legi generali* applies, and the Labelling Directive will be the main reference in *putting Austria's national rules to the test*<sup>74</sup>.

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<sup>74</sup> He uses the noun 'toetsing' in Dutch, which is the original language of the opinion, which can be translated as 'putting to the test'. This has been translated by the verb 'examining' in the English version of the Opinion.

## Article 2 (1) (b): The Scope of Medicinal Claims

With the field delimited and the role of the Labelling Directive clarified as the main reference, the core of the matter can now be examined. The first issue is the interpretation of the scope of Article 2 (1) (b) of the Directive stating that:

*The labelling and methods used must not (...) attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties.*

For the Commission, this means that no medicinal properties may be ascribed to foodstuffs, and the Commission adds that only drugs may be ascribed such properties as is mentioned in Directive 65/65 on proprietary medicinal products<sup>75</sup>. This narrow interpretation is disputed by the Danish Government, allowed to intervene in the court case to support Austria. Denmark is of the opinion that the scope of article 2 also covers health-related statements. Austria says that it makes no sense to distinguish disease-related from health-related statements. Moreover, one cannot expect *the consumer* to try and make such distinctions. The Commission admits that article 2 doesn't clearly make a distinction, but that under the definition in Directive 65/65, a medicinal product has the property of restoring, correcting or modifying physiological functions in human beings. If, on the other hand, a product is merely 'healthy', such properties cannot be ascribed to it (p. 1028).

Advocate-general Geelhoed's opinion on the matter is:

53. I agree with the view that a distinction must certainly be made here (...).Article 2(1)(b) states unequivocally that the prohibition relates to labelling which is directly or indirectly connected with a human disease. **Disease is a condition** in which a person's organs and vital processes do **not function properly** and normally. **Disease is the opposite of<sup>76</sup> a healthy condition** in which a

<sup>75</sup> Replaced by Directive 83/2001. The definition of 'medicinal product' has remained unchanged.

<sup>76</sup> In the original Dutch version, Geelhoed says that "ziekte is tegenovergesteld aan de toestand van het gezond zijn." The strong sense of *tegenovergesteld* is somewhat weakened by the English translation: "disease is *contrasted* with a healthy condition". The German version of the opinion (which is the

person has no physical or, as the case may be, mental infirmities. For that reason there is a **fundamental difference between statements** relating to the prevention, treatment or cure of a disease, and statements connected with the promotion of human well-being. In the case of disease-related claims, the emphasis is on treating or curing an existing disease or on preventing disease. In the case of health-related claims, they are premised on a **positive basic idea**, namely the maintenance or promotion of health. It may indeed be difficult in marginal cases to maintain a strict division between health-related claims and disease-related claims, since certain health-related claims may give the consumer the impression that the product has a curative effect. For example, by explicitly suggesting that a particular foodstuff 'keeps you healthy', the impression is implicitly given that the product can prevent diseases. **However, that does not detract from the fundamental distinction between the two categories of claims.** The nature of the information in question will need to be determined on a case-to-case basis.

And thus Geelhoed concludes in point 55:

55. A prohibition subject to prior authorisation on health-related information (...) thus goes further than Article 2(1 )(b) of Directive 79/112 (the Labelling Directive, KH) allows.

In this reasoning, disease is opposed to health, but it is an opposition of a particular kind. Disease and health are defined in terms of the functioning of a person's organs and vital

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language of the Process, although the Judgement of 23 January 2003 doesn't mention the phrase) is close to the original Dutch phrase: "Der Krankheit wird der Zustand des Gesundseins gegenübergestellt".

processes. Disease is a condition where organs and processes do not function properly and normally. Health is the absence of physical or mental infirmities. It is a condition where everything functions properly. If this compact medical ontology defines health as merely the absence of disease, the *statements* about health and disease refer to conditions that are no longer related as two opposing extremes on a continuum or two opposite sides of the same coin. There is a *fundamental difference* between statements on health, based on a ‘positive basic idea’ and a *fundamental distinction* between categories of *claims*. This means that very different things can be said and done in the two separate referentials: disease can be cured, but health can be promoted. Health-related statements carry a ‘positive idea’ and health claims would seem have their own conditions of felicity with regards to medicinal claims. The reader will notice that this sounds very familiar, and that the reasoning runs parallel to what we have seen in the FUFOSE Consensus Document (published some 3 years earlier). However, we mustn’t forget that we are in the courtroom here, and that Geelhoed is not interested in real health and disease. He is not referring to physiological conditions in the world, but trying to settle an interpretation of a legal provision. The difference between health and disease, which is an ontological question outside the courtroom, is an issue to ‘get rid of’. As Latour (2002) has shown in his ethnography of administrative law, factual issues must be qualified as quickly as possible: they must be given a legal existence, so that legal questions can finally be treated properly. Once an issue has been qualified, it becomes matter for legal reasoning. The result, then, of Geelhoed’s qualification exercise is the *legal existence* of health claims, *as fundamentally different from disease-related claims*. Through Geelhoed’s qualification, enunciations about health and disease bifurcate as referentials.

At the end of the quotation, Geelhoed reasons that there may be ‘marginal cases’ where the division is less clear, but in the end, the consumer’s *impressions* do not detract from the *fundamental* distinction between two categories of claims.

## Article 15 (1) & (2): Protecting the Consumer/ Protecting Public Health

Article 15 (1) states that Member States cannot prohibit trade in foodstuffs that comply with the Labelling Directive. In this light, *and* because the products in question have been lawfully marketed in another Member State, both Austria’s interpretation of *disease-related* statements (as referring also to health), and its authorisation procedure for health

claims are *de facto* trade barriers in Austria. The question then becomes whether Austria's rules can be justified on the grounds provided in article 15 (2).

Geelhoed announces that the answer to that question will require Austria's rules to be *put to the test*<sup>77</sup> in two stages:

57. (...) First it must be shown that the national measure is suitable for the purpose of achieving one of the objectives of protection referred to in (art. 15 (2)). Then the **proportionality** of the measure must be examined, that is to say, that the measure must not go beyond what is strictly necessary and, more specifically, that it must not be possible to achieve the desired objective by genuine alternative means that are less restrictive of trade.

In other words, it is not enough that Austria justifies its acting contrary to article 15 (1) by referring to the grounds provided in article 15 (2) and substantiating them. Geelhoed also invokes a legal principle that developed through case law and that will be part of the test: the principle of proportionality<sup>78</sup>. The principle is a safeguard against excessive use of legal or administrative powers, and is laid down in Article 5 of the EU Treaty.

The Republic of Austria defends that its action is based on two grounds mentioned in article 15 (2). The first is consumer protection and the second is public health. Geelhoed explains that there is a difference between the circumstances in which those two interests can be invoked by a Member State, and that this difference arises from the Treaty and from the Court's case law on foodstuffs. So the first question is: what is consumer protection and can it be invoked in this case?

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<sup>77</sup> Again, he uses the noun 'toetsing' in Dutch, which is the original language of the opinion. This has been translated by 'examination' in English.

<sup>78</sup> The principle derives from the following case law, as explained in the Commission's guide to the free movement of goods (see footnote 13): Case C-390/99 Canal Satélite Digital [2002] ECR I-607, paragraph 33; Case C-254/05 Commission v Belgium [2007] ECR I-4269, paragraph 33 and case-law cited; Case C-286/07 Commission v Luxembourg, not published in the ECR, paragraph 36.



59. (...) Protection of the consumer means that the consumer is afforded guarantees to **safeguard his economic interests**. In particular, he is entitled to be **protected from misleading information** shown on the products which he wishes to purchase, or on their packaging.

To be sure: consumer protection is not directly related to health, but is first and foremost a question of *information*. Consumers must be protected from misleading information. They must be protected because misleading information may lead to confusion and wrong assumptions as to the properties of a foodstuff. This in turn may lead to risky behaviour (such as not going to the doctor, or eating too much of something). The term ‘behaviour’ is not used by Geelhoed, but I think the term is justified in view of the possible danger to health that Geelhoed mentions:

59. (...) The health of the consumer may be at risk if, in consuming the foodstuff, he **wrongly assumes**, as a consequence of **health-related information**, that the product has a therapeutic effect, as a result of which he may, for example, **neglect** to **change** his dietary **habits** or to **seek** medical help.

Wrong information poses the risk of inducing wrong behaviour, and it is only *then* that ‘health’ has a place in the argument. However, ‘information’ remains the main issue: any possible danger to the consumer’s health depends on the nature of information. More precisely, the ‘nature’ of information is not necessarily its *correctness*. What the Labelling Directive and other legislation concerning advertisements want to provide are a number of protective measures against *misleading information*. Correct information can be misleading too. The Labelling Directive states what misleading information is and forbids it. It thus protects consumers from misleading information. In the case we are following here, it becomes clear that, from a juridical point of view, *health* cannot be directly addressed through the notion of ‘consumer protection’. *Information* can, but the Labelling Directive has been designed to deal with that.

So can Austria justify its policy (which deviates from the Labelling Directive) on the grounds of consumer protection, i.e. *misleading health-related information*? The answer is no, because the Labelling Directive *already forbids* misleading information in general in article 2 (1) (a). So there is no reason to derogate from the Directive on the grounds it provides in article 15 (2).

The final resort to address the question of health is through the notion of *public health*.

The argument of consumer protection was related to misleading information. But what about health-related information that is *not* misleading? Austria forbids *all* health-related information in a first move, and then subjects it to an approval procedure. The Member State defends its position on the grounds of another provision in article 15 (2) of the Labelling Directive: the protection of *public health*. Austria argues that even information that is *not* misleading might have undesired consequences. Consumers may wrongly rely on the effect of a health-related statement. One might say that if consumers wrongly rely on the effect suggested by a food label, then this means that the label is *misleading*. However, the hypothesis under consideration is that *non-misleading* information may also lead to the wrong expectations. I think that the only way to understand this paradox is that the words “non-misleading” provide a juridical *way out* of the labelling directive’s basic provisions, and a *way into* the derogations it provides in Art. 15, among which figures public health.

The Commission argues, as summarized by Geelhoed in point 62, that “nothing is gained by prohibiting the description ‘healthy’, since foodstuffs harmful to health may not lawfully be marketed”. Geelhoed, however, is prepared to follow Austria’s reasoning, and agrees that the Member States’ rules on health-related statements are, *in principle*, an appropriate manner to protect public health. He formulates this succinctly in point 63, quoted below. But the testing of Austria’s rules is not finished and will take a new direction as we will discover at the end of the quote:

63. Although, in my opinion, the Austrian Government has not provided a great deal of evidence to support its claim that health-related information endangers the physical and mental well-being of the consumer, I am

prepared to accept that in a given context certain health-related information may affect the state of health of the consumer. That is even possible where the information as such is true and does not mislead the average purchaser. The instrument of a general prohibition on health-related information with the possibility of exemption is then appropriate, in principle, in order to eliminate or limit that risk. Whether such a measure, which is effective in principle, misses its target and therefore infringes the **principle of proportionality** is another question, which must be examined in more detail.

Indeed, from the beginning, Geelhoed announced that there would be two stages in his assessment of Austria's rules. Here, we have arrived at the second stage and it will consist of an examination whether Austria's rules respect the principle of *proportionality*. Before definitely passing an opinion on Austria's compliance with the principle, Geelhoed wants to briefly assess the possible risks at stake for public health:

64. It is not easy to state precisely the circumstances in which the health of a consumer may be endangered. The only example which the Austrian Government has given, **the claim 'good for your health', is difficult to assess without knowing the context of those words**. If that information occurs on the labelling of a bag of apples, I really do not see how even a vulnerable consumer could suppose that a visit to the doctor can be postponed simply by eating apples. If the claim appears on the packaging of a food supplement which may be marketed as a foodstuff, such an effect can more readily be envisaged. However, even in that situation health will only be at risk if consumption of such supplements is at the expense of a balanced diet. (point 64)

Leaving aside questions about the appropriateness of Geelhoed's comparison between apples and food supplements, or Austria's example of a health claim, the important move that is made here is the positioning of *risks* with regards to health claims and their context. In points 65 and 66 he concludes that these risks, which he will qualify as 'residual risks' below, need to be assessed on a case-by-case basis, while the principle of proportionality still holds. This is how Geelhoeds concludes the test of Austria's rules:

67. The combination of a far-reaching general prohibition of any health-related information and an onerous authorisation procedure is not, in my view, proportionate to the desired objective. I would point out in this connection that **the risks to public health to be prevented are residual risks**. Article 2(1)(a) and (b) of Directive 79/112 already prohibits incorrect or misleading information on health effects and any disease-related information. Moreover, as the Commission has rightly stated, it must be borne in mind that the foodstuffs in question may on no account constitute a danger to public health. That requirement is laid down in other general and specific Community legislation. In so far as a product possesses particular characteristics which may give rise to health problems for certain categories of consumers, **that risk is catered for by the compulsory listing of ingredients on the labelling. The Court assumes** that the list of ingredients, the display of which is required by Article 6 of Directive 79/112, **will be read by the consumer.**

According to Geelhoed, risks are residual taking into account the provisions of the Labelling Directive and existing food safety legislation. There are other means, less restrictive to trade, to address any risk that may be ‘left over’. The provision of extra information on the food label is such as measure. It is assumed that the consumer reads this information. Geelhoed therefore proposes that the Court declares that the Republic of Austria has failed to fulfil its obligations according to the Labelling Directive, meaning that Austria’s national rules are *incompatible* with Community law. The Court follows Geelhoed’s arguments and proposal and declares in its judgement of 23 January 2003 that:

*1. (...) by laying down a general prohibition of health-related information on the labelling of foodstuffs for general consumption and by subjecting the display of such information to a prior authorisation procedure, the Republic of Austria has failed to fulfil its obligations under Articles 2(l)(b) and 15(1) and (2) of Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, as amended by Directive 97/4/EC of the European Parliament and of the Council of 27 January 1997;*

*2. Orders the Republic of Austria to pay the costs;*

*3. Orders the Kingdom of Denmark to bear its own costs.*

## Summary of the Case

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Let me very briefly resume the multiple test that Austria’s national legislation went through. To begin, there was the exercise which Advocate-general Geelhoed called the *positioning* of the matter at hand within existing legislative frameworks. The Commission and Austria, respectively, called upon different legislative documents to support their arguments and we have seen that some of them have been put aside. The Labelling Directive was the main framework to make the advocate-general and the judges of the Court capable of a systematic step-by-step exercise of controlling consistency of national rules with the Directive and with the principle of proportionality. Then came the main test, of special interest to us, which can be formulated as a question: “must article 2 (1) (b) of the Labelling Directive, prohibiting disease-related statements on food labels, be interpreted in such a way that it also prohibits health-related statements?” For Austria, it could be argued, this was not even a question. The Member State prohibited both types of statements, but a possibility was left open for health-related statements after prior approval. This policy was maintained on the

grounds of consumer protection and the protection of public health. Geelhoed then distinguished the conditions of ‘health’ and ‘disease’, and especially the *statements* about these conditions. Consequently, it was made clear that Austria was not following the Directive and article 2 (1) (b) thereof, but going much further. Austria’s national rules were thus positioned as deviating from the Labelling Directive. But *derogations* are made possible by the same directive, and so the question became whether Austria’s grounds are consistent with the *exception rules*. Geelhoed defined consumer protection in terms of the safeguarding of the consumer’s economic interests and the right to be protected from misleading information. These areas, reasoned Geelhoed, are already covered by the Labelling Directive, so there is no need for Austria to take other measures.

It follows that addressing *health risks* through the notion of ‘consumer protection’ is a *category mistake*. Protecting the consumer is a matter of *information*, whereas health risks derive from consumer *behaviour*. However, the notion of ‘public health’ provides a different framework altogether. Here, the question of health risks could be addressed in a particular and paradoxical way: “what about the consequences of health-related information that is *not* misleading per se, but that may induce the wrong behaviour?”. If these grounds are considered acceptable by Geelhoed, and the associated risks imaginable, it is not until a final test has been done that Austria’s policy can be judged: are Austria’s measures *proportionate* to their objective? The principle of proportionality does not derive from the Labelling Directive as such, but it is a principle that developed through case-law and that has become part of the EC Treaty. In this case, proportionality is measured against the main objective of the Labelling Directive (and also part of the Treaty): facilitating the free movement of foodstuffs (a particular, but important instance of ‘goods’ in the Treaty). With ‘residual health risks’, Austria’s measures are deemed more restrictive on trade than necessary and thus the principle of proportionality is not respected. Austria has thus ‘failed to fulfil its obligations’ under the Labelling Directive. Test concluded.

## Discussion

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How does this court case matter to my overall story about health claims? The court case stabilizes questions about the interpretation of legal provisions, thereby providing a basis for further political decisions and legislation. Right after *Austria*, the Commission makes a legislative proposal for a separate European Regulation for health claims (the NHCR), as I will show in the next chapter. But what has law contributed to this? In what form has the health claim appeared that is of relevance to its further career? Has the issue of health and disease been settled, for example, and can health claims now circulate (as they are in conformity to the Labelling Directive)? Has the question of health risks been settled, and can we now be sure that health claims will not mislead or endanger consumers?

I argue that *nothing*, concerning the *content* of health claims has been settled, and that this is precisely law's significant contribution to the career of health claims outside of the court room. Law's contribution is this conclusion: there are no legal means to justify restrictions on the free movement of goods on the basis of 'health-related statements' on foodstuffs. Stated differently: food-related health claims cannot be granted the power to make national legislation deviate from the imperatives of the Single Market. Austria's national legislation has been put to the test with respect to Community legislation, and the latter establishes a political-juridical framework for the Single Market.

A short pause in order here. Didn't I refer to Latour as an anthropologist, and to Gutwirth as a legal theorist earlier in this chapter, to insist on the fact that law has its proper regime of enunciation – a specific way of connecting things that is not reducible to politics, economy, science, or yet something else? Then how does law, as practices in the Courtroom, relate to the Single Market? The free movement of goods, as I have illustrated earlier in this chapter, is strongly inscribed in law's formal sources like the European Treaty or, for example the Labelling Directive. Previous arrests by the ECJ can also become sources of law, like the principle of mutual recognition that stems from the *Cassis de Dijon* court case. The ECJ's role is, as van der Meulen (2009) said, to 'protect' the uniform interpretation of legislation. This legislation that deals with matters relating to food is, in turn, geared to protect the Single Market project. So even if law has its own regime of enunciation, its legislative sources (here: the Labelling directive) are inscribed in Europe's Single Market project. More broadly, and not specifically related to food, legal theorists De Sutter and Gutwirth put the question of law's 'exteriority' like this:

*(N)ous ne croyons pas que la pratique du droit s'avère entièrement déterminée par les "facteurs sociaux" qui l'influent. Mais nous croyons par contre qu'il est vrai que le droit s'inscrive dans l'état des choses qu'il contribue à construire par le tissage de liens. Autrement dit, le droit ne fait pas que tisser des liens; il les tisse d'abord d'une certaine manière, d'une certaine façon, qu'il n'est pas libre de déterminer tout seul. Il s'autodétermine, certes, mais à partir d'un point de vue, d'un projet ou d'une perspective. Toute la difficulté est donc de se donner les moyens d'apercevoir comment le droit vit ce paradoxe de l'autodétermination de l'extérieur.*

(De Sutter and Gutwirth 2004 : 30)

Following Latour, De Sutter and Gutwirth have no truck with explanations in terms of 'social factors'. Law, as any practice, is not simply reducible to other practices. However, and this is where both authors critique Latour, the latter's ethnography of the French Conseil d'Etat doesn't allow to pose the problem of law's 'auto-determination from the exterior'. Perhaps it is the peculiarity of *administrative* law, De Sutter and Gutwirth suggest, that have enabled Latour to describe a rather purified regime of enunciation. Would Latour have been able to describe law in the same way if he did fieldwork at the ECJ, looking at dossiers concerning *food law*? This question is not mine to answer, as I am not proposing an ethnography or a theory of law. But the question matters, because sticking to a purified version of law as a regime of enunciation would make *Austria* a non-event. It wouldn't help me to understand the stakes involved with something as seemingly trivial as claims about pumpkin seeds. It wouldn't help me either to appreciate the consequences of the case, nor of statements about pumpkin seeds. Like in the chocolate debate, addressing the nature, the properties or the composition of foodstuffs is a troublesome endeavour. It is as if one cannot look food 'in the face' without causing trouble. Perhaps it is even worse yet when food is imputed to affect health. It is troublesome to the extent that countries are prepared to risk and 'fail to fulfil their obligations' with the respect to their participation in the Single Market project, as members of the EC. In other words: food, through human institutions, has the power to obstruct international trade.

As I have discussed earlier in this chapter, one way to counter this power has been the establishment of 'information' as a currency within legislation and food labelling practice. For example, it can serve as a solution to the difficulties of vertical legislation or 'recipe laws' regulating the composition of foodstuffs: in that case it is enough to display the contents of the product on the label, so that the consumer is, indeed, 'informed'. When it comes to consumer protection and human health, jurist Macmaoláin notes:



*In general, the only measure that Member States may be allowed to adopt to protect consumers and human health is to require that products display more explicit information on their labelling.*

(Macmaoláin, 2007: 65)

In *Austria*, Advocate-general Geelhoed had to examine information as a currency in order to settle the legal question of the compatibility of laws. In a sense, the Republic of Austria was challenging the very concept of information. This concept will be given a political meaning in the Commission's proposal for a health claims regulation in 2003, right after *Austria*. I discuss this proposal in the next chapter.

By way of conclusion, *Austria* teaches us more about the internal coherence of the Single Market as a political-juridical project, then about health claims as such. But this is essential, because it creates the political question of *how* such claims must be *kept* in circulation. And this is precisely the objective of the Commission's legislative proposal in 2003, for what would become the NHCR in 2006.



## Chapter 3 Legislation designs a market for health claims

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### Health claims as newcomers in the Single Market

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When a product, or even a simple pumpkin seed formulates an explicit health claim, and a Member State denies or slows down the access to its market, then this poses a European problem, because the establishment of a Single Market is Europe's most important objective<sup>79</sup>.

The difference between the European level and the Member State level is not just a matter of scale, but a matter of qualitative difference and transformation. The EC has, from its inception, put measures into place, through legislation and litigation, to guarantee the free movement of goods, including foodstuffs. Both harmonisation and standardization are practices that have become indispensable to put foodstuffs into circulation through a patchwork of different national sociotechnical and political regimes. Michel Callon and colleagues combine insights from the anthropology of markets with science and technology studies to study how goods are (temporarily) 'pacified', 'domesticated', or 'disentagled' from their multiple linkages with territories and living beings (Caliskan and Callon, 2010). Harmonisation (for example imposing a common 'method' to qualify goods) and standardization (making goods compatible to fixed standards) are two methods used to make 'things' manageable by abstracting or detaching them from their territories. The basic tenet in this strand of research is that products, with a production history and changing forms only become 'goods' if they become temporarily stabilized, i.e. qualified and comparable or 'calculable' (Callon, Méadel and Rabeharisoa, 2002). Markets act through a dialectic of attachment and detachment: an object becomes detached in order to circulate, but, in order to have competitive advantage it must be rendered capable of attaching itself to certain publics, values, etc. The object is at once comparable and singularized (*Ibid.*). In this view, demand and supply do not influence each other at a distance, but through a multiplication of mediations between the two, as Antoine Hennion (1989) had already shown in a study on advertisement and desire. The theory that has been developed with the help of these notions, is one that doesn't want to decide a priori what is 'economic' and what is not, but rather how things *become* economic – in a process called 'economization' (Caliskan and Callon, 2009;

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<sup>79</sup> See e.g. Wallace, Wallace and Pollack (2005); Devuyst, J. (2006)

2010). Attention shifts from the terms of exchange such as production/supply – consumption/demand to all the sorts of mediations and ‘market devices’ (Callon and Muniesa, 2005) that allow comparison, calculation, qualification and valuing - in short: economic *framing*.

In a similar vein, Andrew Barry (2001) has investigated how the European Union is enacted through devices, standards, harmonisations that make up technological zones<sup>80</sup>. He subdivides these zones into ‘metrological zones’ with common measurement techniques (like for air pollution); ‘infrastructural zones’ with common connection standards (ICT, plug sockets); and ‘zones of qualification’ that come about when objects and practices are assessed according to common standards and criteria. These ‘zones’ are not exactly geographical, but they can be read as the conditions of possibility for a specific market and polity, such as the European Union. Put differently, If Europe wants to realize itself, it needs mediating devices that make ‘wild’ phenomena out there calculable and comparable. The point is, like I said before, that this is not just a matter of scaling things up but also of transformation. Zones qualify or requalify new or existing phenomena, objects, goods.

In this chapter, I examine a situation where the devices or rules of the market that qualify and make things comparable do not exist yet. More precisely: many rules exist for the food market, but the Commission’s legislative proposal argues that specific rules are needed to govern health claims. European lawmakers and their many stakeholders (consumer groups, industry, Member States representatives, lobbyists) are confronted to a situation where food is becoming ambitious, and some consider that it starts misbehaving. Some actors don’t see any problem and consider that the right of free expression has to be respected in the food market as anywhere else. In other words, they see the rules on health claims as a form of censorship<sup>81</sup>. Others, including lawmakers, consumer organisations, but also some food producers are, in a sense, embarrassed. They think that food that ‘makes you happy’ or ‘strengthens your immune system’ harms the credibility of the industry and the authorities (see e.g. Heasman and Mellintin, 2001: 97). For the European Commission and the many interest groups that orbit around it in Brussels, *Austria* confirmed the need to harmonize nutrition and health claims on the European level. Health claims must be clearly defined,

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<sup>80</sup> Barry (2001; 2006) See also Callon’s (2007) review of Barry’s book *Political Machines*.

<sup>81</sup> Interview with the Director of a Brussels-based agency for consultancy on regulatory matters, 14/03/2014.

along with a procedure to put them on the market. The term ‘health claims’ as such is already a qualification that differentiates *claims* from ‘functional food’ (which already presupposes its own functionality).

