Working Imagination along the Food-Drug Divide

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Abstract

How can food ingredients be credited to have a beneficial impact on the human body, without calling them drugs? This question occupies nutrition scientists from within and without the industrial sector as they imagine a space between health and disease. This chapter investigates 'functional food' as the coproduction of concepts, methods and objects within a strategically and politically oriented imaginary, providing the context for the emergence of new forms of scientific evidence. Our analysis of this imaginary is accompanied by a concern to cultivate our own socio-anthropological imaginary.

Introduction

Since the 1990s, food producers have increasingly been making health claims about various packaged products, ranging from yoghurts and margarines to biscuits and soda drinks. National authorities have since drafted legislation to limit the scope of possible claims and to assess the scientific validity of claims. In the EU, a regulation entered into force in 2007: Regulation EC n°1924/2006. This was an important event, as it turned the ill-defined and debated 'health claim' into an *object of government*, thereby defining its content and scope. In this chapter, I focus on one particular source that has provided key concepts for the EU Regulation on health claims: an industry-funded think tank and its consortium of life scientists: the European branch of the International Life Sciences Institute (ILSI

Europe, hereafter: 'ILSI'). As a think tank, their job is to 'imagine' and – more precisely – to *formulate problems* with respect to their agenda, and to *anticipate* future challenges with respect to science, politics and regulation in the EU. ILSI's particular concepts have been influential in the drafting of the EU regulation, and these concepts are mobilized by scientists and food companies whenever a health claim is questioned or rejected by the European Food Safety Authority, who is in charge of the premarket approval procedure for health claims on the EU market. I have detailed the problems and debates between industry and EFSA after the implementation of the Regulation elsewhere (Hendrickx, 2013, 2014). What I would like to focus upon here, is the historical emergence of certain concepts, some of which have been taken up in European legislation and that are still being defended today – most notably by adherents of *Evidence-based Nutrition* – in order to demarcate food from drugs as objects and as markets.

The theme of this book is the relation between science and collective imaginaries in shaping the future. These are interesting concepts and heuristics, yet they can mean very different things. I will argue that, on the border between food and drugs, 'science' is rhetorically mobilized to refer to particular concepts and technologies of demonstration. Certain food ingredients are imagined to be good for one's health, but how does one demonstrate that? And how does one prevent this very demonstration from being taken as a token of the therapeutic capacity of food ingredients, thereby qualifying them as drugs? Avoiding this tipping point is the main stake in the health claims debate and ILSI's work in this area. I will show how ILSI engages in defining health differently and imagining the body differently than in clinical trials for drug testing.

ILSI's main concepts and strategies for health claims and 'functional foods' were formulated in two widely cited publications from the ILSI consortium. Both publications are position papers that were the outcome of projects coordinated by ILSI and financed under the European Commission's 4th and 5th Framework Programmes for innovative research. I propose a close reading of both papers, because they attest to the imagination of the scientists involved indeed, and more particularly because the analysis will allow to characterize the nature of that 'imagination': the translation of legal, political

and commercial constraints into nutritional concepts. These constraints can be summed up as follows: *legally*, no genuine therapeutic properties may be attributed to food; *politically*, human health is related to a sectorial divide between food and drugs; and *commercially*, the food industry is not interested in the strictly regulated market of pharmaceutical agents. Throughout the analysis, it will become clear that a particular understanding of the human body is coproduced with the types of trials and evidence for health claims that respond to the constraints just highlighted.

The analysis in this chapter is part of a larger body of research into how health claims became an object of government in the EU (Hendrickx, 2014). My understanding of the documents presented here has been corroborated through interviews with the authors, interviews at ILSI Europe headquarters in Brussels and participation in nutrition science colloquia. Organized as conversations, these interviews have allowed me to check the correct understanding of technical terms, and to trace the history and rationale of these now widely-cited publications. My aim, however, is not to simply describe this rationale, thereby running the risk of reiterating ILSI's vision. The challenge here is to conceptualize ILSI's strategy using my own means as an anthropologist and STS scholar, with the aim of taking a certain position, just like ILSI does – rather than a view coming from nowhere. Conceptually, I draw on literature in STS and the history of science. Of particular relevance to my analysis is the work of the two Belgian philosophers Isabelle Stengers and Vinciane Despret[1].

To begin, I briefly discuss ILSI's self-representation and how the organization is structured. I then move on to one of ILSI's most important and oft-cited publications on the subject of functional foods and health claims: the FUFOSE Consensus Document. I outline the nature of this publication and its strategic role for ILSI along with their conception of nutrition science. The main part of the chapter will consist of a discussion of ILSI's main nutritional concepts presented in the FUFOSE Consensus Document. The aim is to characterize these concepts as either scientific or something else. To complete the picture of ILSI's strategy, a follow-up project will be briefly discussed in the next paragraph, extending the operational scheme established by the FUFOSE Consensus Document into the realm of policy-making. In the final section, I wrap up the main conclusions of my analysis in

relation to the concepts of imagination and imaginaries. In particular, I want to engage with the first part of this book's title: *shaping the future.* What are the *consequences* of the imaginary work that I have described and what does this pragmatically entail for social analysis?