## Performativity of Texts

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Law and legislation are important to the constitution of markets (ref to special issue), and in this chapter I will look into the discussions that lead to the European Nutrition and Health Claims Regulation (NHCR) of 2006. The NHCR establishes, among others, the definition of what health claims are, the scope of health claims and the procedure to put them on the market. It establishes the conditions for marketing health claims. Faulkner (2012) calls this ‘law’s performativity’. He presents a detailed content analysis of one specific European regulation (dealing with Advanced Therapy Medicinal Products), with particular attention to the absence and presence of certain words; terms left imprecise; enshrined expectations about technology; and the documents overall narrative structure. He concludes, referring to Austin’s speech act theory (Austin, 1962), that the text of the document implies actions, and that it is “an important constituent of a polity’s toolbox for shaping, locking-in and legitimating an emergent techno-scientific field,” and that “the document *legislatively enacts* various ‘rules of the game’ in this sector-in-the-making,” while it has also “*socially enacted* further, more diffuse matters, such as an open-ended vision of the future of a safe and publicly acceptable regenerative medicine industry” (Faulkner 2012: 772). Legislative texts, in short, are ‘active texts’ (*Ibid.*). I fully subscribe to this thesis of law’s performativity, but, rather than providing a content analysis of one specific document, I want to pay more attention to the ‘before’ and ‘after’ of the main legislation for health claims – the NHCR. In the case of health claims, the role of one particular document, and its capacity to perform its exact contents should not be exaggerated<sup>82</sup>. First of all, legislative texts are part of an intertextual universe. Reading a European Directive or Regulation is like tapping into a network of other texts that help each other in the act of signifying. On the first page alone, the NHCR, for example, already relies

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<sup>82</sup> And I’m not suggesting that Faulkner *did* exaggerate. He is aware of the limitations of his analysis of one document: “By focusing on a single document, I have not given as much attention to the intertextual aspects and institutional, organisational ‘contextual’ agents. Likewise, I haven’t given much attention to questions of how a legislative document might *sustain* its performativity over time.” (Faulkner 2012: 772) The merit of his article is (next to demonstrating that a legislative document is *doing* something) that he conceptualizes different forms of performativity within the text. It would lead me too far to do justice to these contributions in the main text above.

on various other texts in order to become meaningful<sup>83</sup>. Secondly, *Austria* is an illustration of the ‘help’ a legal document may need in order to perform. Article 2 (1) (b) of the Labelling Directive, stipulating that no medicinal properties can be attributed to food, was being interpreted in different ways. Interestingly, the legislative proposal that I will discuss below *again* presents a re-interpretation of that same provision in the Labelling Directive, despite – or perhaps: *because of* – the court case *Austria*. So the performativity of the Labelling Directive is sustained, but also redirected, by other interventions and actors. Similarly, I will show in chapter 4 that the performativity of the NHCR depends on the European Food Safety Authority (EFSA).

So it would seem that legislative texts definitively perform something, but that they do not do it alone, and that it is not always predictable what consequences they will generate<sup>84</sup>. These are the aspects that I would like to highlight, rather than the entire content of the NHCR itself. The NHCR is, in the perspective of this thesis, one element among others that constitutes the ‘health claim’ as what I have called a ‘space of mobilisation’ (see Introduction). The NHCR will not close down health claims as a problem space, but give a new direction to the issues within it.

## Method

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Before I proceed to my analysis, I will give some background information on the subject-matter and my methodological choices. On the 16<sup>th</sup> July 2003, 6 months after the Court’s decision in *Austria*, the European Commission published a communication with a proposal for a Regulation on nutrition and health claims on foods, along with some explanations on why such Regulation is desirable. I will call this document ‘proposal 424’<sup>85</sup> to distinguish it from the final NHCR it has led to in 2006.

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<sup>83</sup> It refers to articles 95 and 251 of the Treaty establishing the European Community; the Labelling Directive (2000/13/EC); Directive 98/34/EC, laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services ; to different Guidelines of the Codex Alimentarius ; and to Council Regulation (EC) No 2991/94 laying down standards for spreadable fats.

<sup>84</sup> This is also very clear in Van Hoyweghen’s research on genetic non-discrimination acts. See Van Hoyweghen (2007; 2010).

<sup>85</sup> This is a more comfortable name than the official “COM (2003) 424 final”.

This is an important document, because it initiates a law-making procedure in the EC. The Commission has the sole initiative to propose new legislation. The legislative proposal initiates the so-called ‘ordinary legislative procedure’, which, until recently, was called the ‘codecision procedure’<sup>86</sup>. During this procedure - which involves hundreds of people organized in different committees, and taking several years - both the European Parliament and the Council of Ministers (representing the interests of the Member States) read the Commission’s proposal and comment on it. A second and third reading may be necessary, and the proposal may be adopted or rejected in the end. Proposal 424 and reports related to the ordinary procedure (from the Commission, Parliament, the Council and the Economic and Social Committee) are available on the website of the Parliament’s Legislative Observatory<sup>87</sup>. This enables one to track the development of the decisional procedure and the opinions, comments, amendments of the relevant actors and institutions involved.

What follows is a selective analysis of the Commission’s legislative proposal for the NHCR, along with reactions and amendments proposed, mainly by the European Parliament, during the ordinary procedure. The reading is selective because what I look for in these exchanges are points of friction, suggesting the recalcitrance of the object I am interested in: food with health claims. I call the object recalcitrant (cfr. Latour, 2005), because it makes other agents confront each other on its part. I sort out three controversial issues that the Regulation tries to settle, but only for a very short time: the distinction between *health and disease*; nutritional profiles as a way of *addressing food-as-such*; and the *procedure* to put food with health claims on the market. But first I will present the worldview contained in Proposal 424: what is the place, according to the Commission, of health claims in society?

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<sup>86</sup> The Lisbon Treaty, that took effect on 1 December 2009, renamed the codecision procedure and made it the main legislative procedure in the EU. For a short definition, see: [http://europa.eu/legislation\\_summaries/glossary/codecision\\_procedure\\_en.htm](http://europa.eu/legislation_summaries/glossary/codecision_procedure_en.htm) (last verified on the 9th May, 2014). For a more elaborate explanation, see: <http://www.europarl.europa.eu/aboutparliament/en/0081f4b3c7/Law-making-procedures-in-detail.html> (last accessed on 9th May 2014).

<sup>87</sup> The code of this procedure file is 2003/0165 (COD). Weblink: <http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?id=23510> (last verified on 9th May 2014).

## The worldview of Proposal 424

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This proposal, published only a few months after *Austria*, formulates as its main objectives (stated on p. 3):

- to achieve a high level of consumer protection by providing further voluntary;
- information, beyond the mandatory information foreseen by EU legislation;
- to improve the free movement of goods within the internal market;
- to increase legal security for economic operators; and
- to ensure fair competition in the area of foods;
- to promote and protect innovation in the area of foods.

The proposal envisages a Regulation that tackles many issues at once. This means that the objectives stated above are seen as combinable and articulable together. The Commission provides an ‘explanatory memorandum’ for this at the opening of its Proposal 424. This memorandum develops in the form of short statements and numbered paragraphs, expressing what appear as facts about the world. The following quote, for example, is part of a paragraph entitled ‘background’:

*As food production has become more and more complex, consumers are increasingly interested in the **information** appearing on food labels. They have also become more interested in their diet, its relationship to **health**, and, more generally, the **composition** of foods that they are selecting. For these reasons it is important that **information** about foods and their nutritional value appearing on the **labelling** and used for their presentation, marketing and advertising should be clear, accurate and meaningful.*

(European Commission 2003: 3, my emphasis)

The relation between diet, health and the composition of foods is mentioned, but nothing is proposed, for example, to change the composition of foods. The concerns of consumers (called ‘interests’ in the quote) in an industrialized context (‘more and more complex’) are framed as a problem of *information*. It is suggested (‘for these reasons’) that consumer demand for information is the main motivation for the legislative proposal. This is confirmed in the next paragraph:



*The food industry has **responded** to the increased interest of consumers in nutrition by providing nutrition labelling on many foods and by highlighting the nutritional value of products through claims in their labelling, presentation and advertising. Some would argue that this evolution could be considered as a positive one for providing **relevant information** to the consumer. It also provides an opportunity to use claims as a **marketing tool**.*

(European Commission 2003: 3, my emphasis)

What follows is worth quoting at some length:

*The proposed rules ensures (sic) that foods bearing nutrition claims and health claims are labelled and advertised in a **truthful** and meaningful manner. By adopting rules that regulate the **information** about the foodstuffs and their nutritional value appearing on the label, the consumers will be able to make **informed and meaningful choices**. This also contributes to a higher level of **protection of human health**. Appropriate labelling can indeed **point consumers in the right direction** towards adopting a healthy diet, and facilitate positive and informed choice. Through education, information, health promotion initiatives, as well as through appropriate legislation we can act to help diminish the **health risk factors affecting the European public** and improve overall quality of life. Improving **public health** of the European community is a shared responsibility of the EU institutions and Member States. **This regulatory proposal will provide an important and necessary foundation**; and the implementation of effective educational programmes is also required in order to foster **positive behavioural change**, not only related to diet but also to physical activity and other lifestyle factors. The proposed rules also take into account the importance for the food industry to have a regulatory environment thereby allowing them to **innovate and remain competitive** at Community and international level. This also gives the economic operators **legal security** and a more predictable environment. It is expected that the current proposal will to a great extent **benefit the consumer**. By allowing for clearer legislation on which claims are admissible and under which conditions they can be made, the actual communication and the presentation of claims is expected to be more understandable for consumers and will **avoid misleading** them. It is also expected that it will have the benefit of **educating the consumer** thereby rendering the consumer capable of **making better choices** towards healthier dietary patterns.*

(European Commission 2003: 32-33, my emphasis)

I have emphasized a number of words and expressions that could be likened to a ‘tag cloud’ of concepts representing the Commission’s neoliberal programme. I use ‘neoliberal’ in the sense that Foucault analyzed the Chicago School’s version of neoliberalism<sup>88</sup>. This neoliberalism is one where the State doesn’t simply provide the market with the necessary conditions for operating, but where the market provides the State with an economic rationality. The Commission frames public health in economic terms – as a ‘logic of choice’

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<sup>88</sup> Foucault makes this analysis in his famous *Cours au Collège de France 1978-1979* (see: Foucault 2004). Graham Burchell (1996) offers a contemporary appreciation of Foucault’s analysis of liberal government, while relating it to an ‘ethics of intellectual work’ in the face of neoliberal government. The ‘ethics’ he formulates has common traits with the basic posture of ANT of not accepting ready-made categories.

(Mol, 2008) - and it inscribes Proposal 424 for a health claims regulation within a politics that champions the provision of information as a means to conjugate the imperatives of an innovation-driven competitive economy with the promotion of public health. In a historical analysis of the changing shapes and roles of food labels in the US, Frohlich (2011) argues that the ‘information’ that labels provide are a complex of political interests, conjugating demands of food producers with the traditional control function of the State. But this particular conjugation is also dependent on how these various actors imagine consumers to be: are they fairly intelligent, or rather gullible, or...? The version of information that characterizes the historical-political period from the 1990s until today is a neoliberal one: “L’étiquetage a redéfini la gouvernance de la santé publique comme un problème de marché, transformant des questions de gouvernement des citoyens en questions de citoyens-consommateurs se gouvernant eux-mêmes.” (Frohlich 2011: 26). The food label can thus be read as a political space, representing a constellation of interests formulated for a specific type of imagined consumer. The importance of the food label in Europe and the provision of information for the creation of a Single Market for foodstuffs appeared clearly in the previous Chapter. In Proposition 424, the question is under what conditions health claims can figure on a food label. And more particularly how a form of *truthfulness*, dear to the Commission, is composed out of diverging views.

## Health, Disease and the Risk Factor

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The Commission’s legislative proposal starts with an introductory part. The first point specifies the following:

*The European Community has adopted detailed rules on labelling and nutrition labelling of foods. With regard to claims there is the basic provision that claims should not mislead the consumer. Furthermore, Article 2 (1) (b) of Directive 2000/13/EC on the labelling<sup>89</sup>, presentation and advertising of foods, prohibits the attribution of preventing, treating and curing properties to foods. Proper enforcement of these general provisions would go a long way to prevent abuse in this area.*

*However, Member States and stakeholders have pointed out that these general principles are open to different interpretations and therefore are not satisfactory for dealing with some specific claims. Very recently, in case C-221/00, Austria v Commission, the European Court of Justice interpreted the existing labelling*

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<sup>89</sup> The Commission refers to the updated version of the 1979 Labelling Directive: Directive 2000/13/EC. The articles that were relevant in the *Austria* Court case, such as Art. 2 (1) (b) have remained unaltered.

*Directive as banning all health claims relating to human diseases. In the light of the technological innovation in the food sector and the demand from consumers and industry alike it is proposed to set a new legislative framework on the use of claims*<sup>90</sup>.  
(European Commission, 2003:2, point 1)

The mentioning of *Austria* in this first introductory explanation is important. *Austria* clearly meant something to policymakers and their stakeholders. More precisely, the interpretation that has been given to article 2 (1) (b) of the labelling directive, this article being one of the central in the Court case, is questioned here. What Geelhoed had closed down quickly by getting rid of facts that do not concern law, is re-opened here again because it matters where the ‘health claim’ becomes a political and economic space of mobilisation. The article of the Labelling Directive says that no *medicinal* properties can be attributed to food, and the question with respect to this article is *whether law is in keeping with technological innovation*. It is remarkable that, in fact, no question is formulated, but an assertion: in the light of technological innovation, a new legislative framework is needed for claims.

The word ‘claim’ takes importance now. What was called a ‘health-related statement’ in the ECJ courtroom, has now become a ‘health claim’ outside the courtroom. The word ‘claim’, as a noun, denotes both an assertion that something is true (but requiring evidence), or a demand or request for something considered one’s due<sup>91</sup>. So the word relates both to *truth* and *appropriation*. The quote above shows that ‘stakeholders’ *claim* a right of expression about that which concerns human health, and stretch the concept of ‘health’ even a bit further:

*(I)t has to be considered whether this total prohibition is still adapted to the advances of research, science and food technology, as well as to consumers expectations. This proposal for a Regulation on the use of claims maintains the prohibition on claims referring to the prevention, treatment or cure of a human disease, **however a difference between “prevention” and “reduction of a disease risk factor” is made and a derogation is provided**. Indeed, it is acknowledged that diet and certain foods can make important contributions to the support and maintenance of health, and that diet and certain foods can play a role in the management of certain disease risk factors*<sup>92</sup>.

(European Commission, 2003:7, point 26, my emphasis)

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<sup>90</sup> Commission of the European Communities, COM(2003) 424 final, p.2

<sup>91</sup> Based upon the definitions for ‘claim’ as a noun and a verb in the Oxford English Dictionary, consulted online: <http://oxforddictionaries.com/definition/english/claim>

<sup>92</sup> Commission of the European Communities, COM(2003) 424 final, p.7

This can be phrased in a more straightforward manner: *food companies want to make disease risk reduction claims* as a form of ‘health claim’, as had already been advocated by ILSI Europe and its network of experts (Chapter 1). An example of a product with such a claim that was already put on the market when the Commission made Proposal 424 was cholesterol-lowering margarine. Cholesterol is considered a risk factor for cardiovascular diseases. In that sense, lowering cholesterol means lowering a risk factor, without curing the disease. It could be argued then, that it is a form of *prevention*, which would turn Unilever’s claim into a *medicinal* claim, but this is precisely where the concept of ‘reduction of a disease risk factor’ makes a crucial difference: it extends the realm of health, while drawing a new boundary with disease. At the same time it displaces a *sectorial* boundary between the food industry and the pharmaceutical industry. This part of Proposal 424 has been accepted by all stakeholders, and it became part of the final NHCR in 2006. The NHCR would thus start shaping or performing a market of agents, some of which are active compounds like plant sterols, classified as ‘food’. Geelhoed got rid of the question concerning the ontology of health and disease, in order to settle the interpretation of article 2 (1) (b) of the Labelling Directive: he said the article prohibits *all references to disease* for food products, but prohibits no health-related statements. With the introduction of ‘reduction of a disease risk factor’ as a form of ‘health claim’, the Commission and its stakeholders now got rid of Geelhoed. They reinterpret law, because it is deemed not in keeping with technological innovation. In that light, the question of food’s properties and its role in real –not juridical– health is posed. Proposal 424 and the NHCR thus perform a form of *ontological politics* (Mol, 1999). In Chapters 5 and 6 I look into the consequences of this.

I remind that the concept of ‘reduction of a disease risk factor’ was an important element of FUFOSSE. Although the Commission does not trace the concept back to FUFOSSE in the particular quote above, it does mention that the valuable work of FUFOSSE and PASSCLAIM, funded by the Commission, should be taken into account, later on in the document when considering the need for scientific assessment of claims:

*In this context it is worth mentioning that the European Commission has funded valuable projects such as the Concerted Action PASSCLAIM aiming at setting principles for assessing the scientific support of health claims, and that this considerable work should be taken into account when assessing claims.*

(European Commission, 2003 : 8-9, point 29)

FUFOSE is recommended as a scientific touchstone in the compilation of a European list of approved claims:

*The valuable work carried out in the Consensus Document on Scientific Concepts of Functional Foods in Europe, prepared in the context of the Commission's Concerted Action on Functional Food Science in Europe (FUFOSE), shall be taken into account in the compilation of this list.*

(European Commission, 2003 : 9, point 30)

The introduction of 'reduction of disease risk factor' claims didn't pose any significant problems during the negotiations - the 'ordinary procedure' - of the NHCR. The final Regulation distinguishes these claims from 'function claims' that do not make any reference to risk factors. Function claims are about maintaining a 'normal' functioning of a body function. This is, again, reminiscent of the terminology of the FUFOSE stratagem.

## Addressing Food as such: Nutrient Profiles

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To avoid nutrition claims ('rich in calcium') or health claims (function claims and disease risk reduction claims) being made on, for example, soda drinks high in sugar content, alcoholic drinks, or snacks rich in salt and fats, Article 4 of the proposed draft Regulation stipulates the need to establish 'nutrient profiles'. These are criteria concerning the composition of foodstuffs in order to determine *which foods are eligible* to bear health claims in the first place. This was a much more troubling issue during the ordinary procedure than the span of 'health claims' that I discussed above. The Commission cautiously introduces the subject of 'nutrient profiles' as follows:

***Some** consumer organisations in the European Union consider that products that do not have a "desirable" nutritional profile, such as candies, high salt and high fat snacks or high fat and sugar biscuits and cakes should not be allowed to bear claims. For example, a "low fat" claim should only be allowed if the product does not contain high quantities of sugar or salt; or a "high calcium" claim should not be used on a product with a high fat content. **They consider** that such foods would become more attractive because of the way in which they will be labelled and advertised and many consumers that are currently eating them in moderation would consume them in greater quantities. This, **they believe**, would have a more immediate negative effect on the dietary habits of certain particularly vulnerable sections of the population, like children and adolescents. This view is also shared by **some** Member States.*

(EC 2003: 4, point 13)

And the Commission goes on in the next point:

*Although based on understandable concerns and important arguments, a number of **scientific and policy arguments** could challenge such restrictions (based on nutritional profiles, KH). The concept of prohibiting the use of claims on certain foods on the basis of their "nutritional profile" is contrary to the **basic principle in nutrition** that there are no "good" and "bad" foods but rather "good" and "bad" diets.*

(EC 2003: 4, point 14)

If that is so, what then, one could ask, is the point in making health claims for individual foods in the first place? Why make a regulation that allows health claims on individual foods if foods are neither good nor bad? It must be kept in mind that Proposal 424 addresses the Council and the Parliament, and not the general public. The Commission has to try and strike a balance between the interests of its various stakeholders. For industry, represented through special committees in the Parliament (see below), evaluating foodstuffs with nutritional profiles is to be avoided, as it may privilege or disadvantage some sectors over others (e.g. dairy versus snacks and drinks). Industry also fears that such profiles would lead to other uses, such as ‘traffic light labelling’ (a simplified but visible indication of a product’s specific properties or contents); restriction on the contents of advertisements; or the taxation of certain products (ERNA, 2011)<sup>93</sup>. However, ‘some’ Member States, as the Commission says, as well as consumer organisations, have expressed concern about health claims appearing on foods that are rich in sugar, fat or salt. So, for the Commission, the issue of nutrient profiles cannot simply be put aside with the argument that there are “no good or bad foods”. The Commission says the following about this specific argument:

*This argument, **although scientifically valid**, should be considered in the appropriate context. Foods baring (sic) claims are presented by the food operators as products whose consumption would provide a benefit, that is as “good” or “better” products. In most cases, influenced by the promotional campaigns, consumers perceive them as such. This potential bias should be avoided in order to prevent the negative effects mentioned in point 13.*

(EC 2003: 4, point 14)

The ‘negative effects’ of point 13 are that certain individual foods may become more attractive. Point 14 makes a division between scientific arguments and matters of perception and bias. Health claims are put on the side of bias, leaving consumers and their perception at a loss. But the objective of the proposed Regulation is driven by the imperative that health

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<sup>93</sup>ERNA is the European Responsible Nutrition Alliance, an international federation of food and food supplement industries.

claims *must* be possible, to provide opportunities for innovation for the food industry. The envisaged Regulation wants to create legal certainty for industry, equal conditions of competition, and ensure the free movement of foodstuffs. Also, consumers must be protected from bias while, as we have seen, given the opportunity to make informed healthy choices. In this awkward configuration of arguments, it is not entirely clear what it is that consumers should be protected from, apart from *themselves*. ‘Science’ says that there are no good or bad foods, while health claims are an opportunity for promotion offered to industry. Consumer *perception*, however, is a source of bias and may pose a risk. In that sense, nutrient profiles may help reducing the risk of bias. Point 14 goes on:

*Therefore some restrictions on the use of claims on foods based on their nutritional profile should be foreseen. In particular, the amount of total fat, saturates, trans fatty acids, sugars, sodium or salt, at variable levels, are commonly cited as criteria for the "nutritional profile" of products. **Scientific research** identifies an association between the **high consumption** of these nutrients and some chronic diseases, such as cardiovascular disease, diabetes, several types of cancer, obesity, osteoporosis and dental disease.*

(EC 2003: 5, point 14)

Throughout the argumentation so far, ‘science’ appeared as a vector of justification to say that there are no good or bad foods. Now, that vector is directed at *specific nutrients* that are believed to contribute to the major diseases of industrialized nations. However, in the context of this document and its worldview, the vector only *passes through* these nutrients: science shows an association between the *high consumption* of these nutrients and Western diseases. Nutrient profiles, then, need to be developed to tackle the risk, not of nutrients, but of consumer *behaviour*. If health claims make certain foods more attractive, then it must be prevented that consumers start eating too much of those particular foods. So indeed consumers must be protected from themselves. This enables to add an important precision to the description of the neoliberal tenure of the Commission’s proposal. Providing information to have consumers govern themselves and make them responsible implies a *transfer of risk* from nutrients and products, as a source of risk, to consumer behaviour as a source of risk. Rather than proposing to diminish the contents of certain ingredients (like salt, sugar, fats) in foods, the logic of the Commission’s proposal is to leave the composition of foods unaltered, with a restriction on the use of voluntary health claims for certain nutrient profiles.

The proposed draft for an Article 4 in the future NHCR was this one:

*Within 18 months from the adoption of this Regulation, the Commission shall (...) establish specific nutrient profiles which food or certain categories of foods must respect in order to bear nutrition or health claims. The nutrient profiles shall be established, in particular, by reference to the amounts of the following nutrients present in the food:*

- (a) fat, saturated fatty acids, trans-fatty acids*
- (b) sugars*
- (c) salt/sodium.*

*The nutrient profiles shall be based on scientific knowledge about diet, and nutrition, and their relationship to health and, in particular, on the role of nutrients and other substances with a nutritional or physiological effect on chronic diseases.*

(EC, 2003: 17)

In the decision-making procedure that the Commission initiates with its proposal, the proposal is sent to the European Parliament and to the Council of Ministers (representing the Member States) for a first reading with comments and amendments.

In the report of its first reading, the Parliament comments as follows:

*The first remark to be made concerns Article 4, on (...) the use of nutrition and health claims for foods or certain categories of foods. On the basis of this positive approach to the matter, nutrient profiles will be drawn up on the basis of the overall composition of a food and the nutrients that it contains. The aim is to encourage consumers (...) to eat a balanced diet. **The direct references to content levels of nutrients such as fats, saturated fatty acids, trans-fatty acids, sugars and salt/sodium have been removed**<sup>94</sup>.*

(European Parliament, 2005: 38, my emphasis)

Nutrient profiles, in this reasoning, are helpful to encourage consumers to behave correctly, *as long as the nutrients themselves are protected from attack.*

The report goes on:

*It is extremely important for the nutritional criteria to be drawn up on a **sound scientific basis**. Your rapporteur is willing to endorse the comitology procedure if Parliament is included in the process of consulting interested parties. An effective strategy for **helping consumers to choose a good diet in full knowledge***

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<sup>94</sup> report EP, 1st Reading, explanatory statement of the committee on environment, food safety and public health, p.38



*of the facts is not one that classifies foods or categories thereof into 'good' and 'bad' food. It is generally accepted and **scientifically agreed** that there is no such thing as 'good' or 'bad' foods; there are only good or bad diets<sup>95</sup>.*

*(Ibid., my emphasis)*

Science is again mobilized to ensure that nutrient profiles are drawn up 'correctly'. This correctness can be ensured, it is suggested, through closed discussion (comitology procedure) and the consulting of interested parties. The phrase: "there is no such thing as good or bad foods" is repeated again. This repetition, in the discussion about nutrient profiles, even seems to take on the function of a protective spell: a fixed number of magic words, repeated in the same manner.

At the same time, this spell conveys a moral injunction: *it is not right* to think in terms of good or bad foods. Scholars have argued and illustrated that the food market is related to morality (Mintz 1985; Dubois 1996) and some argue that it constitutes a 'moral economy' (e.g. Morgan et al. 2008). The arguments in Proposal 424 and the negotiations that follow in the decision-making procedure, show that a certain morality is already at work in constituting a market.

The Parliamentary committee in charge of the report and the comments above, is the Committee on Environment, Food Safety and Public Health. The citations above are from the rapporteur of that committee. However, the report also contains the input of two other committees: the Committee on Industry, Research and Energy, and the Committee on the Internal Market and Consumer Protection. The committee on Industry, Research and Energy sees the problem as follows:

*Your draftsman takes a very critical view of the Commission proposal, and considers that many aspects require changes. (...) There are reservations, above all, about the introduction of nutritional profiles for foods which is envisaged in Article 4 of the proposal for a regulation. The Commission's intention is that the sugar, salt or fat content, in particular, of foods will have to be measured before they may be advertised with nutrition or health claims. However, the classification of foods into those with a beneficial nutritional profile and those with a less beneficial profile **contradicts** the idea of a balanced diet. **There are, in principle, no good or bad foods.** The decisive factor, instead, is the **proportions in which foods are consumed.** Moreover, the draft regulation largely leaves open the precise definition, and establishment, of the concept of a nutritional profile. **Until this is resolved scientifically**, nutritional profiles should not be introduced.*

*(European Parliament, 2005: 40-41)*

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<sup>95</sup> *Ibid.*

The same protective spell is formulated, and imputations against food are redirected and transferred upon the consumer. Next, science is again mobilized, especially for putting off the introduction of nutrient profiles. Nutrient profiles *should not be* what they are at the moment: a political problem. Waiting for the issue to be ‘resolved scientifically’, then, means avoiding the issue to pose further problems.

Negotiations that followed, involving a second reading of the Commission’s proposal by all parties, and the search for a common position between the Parliament and the Council. Eventually these negotiations *did* lead to an agreement on the introduction of an article 4 about nutrient profiles in the final Regulation – the NHCR in 2006:

*By 19 January 2009, the Commission shall (...) establish specific nutrient profiles and the conditions, including exemptions, which shall be respected for the use of nutrition and health claims on foods and/or categories of foods.*

(European Commission, 2006, Article 4 (1))

Why were nutrient profiles introduced, despite fierce resistance from within the Parliament? This is not clear from written sources alone. Perhaps because the Council, representing the Member States and also involved in the negotiations, always expressed itself in favour of nutrient profiles? Is this the reason why, in the search of a common position, a slight majority in Parliament eventually voted in favour of nutrient profiles? This is not clear and the traceability of texts and con-texts stops here at this highly political point.

The Council, indeed, was always in favour but the reasons for that are not clear from written documents alone. For example, in the Council’s position ‘2003/0165 -08/12/2005’, The Council expressed itself in a dispassionate manner and in favour of nutrient profiles, seeing no problem in establishing them scientifically and objectively. A consultant in regulatory affairs who closely followed these negotiations recounts that most Member States didn’t realize at that time what the consequences of such profiles could be for domestic industry and export (e.g. would cheese get a bad reputation because of its high fat and salt contents?) and that some Member States changed their opinion afterwards, while others kept on defending them<sup>96</sup>. But even the consultant had lost track of the issue at some point. The issue got lost in the political arena. What is certain however, is that at the time of writing, in 2014, 7 years after the NHCR has entered into force in 2007, the question of nutrient profiles

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<sup>96</sup> Interview, 14/03/14.

still hasn't been solved.

Before ending this section on nutrient profiles, another word must be said about science, because it will matter for the next section. The final NHCR mentions a number of criteria to take into account when establishing nutrient profiles, such as the quantities of certain nutrients or other substances such as fat, saturated fatty acids, trans-fatty acids, sugars and salt/sodium; the role and importance of the food in the diet; and the overall nutritional composition of the food. It is stipulated that “the nutrient profiles shall be based on scientific knowledge about diet and nutrition, and their relation to health.” (European Commission, 2003:17) Science, again, is attached here to a political problem. It is expected to offer objective solutions. For that, a trustworthy representative of science was considered needed. Proposal 424 and the final NHCR therefore assigned the then recently created (2002) European Food Safety Authority (EFSA) to provide scientific advice on nutrient profiles and health claims to the Commission, as I will show in more detail in the next section. In so doing, the Commission's legislative proposal and the final NHCR insert a gatekeeper between food ingredients and the market. This gatekeeper, EFSA, will evaluate health claims. With EFSA, a premarket approval procedure is installed, along with an additional translation in the economisation and marketing of food ingredients as agents of health.

## Premarket approval: EFSA and Science as Gatekeepers\_\_\_\_\_

To resume the previous two sections: the Commission's proposal in 2003, and the final NHCR that emerges out of the negotiations in 2006, prepare the way for function claims, and the possibility to make disease risk reduction claims. Setting nutrient profiles was met with resistance, but finally taken up in the NCHR. A third central issue in the Commission's proposal, a pre-marketing approval procedure for claims, was also met with resistance from the Parliament but finally taken up in the NHCR. Both the issue of nutrient profiles and the establishment of a scientific gatekeeper point out again that food is not so easily ‘domesticated’ or ‘pacified’ (Caliskan and Callon, 2010: 5-6). The discussions in the legislative procedure show that science is expected to do exactly that: domesticate foods and nutrients. In that sense, like I already argued in the chapter on ILSI, what is asked of science is something that it cannot give. It is contrary to its particular mode of hesitating with objects, and populating the world with even more objects (Latour, 2005; 2007). A specific practice,

that could be called trans-science or regulatory science with Weinberg (1972) or cameral science with Stengers (2013), is therefore called upon to make judgements. The result is that, in its determination to regulate health claims and thereby facilitate their circulation in the wake of *Austria*, the Commission proposed a premarket approval procedure itself. But where the Republic of Austria was judged not to respect its obligations as a Member State, the Commission needed a device, a procedure, to domesticate food *and* the Member States. Among officials within the Commission, the Member States are called ‘les belles-mères’: the difficult, recalcitrant, ‘mother-in-law’ meddling in the Commission’s affairs<sup>97</sup>. One official within the Commission says that *industry* and the *Member States* appear as *sensitive beings* (‘des êtres sensibles’) to the Commission, to be treated with some caution<sup>98</sup>. However, the role of acting as a gatekeeper amongst sensitive beings, amongst which I include *food*, could no longer be assured by the Commission when it communicated its legislative proposal in 2003. After a number of food scandals, and the 1996 BSE crisis in particular, the Commission had lost credibility (Majone, 2002) as a mediator between Member States and the market. EFSA was created in 2002 to restore confidence in the Commission and the European market, as an agency speaking in the name of science, *independent* from political matters. I return to this in more detail the next chapter. For now, what matters is that Proposal 424 called upon the then recently created European Food Safety Authority (EFSA) to help pacify foods with health claims through ‘science’:

*Health claims should therefore only be approved for use on the labelling, presentation and advertising of foods on the Community market after a **scientific evaluation of the highest possible standard**. In order to ensure harmonised scientific assessment of these claims, the European Food Safety Authority (EFSA) (...) should carry out such assessments.*

(European Commission, 2003: 8, point 29, my emphasis)

The appeal to science is again remarkable. Why bother so much with scientific evaluation of the highest possible standard, if individual foods are thought to pose no risk? Why this obsession with the veracity of information (while many other products make unverifiable claims?)

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<sup>97</sup> personal communication (June 2012) from a former official at the Commission’s DG Research.

<sup>98</sup> Personal interview (April 2013) with Nicole Dewandre, advisor at the Commission’s DG CONNECT, and author of *Critique de la raison administrative. Pour une Europe ironiste*. See: Dewandre (2002)

The preceding paragraph takes importance here:

*A study carried out on food shoppers in the US in 1997 showed that consumers were **less likely to read** the nutritional declaration when the pack was labelled with a health claim. (...) Many would argue that there is a great risk that health claims are not easy to understand and **utilise correctly**, with the consequence that the consumer will not achieve the result(s) wanted. **Thus there is a great risk** that health claims will **confuse and mislead** the consumer and will not help the consumer choose a healthy diet, will not strengthen dietary and nutritional information and will not help promote nutrition policy goals.*

(European Commission, 2003: 8, point 28, my emphasis)

There is a risk, but it is not framed in terms of the properties of foods or nutrients, but in terms of deception. The risk of one's body being affected by certain nutrients or foods becomes the risk of being fooled by food. This tipping point also tips into a different kind of question: from assuring the quality of food to assuring that consumers will *behave* correctly. In other words: creating the right conditions for the consumer "to make choices," as the NHCR says, "in full knowledge of the facts"<sup>99</sup>. The tipping point bascules from intervention in the food supply to a moralisation of individual behaviour. Science of the highest standard is called upon to ensure that deception cannot occur. As such, the role of 'science' is to ensure an environment of free choice, placing the responsibility of health within consumers: information about nutrients must be *accurate, honest, truthful, scientifically-based and reliable*<sup>100</sup>. Misleading information becomes the risk of foods with health benefits. If the concern with misleading information was not new (like we have seen in the previous chapter with the labelling directive), then in the context of this proposal information became a political priority firmly connected to 'science'. As such, science becomes a market device to pacify health claims and create a market for them.

Interestingly, the Parliament reacted to this proposal, questioning why a scientific premarket approval by EFSA should be necessary. A premarket approval is not *proportionate* with regard to the purpose of marketing foods that, according to the stakeholders in the Parliament, *pose no risk*. Coppens et al. (2006) provided a critical discussion of the integration of functional foods and health claims in a regulatory framework of safety. The authors were business consultants and defended the viewpoints of the Parliament at that time. The article, where it is defended that safety is not the issue, is published in a journal that is

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<sup>99</sup> See : European Commission (2006), recital 8, p.2

<sup>100</sup> my collection of the adjectives used by the Commission on p.8 of its legislative proposal.

called, surprisingly perhaps, *Toxicology*. It was argued that a notification procedure would be better and less cumbersome.

More generally, some business actors saw the health claims regulation as a form of censorship<sup>101</sup>, creating a climate of legal uncertainty. This too comes with moral and political arguments. One of the comments of the Committee on the Internal Market and Consumer Protection (within Parliament) was:

*The draftsman does not believe that it should be the role of government – whether local, national or European – to take decisions as to which foods are good for consumers.*

(European Parliament, 2005: 80)

The draftsman in question, however, has no problem with industry suggesting what is good and bad for consumers:

*(I)s there any sense in preventing red wine producers from claiming that moderate quantities of red wine can be good for your heart?*

(*Ibid.*)

To the draftsman, this is no different from the many other claims within the general practice of advertising:

*General claims are a common advertising tool. Most successful advertising campaigns claim that their product will – at some level – make you happier, healthier, richer or more attractive to the opposite sex. In many cases they are not intended to be taken literally and are not taken as being a genuine claim but just an advertising “puff”. Whether the “claim” is made verbally or through the use of pictures or sounds. It would clearly be ludicrous to tell sweet manufacturers that they shouldn’t display pictures of happy children either in their adverts or on their packaging, or to stop a breakfast cereal from suggesting that their cereal sends children to school ready for the day ahead. If this is allowed in advertising, why shouldn’t it be allowed on the packaging or on the in-store display? The Commission’s proposal threatens to create a state of legal uncertainty around the food advertising industry.*

(*Ibid.*: 80-81)

The point raised here is interesting. As advertising constantly tries to convince, seduce, and attract consumers, it could be argued that the latter are constantly being misled in one way or another. And the consumers know it. They are smart enough to know that not

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<sup>101</sup> Personal Interview with the Director of a Brussels-based agency for consultancy on regulatory matters (March 2014)

everything should be taken seriously, and that claims are part of the game in advertising. Why, then, should the case be different with health claims on food, especially if all parties involved in the decisional procedure seem to agree that foods pose no particular risk to health?

This resembles the problem Geelhoed was facing in the previous chapter, although he dealt with it quickly: “the food itself may be safe, but what about the behaviour of the consumer?”, he would say. But then again, nobody seems to worry about advertisements on cars and their spectacular performances in stunning landscapes? Does anyone consider whether such commercials incite drivers to behave dangerously? And even though there are debates about the influence of video games or films, would anyone take a European preapproval procedure seriously? Wouldn’t such an initiative be considered a form of censorship? Why is it so different with claims on *foods*? Because they are about food? Or because they are about health? There are still a number of stops to be made before I can try and address that question. Right now, after many tours and detours through the paradoxes and seeking of compromises in the decision-making procedure, a brief summary is in order.

## Politics of Information

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In this chapter I analysed the political aftermath of *Austria*, which I formulate as follows: *how* can health claims be *kept* in circulation, while avoiding new court cases like *Austria*? The 2003 proposal by the Commission for a special regulation for nutrition and health claims (the NHCR) wants to articulate *legal security* for the food industry with equal conditions of competition; opportunities for innovation and consumer protection. The worldview that provided the justificational framework for this proposal was one in which consumers make informed choices (cfr. Mol 2008). As such, this framework prolongs an already existing current in food legislation and politics, where labels and information are a favoured solution over vertical legislation or ‘recipe laws’ that address the *composition* of foods. The latter put the Single Market much more at risk, as the composition of food is bound up with the particular interests of food producers. In that sense, ‘information’ is a way to domesticate or pacify food-as-such and to make the consumer responsible for further undertakings with food as an *objet chevelu* (Latour, 2007). The provision of information

allows to point out ‘behaviour’ as the main source of risks. The Single Market imperatives generate a specific *morality* about health.

In the decisional procedure that the Commission’s proposal initiated, I gave special attention to three issues. The first is the *ruse* that is proposed to install a difference between ‘prevention’ and the ‘reduction of a disease risk factor’, as had already been proposed by ILSI 4 years before the Commission’s proposal. The second issue is about ‘nutritional profiles’: which foodstuffs are eligible to carry a health claim? This re-introduces the question of the *composition* of individual foods – the Single Market’s *taboo*: composition can be mentioned on a food label but not judged in terms of health. The third issue was the proposal of a premarket approval procedure for health claims on the EU level, in which The European Food Safety Authority (EFSA) would act as a gatekeeper between food ingredients and the market. Its main mission is to verify the truthfulness of claims: claims must be scientifically true because consumers must not be misled. Science serves to validate the political division between ‘clear’ and ‘honest’ information on the one hand, and moralized consumer behaviour on the other.

Despite initial resistance from within the Parliament, the final NHCR *did* establish a premarket approval procedure wherein EFSA prepares a scientific opinion on individual health claims for the Commission. In Proposal 424, the Commission insisted that health claims be evaluated through ‘science of the highest possible standard’. The final formulation in the NHCR is: ‘generally accepted data’. This has a different meaning, and yet, we cannot be sure about how such a formula will be performed in practice. In the next Chapter, I briefly discuss EFSA’s role in EU food policy, and what is expected of its experts. They are the ones who will call the ‘data’ of ‘generally accepted data’ in existence. In the Chapter after that (Chapter 5), it will become clear that, up until today, those ‘data’ are not ‘generally accepted’ at all.



## Chapter 4 EFSA Making Data Available

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Even if the NHCR changed the formulation to ‘generally accepted data’, the Commission deemed that EFSA represented ‘science of the highest possible standard’. In this chapter I discuss how EFSA was created to stand for science. This chapter interrogates the question of expertise in relation to EFSA, in an environment where ‘scientific independence’, transparency, and communication became of the highest political priority. The curvatures of politics had to be made straight.

### EFSA as a Body of Expertise

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EFSA gathers experts around the table. It is perhaps more correct to say that it gathers scientists who then *become* experts-around-the-table. As I have already suggested in the chapter about ILSI and how the organisation turns scientists into claim technicians, the experts’ meeting room is not simply a space where pre-existing knowledge is brought in without translation. It is not a space where scientific knowledge is produced because the laboratory and its equipment to hold scientific statements together (Latour and Woolgar, 1979), quite literally, do not *fit* in the meeting room.

The construction and the ‘role’ of expert advice in society, and the difference with scientific knowledge production, have been investigated by many scholars in the field of science studies. Already in 1972, Alvin Weinberg introduced the concept of ‘trans-science’ to distinguish forms of regulatory advice from scientific knowledge production (Weinberg, 1972): a lot of questions can be asked of science, but can answer them? Later, Sheila Jasanoff (1987, 1990) investigated ‘policy-relevant’ science or regulatory science as an activity where the boundary between science and policy is constantly drawn and redrawn. One of the most important means to draw these boundaries, she argues, is language. She gives the example of the separation between ‘risk assessment’ and ‘risk management’, and shows that in each case science and policy are interwoven and subject to politically charged boundary drawing (Jasanoff 1987).

EFSA is also part of a risk analysis scheme, as I will detail below. But the separation between risk assessment and risk management is not only linguistic, but also institutional. In theory, EFSA only performs risk assessment, and the European Commission, as a ‘risk manager’, makes a final decision in the light of political considerations, with EFSA’s scientific opinions as an input to start from. This means the Commission is not obliged to follow EFSA’s opinions. But EFSA does matter as an authority, and the Commission does depend on its advice in the first place<sup>102</sup>.

Being a member of one of EFSA’s panels is not a paid full-time job. EFSA’s experts have volunteered for the job, and they don’t receive a salary. They sit in EFSA’s panels because they have applied for it, and have been selected on the basis of their CV<sup>103</sup>. They are experts in addition to their paid job as academics, and they have been selected because their CV shows that they have relevant expertise on their subject of interest, but also on sitting in various committees. Most panel members know what it is to sit around the table, and they know something of what they call ‘the government side’ (Demortain, 2011, Granjou et al., 2013). As such they are not only experts in, for example, microbiology, immunology or toxicology, but also in the dynamics of the meeting room – the particular activity that unfolds when ‘science’ and ‘policy’ meet. They know the area of ‘trans-science’, ‘policy-relevant science’ or ‘regulatory science’. How do they reconcile their academic expertise as scientists with their activities as policy advisers? How do they feel about judging scientific evidence, knowing that scientific research, in principle, is about asking more questions? And does this create or displace the boundary between them being part of a scientific community (e.g. the life sciences)? What sort of boundary is this for them? Before returning to these questions, I would like to avoid an answer that is tempting indeed, but that might close down my questions too quickly.

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<sup>102</sup> Within the Commission, it is DG Sanco’s Standing Committee on the Food Chain and Animal Health who receives EFSA’s opinions and considers them. This committee is composed of representatives of the Member States competent on the matter. The Belgian representative, for example, is an official from within the Ministry of Health. He is a scientist who feels that, since he has joined the committee, he’s “becoming more of a jurist.” (Interview, Brussels, 17/02/12).

<sup>103</sup> Interview with panel member 16/12/11.

## The Theatre Metaphor

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There exists a reasonable explanation to these issues of separation and of multiple expertise, suggesting that these issues are, in fact, not so complicated. This explanation says that scientists can take up different roles in society, as if they were in a theatre play. The metaphor of the stage has been used to talk about science by Stephen Hilgartner (2000) for example, and also by Bijker, Bal and Hendriks (2009) in their ethnographic study of the Dutch Health Council as an expert body. The metaphor of the stage and role-playing goes back to the works of Erving Goffman (1959). Bijker et al. (2009) build up their ethnography around what they consider as a central separation in the daily work of the experts in the Dutch Health Council (*Gezondheidsraad*): the difference between *frontstage* and *backstage*. The backstage work are the discussions amongst the experts in the Health Council, which Bijker et al. further characterize with the notion of ‘coordination mechanism’. This mechanism is a double process of drawing boundaries between ‘science’ on the one hand, and ‘social worlds’ on the other, (policy; ethics; or society) (2009: 150-151), and these boundaries then in turn make it possible to coordinate these worlds in order to define problems, to decide upon stakeholder participation in the discussions, to intervene in societal debate. This backstage work makes a frontstage presentation possible, which for the Health Council is the advisory report. This is a public document and the official presentation of the work done by the experts. It is the result of their backstage work. The theoretical framework in terms of role-playing, frontstage and backstage that Bijker et al. (and other scholars) mobilize, could be easily applied to the work of the EFSA panellists. The framework can, in fact, be applied to a very wide range of different situations and activities, which is undoubtedly one of the reasons of its success. However, the ease with which it can be applied might be a good reason to refrain from using it. How can the question of the particularity of any activity or practice be posed if it is made to correspond to theatre? And what is the particularity of *theatre* then, as an art-form, if it can be compared to what experts do when they are deciding upon matters that will impact the very society they live in? The ease with which the theatre metaphor can be used suggests that its applicability is, quite possibly, the result of the fact that it renders invisible what distinguishes different practices.

The metaphor of the stage suggests a division between the reality of a situation and the ‘staged’ roles individuals play in that situation. As such, it risks downplaying the

consequences of the situation that is created. Role-playing on stage doesn't allow to account for the importance of the engagement that the meeting room requires. In chapter 1, I described how ILSI organizes Consensus conferences as a way to translate scientific data into a stratagem to assess food with health claims and put them on the market. What happens in the ILSI meeting room is not the gathering of actors on a stage that is 'at their disposal'. Having a stage at your disposal is precisely what ILSI's metaphor of the 'neutral platform' conveys: ILSI offers a neutral platform where various predefined 'stakeholders' can meet and discuss science, for the sake of society. The platform is presented as something *available*, like an empty stage that is available for anyone to step onto, and to step off again with the same ease. However, as I have argued in Chapter 1, the actual stake with ILSI was the *creation* of that very stage or platform, and the *creation* of a credible body of scientific concepts and expertise.<sup>104</sup> Likewise, the expertise of EFSA is *part of the problem* of health claims, and conflicting definitions of expertise are generated by the health claims problem as a space of mobilisation (chapter 5). That is what I want to ask in this chapter with respect to EFSA: how and why can this agency speak in the name of science?

This aim is in line with some of the critiques that have been formulated when Collins and Evans (2002) announced a 'Third Wave' in science studies – that is: expertise as a new topic for social theorizing and normative questions about experts in society.<sup>105</sup> Jasanoff (2003) and Rip (2003) replied that such theorizing is not new, and that Collins and Evans' conception of a 'normative' theory is somewhat naive<sup>106</sup>. Both Rip and Jasanoff insist that the problem of expertise cannot be detached from specific problems and historical circumstances. What counts as knowledge in the first place? Who decides upon that, and what are the consequences? As Jasanoff puts it:

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<sup>104</sup> Keating and Cambrosio (2000) argue in a similar fashion, while introducing the notion of the (biomedical) 'platform'. If we give 'platform' that particular meaning, then ILSI's use of the word 'neutral platform' becomes something of an oxymoron.

<sup>106</sup> Jasanoff says: "The bottom line advocated by C&E, then, is that there can be too much as well as too little public involvement in technical decision-making, and we need better conceptual tools with which to determine how much is 'just right' in any given situation." This remark could also be made for Bijker et al. (2009) proposing an evaluation scheme based on the nature of risks (defined by whom?) to broaden or restrict participation, which is their idea of a theory of democratic society.

*(T)he intellectually gripping problem is not how to demarcate expert from lay knowledge or science from politics (though reflexive attempts to make such demarcations should be taken seriously). Such demarcations will keep being produced in any case, in the everyday work of scientists, citizens and institutions of governance. Showing what is at stake in the making of such boundaries is another matter. That is a fitting place for critical science studies scholarship.*

(Jasanoff, 2003, p. my emphasis)

In what follows, I briefly discuss how ‘science’ became a mobilizing concept after a number of food scandals. Therefore I call science a political ‘operator’<sup>107</sup>.

## Science Reinforcing the Market

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The European Food Safety Authority (EFSA) is a European agency based in Parma, Italy. Its creation in 2002 was part of a larger reform of European food policy in the wake of the BSE contamination scandal in the late 1990s<sup>108</sup>. This food scandal triggered a political crisis on the European level. Confusion abounded as to who decided what within the European Commission. The latter was criticized of being an obscure body where political interests and technical expertise (mainly British veterinarians) coincided in committees outside public view. As a consequence, the health risks for humans eating British beef would have been minimized under influence of British veterinarians in the expert committee<sup>109</sup>. In other words, scientific judgment about the risks of contamination was deemed to be contaminated itself by commercial interests of British meat producers, leading to a delayed reaction of the European Authorities, and a number of human casualties (ref). The trade embargos against British beef that followed, and the sudden drop in meat prices all contributed to the qualification of these events, by the European Commission, as a crisis of political credibility:

*The BSE crisis not only revealed the failure to establish a stable and internationally credible community of scientific experts on food safety, but also exposed serious shortcomings in the overall co-ordination of European policies on agriculture, the internal market and human health. European citizens and the European Parliament have raised concerns that various Member States might have used their position in the comitology system to further national economic interests rather than Community health and safety goals.*

(Majone, G. 2000, p.282)

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<sup>107</sup> I draw inspiration from Dodier and Barbot (2008) and their research on controversies around the treatment of AIDS. I will make a more elaborate use of ‘operators’ in chapter 5.

<sup>108</sup> bovine spongiform encephalopathy, known popularly as the ‘mad cow disease’.

<sup>109</sup> Fallon, C. (2002) ‘Apprendre des crises: la “vache folle”’, In: *L’expertise en questions. Domestiquer l’incertitude dans la société du risque*. Bruxelles: Peter Lang

It was a crisis, above all, because it posed a threat to the Single Market (Fallon, 2002). To restore citizen's and consumer's trust, it was decided to reconfigure the area of food policy (Demortain, 2007; 2011), and agri-biotech policy more generally (Levidow and Carr, 2007). This, by europeanising expert advice (Levidow and Carr, 2007), or – perhaps more correctly – europeanising existing expertise *differently* (Majone, 2000). Before EFSA was created, the Commission had a Scientific Committee on Food, and many of these experts have been displaced to EFSA, while others took up a position at the Directorate General of Health and Consumers of the European Commission. A core of staff members was necessary to ensure continuity<sup>110</sup>, in the transition from the old system to the new system separating scientific advice from political decisions.

The European Food Safety Authority (EFSA) was created to centralize scientific expertise in Parma, removing it physically from decision-making bodies in Brussels. Decision-making would now rely upon information obtained elsewhere through the scientific practice of risk assessment. It was the principle of risk analysis, as originally proposed by the US National Research Council in the 1980s, that inspired European policy-makers to reform the area of food policy and create EFSA as a separate scientific agency<sup>111</sup>. The principle of risk analysis separates risk assessment from risk management, the latter depending on the former to provide a politically “neutral” evidence-base for subsequent decision-making.

The BSE crisis in 1996 and the dioxin scandal of 1999 have led to the integration of different pieces of legislation and to amendments of existing legislation. The Commission drafted a White Paper on Food Safety in 1999, and published it in 2000 (European Commission, 2000). It is here that the Commission first laid out an institutional design for EFSA (Demortain, 2008). The White Paper also proposes a new legal framework for the circulation of foodstuffs and the protection of health. It introduces the ‘farm to table’ approach and the related primary concern of *traceability*. In the wake of the food scandals, efforts had to be made to monitor the entire food chain. This, in order to trace the origins of possible contaminations. Such an integrated approach asks for monitoring devices, and also for collaboration and networking between the different Member States:

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<sup>110</sup> Personal interviews with EFSA panelists (16/12/11 and 25/03/12), and with an official of the Commission's DG Sanco (23/04/13).

<sup>111</sup> See Demortain (2011) for a history of the principle of risk analysis. The principle as such was proposed in the Commission's 2000 White Paper on food safety. See: European Commission (2000)

*After Years of piecemeal legislation, the system that emerged after 2000 created a web of legal obligations that would eventually make every cow and beef product in Europe fully traceable at all times. Stock was to be identified through individual ear tags (...), computerized databases and animal passports (...). Cows became, in this sense, the first truly European citizens, caught throughout their life in a transnational network of identification and surveillance.*

(Lezaun and Groenleer, 2006)

Lezaun and Groenleer further explain that the EU has become an increasingly *territorial* actor in response to several food control emergencies. Such emergencies are a threat to the internal market as they lead to embargos, border controls, conflicts and mistrust amongst Member States. The establishment of a homogeneous control space imposes obligations, makes collaboration necessary, and harmonizes up to a certain degree the heterogeneous and incompatible monitoring systems across Europe. Andrew Barry (2001) described a similar process of harmonization and monitoring with respect to air pollution, leading to a specific *technological zone* related to that problem.

The building up of an international monitoring network, goes on a par with a certain degree of centralisation: the White Paper proposes the establishment of a ‘European Food Authority’:

*This Authority would be entrusted with a number of key tasks embracing independent scientific advice on all aspects relating to food safety, operation of rapid alert systems, communication and dialogue with consumers on food safety and health issues as well as networking with national agencies and scientific bodies.*

(European Commission, 2000: 3)

Later, Europe’s General Food Law, published in 2002, details the missions and procedures of this new Authority and notes the importance of not confusing it with the European Medicines Agency<sup>112</sup>. The White Paper states that: *the use of scientific advice will underpin Food Safety policy, whilst the precautionary principle will be used where appropriate* (p.3).

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<sup>112</sup> General Food Law, p.6 recital 65. See: European Commission (2002).

Both the White Paper and the resulting General Food Law introduce the necessity of the ‘best available science’<sup>113</sup> or ‘a science base’<sup>114</sup> to support food safety policy. Loeber, Hajer and Levidow (2011) argue that there has been a change in vocabulary of the media as well, since the reform of EU food policy: if dioxins found in milk in the late 1980s were called an ‘environmental scandal’, the presence of those same dioxins 10 years later were called a ‘food scare’. This shows that a pervasive institutional and discursive change with regards to contamination has taken place. I argue that the introduction of ‘science’ takes part in that change. The answers given to the food crises have not led to a questioning of the system of food production and distribution, but to an increase in control (Lezaun and Groenleer, 2006). Collecting data became important for things to become traceable. This permitted, at the same time, to keep the system of food production and distribution – the Single Market - in place (Fallon, 2002). Political questions about Europe’s complex food production system were now to be formulated in such a way (a ‘scientific way’) so that the response would have to be pronounced in terms of ‘data’. The previous chapters showed that the question of health claims had already led to discussions about consumer protection, different attitudes amongst Member States, and a court case. Health claims promised to be a political problem, so the best way to have them on the market (a ‘stakeholder’ request) while ensuring consumer protection (a task of the Commission) would be to tame the issue by establishing data through ‘science’. In the following sections I discuss EFSA’s economic and juridical constraints; EFSA’s task for assessing health claims; and how scientists become experts in EFSA’s panel on Nutrition, Dietetic Products and Allergies (hereafter: ‘the NDA panel’ or ‘Nutrition panel’).

## Economic Constraints

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EFSA’s mission is: “(to) ensure a high level of consumer protection and restore and maintain confidence in the EU food supply.”<sup>115</sup> This is a political mission, and it establishes a gatekeeper between industry and the market. However, EFSA’s existence, and the mission of its Nutrition panel in assessing health claims, is not the result of a long project, over

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<sup>113</sup> see for example: White Paper, p.9, where science is mentioned as one of the principles of food safety, along with the principle of risk analysis.

<sup>114</sup> General Food Law, p.6 Art. 1 (1).

<sup>115</sup> Source: efsa website: <http://www.efsa.europa.eu/en/aboutefsa.htm> (accessed 15 March 2014).



generations, of a community of ‘therapeutic reformers’ (Marks 1999). What politically holds together EFSA’s experts, is a different trans-generational project: the Single Market.

Irrespective of differing personal convictions of these experts, EFSA’s *collective* mission is not anti-commercial in nature. They are market gatekeepers that have the assignment to *make scientific research results comparable*. As I will explain further below, they have to ‘gather data’ from various sources and various types of trials and research results involving molecules, bacteria, contaminants, pesticides, GMO’s, humans, rats, test tubes, and review papers.

EFSA’s panelists do not develop their entire career through the NDA panel either: they have mandates of 3 years, renewable<sup>116</sup>. And as I already mentioned: it is a mandate that they exercise on top of their normal job and other functions. In other words, EFSA’s missions and working doesn’t coincide with the biography of persons and groups. “Everyone is replaceable”<sup>117</sup>, and this is precisely what happens.

Created after the BSE crisis, communication and stakeholder involvement are amongst EFSA’s values. The agency regularly organizes a Stakeholder Consultative Platform<sup>118</sup>, composed of a small portion of environmental NGO’s and consumer organisations, and a larger portion of organisms (federations, NGO’s) defending the interests of the agri-food and chemical industries<sup>119</sup>. I attended one of those Platforms in december 2010 as an observer<sup>120</sup>, at a time when EFSA was soon to be evaluated for a second time by an external consultant. EFSA’s executive Director at that time, Catherine Gheslain-Lanéelle, made up a balance at the changes in EFSA’s work since its creation in 2002. The points she raised give an indication as to what extent EFSA’s scientific advice must be operationalized *as part of an environment* that is conditioned by the imperatives of the Single Market<sup>121</sup>:

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<sup>116</sup> See EFSA website: <http://www.efsa.europa.eu/en/scpanels/newpanels.htm>

<sup>117</sup> Remark of the former vice-chairman, whose mandate was running to an end (interview 16/12/11)

<sup>118</sup> Again, the notion of the *platform* makes its entry.. EFSA’s platform meets three times a year.

<sup>119</sup> For more information and a list of organizations that make up the Platform, see: <http://www.efsa.europa.eu/en/stakeholders/cp.htm>

<sup>120</sup> This requires prior demand and inscription. An observer cannot participate in the discussions.

<sup>121</sup> The points detailed are from my personal notes during participation in an open meeting of EFSA’s Stakeholder Platform, 8-9 December 2010.

- The number of questions EFSA has to deal with has doubled the past year (940 in 2010 vs approx. 450 in 2009). These questions mainly come from risk managers and the Commission.
- The output is becoming more and more oriented towards **applications**: risk assessment for new products and technologies, health claims etc. Currently (December 2010), 70% of EFSA's output falls within the category of 'applications'
- EFSA is now being asked not only to look at risks, but also at 'efficacy' or **benefits of products**. Work has already been done on GMO's, and other work is being initiated on pesticides and feed additives.
- EFSA is now being asked by the Commission to look at **environmental impact**, and not only public health, in its risk assessments. Ensure that the food chain is sustainable (e.g. pesticides, GMO's, feed additives....)

Lanéelle also mentioned criticisms from within the Platform: EFSA does not deliver the same service to applicants as for example the EMEA (European Medicines Agency) or the ECA (European Chemical Agency) do. She also referred to a question, posed by the CIAA (Confederation of the European Food and Drink Industries) during a 'scientific workshop' on health claims, on guidance and pre-submission meetings between EFSA and applicants (as EMEA does). Lanéelle stated that, at that time (2010-2011), this was not possible because of budgetary restrictions. But, said Lanéelle, a part of the budget had been shifted to applications research (40%, and expected to increase to 50-60% in the coming years). This was necessary to 'deliver on time'. Still, even a shift of all resources to application would not have enabled EFSA to process the same number of demands as the EMEA was doing. Lanéelle assured that EFSA was now 'streamlining its workflow' in an efficiency project. Then Lanéelle communicated what she said to be the key message she wanted to give to the Platform: *EFSA does not want to be a bottleneck for innovation.*

The need to 'deliver on time', and the comparisons that EFSA's industry stakeholders make with an agency such as the EMEA, shows that EFSA is constantly put under pressure to adapt and review its 'workflow'.

## EFSA and the Health Claim: Making Data Available

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In 2007, The NHCR was adopted by the Parliament and the Council of Ministers, and entered into force. The main objectives of this Regulation are: “to ensure consumer protection from misleading messages on food labels; to ensure fair competition for industry and opportunities for innovation; and to contribute to Europe's single market policy for food products<sup>122</sup>. However, these main objectives are easier to cite on paper than to reconcile in reality.

The particularity of EFSA's NDA Panel, is that they have to assess the scientific evidence for the *efficacy* of claims: is there enough evidence to support the claim? Is the claim true? The Commission then makes the final decision about the adoption of the claim. In this sense, the NDA panel's task is somewhat different from the other panels, because they are not preoccupied with *risk*. They assess the veracity of claims on food components that are a priori considered safe<sup>123</sup>.

Food companies must transfer a scientifically substantiated dossier (also called portfolio) for any health claim they wish to make on a product to the competent national authority. The latter then sends the dossier to EFSA, and to EFSA's Nutrition, Allergies and Dietetic products Panel (NDA Panel) more precisely, for scientific evaluation. The portfolio is what makes the Panel's work possible: it obliges the applicant to provide structured information, and it sets the terms of the assessment exercise that the Panel has to do. The portfolio provides a first basis for the existence of 'available data', precisely by making various published (or unpublished) research results available. Before becoming 'data', these were various research results from various sources.

The evaluation is transferred in the form of a scientific opinion to the Commission's Standing Committee on the Food Chain and Animal Health. This Committee makes a final decision, based on EFSA's expert opinion.

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<sup>122</sup> NHCR, L404/9, recitals 1 and 2.

<sup>123</sup> Interview with Vice-Chair of the NDA Panel 16/12/11.

The NDA panel is a multidisciplinary panel of 20 members and a chairman. The panel includes members from a variety of disciplines such as immunology, microbiology, toxicology, epidemiology, genetics, chemistry and paediatrics. Together, the panel members assess the available data that support the health claim, in an exercise that consists of *weighing* the evidence from different types of trials, reported in peer-reviewed journals and unpublished studies presented in the dossier, together with review studies and meta-analyses if these are available. The final judgment, EFSA's scientific opinion, is thus the result of the weighing of different types of data through a hierarchy of types of scientific evidence and the search for consensus among the Panel Members – a search which has, according to the panel members always been successful until today<sup>124</sup>. In June 2011, EFSA finalised the evaluation of the "general function" health claims prioritised by the Commission. This is a list of generic claims, the so-called Article 13.1 claims, the completion of which was programmed by the NHCR for January 2010 'at the latest'<sup>125</sup>. Establishing the list had proven more difficult than was thought, and contestations built up while EFSA was publishing its opinions through different batches between 2008 and 2011 (chapter 5).

The generic claims refer to: "the role of a nutrient or substance in growth, development and body functions; psychological and behavioural functions; slimming and weight control, satiety or reduction of available energy from the diet"<sup>126</sup>. These claims must also be "based on generally accepted scientific data" and "well understood by the average consumer"<sup>127</sup>. These claims do not include those related to child development or health or disease risk reduction. On the 14<sup>th</sup> December 2012, a list of permitted health claims entered into application under Regulation (EC) No 432/2012. Next to 222 general function health claims, the list also contains 30 nutrition claims, and 21 health claims referring to the reduction of disease risk factors or child development. 1631 health claims have *not* been authorized, and 2303 health claims remain under consideration, still awaiting more data. (Mathioudakis, 2013).

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<sup>124</sup> Interview with Member NDA Panel, 22/01/14.

<sup>125</sup> NHCR 404/17

<sup>126</sup> *Ibid.*

<sup>127</sup> *Ibid.*

## Legal Constraints

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Earlier I already discussed an important constraint of the working environment of EFSA's nutrition panel: the demands of the Single Market and its agents in terms of 'delivering in time' and more dialogue with stakeholders, preferably with guidelines on how to submit applications for the approval of a claim. At present, EFSA has created a number of guideline documents and a virtual helpdesk on its website. Another (yet related) constraint is legislation.

EFSA's NDA panel is a multidisciplinary panel of scientists from different branches in the life sciences. Within the panel, these scientists, as experts, are not concerned with the active search for ways to put molecules to the test, but their task is to judge the evidence provided in dossiers or 'portfolios'. They act on behalf of the regulatory authorities, and according to the health claims Regulation NHCR and the relevant food law the NHCR refers to. Their discussions relate to science and the setup, rigour, flaws and outcomes of clinical trials about the efficacy of claims. But despite the scientific content of their discussions, their practice is essentially judicial or regulatory, putting together the results of unrelated scientific experiments and then *weighing* the totality of the evidence. A decision on the science-base of a claim must be made preferably by consensus. In parallel, the dossier must comply to the NHCR. EFSA's nutrition panel is obliged to work within the framework of the NHCR. The NHCR assigns a mission to this panel, and this mission obliges them to deliver decisions. How do scientists become experts? Is this simply a role they take up? Do they fluently coordinate and distinguish the scientific backstage from the advisory frontstage?

This is how a former Chairman of EFSA's NDA panel put it:

*I think the challenge comes when you're called upon to make a **scientific judgment**. So when you put the data together from many different studies, (...) and you put that evidence together in totality, and you then say: what does the evidence in totality show? So you might have studies showing one thing, and you might have contradictory studies, showing something different, you know. And now you have to weigh the evidence. And **so you have to make a judgment** on what you think is the truth, because the evidence may point sometimes in different directions. And I think that is the most critical part: it's when you have to **weigh the evidence** to come to an overall conclusion. And that's where you can get different opinions, because people might give different weight to different data. And depending on their own expertise and background they may give extra weight to some types of studies. Now that's really the most challenging part I think.*

(Interview 25/03/12, my emphasis)

The EFSA panel doesn't directly put a molecule or nutrient to the test, but it evaluates the different ways in which a molecule or nutrient has been put to the test *by others*. The panellists all have a scientific background and their discussions have a scientific content, but they essentially evaluate the rules, protocols, and setups of trials, and the trustworthiness of evidence and sources. In their advisory role to the Commission, they perform a judicial/regulatory task: their mission is to 'implement' European legislation on health claims. The specificity of the panel's work becomes clear in the next citation of the same Chairman:

*I find, and I have experience in chairing this panel and other committees for some years, and you can get scientists to look at the evidence and to agree on a draft which describes all the data. And where you find the scientists **hesitate** is when you say: ok, we've discussed the data for hours and hours and hours, we've got the draft, **what do we conclude?** And this is where experts will always stand back and say: I'm not sure. And the first reaction you will get from an expert (starts laughing)....is.... "we need more data" (laughs out loud). And that is the **freedom** that a researcher in academia always has: (this is how many papers) conclude: " we have discovered this, but we can't conclude, we need more data. But, in the area of scientific advice, **you cannot conclude that way**. You have to make a conclusion with the data you have. And this is the big challenge for these expert committees: with the data here in front of us today, what is our conclusion? Because the BIG fear, the big fear of experts, and this is (starts laughing while emphasizing) BASIC fear.... They're afraid they might draw the wrong conclusion.*

*(Ibid., my emphasis)*

The Chairman neatly describes the tension between the search for new data on the one hand - the 'freedom' of academic researchers- and the need to draw a conclusion, which is the panel's mission, on the other. The scientists of his panel hesitate, and the Chairman's has to channel these hesitations towards a conclusion. He recalls them that they must behave as scientific advisors and not as academic researchers *while in the panel*. He must recall them what their 'role' is, because scientists do not take up the role of being an 'expert' like an actor takes up a role on stage. It is more difficult than that. This may explain why their fear of drawing conclusions, and certainly 'wrong' conclusions, is so basic or primeval. The Chairman's insistence of fear is remarkable, all the more because many of these experts *already have experience* with 'being an expert'. Demortain (2011) and Granjou (2013) are just two examples where experts (in other bodies than EFSA) are shown to have specific career paths in which they cumulate mandates. The fear that the Chairman mentions, is important because it points to the fact that scientists have difficulties with their attachment to different *practices* (judging versus knowledge production), rather than to 'social worlds'. The

Chairman's interventions are there to detach experts from their scientific practice and to attach them to an environment of political, legal and commercial constraints. These constraints create an entirely original category, which is often presumed to exist before hand: 'the data available'. The imperative to form a judgement creates the category of 'available data', and not the other way around, because, as the citation indicates, 'academic' scientists *have the freedom of not accepting the category of available data*. They say: "we need *more data!*"

EFSA has been created to make 'available data' exist. For the NDA panel, the portfolio's are a first proto-structure of a possible claim as it makes data comparable. The exercise of comparison and judgement, which the Chairman must help channelling out of hesitation, stabilizes what are called, after the fact, 'available data' or *evidence*. And evidence may be sufficient or lacking. While food companies target human bodies as bodies of suboptimal health, EFSA – in conjunction with the portfolio's provided by those companies – establishes bodies of evidence.

As an original category, the *evidence* generates a space of mobilisation of its own, and, as I argue in the next chapter, a *morality* of its own.





## Chapter 5 Food and Scientists Put to the Test

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*Article 6 of the Claims Regulation bears the title: 'Scientific substantiation for claims'. This requirement of scientific substantiation is rather vague. Moreover the wording of this requirement has changed during the legislative process. According to the initial proposal put forward by the Commission, health claims should be substantiated by "generally accepted scientific data". This phrase has subsequently been changed into "generally accepted scientific knowledge" and "generally accepted scientific evidence". The Claims Regulations as published on 20 December 2006 uses the phrase: "generally accepted scientific data". This turned out to be one of the errors made in this text that necessitated the publication of a corrigendum on 18 January 2007. "Generally accepted scientific evidence" is what it is going to be. The Claims Regulation does not give a further clue as to the interpretation of the concept "generally accepted scientific evidence". It seems to have been left to the scientific community – if such a thing exists – and to case law to provide a further interpretation of this legal norm.*

(Povel and van der Meulen, 2007: 1)

*Ladies and Gentlemen, research on nutrition has two faces. You could call it Dr. Jekyll and Mr. Hyde: on the one hand, if you talk about food patterns, then most nutritionists will agree that a nutritious diet will be good for health. But on the moment that you move to individual food(s), the situation is euh, completely euh... different.*

(Daan Kromhout, Conference Chair, my transcription.)

The first quote is from two jurists writing about the NHCR, when it had just entered into force. They observed that the category 'generally accepted scientific evidence' didn't come with a manual. They wonder what sort of scientific community will tackle the question. The second quote addresses a public of scientists. It is not clear whether they are a 'community', but they do have a shared concern. In the quote we read the opening words of a conference held in Amsterdam, in March 2012, at the Royal Netherlands Academy for Arts and Sciences (Koninklijke Nederlandse Academie voor Wetenschappen, hereafter: KNAW)<sup>128</sup>. The shared concern of the scientists gathered was: what is scientific evidence for nutrition and health claims?

Isn't that a strange question, 6 years after the Nutrition and Health Claims Regulation (NHCR) was drafted? Hadn't EFSA been charged with the mission of evaluating health

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<sup>128</sup> I attended this symposium in Amsterdam on the 26th March 2012 and recorded the discussions. The keynote presentations have been made available on the KNAW website as audio files, and the slides can be downloaded as pdf files: <https://www.knaw.nl/nl/actueel/beeld-geluid/wetenschappelijk-bewijs-voor-voedings-en>.

claims according to generally accepted evidence? During these years, however, a problem has taken form. The problem is that EFSA has rejected some 80% of health claims submitted<sup>129</sup>. A particularly problematic point for certain food companies is that not a single probiotic product (containing ‘beneficial bacteria’ like Yakult, Actimel, Valio) has been approved to date. However, criticism against EFSA’s evaluations not only came from industry, but also from academic researchers. But, in the realm of health claims, does it make sense to distinguish the two?

In what follows, I focus on a discussion between EFSA and its stakeholders on the nature of scientific evidence and how to assess health claims on food. I delineate the contours of a *space of mobilisation*, and the *political operators* that mobilize actors within this space. I draw inspiration here from Nicolas Dodier and Janine Barbot in their research on disputes around AIDS research and clinical trials<sup>130</sup>. I propose two political operators, as controversial topics, or matters of concern (Latour, 2005): ‘evidence’ on the one hand, and ‘affiliation’ on the other. The distinction between these operators is only useful for analytical purposes, because they do not exist independently from one another. Together, these operators ask the question of the *provenance* of ‘good science’: what is good evidence and where does it come from? Who has right of speech? ‘Evidence’ and ‘affiliation’ are political operators because they create the debate and serve as political resources. Both operators suggest that good science is related to specific spaces, and to a specific way of being or operating in the world.

## Food and Drugs

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When the NHCR charged EFSA to assess health claims on food products, it appointed EFSA as an expert body on the matter. However, EFSA’s many rejections has spurred reactions from different angles, questioning EFSA’s scientific method of assessment, and even its expertise altogether. For example, NutraIngredients, a business newsletter for the health foods and ingredients sector, resumed the state of affairs mid-2011 in this rather straightforward manner:

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<sup>129</sup> [http://www.just-food.com/news/efsa-rejects-80-of-health-claim-proposals\\_id114931.aspx](http://www.just-food.com/news/efsa-rejects-80-of-health-claim-proposals_id114931.aspx) (last accessed on the 3<sup>rd</sup> April 2014)

<sup>130</sup> Dodier, N., Barbot, J. (2008)

*EU Researchers Revolted as EFSA Clears Health Claims Vault*

*The European Food Safety Authority last week delivered the fifth batch of article 13, general function health claim opinions bringing the total issued to 2723. There are just 35 to go – to be published next month in a final mini-batch that will conclude the task begun in August 2008.*

*The Parma-based agency is no doubt slapping itself on the back for completing an exhaustive and gargantuan task, but industry and academia would prefer slapping the face of EFSA's health claim panelists who have for the best part of three years relentlessly rejected so much nutrition science.*

(Starling, 2011)

The title already opposes 'researchers' to EFSA 'clearing a 'vault'. According to the definition of the Oxford English Dictionary a vault is "A large room or chamber used for storage, especially an underground one"<sup>131</sup>. The expression 'clearing a vault' then suggests that EFSA's Nutrition panel (the NDA panel) has not done a very delicate job, but more of a general sweep-up in a storage room, throwing away things without much consideration. The last phrase goes in the same direction: EFSA has 'relentlessly rejected so much nutrition science'. What does this mean? Isn't EFSA's NDA panel the very specialist in the field of nutrition science?

Different scene. In October 2012, I attended a small conference organized at the University of Liège, entitled: "Faut-il croire aux vertus des probiotiques"? The conference was one in a series of talks called 'parole d'expert', within the general theme of research and innovation<sup>132</sup>. The expert invited was Professor Bruno Pot, microbiologist and Research Director at the Institut Louis Pasteur de Lille. Prof. Pot started his slide presentation by immediately answering the question about believing or not in probiotics with his first slide: "Nobody knows anymore..."<sup>133</sup>. Probiotics is a term used for bacterial strains with supposed beneficial effects for human health, or for a product containing such bacteria like certain brands of yoghurt. Prof. Pot was particularly worried about the fact that EFSA's NDA panel had not approved any single probiotic claim at that time (which still is the case at the time of

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<sup>131</sup> Definition according to the Oxford English Dictionary. The word 'vault' also has a different meaning: "A roof in the form of an arch or a series of arches, typical of churches and other large, formal buildings". This definition, of course, makes no sense in the context of the title of the article I discuss. See: <http://www.oxforddictionaries.com/definition/english/vault>

<sup>132</sup> Organized by Liège Créative, a 'platform' or 'interface' between academic research and commercial development, societal utility, etc.

<sup>133</sup> The slides were made available to participants of the conference.

writing). The summary of his presentation which announced his talk on the University website expressed the concern like this<sup>134</sup>:

*Les raisons ne sont cependant pas claires. 300 dossiers qui représentent plusieurs centaines de millions d'euros ont été jetés à la poubelle... Un débat de fond semble aujourd'hui nécessaire. Celui-ci concerne à la fois les producteurs qui ont perdu leurs investissements en "recherche" santé, les scientifiques qui ne savent plus comment orienter leurs recherches, mais aussi et surtout les consommateurs qui n'ont plus aucun moyen pour faire la distinction entre les produits sérieux et les produits "cowboy" présents sur le marché : cela au risque de perdre des bénéfices importants pour leur santé !*

This summary is interesting because it points to three specific types of concern, voiced by three different groups<sup>135</sup>: first of all, *producers* have lost on investments, and *this can't be right*. Secondly, *scientists* no longer know how to orient their research: they are said to be 'lost' and this conveys a sense of *abandonment*. Thirdly, *consumers* are said to have lost all references and sense of distinction between good products and 'cowboy' products. This third argument makes a dramatic qualitative leap: not recognizing the promises of probiotics may pose a *risk to public health*. This is reminiscent of ILSI's insistence on the role of functional foods to public health<sup>136</sup>. Differently put, both ILSI and Prof. Pot here directly relate 'science' and the market, with 'science' as an arbiter that protects human health by asserting its own validity in contrast to imposters, charlatans, or, as Pot has it, 'cowboys'. Isn't this precisely what the NHCR asks EFSA to do: acting as a scientific arbiter to protect both the market and the consumer? For Pot, EFSA puts aside good science and hampers innovation. He talks of an unjust loss of investment and suggests abandoned, perhaps even discouraged, scientists.

Others defend EFSA precisely because it uses good science to prevent the circulation of profit-driven, false, or misleading health claims from entering the European market. For example, Nutrition scientist and member of the KNAW Professor Martijn Katan, who also has a regular column in Dutch newspapers, concluded a short piece on health claims in the EU as follows:

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<sup>134</sup> The summary is no longer available on the website. However, Pot pointed out the same concerns in an interview with the business magazine NutraIngredients, which is available at: <http://www.nutraingredients.com/Regulation/Valio-EFSA-ignored-peer-reviewed-data-in-probiotic-claim-rejection>.

<sup>135</sup> I elucidate the sense of the citation and prolong it, to get a grip on the arguments presented. I am not taking the description for granted.

<sup>136</sup> And Pot makes explicit reference to ILSI's probiotic task force and its latest publications, by way of a positive note, despite all bad news concerning EFSA's assessments. He says that organisations like ILSI or 'on it' and are making progress in the matter.

*If science remains the standard, then a lot of stuff will disappear from the shelves of your local drugstore. This is unfortunate for the producers, because the profit margins on those little bottles are very interesting. But the consumer is better served by supplements that really help.*

(Katan, 2009)<sup>137</sup>

Again, science is the arbiter, but Prof. Katan predicts that a lot of ‘little bottles’ (e.g. Actimel, Yakult) will disappear if science ‘remains the standard’<sup>138</sup>.

As I have argued in the previous chapters, once the word 'science' is being mentioned, things can get complicated. It is a word that is central to what I want to describe; it is central up to the point that it can even stand in the way. If many different actors attach ‘science’ to different kinds of arguments, like I have shown in chapters 3 and 4, ranging from the political, the commercial to the moral, then what is there left to say about ‘science’?

The majority of health claims have been rejected by EFSA, and both academic researchers and the food industry feel that this is unjustified, as they consider that their dossiers have been firmly backed up by scientific evidence. EFSA thinks the contrary and points to the flaws in the dossiers, the insufficient characterization of substances, bad statistics and other problems<sup>139</sup>. I have attended several symposia where terms as 'good science' and 'sound science' are being opposed to 'bad science' and 'old science'. And these terms travel in several directions: different parties are accused of pertaining to bad or old science, and all parties self-proclaim their adherence to ‘sound science’. In addition, throughout the debates, 'science' has become attached to the notion of *independent advice*, and different views exist on what this means. Finally, issues about responsibilities, innovation, public health, chronic diseases and health care costs all get drawn (and sometimes drowned) in the pool of polite or less polite animosities that characterizes many meetings between EFSA scientists and others.

In the health claims debate, one notices that science is a concept that is attached to, or detached from, different sets of practices, spanning from the political, to product development, to regulatory procedures and others. This is why I said that science's centrality

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<sup>137</sup> Press article of 2009, reproduced on Katan's website. Original publication not specified. See: <http://www.mkatan.nl/radio-en-tv/134-gezondheidsclaims-en-de-eu.html>

<sup>138</sup> Originally in Dutch: “als wetenschap de doorslag blijft geven”.

<sup>139</sup> Interview with a former vice-Chair of the EFSA NDA panel, 16/12/11.

makes it stand in the way. To produce an account that doesn't drown in its own polysemy, I will follow Isabelle Stengers' proposal to seek out the practices and practitioners that all claim to be involved in 'science', and more precisely in the life sciences<sup>140</sup>. My aim and challenge is to produce an account that makes *difference* intelligible in other terms than that of a single 'science' which is limited in its modes to being either good or bad, or independent versus biased. I would like to avoid leaving the reader with the idea that "in the end, it's all about...". About money for instance. Or marketing. These issues are definitely important to product developers in the food industry. But this doesn't in itself explain why a controversy should arise in the first place, and why the health claims arena has become so densely populated, not only with food companies, but also lawyers, doctors, toxicologists, gastroenterologists, pediatricians, microbiologists, rats, mice, bifidobacteria, chicory root, and European health strategies<sup>141</sup>. A first reason, I argue, why health claims and the evidence for them have become so debated, is that functional *foods* may look too much like *drugs*. I turn to this problem now.

## Putting Molecules to the Test

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In general terms, health claims are about separate ingredients, often molecules, but also bacteria, and an effect on the human body. But what kind of effect? If it is *therapeutic*, by curing, treating or preventing a disease, then the claim becomes a medicinal claim. And such is prohibited by law, as we have already seen.

In *Qu'est-ce qu'un médicament*, historian Philippe Pignarre (1997) explains that a 'modern drug', sold in the pharmacy in exchange for a doctor's prescription, comes into existence in a very specific way. Shortly after the Second World War, the placebo controlled double-blind test, or randomized controlled trial (RCT), became the standard method to test the efficacy of drugs<sup>142</sup>. Otherwise stated: the RCT puts the candidate molecule to the test. The answer to the question if a substance 'works' or not, determines if the candidate molecule actually becomes a drug, and the RCT proposes a specific dramaturgy to make the molecule

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<sup>140</sup> On the notion of practice and 'ecologies of practice', see Stengers (2006).

<sup>141</sup> The word 'controversy' is used occasionally by the actors involved, but the discussions remain fairly restricted to specialists. I do not search for the definitive correct term (polemic, debate, controversy, ...) but attempt at understanding the different uses of the word 'science' by actors and how this generates new discussions.

<sup>142</sup> For a general history of the rise of the clinical trial, see Marks (1999).

enter the world of human organisms. When a molecule engages into interactions with the human body it becomes socialized. The specificity then, of the modern drug, is that the socialization of molecules consists of a confrontation with the placebo effect. Without this confrontation, we would have no reason to attribute the cause of curing to the molecule only<sup>143</sup>. In Western biomedicine, the molecule is what counts as a valid cause. If the test group in an RCT shows a higher percentage of recovery than the control group, then the drug obviously works in some way. However, all mechanisms involved in the healing process are never known, *and the RCT has not been designed to discover these mechanisms*. The passing of status from molecule to drug depends on a statistical comparison between the number of recoveries in the test group and the control group. As such, the RCT is not about the testing of hypotheses in order to advance and modify theoretical and experimental models, but it proposes a *fixed* procedure to test efficacy. The RCT poses the question: “does the drug work or not?” And the possible answers are limited to either “yes”, or “no”.

Referring to Deleuze and Guattari, Pignarre sees the RCT as an *axiomatique*, defining itself and its environment; a ‘middle’ preformatting what enters and sanctioning what leaves. Preformatting refers to the tests that a molecule goes through before being put to trial in the RCT. Pignarre calls this ‘the molecule's learning process’. After tissue tests, the molecule is gradually 'accustomed' to interacting with living beings, seeking out those that have a certain predictive value for later tests on humans. In other words, the requirements of the RCT are moved *upstream*, defining the sort of animals, such as rats and mice, required as laboratory elements in experiments designed to make statements possible about a molecule's agency in laboratory conditions.

In the case of food ingredients: if a molecule, say oligofructose, is said to enhance immune function, then EFSA's panel on Dietetic Products, Nutrition, and Allergies (NDA) wants to see studies that show clinical outcomes in human study groups. Rats and mice may provide additional information, but no health claim can be allowed if the clinical effects have not been proven in/for a human population. We might expect oligofructose to be simply tested for its efficacy on immune function, Calcium absorption, decreasing of pathogens in the gut flora -or whatever claim- and that would be the ‘end of story’. But the story actually only begins here... In fact, the socialization of the molecule, or the *resocialization* in the case of an

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<sup>143</sup> Pignarre explains that, *in fine*, the confrontation with the control group doesn't allow to attribute the recoveries in the test group to the molecule only either.

existing food ingredient, through interaction with the human body, cannot occur under the same terms as in the RCT for drug testing. The molecule is forbidden by law to cure or alleviate disease. Differently put: the ingredient cannot be put into any direct relation to disease symptoms. If it *were* to be involved into such a relation, then the molecule would *switch register* and become a drug. It would actually change different registers at the same time: commercially, legally, technically, the molecule becomes a drug. The consequences of that would be problematic for the food industry. Drugs and disease are not their business. They would have to operate under a different legislation and different technical requirements. They would have to operate in a market that is not theirs, and at higher production costs. The importance of the consequences, also upstream, for a molecule to *change register* in such a way, shows how much the RCT is 'axiomatic' and part of an entire *agencement* making drugs to what they are<sup>144</sup>. An 'agencement' can be explained as a dynamics of imbricated beings affecting one another, a play of forces that cannot be dismembered<sup>145</sup>. If one connection is broken in the molecule's socialisation process with human bodies, then it will never become a drug. If everything holds together, and a significant effect is demonstrated, then the molecule becomes a drug. With this agencement or 'axiomatique', as Pignarre calls it, in place, it can be said that drugs have their own 'territory'.

Since the 1990s, drugs safety standards and pre-market approval procedure have been increasingly harmonised throughout Europe, by creating the European Medicines Agency and a common premarket test. Sociologist Boris Hauray (2006) speaks of 'l'Europe du médicament'<sup>146</sup> and *regulation through networks* across Member States with a common regulation tool: the premarket test. With Andrew Barry (2001, 2006), we could call this territory a *technological zone*, which is a zone defined by the circulation of an object or a common standard<sup>147</sup>.

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<sup>144</sup> I use the French term 'agencement', rather than the English translation *assemblage*, for the same reasons put forward by Callon (2007) and Despret (2013): it better conveys the agency (agence-ment) and dynamic play of forces, as originally intended by Deleuze. See: Deleuze and Parnet (1996).

<sup>145</sup> For a clear description of what an agencement is, as a form of *agency*, with many examples, see Despret (2013).

<sup>146</sup> See Hauray's (2006) book on the history of this Europeanisation process with a special focus on private interests in relation to expertise and politics on the Member State and European level. His central 'object' of focus is the premarket approval procedure.

<sup>147</sup> His book *Political Machines* (2001) focuses on technological zones in Europe and Europe as a technological zone. He also highlights the role of technological devices in making a zone.



So drugs seem to have their own territory, and this has, to a large extent, also become a European territory, defined by common standards across the Member States<sup>148</sup>. In line of these considerations, my chapter on ILSI can now be read as ‘functional foods looking for a territory’. The network of experts that ILSI gathered around the issue of functional foods, has done a lot of conceptual work to avoid food ingredients and health claims being considered as ‘drugs’ with medicinal claims. The functional food stratagem was built to convince peers reading the *British Journal of Nutrition*, or the *European Journal of Nutrition*, that food is a *different* matter, and that a territory, unoccupied by the pharmaceutical sector, lies open for food. That territory, or *market* is that of ‘health benefits’. It is possible, the claim technicians argue, to alter, add or remove components of industrial foodstuffs to the benefit of public health. Food companies want to occupy the territory where the pharmaceutical industry and Western medicine have no solution for the moment<sup>149</sup>: non-communicable chronic diseases such as diabetes, cardiovascular diseases, cancer, and problems related to ageing such as osteoporosis and antibiotics-related gut infections.

But as the modern drug is defined and impossible to dismember from its agencement of production, then functional foods, if they ever want to occupy the territory of ‘health benefits’ must have their own agencement including premarket tests. This is what FUFOSÉ and PASSCLAIM were all about, in anticipation of a European Regulation for health claims. And, indeed, the creation of a European ‘Agency’ for Food was already being discussed in the wake of several food crises in the late 1990s, when the FUFOSÉ project was running. We can now better appreciate why the project was called ‘functional food science for *Europe*’. This was not only because the project had received funding from the Commission’s Directorate General for Research, but also because food companies wanted to create a European market or territory for functional foods. And, even though nutrition research is not a new discipline, everything had to be invented, and existing research *translated* – to make a first *claim* (in the sense of claiming one’s right) to the territory of health. Everything had to be invented at the same time to try and make it hold together like an agencement as powerful as that of drugs:

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<sup>148</sup> I say, ‘to a large extent’, because the Member States still have a role to play, as Hauray (2006) shows. This is why, in the case of drugs, European regulation works through networks relating the Member States to the EMEA.

<sup>149</sup> I refer again to Pignarre, explaining in his 2004 book on the pharmaceutical industry, why innovation has stifled. Western pharmaceuticals are specialized in treating infectious diseases – in combatting targets like viruses and microbes. Many similar drugs were protected by patents, but

the *object* (functional food), the '*science*' (in terms of functional components and target body functions), the *premarket test* (with a privileged role for biomarkers), and the *experts*.

This entire programme, which I have called a *stratagem*, bears resemblance to what Keating and Cambrosio (2000) have called a 'platform' as a heterogeneous dynamics involving humans, objects, techniques, and political referents. A platform is above all a "way of arranging things in both a material and a discursive sense."<sup>150</sup> More precisely, the ILSI stratagem, geared to produce a particular kind of evidence, bears resemblance to the type of platform that generates what Cambrosio et al. (2006, 2009) call 'regulatory objectivity'<sup>151</sup>. As I have shown in chapter 1, ILSI *refers to itself* as a platform: a 'neutral platform'. I therefore stick to the term *stratagem*, which, as I explained, suggests both a strategy but also a *ruse*. I follow Latour's and Stengers' (cosmo)political argument that the world is constantly being composed through hybrid interactions, but that *the ways in which* hybridity is composed and held together matter also (see Introduction). In line with this, I argued that ILSI produces claim technicians. This is a pragmatic distinction that I made between the collective practice of science (where individuals become scientists) and that of claim technology or 'functional food science'. The distinction makes visible an operation, a translation or a specific kind of detour that is essential for ILSI to try and have authority in the political arena: the claim technician, doing something else than producing scientific knowledge, *draws in* the authority of the scientist for other purposes than the creation of scientific knowledge.

When ILSI speaks in the name of science, it is contradicting precisely what constitutes science as a *practice* (Stengers 2006), or a *mode of (exploring) existence* (Latour 2013): taking the risk of allowing the object to redefine the questions addressed to it<sup>152</sup>. The claim stratagem does the opposite as it looks for *fixed* testing protocols that can be used every time.

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<sup>150</sup> when these rights expired, innovation became more costly, especially because the causes of morbidity have changed in the Western world. See Pignarre (2004).

<sup>151</sup> Cambrosio, Keating, Schlich and Weisz (2006) propose the concept in the context of biomedicine and define it as: « the systematic recourse to the collective production of evidence » (p.189 and in a later publication as : « a new form of objectivity in biomedicine that generates conventions and norms through concerted programs of action based on the use of a variety of systems for the collective production of evidence. » (Cambrosio et al., 2009, p. 651)

<sup>152</sup> For Latour characterizing Stengers' approach to science, see: Latour (1997). This risk of having one's questions altered by the object is also a concern that runs through the work of Vinciane Despret, allowing her to offer rich and engaging accounts of ethology in terms of human-animal relationships and *mutual questions*. See, e.g. Despret (2009; 2013).

This is what characterizes clinical trials more generally as a practice in their own right (Pignarre 1997). However, this doesn't mean that they are not rigorous and executed with care. For drugs, practices and regulations have developed to ensure that drugs enter the market after careful tests and verification by the regulator (Marks 1999, Hauray, 2006). The complexity of clinical trial for drugs, and even their side-effects after having been placed on the market, are precisely an indication of the uncertainty about the confrontation between an active molecule and the human body. This uncertainty should not be trivialized by assuming that 'science' knows all about the human body.

To return to food with health claims, EFSA's mission is to verify the evidence provided for claims. The peculiarity of the NDA panel is that it only checks whether the efficacy of claims has been substantiated and doesn't look into safety aspects, if the food or food ingredient is recognized as a *food* and not a 'novel food'<sup>153</sup>. As I have shown in the previous chapter, EFSA's panellists recognize that, within EFSA's meeting room, their job is not purely scientific but regulatory: they have to make a decision where they would have preferred 'more data' and further research. Claims have been rejected for many different reasons, also within one specific category of components such as probiotics<sup>154</sup>. The NHCR did not specify what scientific evidence for health claims should precisely consist of, but other legislation to which the NHCR refers, prohibits the attribution of medicinal claims to foodstuffs.

The effect of legislation is that the efficacy of claims must be demonstrated *in a normal, healthy population*<sup>155</sup>. Extrapolation from studies on a population with disease symptoms is managed on a case-by-case basis. But these restrictions were already well-understood, anticipated and recommended by the authors of FUFOSE and PASSCLAIM, as we have seen in chapter 1. Nevertheless, the results from EFSA's evaluations were problematic for many, especially researchers and companies working in the field of

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<sup>153</sup> Novel foods are covered by different legislation than health claims. The Commission considers foods and food ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997 novel foods and novel food ingredients. See: [http://ec.europa.eu/food/food/biotechnology/novelfood/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm)

<sup>154</sup> This is easily verified in the NDA panel's opinions, published on EFSA's website: <http://www.efsa.europa.eu/en/nda/ndascdocs.htm>, or in the EU Register of nutrition and health claims: <http://ec.europa.eu/nuhclaims/>. I have also discussed this with the EFSA's former vice-Chairman in a personal interview, 16/12/2011.

<sup>155</sup> See for example the EFSA guidance document (EFSA, 2011a:17)

probiotics. EFSA brings back what projects like FUFUSE and PASSCLAIM wanted to exclude as much as possible: the clinical. Because the agency insists on the primacy of *clinical* results over other forms of evidence, and especially the RCT (EFSA, 2011a), EFSA is accused of treating food like drugs, and of adhering to *evidence-based medicine*. As I will show next, the food/drug divide sets the terms of a space of mobilisation where both evidence and affiliation become political operators.

## Operator #1: Evidence

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### Evidence-Based Medicine

After the Second World War, when the RCT became common practice<sup>156</sup> for putting drugs on the market in all Western countries, it also became a reference, or the ‘gold standard’ (Timmermans and Berg, 2003) for what in the 1990s would be called ‘evidence-based medicine’. Evidence-based medicine (EBM), in a nutshell, systematically reviews data from clinical trials internationally. Through statistical calculations, different RCT’s and other clinical trials on a same treatment are put together to assess the efficacy of that treatment. EBM hierarchizes different sources of evidence and the RCT is placed at the top as the gold standard<sup>157</sup>. EBM is a controversial subject today, and critical questions are raised both by practitioners and social scientists about its consequences for the medical profession<sup>158</sup>. Critiques are also made because EBM imposes the same requirements on different forms of therapy, including alternative and complementary medicine<sup>159</sup>.

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<sup>156</sup> The RCT was initially met by resistance from the pharmaceutical industry, but later on became its strength, allowing it to become a full-fledged capitalist enterprise based on serial mass production, see Pignarre (2004). See Pignarre (2001) for an ecological analysis of this production system and the emergence of depression as an ‘epidemic’.

<sup>157</sup> For a genealogical type of history of EBM and its relation to professionalism, see Armstrong (2007); on the relation with medical authority see Denny (1999). A short history of the EBM movement is also given by Marks (2009).

<sup>158</sup> See e.g. Timmermans and Kolker (2004). They argue that medical knowledge has been reconfigured through a shift from pathophysiology to epidemiology, through the creation of practice guidelines, and the effects of these guidelines on the autonomy of health professionals. See also Timmermans and Oh (2010) for the role of EBM in the transformation of the medical profession. Sinclair (2004) considers the changes EBM has induced in medical teaching, where published papers have largely become the main source of pedagogic illustration instead of patients.

<sup>159</sup> For the implications on the profession of the chiropractic, see Villaneuva-Russell (2005); For a critique of EBM in alternative medicine, see: Barry (2005). A general philosophic and critical discussion of EBM is provided by Goldenberg (2006).

In the health claims debate, as we will see below, EBM is also criticized as imposing standards that are deemed unsuitable for nutrition research: EFSA's NDA panel asks for studies (verifiable bibliographic references) with clinical outcomes, preferably RCTs. In view of the functional food stratagem discussed in chapter 1, privileging biomarkers and insisting on the difficulties and drawbacks of RCTs, we can imagine reasons for discontent on the part of claim technicians. EFSA is said to adhere to EBM, while nutrients, according to claim technicians, should be assessed according to different standards. Chapter 1 already indicated that claim technicians defended a discipline proper. In the space of mobilisation of health claims, they re-baptise the movement of functional food science as: *Evidence-based Nutrition*. Indeed, the community of claim technicians (many of them affiliated to ILSI) will define itself in opposition to EFSA and EBM.

If the food industry wants to relate food components to human health, it must look for ways to socialize these components without them losing their identity as *food* components. EFSA asks for dossiers with a description of the active component, its claimed effect on human health (EFSA also evaluates the proposed wording for the claim), and why this should be a benefit, and evidence for a causal relation between the component and the benefit (EFSA, 2007; 2011a). The best evidence is considered to stem from RCTs. Like in EBM, EFSA puts RCTs at the top of a pyramid of proof. In chapter 1 discussed how claim technicians proposed to rank RCTs *among* other studies, rather than on top of them, and their reasons for doing so: such studies are very costly, time-consuming, and not the area of expertise of food companies. However, submitting a claim dossier doesn't *have to* be so complicated. EFSA approved a claim, for example, on sugar beet fibre for which the applicant (Nordic Sugar A/S) had done an internet search on the MEDLINE database and Google for relevant existing studies (EFSA, 2011b). The applicant had found 4 human intervention studies (of which two randomized) and three animal studies. Two randomized studies showed the claimed effect, and the animal studies were considered to provide additional supportive information. EFSA approved the claim, formulated as follows: "sugar beet fibre increases faecal bulk", for a target population of "people who want to improve or maintain a normal bowel function", and for foods "high in fibre" as listed in Annex to the NHCR of 2006

(EFSA, 2011b: 2). The stakes, here, are not the same as with probiotics for example, the bacterial strains of which can be patented<sup>160</sup>.

## Ways Around the Drug Trial

*Dear Mr. Barroso,*

*We kindly ask your attention for a difficult matter: In 2006 the European Commission has adopted a law requiring health claims made on foods to be approved prior to their use. (...) As scientists in gut research, we have followed these developments with great interest and have observed with increasing worry the outcome of these assessments and their consequences for our field of expertise: To date, we have not seen a single positive pro- or prebiotic claim accepted by EFSA, despite the large convincing and generally accepted body of scientific data available. (...) At a stakeholders meeting organized by EFSA on 2 December 2010 in Amsterdam on this topic, we have tried to obtain further information on the underlying reasons for these rejections. The outcome of the meeting was unsettling: the way the claims requirements are formulated and applied is making it virtually impossible for the benefits of pre- and probiotics to be recognized. One of the major obstacles is the regulatory ban on clinical endpoints. A striking example is that in case of studies on prevention of traveller's diarrhoea, diarrhoea itself is not accepted as an endpoint but validated biomarkers and risk reduction factors are required.*

*(Petition on the website [www.gut-health.eu](http://www.gut-health.eu))*

This is an extract of a petition that has been signed by 192 scientists from more than 20 different -mostly European- countries<sup>161</sup>. The petition is to be found on a website called *gut health - website for basic and clinical gut scientists*. The homepage shows a picture of Elie Metchnikoff, an early 20<sup>th</sup> century scientists, in front of a microscope and taking notes. Different things can be learned from this extract. The writer speaks on behalf of scientists in gut research and they are worried. They feel that their field of expertise is being threatened. This field encompasses not only 'gut research', but also a specific sort of product and technology, designed to try and alter the gut microflora: pre- and probiotics. By putting a photo of Metchnikoff on their homepage, they claim an affinity between the practices of this early 20th century scientist and their own: they inscribe themselves in a history starting from fermented milk in Bulgaria that Metchnikoff researched, to the development of a convenient product in the 1930s in Japan, and to Yakult and other products in Europe today. This would

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<sup>160</sup> For a company that does research on bacterial strains, patents them and sells licenses to companies, see: <http://probi.se/en>

<sup>161</sup> Last consultation of the website on 3/10/2012.

imply that if EFSA doesn't allow any pre- or probiotic claims, and rejects the science behind it, the agency is actually throwing away a century-old knowledge of the influence of bacteria on the human gut microflora and human health. And, as the gut researchers add in the same letter to Barroso, "we feel that this is not benefiting public health". In their collaboration with industry, these scientists feel frustrated that the development of certain products is compromised. As 'scientists in gut research', they feel that their identity is threatened and they feel offended that the benefits of their science and products are not recognized. It is interesting to note that 'gut health' and 'gut science' are rather new terms, and the website has been called into existence because of the problems with EFSA. This means that a group of scientists within the larger community of the life sciences has gathered around a certain product, technology and science to forge an identity. The space of mobilisation of health claims has in fact called into existence a *new* concerned group. Next to the gut scientists<sup>162</sup>, there also emerged the gut flora foundation with its annual 'gut day'<sup>163</sup>. The issue at stake has to do with putting molecules (for prebiotics) and bacteria (for probiotics) to the test. As the gut scientists argue in the letter: "One of the major obstacles is the regulatory ban on clinical endpoints". This is not entirely correct. Clinical endpoints are actually *demande*d by EFSA, but they must not be related to *disease symptoms*. Indeed, the disappearance of *diarrhoea* is not accepted by EFSA as a clinical endpoint. If a substance can alleviate diarrhoea it is no longer a food but a drug. *Enterol*, for instance, is a probiotic drug. Yakult, anno 2012, is – according to this definition – only a yoghurt. But EFSA is not necessarily hostile towards health claims. From the conversations I had with the former Chairman and vice-Chairman of the NDA panel, I learned that they are genuinely interested to see if probiotics 'work' when inserted in 'normal' doses in a food matrix. "But you need a healthy population to put your bacteria or molecules to the test, as you're not allowed to make statements about disease and symptom relief"<sup>164</sup>. One option that is explored by functional food adherents are 'challenge tests': inoculating a virus for instance, without making people sick, but to see if immune parameters react more efficiently under a pre/probiotics regime (see e.g. Biesalski et al. 2011). But it is feared that this would cause ethical problems, and raise questions similar to those raised around vaccination. *Extrapolation* would be another way to get round the problem of the disease endpoints. In this case, RCTs are performed on a population with disease symptoms, and if more is known about the exact mechanisms of the product's action,

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<sup>162</sup> <http://www.gut-health.eu/>: "website for basic and clinical gut scientists"

<sup>163</sup> <http://www.gutflora.org/index.html>

<sup>164</sup> Interview, 16/12/11.

then extrapolation to a 'healthy' or 'normal' population would be an option, depending on the case and the strength of the evidence. Specialized Research and Development labs have designed yet another solution to be able to perform RCTs: *borderline populations*<sup>165</sup>. These are people that are in a 'suboptimal' state of health. For example, a study group with a body mass index between 25 and 35 kg/m<sup>3</sup> are neither obese, nor 'normal'. With such a group, molecules, claimed to regulate a person's appetite, can then be tested for 'weight management' products. Similar setups can be designed to test a molecule's agency on a population with 'suboptimal' cholesterol levels, and to relate this agency to the reduction of risk factors for cardiovascular diseases. Throughout all of these potential test solutions, the active agent (a nutrient, a molecule, a bacterium) remains unchanged. *It is the environment (the trial, the population,...) that must adapt to the molecule or bacterial strain*. Concomitantly, with the concept of suboptimal health, the boundary between health and disease is pushed.

## Evidence-Based Nutrition

In the previous section, I have given examples of ways to get around the problem of the RCT based upon disease symptoms. These solutions still favour what are called 'hard clinical endpoints'. Clinical trial expert Joerg Gruenwald, a much invited keynote at health claims conferences, and president of the private lab *Analyse & Realize* says that:

*You need at least one good clinical trial, randomized placebo controlled, which is in the population that is 'accepted' by EFSA. It doesn't have to be totally healthy, but it has to be accepted, and there are all these borderline cases where they say: ok this is still a reflection of the general population.*<sup>166</sup>

Even though EFSA is not a medicines agency, its evaluation criteria remain close to those for drug trials. Industrial scientists search for ways to comply to what EFSA wants by working on classification margins, as the citation of Gruenwald indicates. There is, however, a community of industrial and academic scientists that don't agree with EFSA's evaluation criteria at all, claiming that they are unsuitable for a 'true science' of nutrition:

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<sup>165</sup> [www.nutraingredients.com/Regulation/Clinical-trial-design-in-the-new-EU-health-claims-regime-Now-we-have-to-work-on-the-borderline](http://www.nutraingredients.com/Regulation/Clinical-trial-design-in-the-new-EU-health-claims-regime-Now-we-have-to-work-on-the-borderline) (last accessed on 03/04/14)

<sup>166</sup> I took this citation from a broadcasted interview by NutraIngredients reporter Shane Starling: <http://www.nutraingredients.com/Regulation/Clinical-trial-design-in-the-new-EU-health-claims-regime-Now-we-have-to-work-on-the-borderline>



*Research in the field of nutrition has entered a new stage, where it deserves **its own nutritional methodologies** that are distinct and more diverse than evidence-based medicine. It **requires redefining health** in terms of an individual's **potential to adapt** to internal and external **stimuli** rather than using the pharmaceutical paradigm. Any claims assessment system that is not **able to accommodate** the wide spectrum of health effects **should be adapted** to reflect the science available. It **should be capable** of stimulating these developments toward new research and the development of innovative products and useful information to the benefit of the consumer, including but not limited to public health messages.*

(Biesalski et al. 2011, pp.17-18, my emphasis)

This is the conclusion of an article on ‘evidence-based nutrition’, published in *Nutrition* in 2011. It is authored by thirteen life scientists with specialisations in biology, biological chemistry, nutrition, ‘gut science’. The second author was also second author of the FUFOSSE Consensus Document, published in the *British Journal of Nutrition* in 1999, and he was the first author of the PASSCLAIM consensus on criteria article in the *European Journal of Nutrition* in 2005. In other words, the ILSI ‘functional food science’ community has renamed itself in opposition to evidence-based medicine, and they make more explicit claims on having a discipline proper. This new nutrition seems to demand the same adaptations and capabilities of *health* as it does of *claims policy*: systems capable to adapt to, or accommodate, new stimuli. Their political agenda and its relation to evidence is also more explicit in this article, which is again the result of a Consensus Conference<sup>167</sup>:

*There is a need to consider the “inverse precautionary principle”: if the evidence is not absolutely conclusive but substantially indicative of the effect, then take a management decision to allow the claimed effect for the benefit of the consumer.*

(Biesalski et al. 2011: 15)

A bit further, they go on:

*Society does not need the same level of certainty concerning the effect of a low-risk nutrient or food as it does for a potentially higher-risk (and much more expensive) drug. For example, if the input/exposure concerned is lower than the amount listed as safe by responsible authorities (...) and if observational studies indicate the likelihood of a favorable effect, such a claim could be accepted because the harm of not accepting (i.e., possible benefits forgone) would outweigh the harm of approval (which would appear to be negligible even if the effect is actually null)*

(Biesalski et al. 2011: 16)

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<sup>167</sup> This conference had taken place at the University of Hohenheim where “(T)he experts spent a day presenting and discussing their views (...)” Biesalski et al. (2011), p.2

So according to these authors, there is no harm in accepting, and even the slightest *indication* is good enough a reason to accept. An active component can only have good intentions, it would seem. It would never bend its capabilities to other purposes, like side effects.

In distancing themselves from the practices of putting molecules to the test in pharmacology and medicine, these authors carve out a territory for their *own* practices and statements. Chronologically, EFSA became operational between the PASSCLAIM project and the here discussed 2011 article on EBN, enabling the authors to write their history in a certain manner by stating that the prominence of the RCT in the evaluation of functional foods "was not part of their intentions"<sup>168</sup>. Thus, it would almost seem that Europe has misunderstood and let down an emerging new science. This is reminiscent of the figure of the 'abandoned scientist' that Prof. Pot evoked earlier.

Health claims' space of mobilisation has encouraged the actors involved to re-formulate their programme and take on the identity of a professional group. Targeting the general *population*, and certain subgroups with 'risk factors', this community envisages a market bigger than that of the pharmaceutical industry, and a scientific territory composed of the same elements that have granted a historic authority to medicine: its own expert and guideline groups, conferences, journals, etc. Like functional foods that enter into an ambiguous relation to drugs, the professional community adhering to EBN, enters into an ambiguous relation to EBM. Functional food and EBN mirror what they wish to distance themselves from: drugs and EBM. This uneasy exercise is maintained right up to the choice of specific words, exactly like in the FUFOSE project. As we can read in the 2011 article:

*Perhaps the final step is to skip the word 'biomarker', which has become a paradigm in itself. We are now approaching the stage in biological research where we describe, understand, and quantify the molecular physiologic processes instead of a single parameter in a single point in time that is supposed to capture biological complexity. Nutrition is about health, and once we capture the relevant processes involved in maintaining optimal health, i.e., that continuously adapt under a variety of perturbations, we refocus on the real role of nutrition. In contrast to 100 y ago, we can do this with the help of rapidly increasing biological knowledge and a wide array of newly emerging technologies.*

(Biesalski et al. (2011): 17, my emphasis)

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<sup>168</sup> Biesalski et al. (2011), page 5 and repeated page 15.

This extract reveals three fundamental tensions, which in fact rephrase the same concerns as those I have identified in the FUFOSSE Consensus Document. Firstly, the authors propose to strategically avoid the term *biomarker*. They see it as related to pathology and 'laboratory-oriented markers'<sup>169</sup> that deal, like drugs, with single end points, single effects, etc., *rather than with complexity*. This tension then, is that of 'complexity' versus what is seen as the one-dimensional approach of drug research. Secondly, nutrition's *true role* is related to *health*. Health is again played out against disease, the latter pertaining to the realm of drugs. Related to this is a third tension: the definition of health itself. Health is sometimes presented as the *ability to adapt* to one's environment and perturbations<sup>170</sup>, and this idea is seized upon by the EBN community. Through the concept of homeostasis, health and disease are put into a competitive scheme: perturbations and challenges put stress on bodily functions, and when these attacks amount *above a certain threshold*, health becomes disease. Body functions and parameters (which become 'markers' in experimental research) must be kept within a normal range of variability to maintain health. This range is where specific food components may help to maintain or reinforce for instance our immunity. Health and disease are placed on a continuum, but a threshold keeps them well apart at the same time. The homeostasis concept is of course more widespread than among the EBN community. It is seen as a promising area of research, also by some of the EFSA panellists<sup>171</sup>. But EFSA does not accept all markers proposed, and privileges hard clinical endpoints, preferably RCT data. This is where the EBN movement advances an *alternative*, since research designs that focus on these clinical endpoints do not allow the analyst to take into account the more subtle responses of the body to food components. By emphasizing complexity and subtle interactions between nutrients and body functions, the claim technicians lay a claim on the body itself: *they* are the ones who develop the fine-grained tools to understand all the mechanisms. The RCT would then appear as a rough and clumsy tool with respect to the new nutrition science in EBN.

A variety of ways to provide exactly this kind of evidence are proposed in the EBN article quoted higher (Biesalski et al. 2011), sometimes referring to methods yet to be

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<sup>169</sup> " (...) they are markers of, really, chemical pathology, you know what I mean: they are laboratory oriented markers. We felt that there were opportunities for other markers." Personal Interview with one of the authors of PASSCLAIM and the article on EBN (Biesalski, 2011). Brussels, 15/03/11.

<sup>170</sup> See e.g. Biesalski (2011) and an anonymous short article in *The Lancet*. In this article, the idea of health as the ability to adapt is supported with arguments of physician and philosopher Georges Canguilhem. These arguments are seen as a basis for personalized medicine. See Anonymous (2009).

<sup>171</sup> Interview with EFSA panel member, 16/12/11. Repeated at an informal conversation in March 2012, during the conference organized by KNAW in Amsterdam.

developed. A key role in all these methods, the article explains, is reserved for 'markers', as an intermediate step between the body's response to a component on the one hand, and a clinical outcome *to be expected* on the other. The marker is only valid if it has a predictive value with regards to a person's health state. Immunoglobulin levels, systemic cytokine concentrations, or number and activity of phagocytic cells are mentioned as possible markers for modulations of the immune system. At the same time, the difficulty to draw general conclusions about a person's immune system from a single marker is recognized. The challenge, then, is how and which markers *can be made to represent* a 'good reaction' of the body - a reaction beneficial for health. Markers are to become the body's reliable witnesses, but they do more than responding to a stimulus: they also make a *promise*. And as ILSI's projects have shown, along with the uptake in the NHCR of the concept of 'reduction of a disease risk factor', *to make promises in the realm of health requires the cultivation of concepts related to risk*.

The challenge for marker-oriented research into functional foods is to inscribe and stabilize a future therapeutic scenario in one or several (bio)markers. In this way, nutrients or food become 'charged' with a health claim. For EBN, markers are not only the articulation point between a nutrient and a promised outcome, but also between that nutrient and the market. EBN thus develops a specific version of the human body as a body of evidence: the evidence is a promise inscribed in a marker. The marker indexes a future state of health. The marker creates a *body-as-index* as the point of articulation between a nutrient and the market. The relation of this body to the *clinical body* of EBM is ambiguous. The clinical is preferably excluded from the premarket test, while a relation to the clinical is essential. The promise entertains this relation and *lays a claim* on the clinical for its own purposes. In EBN, health and disease have a similar ambiguous relation: there is a sectorial and legal imperative to keep them well apart (industry and authorities agree on this point, each for their own reasons), while a new relation must be created and entertained between the two at the same time. In the dynamic conception of 'health', health and disease form a continuum. Health and disease are not two sides of the same coin: they are not opposed. Instead, they are at once on the same side of the coin, and on two different coins. In the next section, I will discuss how these conceptions of different bodies, and of health and disease, affect how *scientists* conceive of one another.

## Operator #2: Affiliation

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The second operator that structures the health claims debate is institutional affiliation. This operator is very much related to the first one that I have discussed: scientific proof or evidence-bases. I want to make this operator analytically salient, because it gives the space of mobilisation that I am describing an explicit *moral* dimension.

By ‘institutional affiliation’ I mean a scientists’ relation to the EFSA panel or to industry, and I consider it another operator because the actors in the debate use affiliations as a political resource to enhance their own credibility or to question that of others, thereby challenging their respective evidence-bases at the same time. This operator does not exist independently of the first one, but distinguishing it analytically will help me to better qualify their relation and to ask: *what* enters in opposition with two ‘rivalling evidence-bases’ (Hendrickx, 2013)? The operator of ‘affiliation’ offered a rich repertoire of mobilisation during a conference at the Royal Netherlands Academy of Arts and Sciences in 2012. I will describe a particular exchange during this conference from a pragmatic stance. This means that I look at what a particular situation – as a space of mobilisation - *produces* (cfr. Clarke, 2005). My question is how the health claims debate affects the way in which actors *address* one another? So what follows is not a search for intentions, or fixed characteristics of individuals. What I will try to characterize is a *mode of address* and its effects.

### “First say where you come from!”

"What is scientific evidence for nutrition and health claims?" was the title of a conference at the Royal Netherlands Academy of Arts and Sciences.<sup>172</sup> In his introductory speech, the Conference Chair says the following about EFSA’s review process of health claims submitted to the agency:

*(T)he food industry became quite frustrated about the whole process, and they have their own vision on the foods and their quality in relation to health. The idea behind this meeting is that we would like to find out whether we can bridge the different visions on what is healthy food? And to do that we would first like to have the evaluation - what is the state of the art in relation to the relationships between foods and health?*

(My transcription, original emphasis)

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<sup>172</sup> I attended this symposium in Amsterdam on the 26th March 2012 and recorded the discussions.

This is a very intriguing statement: how can a ‘state of the art’ of the relations between food and health be made, if the state of the art is precisely what is at stake? For example, Hendrik Van Loveren, at that time Vice-Chairman of the EFSA NDA panel, started his presentation like this:

*My assignment (for this presentation) was: the case of probiotics. But EFSA has given a negative opinion on all probiotics so I consider that we don't have a case. I decided to just give you a flavour of how we look at probiotics.*

(My transcription, original emphasis)

In just two phrases, he made very clear what he thinks about probiotics. First of all, he suggests that the subject had been imposed, whether he liked it or not: he talks of the ‘assignment’ of this subject for his presentation. He hasn’t chosen himself to talk about that. If this is perhaps a way to delegate responsibility to EFSA or KNAW, he suggests that he *wouldn’t* have chosen this case because there actually ‘is no case’. And why is there no case? Because *EFSA* hasn’t approved one single probiotic claim. EFSA is the only valid arbiter in his opinion. This is in line with the view of Martijn Katan, a well-known nutrition scientist in the Netherlands and member of the KNAW. Professor Katan is not a member of EFSA himself, but he is very supportive of the agency<sup>173</sup>. He was also one of the invited speakers at the KNAW conference, and he started his keynote by contextualizing the symposium itself, by way of an explanatory note and perhaps a gentle correction of the problem formulation proposed by the Conference Chair quoted above:

*But first, how did this meeting arise? As already mentioned, it was one of the scientists from the probiotics field who suggested that the Academy organize a meeting about this. For those of you who don't know: probiotics are so-called beneficial microbes, they are bacteria and yeasts which you eat and which are supposed to benefit your wellbeing and health.*

(Katan, my transcription)

Probiotics emerge again as a problem. In this context, it is important to note that a conference took place, also in Amsterdam, two years earlier, to open a ‘dialogue’ between EFSA and probiotics researchers and food companies. This, because EFSA’s assessment criteria were considered unclear and in need of specification, preferably in the form of guidelines (EFSA, 2011c). I will not develop this case here, but when Katan mentioned who

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<sup>173</sup> For example, his article in the journal *Beneficial Microbes*, was entitled: ‘Why the European Food Safety Authority was right to reject health claims for probiotics’. See Katan (2012).

took the initiative for the meeting at the Royal Academy, it must be reminded that probiotics already had a controversial prehistory. What interests me most in Katan's quote is a similar suggestion as that in Van Loveren's speech: *this meeting wasn't their idea*. This, because the state of the art about food and health is quite clear: if EFSA approves or disapproves, the case is closed. This vision was confirmed in the discussion after Katan's presentation. Someone in the audience asked Katan: "What is your definition of a healthy food?" And Katan replied: "I think a food is healthy if it carries a health claim approved by the EFSA panel."<sup>174</sup> Katan uses EFSA's authority to close a controversy. So the *provenance* of science matters to Katan.

Another man then stood up in the audience and presented himself when addressing Katan: "Martijn, my name is WVG<sup>175</sup> - we know each other – and I enjoyed the first part (of your presentation) because there you show you still know what you are talking about, but the second part I cannot agree with at all." Katan's first part was about different types of clinical trials and evidence. The second part was about the role of science in society. Here, Katan had shown a slide saying: "the loss of trust in science forms a threat to the health and well-being of society"<sup>176</sup>. He had ended his presentation with the proposal to abolish industry-funded nutrition research in universities, and to exclude industry-funded researchers from giving scientific advice. This is again an example of the importance Katan attaches to the provenance of science, but also its societal mission. This had caused some coughing and shuffling of feet in the audience, and WVG was now about to tell why he didn't agree with Katan's vision "at all". What happens next merits our full attention. Katan interrupts here and asks the man, whom he personally knows: "Maybe you should tell the audience a little bit about *where you come from*".<sup>177</sup> Posing the question this way, Katan makes it seem as though the mention of a relationship with marketing or industrial research is a sort of *coming out* or the *unveiling* of a hidden truth.

Katan personally knew his critic in the audience. His question to publicly unveil his 'hidden connections' with industry could, in the context of the conference, be read as an argument *ad hominem*. But was it? Here, I would like to refer to a citation of the 17<sup>th</sup> Century

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<sup>174</sup> Personal notes during the debate.

<sup>175</sup> I've anonymized, as the discussions have not been made public on the KNAW website. The keynotes were made available after the conference.

<sup>176</sup> Slide presentation, downloaded from the KNAW website in april 2012: <https://www.knaw.nl/nl/actueel/beeld-geluid/wetenschappelijk-bewijs-voor-voedings-en>.

<sup>177</sup> Personal notes during the debate.

natural philosopher Robert Boyle: “for I love to speak of persons with civility, though of things with freedom.”<sup>178</sup>

Manners in dispute were important for Boyle, and ad hominem arguments had to be avoided. The book where I discovered this quote, Shapin and Schaffer’s *Leviathan and the Air-Pump*, explains that the invention and (re)production of experimental ‘matters of fact’ cannot be seen independently of the social, material and literary conditions (‘technologies’, p.25) that produce them. The authors discuss this through a seventeenth-century debate between Hobbes and Boyle, both of whom had different views on how valid knowledge was obtained. What both protagonists had in common, though, was that they directly related the question of knowledge to that of *social order*, albeit in very different ways. For Boyle, matters of fact were collectively agreed upon by a collective of individuals (a ‘union of eyes and hands’), in a space conceived around the performances of an experimental device.<sup>179</sup> The individuals gathered (in casu: *gentlemen* only) became witnesses who could ‘publicly’ agree or disagree on what was the matter of fact<sup>180</sup>. Paradoxically, this experimental space, where things could be discussed according to the good manners of the time, also factored out human agency: it is the machine that produced the finding. So the machine made it possible to say that one can talk freely of things (‘facts’), but with civility of persons (who are different from things and only witnessing them).

I would like to be careful and not draw hasty parallels between this complex and situated 17<sup>th</sup> Century case and the KNAW symposium that I am discussing. But let me try and open up one entry that enables me to question the health claims debate in similar terms as Shapin and Schaffer. The point of entry that I propose is the question if Katan’s request to a man in the audience for speaking out publicly and bear testimony to industry relationships should be taken as an ad hominem argument. I argue that, even it *could* be a personal attack for biographic reasons of the two persons concerned, it is also much more. It is related to the validity of scientific knowledge and social order. And the relation between knowledge and social order involves things – food ingredients – as much as human beings. Boyle separates things and persons, and attaches a different moral code to the way each of them should be

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<sup>178</sup> Quoted in: Shapin and Schaffer (1985): 73

<sup>179</sup> Boyle considers this space to be ‘public’, but it was very restricted at the same time, see e.g. p. 39, and p.78.

<sup>180</sup> For Hobbes, concerned with the atrocities of civil war, such a dependency on belief and artifacts couldn’t possibly constitute a safe basis for social order.



addressed. However, Shapin and Schaffer's analysis of experimental space shows that it is difficult to draw Boyle's strict separation between persons and things: while the gentlemen are free to discuss what they witness, their witnessing activity is bound up (through an *agencement* we might say) with a device that is seen to produce 'facts' of its own. How this came to be conceived as such precisely points to the conditions that made witnessing in experimental life possible. Indeed, Shapin and Schaffer explain that in seventeenth-century England, *testimony* was a problem: is plain trust in (religious) authority still possible? Can the testimony of secretive alchemists be trusted? Shouldn't new forms of testimony be created *publicly*, for example in the empirical experimental spaces that Boyle defended (the 'public' nature of which was questioned by Hobbes)? This form of public testimony involved an *agencement* of persons and things, testifying *together*.

I return now the Amsterdam conference room. Katan had just testified for EFSA as an authority, and he asked his critic to testify of his industry relationships. Was Katan's argument an *ad hominem* argument, a personal attack? Another keynote speaker gave what I deem to be an answer to that question: he displayed his competing interests on a slide saturated with logos of universities, research institutes and food companies. He also remarked, casually, that he hasn't reached the age of retirement yet, 'and so' has to work with industry. An *ad hominem* attack to Katan, who spoke earlier? Definitely. But also much more.

Katan, to be sure, had collaborated with industry in the past, but he had emphasized that he has no relations with industry *anymore*. With this statement, he created a *difference* - one that matters to him - between two periods in his professional life. Placing this difference within the frame of Katan's earlier comments about the importance of trust in science for society (and the necessary abolishment of industry-funded research), one could arguably label Katan, within the context of the symposium, as a 'purified' scientist.

Then came Wim Saris. Saris' slide showed about twenty logos of private companies and public institutes. Such a slide, often used at conferences to display one's multiple attachments and prestige, now took on a new meaning. It became an argument *ad absurdum*, much to the audience's amusement. At the surface, his message seemed to be: here are my declarations, and *so what?* As a self-confident expert, Saris feels at home in these heterogeneous relations, represented by the logos:

*Because I am working in the Top Institute Food and Nutrition, I also have to declare my, euh, competing interests.*

(Saris, my transcription with original emphasis)

For a very brief moment, just long enough to accommodate the loud laughter of the audience<sup>181</sup>, Saris did not move, gesticulate, or argue. Katan, two keynotes earlier, had declared that he didn't work with industry anymore. Now, and for a very brief moment, Saris' body language made him exist as a *victim* of his logos ("I have to declare"), but in an ironic way, as if he were saying: "surely all these logos are bad, but it's not *my fault* if good scientists, working in the Top Institute, are called upon by institutions and companies of all sorts."

The result of this casual and ironic attitude about the logos was that they charged him with even more public authority and with the support of many in the audience who started to laugh. The logos formed a personal CV, appreciable in one glimpse because of their disposition and the many colours on one slide. With a single slide, he was able to suggest his being a traveller of many different spaces, and his authority as the *accumulated result* of all these activities, missions, performances, and tests.

Saris enacted what could be loosely called a 'moral economy' in which humans and food ingredients become mobilized in the same manner to obtain public authority<sup>182</sup>. Saris displayed his logos; his former and current collaborations, performances, tests. Saris, as it turned out in his presentation, was also a fervent adherent to evidence-based nutrition. He showed himself to be a critic of the RCT and of 'pharma-biomarkers', as he puts it, for nutrition:

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<sup>181</sup> The audio file is publicly available on KNAW's website. The moment where Saris shows his logos and the audience laughs occurs at 00':53" – 00':57" in the recording.

<sup>182</sup> The concept of 'moral economy' has already been put to use by scholars with various backgrounds. It is never quite well-defined. My use here is inspired by Lorraine Daston (1995) and her historical approach to different forms of objectivity, empiricism and quantification. She sees these forms and their historical variations as the result of 'moral economies' and how these change through time: "Although it is a contingent, malleable thing of no necessity, a moral economy has a certain logic to its composition and operations. Not all conceivable combinations of affects and values are in fact possible." (Daston 1995: 4)

*What EFSA has done is really taking the evaluation system which is available from the pharmaceutical, euh, area, where you have one single target and you have mostly a very strong effect, and if you talk about food you have (...) small effects in multiple targets, and that makes it quite difficult to make a judgement whether something is working or not (...) That is not an easy task and randomized control cannot solve that at all.*

(Saris, my transcription)

Many small effects in multiple targets are opposed to what appears as EFSA's chunky evaluation system based on one single target and one effect. Whether Saris is right or not is not the question. What is remarkable, is the opposition between the singular, simple, and one-directional as 'unsuitable', and the multiple, complex, multi-directional as 'suitable'. This parallels the way Saris presents his person, through a complex of many different logos. As I have shown throughout this chapter, and also in chapter 1 on ILSI, the logic of functional food science or EBN is one where evidence stems from heterogeneous sources, without privileging one specific type of test. A molecule's authority accumulates through these different tests. The molecule, according to EBN, must arrive at EFSA's desk with a rich CV of former collaborations (with mice, in vitro cells, different biomarkers in human beings, ...). Like Saris, the molecule must be able to display its logos.

Saris' presentation contrasts strongly with Katan's solemn defense of science, coming from a single authoritative source, namely EFSA, privileging RCTs. Katan himself declared to have worked with industry in the past, but he didn't anymore. He could, then, safely ask his critic in the audience to reveal that from which Katan himself was *purified* from. EFSA, for that matter, is also the result of a purification exercise and a detachment from the Commission after the food scandals (chapter 4). NDA panel members are not allowed to have professional relationship to industry, and a 'cooling-off period' is required before being eligible to the panel. Katan and Saris represent two extreme positions in the space of mobilisation that I am discussing. Evidence and provenance, or affiliation, reinforce each other and, as such, they can appear in two forms, two modes of becoming socialized in the world, two moral codes: one code gains public authority through *purification*, the other through *accumulation*.

When showing his logos, Saris also mentioned, in a very casual way and without insisting, that he had not reached the age of retirement yet, 'and so' he collaborates with industry. An ad hominem response to Katan? Yes. And yet, at the same time, in the 'moral

economy' of the health claims debate, it means much more: independent science, EFSA, and Katan's criticism of industry are put under the sign of retirement, isolation, stepping out of professional life, out of networks - in short: Katan, nor EFSA, are there where innovative knowledge is being produced. Saris concludes his presentation with a worldmap full of arrows pointing away from Europe<sup>183</sup>. "Innovation moves out of Europe", it says (slide 27), while EFSA continues to use "old science" to judge health claims (slide 28). The final slide concludes that EFSA is "discouraging innovation and research". The figure of the discouraged scientist that Professor Pot from the Institut Pasteur de Lille evoked earlier in this chapter turns up again. The confident entrepreneur with many logos, it would seem, *needs* the discouraged scientist to be the victim of the battle between evidence-bases, and especially the *clinical* evidence-base of EFSA. Promises need a world and an economy of their own.

The 'space of mobilisation' I have described has its axis in the human body itself. The human body is the site of conflict where the difference between food and drugs, or between health and disease is contested and displaced. As such, the human body is also the site of struggle for the boundary between two *markets*: a controlled market for drugs, and a market of free choice for 'safe' foods with 'health benefits'. The 19<sup>th</sup> and 20<sup>th</sup> Century have stabilized medicine as a scientific discipline (though of a particular kind) and a market for drugs, in which a form of intervention with gatekeepers (the EMEA, the general physician, the apothecary) has been established. Food with health claims, and the related debates about health and disease, upset categories and bring into play questions of *governance*, and hesitations between forms of control and of free choice. Before turning to this question in the final chapter, I need to make one more stop and look at a concrete example of a product that has *not failed*, but that has *passed* all the tests to be placed on the market: cholesterol-lowering margarine. I limit myself to a brief analysis of an advertisement campaign. My questions are: how is the consumer addressed? And what is required to make the product 'work'?

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<sup>183</sup> slides available at: <https://www.knaw.nl/nl/actueel/beeld-geluid/wetenschappelijk-bewijs-voorvoedings-en>

## Chapter 6 Anatomy of a Promise

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The European ‘market’ or Single Market has remained abstract and detached from itself in the previous chapters. It has been there all along, especially as a juridical entity, but not in a tangible way. Neither have functional foods or foods with health claims as objects. In this chapter, I look into a product that has passed all its tests and that is available ‘on the market’: cholesterol-lowering margarine. I will not delve into the products’ history, which has been richly described by Heasman and Mellentin (2001) and Lehenkari (2003). The corporate marketing strategies to make the product credible have been studied by Penders and Nelis (2011).

What interests me here is the products’ articulation with science, and cholesterol as a biomarker. I briefly and speculatively analyse an advertising campaign and its conjugation of images and text. I argue that references to science and cholesterol turn the margarine into a moral agent. The product needs help to realize its promises. Both human bodies and the notion of risk are mobilized in the advertisements. For the margarine, risk lies at the heart of its promise. And the body marks the promise.

### Three Gazes and a Marker

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In this section, I will briefly analyse how the visual field of the advertising campaign is ordered, arranged or composed with different elements, and how these different elements are conjugated to communicate. I draw inspiration from research by Maria Guilia Dondero, on the semiotics of images and photography (Dondero, 2014).

Images can interact with verbal language, but they can also communicate through a language of their own, as Dondero explores in several of her works. Of particular interest for my own work is her analysis of images of scientists and their bodies in popular magazines, in conjunction with the discursive genre of the accompanying article: ‘interview’; ‘brief update’ on work-in-progress; ‘historical portrait’ of an important scientists, etc (Dondero, 2014). She shows how the images of scientists vary from close-up portraits to laboratory scenes, and that this variation occurs according to the type of article to which the image is added as an ‘illustration’. More than an illustration, Dondero argues, the image has its own language,

expressed for example through resolution and the distribution of what is clear and hazy, the line of communication between the object and the camera, light and dark, and much more. Just like verbal expression, images are a form of ‘text’, or rather *enunciation*. In the image below, I will pay attention to the solidarity between the verbal and the visual as two forms of enunciation, using some of the variables that Dondero used for images of scientists, and applying them to a poster starring our margarine.

**Voici Lionel.**  
**Il y a 4 semaines**  
**son cholestérol**  
**s'élevait à 216**  
**mg/dL. Il est**  
**bien en-dessous**  
**aujourd'hui.**

Beaucoup de personnes  
 comme Lionel ont fait baisser  
 leur cholestérol significative-  
 ment en utilisant Becel  
 pro.activ dont l'action est  
 prouvée scientifiquement.  
 Apprenez-en plus sur  
[www.reduisonslecholesterol.be](http://www.reduisonslecholesterol.be)

**Becel pro-activ**  
 pour réduire le cholestérol

Réduit activement  
 le cholestérol.

*Amis bies  
 Lionel et  
 SOS FRANGE  
 de L. Absolut*

De 216 mg/dL à 184 mg/dL. L'apport journalier de 1,5 à 2,4 g de stérols végétaux  
 peut réduire le cholestérol sanguin de 7 à 10% en 2 à 3 semaines. En  
 combinaison avec le changement vers une alimentation et un mode de vie  
 sains, une réduction de 15% peut être atteinte.

What we see in the composition above is an arrangement of three different ‘gazes’ that all look straight at the lens and the spectator. The first gaze is that of a smiling man, slightly decentered to the right, the second gaze is that of a German Shepard, centered in the lower half of the frame, and the third ‘gaze’ is that of a tub of margarine, centered on the vertical axis, and slightly decentered to the left on a horizontal axis. What do these gazes express? A number of words with related meanings are possible if we consider for example Lionel’s face in isolation (Happiness? Pride? Health?) but since we are facing a *composition*, there are a number of other signs and visual modes that can help to reposition the question about the gazes. One such communication or cue that immediately stands out is the number ‘184’ that the man is holding. As the number says ‘184’ *and just that*. The number could mean anything, but some form of competition or achievement comes to mind. Note that the man’s entire body is visible, as well as that of the dog<sup>184</sup>.

Both bodies are implicated in a scene where the background also suggests a competition of some sort. The written text provides an additional direction. Interestingly, the first phrase is “Voici Lionel.” So the man has a name. The commercial is about a *person*, who could be your neighbour for example.

The text continues and I translate: “4 weeks ago, his cholesterol attained 216 mg/dl. He is well below that today.” In conjunction to this communication, we understand that Lionel’s ‘184’ is in fact a technical *measure* expressed in mg/dl. The fact that the measure is *not* indicated on the board Lionel is holding, creates an ambiguity, or rather a *conjugation* of the number as a measure and the number as an achievement, one meaning embracing the other. Different more or less related qualifications remain possible for Lionel’s beaming gaze, especially pride and a sense of health. The text continues: “A lot of people like Lionel have significantly lowered their cholesterol by using Becel ProActiv whose action has been proven scientifically. Learn more about it at: [www.letslowercholesterol.be](http://www.letslowercholesterol.be)”. A potent agent is revealed (Becel) in this scene of success, and it is beaming straight at the spectator. The tub of margarine seems to be as proud as Lionel of the achievement.

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<sup>184</sup> This is not always the case in visual campaigns. Retzinger (2012), for example, analyzed the images of obese in visual campaigns. He observes that photos always show their backs, or that they look down on their necks.

Consider this statement: “A lot of people like Lionel...”. Here, Lionel’s personal victory, and indeed the entire scene becomes reformulated as one in a *series* of successes. Here, Lionel’s person becomes qualified as a *case*. A personal case is not opposite to the series of which it is part, but it conjugates the personal and the impersonal in a specific way.

## Evidence and Matters of Fact

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There is no apparent play of haze or fuzziness around the foregrounded subjects (Lionel, the dog, the margarine and its textual message), nor is there in the background. Depending on the genre, as Dondero (2014) notes, fuzziness or haze (*flou*) can mean different things. In scientific photographs for example, fuzziness can mean an unsuccessful experiment, but also the approximation of a discovery. If the Becel poster were a scientific photograph, then the crisp and clear, face-to-face arrangement of the photograph might want to communicate that the scientific content is *fully accepted*, much like in the type of portrait that Dondero identifies in popular scientific magazines as belonging to a certain type of column: ‘*l’actualité de la recherche*’. These short columns give brief matter-of-factly information about the state of the art in a certain branch of research. However, Dondero notes that in those cases the body, nor the action of the scientist are shown. They are face-to-face portraits where the scientist only represents his/her role within a larger scientific institution.

The similarities and contrasts with the Becel photo are interesting. For example, the text above the tub of margarine is indeed matter-of-factly: despite the hints of victory we have already discussed, plus the *obstacles* that are visible with the same sharpness as the other elements in the scene, the text itself makes no use of exclamation marks or sensationalism. Lionel’s victory, and his surpassing of obstacles *were to be expected*. Indeed, *a lot of people like Lionel* have lowered their cholesterol and the action of the margarine has been *scientifically proven*. The margarine’s has a matter-of-factly face, even though there is a hint of pride or perhaps fitness. Just like Lionel and the dog, the margarine is portrayed in full, glaring straight at the spectator. There is no fuzziness or haze, and the margarine is not shown from a different angle or slightly turned away, as is often the case with advertisements for cars for example. No mystery nor sensationalism, *only straight evidence*.



Two additional cues are interesting and they fit in with what I have described so far. Firstly, the margarine and its accompanying ‘credits’ appear on a green rectangle that is not without resemblance to a banner just unrolled, or even a medal with Becel as its emblem. Again, the theme of victory is played with and conjugated with the naturalness of ‘what was to be expected’ or that which is ‘evident’. Scientific ‘evidence’ takes on a double meaning in that case. Secondly, the green ‘banner’ is transparent. As such, it is in touch with reality while at the same time being superimposed on the picture. I see this as another play or conjugation of the general and the particular; the series and the case. Lionel is a case, but with regards to the margarine he is like the scientist in *l’actualité des sciences*, representing an *institution* that is more general than himself. Although in touch with Lionel’s particular case, Becel’s reality is also located in a space of more general ‘causes’ that give a certain direction to a series of conjugations between people, obstacles, and fit animals.

## Testimony for the Good Cause

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How can we characterize this composition? What is being communicated through the conjugations of science and promotion; the evident and the achievement; the case and the series? What is being *done* in this particular advertisement?

I propose to qualify the composition as the generation of a form of *testimony*. Lionel is not only proud of an achievement, he is also testifying in favour of Becel. He testifies with his entire body, and the dog testifies for his master’s body. The photo above of a poster at my local bakery, is signed by Lionel, and Lionel signed for the dog too. Lionel has replicated one testimony upon the other.

Lionel’s personal achievement is conjugated with the theme of scientific proof, and I can now be more precise about Lionel’s expression as not only conveying a sense of pride and fitness, but also as a mild injunction to the spectator: I’ve lowered my cholesterol and *so can you*. This injunction is translated by the website address where the spectator or addressee can learn more about Becel: “réduisonslecholesterol.be”: *let us* lower cholesterol, the proposition for action being an effect of the conjugation of the verb ‘réduire’<sup>185</sup>. The testimonial character

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<sup>185</sup> Or in Dutch/Flemish: verlaagcholesterol.be, where ‘verlaag’ is conjugated in the *imperative* form of the verb ‘verlagen’.

of the visual space also explains why the self-presentation of a tub of margarine should commence with: “*Voici Lionel*”, rather than “*Voici Becel*”. With these words, and the conjugation of three gazes, the spectator becomes, like in many advertisements or demonstrations of different sorts, a *witness*. Schematically, this is the triangulation at work: packaged product (agent) – Lionel+dog (testifier) – spectator (witness). The triangulation presents the lowering of cholesterol as a *common cause* to strive for. I explore this more in detail in the next section.

## Cholesterol as a Common Cause

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I have discussed a particular image in some detail, but the image as such doesn’t stand alone, and its messages are repeated in different forms and constellations throughout a more encompassing visual space, made not only of this and similar posters, but also TV commercials, websites, and personal communication to the consumer once you order Becel’s free *starter’s kit* to lower cholesterol. In other words, the different types of images and texts communicate with one another. The margarine is a world of intertextuality in itself. A detailed analysis of all these different sources is beyond the scope of this thesis, but I will briefly consider some of them, with special attention to the role of cholesterol as a marker.

## Lionel in Motion

The somewhat museum-like scene that I just discussed is also put in motion in a TV commercial of about 30 seconds<sup>186</sup>. Without entering into all the details of the commercial, let me just emphasize some of the elements that are added in the video, and that are consistent with the previous. First of all, at the very beginning, the camera is placed in line with an obstacle in a dog training park. Lionel and the dog run straight towards the spectator and the dog jumps on the obstacle, which is a sort of small wooden bridge. In the left hand upper corner a text appears: “*Lionel, 55 ans, Fallais*”. This is in line with the factual tone of the text on the advertisement discussed. These are personal coordinates presented as matters of fact: name, age, place of living, separated by commas. The commas make the information personal and impersonal at the same time, as with a fill-out form. The facts given are *variables*, again evoking the *series* as a theme. The scene is accompanied by a cheerful, uncomplicated tune

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<sup>186</sup> <https://www.youtube.com/watch?v=TbHhT-rX5lo>

that is whistled over an easy-going three-chord musical line played on an acoustic guitar. As Lionel and the dog continue their agility training, another ‘fact-set’ appears in the lower half of the screen: “*Réduire le cholestérol: De vraies personnes. De vraies Résultats.*” Both ‘persons’ and ‘results’ are in the plural, implicating that Lionel is *one of* the cases. The ‘reality’ of Lionel and Becel’s action are emphasized, like the red arrow on the margarine tub that says ‘scientifically proven’. The message of the red arrow is repeated twice in the video: one time by Lionel’s off-screen voice (‘scientifiquement prouvé’), and shortly after by *another* off-screen voice (‘cliniquement prouvé’). The switch to a second voice marks the transition from Lionel’s case to a higher order of generality, like the transparent green banner in the advertisement above. It is a female voice and, as such, audibly installs the transition. This is the moment when the margarine becomes visible in its packaged form, just like in the green banner.

## Series

I mentioned that Lionel’s coordinates (name, age, place) are variables. A similar video exists with another real person called: “*Isabelle, 45 ans, Gozée*”. Isabelle is not running with her dog, but swimming. The clip starts as she takes a pause in the swimming pool. We see her chatting with friends as they all take a rest after the sporting test. The video has the same narrative structure as the one with Lionel. But the dog training park has been replaced by a swimming pool, and the dog has been replaced by chatting human friends as ‘corroborators’ of the main testifier, Isabelle. Isabelle’s and Lionel’s profiles can also be visited on the Becel website under the rubric ‘Real people. Real results.’<sup>187</sup> And the visit comes with a surprise:

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<sup>187</sup> <http://www.becel.be/fr/proactiv/real-people-real-result/>



Lionel (upper left) and Isabelle (upper right) now appear in the series, as if the commercial reflected a clinical trial. The role of cholesterol values as a biomarker now stands out. *Now notice the absence of the margarine itself.* The Becel website in general shows more pictures of sporting (mostly middle-aged) people than of margarine. Somehow, the more testifiers multiply, *the more the margarine itself disappears into its own environment.* As can be seen on the photos, the margarine makes room for the lowering of cholesterol as a common cause and an injunction.

It is here that Becel most clearly becomes a moral object. Like in clinical trials and in conference rooms, a specific version of the human body is presented: a body that can be known through *markers*. From FUFOSÉ and PASSCLAIM, to the conference room and into advertisements and commercials, the marker, as a reliable witness within the body, has a central role as the point of articulation between a particular food as a potent agent and the ‘market’ or supermarket.

## The Marker as an Index

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In clinical trials and in advertisements, the marker is central because it points to something that is absent at the same time: cholesterol, as a marker, stands for the margarine, and for a healthier life. And it can only point to a healthier life by emphasizing cholesterol as a factor of *risk*.

Anthropologist Alfred Gell (1998) has investigated the agency of art objects, and he calls the object a ‘social agent’ that puts to work its beholder because it provides an ‘index’. His theory is more a theory of agency and social relations, than it is a ‘theory of art’. What Westerners call ‘art’, when qualifying objects of another culture, is not necessarily considered as ‘art’ within these other cultures. Often these objects do something, irrespective of their being ‘beautiful’ or not. A shield, for example, may be considered as a ‘beautiful shield’, but it is first and foremost a ‘fear-inducing shield’ (Gell 1998: 6). Art objects, then, are social agents because they make humans act: the objects mediate social agency. Put differently, the mediating object acts as a ‘material index’ (*Ibid.*: 13) it induces an operation which in semiotics and logic is called *abduction*: “abduction covers the grey area where semiotic inference merges with hypothetical inferences of a non-semiotic (...) kind.” (*Ibid.*: 14). Stated otherwise: abduction is an inference “where we find some very curious circumstances, which would be explained by the supposition that it was the case of some general rule, and thereupon adopt that supposition (Eco, 1976, cited in Gell 1998: 14). Is this not precisely what evidence-based nutrition is about, or what EBN adherents called ‘evidence-based mechanistic reasoning’ (Aggett, 2011). Isn’t abduction the basic operation of this new nutrition science, turning the resulting object into a social agent like Gell’s art objects? The role of markers in clinical trials has been discussed at length throughout the previous chapters, but in this chapter we see how markers are extended into tangible objects that have been placed on the market.

A marker in clinical trials, cholesterol becomes an index through margarine as an object. Not through causality, induction or deduction do we relate margarine and health, but through abduction. If this may perhaps be said of many, if not all advertisements, mixing seduction and abduction in various ways, the particularity of this cholesterol-lowering margarine is that *science* continues to play a role in this constellation of inferences. The red arrow on the margarine tub states that the margarine’s agency has been ‘scientifically proven’. This statement can be interpreted simply, as a way to enhance credibility, like the occasional scientist explaining how a washing powder attacks the fibres of a stained tissue with small active components. But the Becel advertisement and commercials, however, ‘science’ does something much more important: it presents the lowering of cholesterol as a common cause, and thereby introduces the notion of *risk*. The material index, the conjunction of the margarine tub and the number ‘184’ are an injunction to change people’s behaviour. This makes the margarine a politically and morally charged object.

Isabelle Stengers observes that scientists are becoming increasingly dependent on industry, but not for collaboration and funding as such (they have always collaborated with industry, see: Latour, 1987). What Stengers advances as a concern is that industry increasingly has the power to *define the terms* of that collaboration and the questions scientists must ask. The promises of technology have become a drive involving states, industry and scientists in the fabrication of promises for a better future. This is what Stengers (2011, 2013) labels 'l'économie de la promesse' or the economy of the promise. Thoreau (2013), for example, explores this economy in the domain of nanotechnology.

The Becel commercials show that this economy of the promise not only affects scientists, but that it extends to consumers and how they should help realizing the promise of better health.

But a nagging question remains: if health claims are promises, promising not only better health for people but also a healthier economy, then why have they been made subject to such a stringent control? Why do EBM and the clinical body control the body-as-index?

# Uprooting the Promise

## Conclusions and further engagements

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### Legislation and Escape Routes

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*Catch-22* is the title of a famous novel by Joseph Heller, published in 1961. The title has now become a term in itself to refer to a paradoxical situation, governed by contradictory rules that make it impossible for a person or a thing to escape from that situation. A 'catch' in English is indeed a form of capture, a trick, or even a trap. Heller's novel is a satire about the daily activities of a squadron of air pilots, camped in Italy during the Second World War. The recurring theme in the book is the absurdity of the bureaucratic rules that govern the life on the military base. The fundamental *catch-22* rule always has the last word, although none of the characters, including the superiors, seems to know where it comes from. The most famous example is about the quota of dangerous flying missions that a pilot is obliged to do, and the conditions to get exempted from having to fly them. Basically, if you're considered mentally insane, you can be grounded and you don't have to fly any more missions. But there's a catch. In the novel, this is explained in a conversation between Yossarian, the main character in the novel, and Doc Daneeka, the army psychiatrist:

*"You mean there's a catch?"*

*"Sure there's a catch", Doc Daneeka replied. "Catch-22. Anyone who wants to get out of combat duty isn't really crazy."*

*There was only one catch and that was Catch-22, which specified that a concern for one's own safety in the face of dangers that were real and immediate was the process of a rational mind. Orr (a colleague of Yossarian, KH) was crazy and could be grounded. All he had to do was ask; and as soon as he did, he would no longer be crazy and would have to fly more missions. Orr would be crazy to fly more missions and sane if he didn't, but if he was sane, he had to fly them. If he flew them, he was crazy and didn't have to; but if he didn't want to, he was sane and had to. Yossarian was moved very deeply by the absolute simplicity of this clause of Catch-22 and let out a respectful whistle.*

(Heller, 1961: 56)

So the catch plays on the difference between being considered sane or insane, in function of a person's initiative. Let me now propose a similar - albeit hypothetical - situation, where the main players are not people but molecules, and where the issue is not a

performance that leads to the qualification of a mental state as sane or insane, but a performance that entails the qualification of the molecule as either a food or a drug.

The rules of the European Union make a strict separation between food and drugs, or rather between their respective markets. In theory, the risk of falling into the disturbing logic of *Catch-22* is imaginable: if food aspires to be a therapeutic agent, it must demonstrate its therapeutic capacity. If it succeeds, it is no longer a food but a drug. If it fails, it cannot be a therapeutic agent and then there's no sense in making claims about its agency.

This situation evokes the theoretical impossibility to put on the market a so-called *functional food*. Functional food, or food with a quasi-therapeutic claim, is caught in between the difference between food and drugs according to what it does, very much like the air pilots in Heller's novel: if it is able to substantiate its claim, then it loses the benefits of being marketed and widely distributed as a food, because effective therapeutic agents are actually drugs. For a functional food to remain in the lucrative (because less restricted) food market, it is not allowed to display a genuine therapeutic effect. But then it is no longer a functional food and it no longer has its potential added value.

In reality, this situation does not really occur. Functional foods have become a real possibility, and some of them have been placed on the market, while many others like probiotics haven't, at least for the moment. They have become a real possibility, because the concept of 'functional food' itself, as I have show in Chapter 1, traces an escape route to stay away from the *Catch*. Functional foods now exist legally as foods with health claims.

Molecules, nutrients, and some bacterial strains are not evaluated in such a simple manner as Heller's air pilots, and unlike the situation in the novel the *Catch-22* rule is not an unchangeable transcendent principle. What I discussed in this thesis shows, in a way, the opposite: it is not about the impossibility to escape a transcendent paradoxical rule, but about the escape routes that are constantly being made, thereby changing the situation. In fact, in each chapter there was a moment where a paradox or contradiction arose at some point.

More importantly, these escape routes had consequences, and I will gather the most important ones by way of conclusion.

An overall conclusion that can be drawn is that, in the EU, foods with (quasi-) therapeutic ambitions have a legislative 'before' and 'after'. This may sound evident: is it



really surprising that legislation makes a difference? It is not, but the kind of difference that legislation would make was impossible to predict in advance.

## Before the NHCR: The Problem of Addressing Food and Health\_\_\_\_\_

The *Functional Food Science for Europe* (FUFOSE) project driven by ILSI, and funded by the Commission's DG Research, was already preparing an escape route and a territory for functional foods in *anticipation* of legal developments and the drafting of the NHCR. In that sense, the NHCR made a difference before it existed. It could be anticipated, because the EU's food policy was going through changes, and this provided the opportunity to have a first-mover advantage: if rules have to be made, then it is better to propose rules that fit one's own terms.

Would the NHCR have seen the light without the FUFOSE project? That is difficult to say, but it definitely came at the right time. The funding that the project had received from the Commission, and the latter's own concerns about the competitive position of the EU's food and drink industries, indicate that ILSI operated in a receptive environment for new ideas. So I wouldn't grant ILSI the role of a causal factor in the chronology I have sketched.

Chapters 2, 3 and 4 all deal with a knot of related events that occurred during the same period. An important event detailed in Chapter 2 was *Austria*, and the question whether health claims on foods justified restrictive measures upon free trade in and by themselves. This happened in 2000-2002, when the results of the FUFOSE project and its definition of functional foods had just been published in 1999. This was also the period in time when the EU was reviewing its food policy and legislation, as explained in Chapter 4, and when 'science' became a major political operator and gatekeeper between food and the market, after a number of food scandals. Chapter 3 discussed the negotiations, between 2003 and 2006, to establish a European Nutrition and Health Claims Regulation (NHCR) in the wake of both *Austria*, and the EU's General Food Law. Also, EFSA had just been established in 2002. So a number of events – a 'knot' of interrelated events – can be said to have formed the NHCR of 2006.

The combined efforts and negotiations that have led to the NHCR were contentious and ridden with conflict, but conflicts arose on a rather precise point: the evaluation of food-

as-such. To put it very succinctly and somewhat crudely: everyone agrees that it is interesting to promote the health benefits of food, but some add: “... *as long if food itself is not judged*”. Those who are most in favour of using claims as a promotional tool are also those who want to protect food itself from attack. More precisely: the problem of nutrient profiles, discussed in Chapter 3, is a problem because it opens the possibility to *judge* the nutritional composition of foods. The proposal to set up nutrient profiles has been taken up in the NHCR, but they still have not been established today. What EFSA judges are nutrients outside of any food matrix that makes up actual products. A generic list of ‘scientifically’ proven claims, with minimal conditions of use, has been published on the Commission’s website<sup>188</sup>.

## After the NHCR: Bodies of Evidence

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We have seen how ‘science’, or cameral science (Stengers, 2013) became a political operator, as it calls into existence a specific type of ‘available data’ or ‘evidence’ – as a composite body of different types of trials, performed in different laboratories.

Law required “science of the highest standard” to judge health claims, and this was interpreted by EFSA as the development of a hierarchy of proof with the RCT at the top (EFSA, 2007, 2011a). This reinvigorated a tension that FUFOSE and PASSCLAIM hoped to avoid in their anticipatory creation of concepts and boundaries: the tension between food products and pharmaceutical products. The most important characteristic that I identify in the ‘legislative after’ is that the notion of ‘evidence’ has displaced the main source of conflict from food-as-such and nutrient profiles to the *human body*. The difference here is no longer between healthy and unhealthy food, but between food and medicine, or health and disease. The body becomes the space of mobilisation of the health claims debate and a site to decide where the boundaries between food and drugs are, and between health and disease. It would even seem that EBM and EBN come up with at least two different bodies<sup>189</sup>: a clinical body and an indexing body or a body-as-index. If a product passes all the tests, like Becel’s margarine, then the body-as-index extends into a product, an advertisement campaign involving other bodies, and moral imperatives about lowering cholesterol and considering one’s health at risk - or at least as deficient. At the risk of overdoing the body-metaphor:

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<sup>188</sup> <http://ec.europa.eu/nuhclaims/>

<sup>189</sup> I wouldn’t have been able to make this distinction if I hadn’t read Annemarie Mol’s *The Body Multiple*. See Mol (2002).

evidence-bases are often called bodies of evidence. In the health claims debate human bodies are indeed enacted as bodies of evidence, not only in debates, but also in clinical trials. Borderline populations are an example of a new category of people, not healthy and not ill, designed to provide evidence and enacted as such. The polarisation within the debate even led to a differentiation between scientist's bodies: EFSA scientists are isolated geographically (in Parma! Far from Brussels) and they must have, at least for a certain number of years, a 'straight' CV with the right collaborations. Against such an image, the linked in entrepreneurial scientist can become a dynamic body: a collection of multiple collaborations.

## The Anxiety to Tame

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*Austria* had not answered the question of *how* to regulate health claims. It just said that they didn't justify trade restrictions. The negotiations that have led to the NHCR (Chapter 3) concerned the conditions of possibility for a market of health claims. Addressing food-as-such though nutritional profiles was a source of discussion, and in that sense food turned out difficult to pacify. The legislative 'after' of the NHCR can be characterized as a failure to lay to rest discussions about the relation between food and health, but a *success in setting the terms of the health claim as a – perhaps continuous - space of mobilisation*. With complex matters such as food on the one hand, and human bodies on the other, discussions would be inevitable, but at least the Commission would be in control. Hence the frustration or even despair of many scientists and industrials.

The NHCR, then, didn't want to settle the question of health and the human body, but designate who would be in control of the discussion. This doesn't necessarily mean that the Commission is impermeable to industry influence, but the Commission wanted to set the terms of that influence. PASSCLAIM and FUFOS have been carefully read and to a large extent applied, but the emphasis on the RCT and clinical results was entirely the initiative of the Commission. Calling upon 'science of the highest possible standard' set the terms of the debate and ensured control. Proposal 424 stipulated that this highest possible standard was to be represented by a central European agency. The independence of EFSA, as I have discussed in Chapter 4, has a political role: making science independent was to restore the credibility of the Commission and the Single Market. I have also discussed that, instead of representing independent science, EFSA performs it. The requirement to judge health claims makes these

claims exist as ‘available data’, in the form of dossiers or portfolios with a fixed structure to be sent to EFSA. In that sense, the risk analysis tandem formed by the Commission and EFSA have created a type of health claim on food that they could manage and control.

But why, it could be asked, was the Commission so anxious to establish this control? After all, we are talking about yoghurt, margarine and fruit juice here. Where is the harm in these products? I argue that the harm is not in the products, but in the relation between food and the body. And this relation is part of a complex question about *therapeutics*, which has been partly stabilized in modern drugs and scientific medicine after long historical struggles (e.g. Marks, 1999; Timmermans and Berg, 2003).

Nation States have traditionally watched over the health of their populations (Foucault, 2004; Kamminga and Cunningham, 1995) for economic reasons, and the medical profession has constituted itself as a profession in relation to the State (Foucault 2001; Freidson 1988; Adam and Herzlich, 2010). I cannot delve into this history here, but I want to place health claims within this history and try to understand why the control of health claims is such an important stake to the Commission. On the surface, the stake is sectorial, because drugs have been to a large extent Europeanized as well, with the European Medicines Agency controlling the premarket approval of pharmaceuticals (Hauray, 2006). The pharmaceutical industry occupies a strong position within this European arrangement (*Ibid.*). But this sectorial division, now on a European scale, already existed within nation states before. The division has historically grown. In that sense, if health claims on food pose a threat to sectorial boundaries (Bourlioux, 2008), this threat also has a deeper level because these boundaries are the result of a long history that created these divisions of substances, sectors, and authority. My argument is that this history is at stake because its divisions are *fragile*. And this fragility is rooted in an ontological uncertainty about therapeutics that relate substances to the human body. We don’t know what bodies are capable of. One need only to consider the particularity of what has come to be the Gold Standard of scientific medicine, so much contested by nutritionists: the RCT. This experimental design is so particular that it can be likened to a conjuring trick.

The ‘conjuring trick’ that made the existence of modern drugs possible was to make the *unknowns* of the human body *part of the trial* that became the gold standard. Naming the ‘placebo effect’ and including it the clinical trial as a benchmark, has allowed to create a

distinction between the *reasons* why people cure (Pignarre, 1997; Nathan and Stengers, 2004). In the placebo group there is 'spontaneous recovery' but we don't know why. The only thing we know is that these recoveries are not related to the tested molecule. In the placebo group, the body goes its own erratic way. However - and this is the trick - in the test group all recoveries are attributed to the molecule *only*. Here, people cure for the *right scientific reasons*. There is no means to know whether in the test group active compounds really act *all by themselves*, or that they interact with the bodies many capabilities, including the placebo effect (Pignarre, 1997). But it doesn't matter because the RCT is not designed to find out about it. The RCT is has been designed – inspired by agricultural experiments to have better harvests (Marks, 1999) - to detect a significant statistical difference between the test group (molecule) and the control group (placebo).

This consideration of the trick of the RCT doesn't question drugs' efficacy, but only the reasons for their efficacy: we don't fully know these reasons (hence the long list of possible side effects, and the regular retreat of drugs from the market because of their unforeseen interactions with concrete human bodies). These reasons are an opaque space where medicine lives under the constant threat of loosing its *modernity*. This is the space where healers, magical potions and sorcerers dwell. These have been consistently called 'charlatans' by modern medicine, and the RCT has been designed to keep them at bay. This makes the RCT not only an experimental space, but also a political space that sets the terms of the 'debate' between the scientists and the charlatan. It is a form of control, and the placebo group is indeed called the 'control group'. However, the construction is fragile: medicine, in the words of Isabelle Stengers (Nathan and Stengers, 2004), is *haunted* by the charlatan. This, as she notes, is not the case for all scientific disciplines. The astronomer is not worried about the astrologer, and the chemist is not too anxious about alchemy, because the astrologer and the alchemist can be given a place in the *history* of their discipline. Within modern scientific medicine, the charlatan is constantly *present* at the very heart of the trial that made medicine scientific and modern.

With the aid of these considerations, I think there are good reasons to assert that the sectorial boundaries between food and drugs are rooted in an ontological uncertainty about the relation between specific substances and the human body. For the modern State and its pact with modern medicine to control the bodies and health of populations, this ontological uncertainty, this space of the unknown, becomes an *anxiety*.

## Information as Capture

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Health and food *must* be different from disease and drugs. At the same time, the Single Market, innovation and competition *must* be encouraged. Food *must* be shown to be fully domesticated and *safe* (chapter 4). In this conjugation of imperatives, the concept of the health claim has constituted a niche to make *promises* and have people pay for them. Not only must people pay more for these industrial products, but they have to carry the responsibility of their health as well because they are provided with ‘information’. If the relation between food and health/the body is difficult to judge, for commercial, political and ontological reasons, there is current labeling policy sees no problem in transferring this judgement upon the consumer for each and every product, and in each and every individual act of purchase. This situation was recently characterized as a binome of ‘endless qualification’ and ‘restless consumption’ (Lezaun and Schneider 2012).

But ‘information’ is a deceptively abstract term. In the case of health claims in the EU, I have shown it to be politically and morally charged. The linear relation between ‘first’ informing and ‘then’ judging is misleading. This means that the opposite of ‘not misleading the consumer’ is not telling the truth, but leading the consumer in the ‘right direction’, as Proposal 424 has it. It is about leading the consumer to where he *has to* go, and to protect the consumer from himself. This ‘pushing in the right direction’ or *nudging*, as it is called<sup>190</sup> is again reminiscent of labyrinths and mazes. Many supermarkets are designed like mazes, with a specific itinerary to follow (Grandclément, 2011).

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<sup>190</sup> In December 2012, the University of Liège, Belgium, organized a conference called: ‘Nudging in Europe. What can EU Law learn from Behavioural Sciences? See: [http://local.droit.ulg.ac.be/sa/nudging\\_europe/?utm\\_content=buffer4f2c3&utm\\_source=buffer&utm\\_medium=twitter&utm\\_campaign=Buffer](http://local.droit.ulg.ac.be/sa/nudging_europe/?utm_content=buffer4f2c3&utm_source=buffer&utm_medium=twitter&utm_campaign=Buffer) (last accessed 19th May 2014)

## The Elusive Consumer

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Chapters 2 and 3 highlighted the role of information and its relationship to the consumer. I qualified the worldview of Proposal 424 as a neoliberal one. Although the questions of health claims is somewhat different, the history of food labelling in the US has currently arrived at a similar neoliberal labelling politics, aimed at free choice and consumer education (Frohlich 2011). But if labels and supermarkets, though the bias of information and material disposition (Cochoy 2008; Grandclément, 2011), try to capture the consumer, doesn't this point at the same time that the consumer is elusive? Not only is the consumer body elusive, as I discussed in the previous section, but the consumer as a category is in itself hard to pin down. The consumer has to be re-invented together with products and legislation. Lawyers are familiar with this problem. Meisterernst (2013) for example, distinguishes three co-existing profiles or versions of the consumer in European Food Law: the *average* or *empowered* consumer (*mündiges Verbraucher* – with a mouth to say things); the *casual* consumer (confident and not critical) and the *vulnerable* consumer (in need of special protection)<sup>191</sup>. The average/empowered consumer is a consumer who is “reasonably well-informed, reasonably observant and circumspect” (2013: 92). This consumer emerged through ECJ case-law as concept to settle juridical questions. Related to single market politics, a European concept of the consumer was necessary, because different Member States used different images. In that sense the Market, and the legislation that underpins it, creates consumers before actual people can buy products. Legislation cannot be written without it. Meisterernst notes that in EU legislation, different images have been created that still co-exist today, for example in the NHCR, and in the new Regulation No. 1169/2011 on the provision of food information to consumers (which is the latest descendant in a genealogy of food information provisions since the Labelling Directive of 1979). He notes a slight shift between the NHCR to the directive of food information from the empowered consumer to the vulnerable consumer. What I would like to bring attention to with this example, is that law (as legislation) *hesitates*. Amid the interests of the food industry and the political and economic consumer agenda of the Commission (European Commission, 2007; 2012a; 2012b; 2012c), there are moments of hesitation. There is hesitation, because law- and policymakers don't know what consumers are up to. In its report on consumer policy, the Commission referred to

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<sup>191</sup> Meisterernst, A. (2013) 'A New Benchmark for Misleading Advertising.' *European Food and Feed Law Review* 2: pp 91-96.

eye-tracking experiments to know more about how consumers process information on food labels (European Commission 2012b). This can be theorized as a form of control, but it can also be seen as an indication of the authorities being at a loss as to who consumers are, and making use of high technology to validate primitive behaviourist theories.

Now consider this reflection that I took from the website of the US-based Hartman consulting group:

*To be sure, this does not mean there is no market for functional foods; however, the way we go about understanding the adoption and diffusion of these products is not as simplistic as inventing a category and naming it. It needs an understanding of actual consumer behavior and the recognition that it is not as simplistic as addressing consumers' perceived attitudes. It incorporates a function beyond just adding ingredients and a benefit and requires an understanding of consumer lifestyles, how they relate to a lifestyle that includes other products, even beyond foods. As we have said often, real comprehension of consumer behavior is an integration of how consumers live, where they shop and how they use today's products and brands. In this potentially lucrative arena, it becomes even more important. Success is going to come, but the leaders will understand the rigor of the journey.*

(Hartman Group, 2005)<sup>192</sup>

Between the analysis of the neoliberal version of the consumer, and the examples above lies the possibility for a pragmatic switch of perspective. The therapeutic question that I briefly discussed higher allowed to place an analysis about political control under the sign of *anxiety* on the part of those who place themselves in charge of a question. This anxiety can also be related to the consumer – not as a subject of control in its neoliberal version – but as an elusive being that threatens to escape control and upset established categories. What I have called a ‘switch’ is the establishment of a difference in what is made to matter - between the analysis of control to an apprehension of anxiety. I relate this to the pragmatic gesture that Stengers (2009) performs when she develops, in and through her writing, a specific mode of address to apprehend those who are in charge (“nos responsables”). What I call the ‘apprehension of the anxiety of those in charge of a problem’ then allows for the cultivation of a mode of address under the sign of ‘pity’ in the face of ‘those in charge’.

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<sup>192</sup> See: <http://www.hartman-group.com/hartbeat/2005-06-23>



## Breaching the Evidence

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*S'adresser sur le mode de l'apitoiement à ceux qui, aujourd'hui, peuvent être caractérisés comme "nos responsables" ne signifie pas une quelconque sympathie, loin de là. C'est plutôt une question de distance à prendre, de refus déterminé de partager leur mode de perception, de nous laisser prendre à témoin de leurs bonnes intentions. Il n'y a pas à attendre grand-chose de leur côté, au sens où il n'y a pas à s'adonner aux tourments de la déception et de l'indignation. Mais il n'y a pas non plus, et c'est peut-être plus difficile, à s'engager dans une opposition frontale armée par l'évidence d'une situation conflictuelle et intelligible à partir de ce conflit. Ce n'est pas que le conflit soit inutile ou "dépassé", c'est son lien avec la production d'intelligibilité qui est en cause, qui menace de donner des réponses avant d'avoir appris à formuler des questions, de proposer des certitudes avant d'avoir fait l'expérience de la perplexité.*

(Stengers 2009 : 37-38)

This citation resonates with the citation of Michel Foucault that I discussed in the introduction about 'eventalization', and that informed what I consider to be a *mode of inquiry*, or a mode of problematisation, from an engaged position<sup>193</sup>. Both citations evoke a sense of perplexity – the cultivation of a problem – which is only possible by a breach of self-evidence, thereby changing the terms of the production of intelligibility. Foucault spoke of a polygon of intelligibility to be created, with multiple facets, the number of which cannot be determined in advance. Deleuze spoke in terms of tracing 'lignes de fuite' (e.g. Deleuze, 2003; Deleuze and Parnet, 1996). Perhaps I should translate 'lignes de fuite' as 'escape routes' and liken them to the escape routes I have described above. The scientists and industrials I have described are not afraid to try and change the terms of the problem, from their *very engaged* positions. This is an additional reason to put oneself at risk as an ethnographer (Haraway, 1997): either you share - and thereby stabilize - the mode of perception and the terms of the problem of those who are *in charge of the problem*; or you engage in a concurrent pragmatics and cultivate an equal, but different, potential of worldmaking.

I would like to finish these conclusions and reflexions with two small examples from outside the textual and academic universe, pointing to other types of practices that breach evidence and provide new lines of reflection in the realm of food, labelling, and health claims.

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<sup>193</sup> Mode of inquiry, rather than method, is considered to be characteristic of anthropology. See: Kontopodis, Niewöhner and Beck (2011).

## The Golden Wind Egg

A wind egg is an egg that is imperfect – it lacks its calcareous shell. It can also be an egg which is either unfertilized or fertilized but without further embryonic development. According to an online dictionary, the origin of this name is a former belief that such eggs were the result of conception by the wind<sup>194</sup>.

The Golden Wind Egg is a prize awarded to products with the most misleading advertising. After a short voting procedure, consumer organization Foodwatch awards the prize to the product with the most votes. The 2012 winner of the Golden Wind Egg was Unilever's Becel ProActiv, with 6,601 out of almost 19,000 Dutch votes<sup>195</sup>. Foodwatch is a consumer organization, founded in 2002 by former Greenpeace director Thilo Bode, and the organization has offices in Berlin and Amsterdam. Its aim, as can be read on its website, is to build a campaign organization that is represented in all EU Member States<sup>196</sup>. At the time of writing, a Youtube video, posted by Foodwatch, is available that shows the handing over of the Golden Wind Egg award to Unilever<sup>197</sup>. The handing over takes place at the company's offices in Rotterdam. The Foodwatch team arrives with a banner that says: "stop misleading" and a man or a woman disguised as a walking ProActiv margarine tub. A Unilever representative receives the team in front of the building's main entrance. The Foodwatch representative explains the award and the number of people that voted for Becel ProActiv. He then asks, in the name of all those consumers, to "please stop misleading marketing". Unilever's representative responds<sup>198</sup>:

***Unilever:** (N)ow thank you. There are other awards that I prefer to win than this one – The important thing is that Becel ProActiv has been proven to be safe and proven to lower cholesterol your cholesterol levels. That's very important if you want to work your cholesterol levels (...).*

Unfortunately, the video editor has cut the explanation here, so we don't know if anything else followed and, if so, what. Nevertheless, it is interesting that the representative, who identifies with Unilever with the "I" form, defends the margarine by referring to *proof*.

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<sup>194</sup> See: <http://www.merriam-webster.com/dictionary/wind%20egg>

<sup>195</sup> Source: [https://www.foodwatch.nl/pers/persberichten/06\\_\\_2012](https://www.foodwatch.nl/pers/persberichten/06__2012)

<sup>196</sup> <http://www.foodwatch.org/en/homepage/>

<sup>197</sup> <http://www.youtube.com/watch?v=FiYpQXTdAoY>

<sup>198</sup> I transcribe and translate from Dutch to English.

If you look at the butter tub of Becel ProActive you will notice a big red arrow pointing downwards. It not only visualizes the downward trend of cholesterol levels, but it also has ‘scientifically proven’ written on it<sup>199</sup>. In the response of the Unilever representative, this red arrow appears again as a vector of justification. The representative uses the notion of ‘proof’ to counter an argument about Becel being a misleading product. However, for Foodwatch, ‘misleading’ is not entirely opposed to proof:

**Foodwatch:** *The most important issue is that you haven’t proven that it really lowers your risk of cardio-vascular diseases. So lowering cholesterol: yes. Cardiovascular diseases: no.*

An important shift has been made in these two phrases. It is not Becel’s cholesterol claim that is misleading, but the product’s *association with disease*.

The Foodwatch spokesman then continues, after another editor’s cut:

**Foodwatch:** *In addition, German research points out that plant sterols may have negative side effects. If you had registered this product as a drug, you would have had to do research into this, and all that would have appeared in a patient information leaflet. Now people are in fact being used as guinea pigs and they are exposed to possible long term risks they are not aware of. I regret that you’re not accepting our award (...).*

What is interesting here, is that Foodwatch takes the product seriously. The organisation is not posing its questions in terms of a choice between a product that lives up to its promises, or one that doesn’t work and, therefore, is just quackery. Foodwatch is worried *because* it works. The question is what it possibly does, as an active agent, besides lowering cholesterol. A product can be misleading for reasons that are not related to the veracity of a health claim: Becel lowers cholesterol and cholesterol is one of many risk factors of heart disease. This is probably true, but a true statement is not enough.

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<sup>199</sup> This is the translation of ‘wetenschappelijk bewezen’ in Dutch, and ‘scientifiquement prouvé’ in French. In anglophone countries, where the product is called Flora ProActiv, the arrow is green and it says ‘clinically proven’. I haven’t investigated the reasons of these differences, but I am inclined to believe that nothing is fortuitous in advertising. See for example: Hennion, A. and Méadel, C. (transl. Bowker, G.) (1989).

## Label it Yourself

The first example, which I learned about through an article by Javier Lezaun (2014), is LIY or ‘Label it Yourself’ movement. This is a decentralized grassroots campaign, existing though social media like Facebook and Twitter, that designs its own labels or warnings and puts them over food labels in the supermarket, like for example a sticker that says ‘contains GMOs’:

*Like other forms of graffiti, writing on food packages introduces in the ostensibly public but highly controlled environment of the supermarket a surreptitious, clandestine channel of communication between consumers. The food product becomes a vehicle for delivering unsanctioned messages, and the act of perusing the supermarket shelves suddenly acquires a new, suspenseful quality.*

(Lezaun 2014)

The practice is lauded by some and condemned by others. In the US, the food industry lobbies for its criminalization. Rather than judging whether this is good or bad (vandalism, anti-GMO propaganda, ...), the question is what it sets in motion. The movement has structured discussion fora on the internet, and it is a well for ideas, including alternative forms of LIY:

*(I)t is possible to imagine an alternative version of LIY: a form of activism that would operate by subtracting, rather than adding, product identifiers. A movement that, instead of enriching the informational content of the package, would aim to emphasize its opacity, and in so doing reveal the radical inscrutability at the heart of food production and distribution systems.*

(Lezaun 2014)

Such practices are irritating as it may be for industry, and also for those consumers who have no truck with what they might consider as propaganda, or who may be hindered because they cannot read the real label. But apart from calling attention, it also introduces a very brief interruption in the act of buying in the supermarket, the politics of which have perhaps become too evident?

## Addressing Science

Against the imperative to ‘deliver on time’ (chapter 4), many now plea for an interruption, and a slowing down of science. Propositions abound when one enters the terms ‘slow science’ in a search engine. Throughout the different chapters of this thesis, various actors have spoken, time and again, in the name of Science, but science as an original practice was never addressed as such.

EFSA, as we have seen in chapter 4, has been designed to answer political questions by providing data and constituting a body of evidence. To make sure that this evidence can be placed under the sign of ‘science’, EFSA panel members are governed by stringent rules on conflicts of interest. The drawback is that conflicts of interest become even more visible. Indeed, EFSA has several times been accused of being too close to industry, and ILSI in particular (e.g. Butler, 2010; 2012). I haven’t discussed these issues because I wanted to show in this thesis that things are more complicated, and that *other* questions may be more arresting than the focus on conflicts of interest alone. Indeed, another drawback of the focus on conflicts of interest is that such a policy suggests that, if these interests are properly managed then nothing else can go wrong and Science will speak. Similarly, if a conflict of interest is discovered, then it is often formulated as a problem concerning a specific individual. I hope that this thesis has been able to convince the reader that more and other questions can be posed, concerning food production and distribution in industrialized societies on the one hand, and the state of therapeutics in those same societies on the other.

Neither EFSA nor ILSI allow scientists to hesitate with their objects, and to address each other in other terms than violent ones. The presentations of Katan and Saris - which developed as ‘power points’ quite literally - may have provided some entertainment to the audience, but violence is not necessarily overt, noisy, impressive or overwhelming. It can be seemingly lighthearted, like an advertisement, or it can be ‘nonsensical’ and factual, like two of the citations in the introduction of this thesis. One citation was from a newspaper reader who had no truck with social scientists talking Science. The other one was the title of an article on EFSA in the prestigious journal *Science* (see Kupferschmidt, 2012).

The remaining citation was from Hippocrates, echoed by a representative of Kraft foods.

What would Hippocrates make of all this? Could he have expected the stakes involved for ‘the moderns’ in treating food as medicine? Perhaps not, and maybe all the better: chances are it would have given the poor man a headache.

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# List of abbreviations

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**BSE:** Bovine Spongiform Encephalopathy

**CIAA:** Conferderation of the European Food and Drink Industries (now: FoodDrinkEurope)

**DG SANCO:** Directorate General of Health and Consumers (European Commission)

**EBM:** Evidence-Based Medicine

**EBN:** Evidence-Based Nutrition

**EFSA:** European Food Safety Authority

**EMA:** European Medicines Agency

**ERNA:** European Responsible Nutrition Alliance

**NDA Panel:** Nutrition, Dietetic Products and Allergies Panel (EFSA)

**NHCR:** Nutrition and Health Claims regulation

**RCT:** Randomized Clinical Trial

**WHO:** World Health Organization



## Annex Fieldwork

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Apart from the manifold bibliographic sources that I have used throughout the research, the fieldwork consisted of interviews (semi-structured and some open formats) and participation in conferences on themes related to health claims, scientific or juridical.

This annex gives an overview of in-depth formal interviews that I carried out, and of my conference participations. I start with a methodological note.

### Access and methodology

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The points of access one has to the ‘actors’ already reveals certain characteristics of the field one is studying. Functional foods/health claims show up at different places, at different times, and they are composed of those times and places. One can organize participant observation in a laboratory for several months and learn in the intricacies of experiment in detail. But is one learning how foods are made ‘functional’ then? Does one witness a health claim being made?

Health claims are composed of different actions and decisions, made by various actors at different places. EFSA judges in the end. And then EFSA’s judgements are disputed, and new spaces (conferences, stakeholder platforms, ...) are set up to discuss this. Reports are written on that, new guidelines published etcetera. So there are multiple points of access, *and the time is always limited*. Put differently, actors do not routinely go to the same place where the ethnographer can observe them and get accustomed to their local habits or culture. Actors from different countries and laboratories, universities, advisory committees, etc. have to be united. So, as an ethnographer you have to go and find them, or take the advantage of those specific gatherings, conferences, where many of them are present. In both cases, time is felt ticking away. Time is always sparse. And this counts for everyone.

I did interviews over coffee at conference tables, in hotel lobbies, over the phone, on some occasions in the person’s professional habitat, and at a person’s private home on two occasions. I gathered a total of 24 in-depth interviews that I fully transcribed after recording, and to which I returned several times in the course of research, partly re-analysing the earliest

interviews. They are presented in chronological order below. Managing these limited time frames between approx. 45 minutes and 1h30 was a learning process, of course. And so was the practice of ‘doing an interview’.

One doesn’t get ‘data’ by asking questions, like putting money in a machine to get a can of soda. What you do get are responses to questions, and the nature of your questions will change the responses. There is an evolution and you are not the same researcher after three years as in the beginning. You get credit because you know the subject, your attitude changes vis-à-vis persons with a certain authority (based on technical knowledge). There is indeed a difficult asymmetry that one can overcome, not by showing that one understands it all, but by proposing a different view. Interviews also became moments of validation, and they turned into conversations in the later stage of my research.

Apart from formal interviews, a lot is learned when assisting to conferences and meetings. Usually these provide documentation that can be used as ‘materials’ as well. But the most valuable moments are the informal chats with participants during breaks, or longer conversations at conference dinner tables. I always took notes during conferences. In personal conversation, however, the taking of notes is not always appropriate. In those cases, I noted my observations after the fact, back in the hotel, on the plane, etc. The alternation with more formal and organized interviews provided for occasions to validate certain impressions, unclear or partly forgotten bits of conversations, etc. It is not possible to enlist all these informal moments, so the overview that follows is limited to formal interviews on the one hand, and a list of conferences to which I participated.

## Interviews

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1. **V\_20/10/2010**: Director Belgian Consumer Organisation.
2. **V\_11/11/2010**: Professor Agronomy (ULg -Gembloux Agro-Biotech), formerly at the Belgian Food Safety Authority (AFSCA- FAVV).
3. **I\_16/11/2010**: Project manager at ILSI Europe.
4. **I\_26/11/2010**: Two project managers at ILSI Europe.
5. **V\_03/02/2011**: Researcher and Head of Unit at ILVO, Flanders.



6. **I\_25/03/2011**: Former Scientific Coordinator PASSCLAIM project; author FUFOSE Consensus Document.
7. **E\_30/05/2011**: Professor Food Law (University of Leuven), Flemish Farmer's Association (Boerenbond), Member of EFSA Board of Directors.
8. **I\_10/06/2011**: Former President of ILSI's Scientific Board and Coordinator of the FUFOSE project.
9. **V\_07/06/2011**: Researcher and developer of prebiotic products (ULg -Gembloux Agro-Biotech).
10. **V\_05/07/2011**: Researcher gut microbiota (UCL, Belgium).
11. **I\_26/08/2011**: Deputy Director ILSI Europe.
12. **V\_20/10/2011**: Former R&D Manager at Orafiti (Beneo); current R&D Manager at Cargill<sup>200</sup>.
13. **E\_16/12/11**: Vice-Chair EFSA NDA Panel.
14. **E\_17/02/2012**: Official at Belgian Ministry of Health; Member of the Commission's Standing Committee on the Food Chain and Animal Health.
15. **E\_15/03/2012**: Official at Belgian Ministry of Health; formerly in charge of health claims (post market/ Belgium); currently in charge of National Health Plan.
16. **E\_15/03/2012**: Official at Belgian Ministry of Health; currently in charge of National Health Plan.
17. **E\_25/03/12**: Chair EFSA NDA Panel.
18. **E\_13/06/2012**: Official DG SANCO, European Commission
19. **V\_11/10/2012** Researcher probiotics Institut Pasteur Lille.
20. **V\_09/11/2012**: Probiotics researcher, University College Roosevelt.
21. **E\_19/04/2013**: Head of Unit, DG Connect, European Commission.
22. **E\_24/05/2013** Head of Unit, DG SANCO, European Commission.
23. **E\_22/01/14**: Member EFSA NDA Panel; formerly in ILSI probiotics Task Force.
24. **V\_14/04/2014**: Consultant in scientific and legal affairs; Member of ERNA; formerly at Nutricia.

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<sup>200</sup> 'Currently' means at the time of the interview.

## Conferences

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- *Que mangerons-nous en 2020?* Gembloux, Agro-bio-tech, 28 November 2009.
- *European Food Science Day* Bruxelles, 18 December 2009.
- *Santé: l'expertise en question* Parlement Européen, Bruxelles, 4 March 2010.
- *Health Claims. Designing Clinical Studies for Success* Bruxelles, 29 April 2010.
- *Science for Health - ILSI Annual Symposium*, Bruxelles, 24-25 March, 2011.
- *Health Benefits of Foods – From Emerging Science to Innovative Products*, ILSI Symposium, Prague, 5-7 October 2011.
- *EFSA Stakeholder Consultative Platform Meeting*, Brussels, 9-10 December 2011.
- *What is Scientific Evidence for Health Claims ?* KNAW Symposium, Amsterdam, 26 March 2012.
- *Faut-il croire aux vertus des probiotiques ?* Lecture Bruno Pot, Liège, 11 October 2012.
- *14th Gut Day Symposium* Leuven, 9 November 2012.
- *Une bio-économie basée sur les OGM ?* Lecture Marc van Montagu, Liège, 6 February 2013.
- *Updates on Nutrition and Health Claims* EFFL Seminar, Brussels, 11 April 2013.
- *Bridging the Gap - Evidence-Based Medicine vs. Social Expectations* KCE Symposium, Brussels, 12 September 2013.

### *Presentations Author*

- *Reflections on the notion of 'consumer behavior'*. Keynote 3rd Annual Symposium of the Belgian Nutrition Society (BNS) 'Nutrition and Behaviour'. New insights for better solutions?", Librairie Royale de Bruxelles, Brussels, 20 April 2012.
- *Les aliments fonctionnels à la quête d'une science*. Oral presentation at the 6th Symposium of Groupe de Contact Nutrition, Alimentation, Santé (GCNAS), Louvain-la-Neuve, 1 June 2012.