ILSI Europe

I have been rather sparse with information as to the how and why of health claims in the EU: what are they, why are they defended, when did they emerge and why. In short: I have not placed health claims in their context so far. It is customary to draw up the context of a question to readers before delving into the specificities or technicalities of it. Such an approach is conventional, for reasons of clarity and pedagogy. At the same time, such an approach runs the risk of reiterating what others have defined as the 'context' for health claims. Indeed, drawing up a context for health claims and defining what they are form part of the technology of demonstration designed to make health claims on food products possible. Health claims have emerged together with their definition and a rationale for their pertinence and necessity. Rather than separating context and subject matter, I propose to discover the two together through a scientific paper that stands as a landmark for the concept of functional foods and health claims *in the EU*. It is important to emphasize 'in the EU', as this is another instance, as we will see, of how subject-matter and context inform each other. Put differently, I will analyse a context-building document or the *setting of a problem*. A concrete entry point into that document to start with is its authorship: a consortium of life scientists interested in nutrition. Their texts are geared to turn their interest in nutrition into a specific nutrition science that they call 'functional food science'. The consortium was gathered by the European branch of an industry-funded think tank called the International Life Sciences Institute (ILSI). This is how ILSI presents itself on its website[2]:

> 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)

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 visionary'[3]. 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 was determined to 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[4].

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[5]. ILSI Europe (henceforth: 'ILSI'), gathers scientists from all over Europe into thematic task forces. Currently, there are 21 task forces[6], covering themes like: 'dietary carbohydrates', 'threshold 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[7]. 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'[8].

Functional food science for Europe

ILSI Europe successfully applied for a European grant from the European Commission's 4th Framework Programme, and in 1995 it started to extend its network through a project called *Functional Food Science for Europe* (hereafter: FUFOSE)[9]. This project resulted in the publication of a programmatic paper for functional food science in the British Journal of Nutrition in 1999. The paper has now become a landmark reference to cite in any report, paper or article that deals with functional foods, its science or its history.

The aim of the FUFOSE project was to 'establish a science-based approach for concepts in functional food science'.[10] 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, p.1)

The ILSI think tank starts thinking from the answers and solutions they already have. The *answer* is that 'specific' nutrients and food components positively affect the human body.

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 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, consider that certain products, like yoghurts, are 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. Yet, ILSI needs to find an inclusive approach for its 62 different member companies. A second and related reason for eschewing a 'product-driven' approach is Europe's market itself. The composition of food products is a problematic issue that often divides the Member States, one that risks obstructing the free movement of foodstuffs within the Community. 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[11]. Aware that certain countries were sceptical about this health niche, ILSI wanted to benefit from a first-mover position 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. 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, Méadel and Rabeharisoa, 2002). The detachment that ILSI proposes, however, is peculiar: to value and qualify food *ingredients*, food *products* must become invisible. Historian and philosopher of science Gyorgy Scrinis has coined such a strategic focus on separate nutrients 'nutritionism'[12].

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 speak in the name of public health. ILSI wants to contribute to the 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. Roberfroid, 2000; Howlett, 2008; Chadwick, 2010).

In its mission and faith to connect science and public health, ILSI and its nutrition community envisages a form of specialism or even professionalism through a common approach to health around the object of functional foods (instead of drugs): '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 FUFOSE project (Roberfroid, 2000, p.1661). However, in contrast to past communities of advocates for more rigorous drug trials in the form of the randomized clinical trial (Marks, 1999), the community that the FUFOSE project created is not anti-commercial. The boundary that this community wants to set 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)[13]. If Marks' therapeutic reformers operated according to a certain moral economy with the authority of evidence as its point of gravity (Marks, 2009), then, I argue, the functional foods community is trying to establish a point of gravity and a form of evidence of its own, in a moral

economy where 'stakeholders' 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

The FUFOSE project ended in 1998, and in 1999 the results of their final consensus meeting 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, p.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. (Diplock et al., 1999, p.6*,* 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 is rather 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. (Diplock et al., 1999, p.6, 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[14].

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 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*.

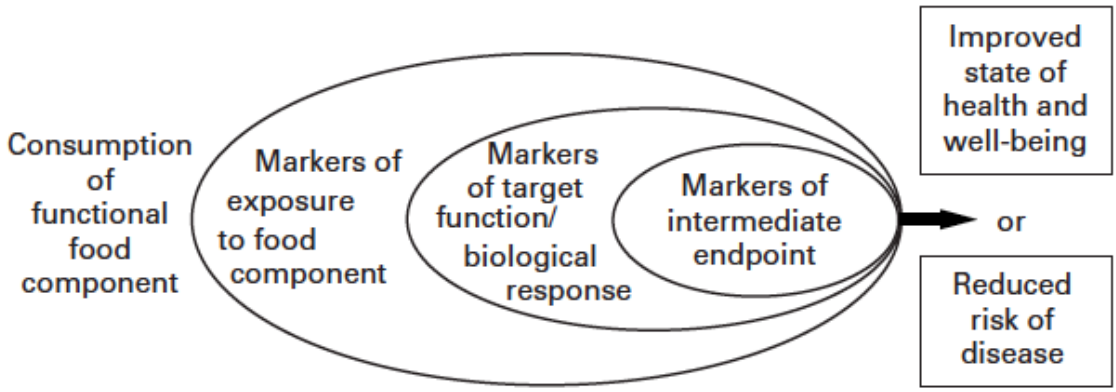

Figure 3.1: Classification of markers relevant to the effects of functional foods
(Reproduced from Diplock et al. 1999, p.7)

Figure 3.1 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.

Two key issues about this classification of markers are of importance for my characterization of functional food science. Firstly, the word 'clinical' has no significant role 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 mentionings is pertinent to this study. In a paragraph on 'safety considerations' the following is stated: '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 occurring 'directly 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, p.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[15].

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.
> - 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, p.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 et al., 2011) of ILSI Europe-affiliates explains:

> The FUFOSE 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 et al., 2011, p.4)

To summarize, 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. FUFOSE 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[16]. 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 sum up 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 of association or 'articulation', which is *constitutive* in theoretical-experimental sciences (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 scienists here. Competence is not the issue. 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 researchers 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), the functional food science imaginary turns the body into a site to differentiate food from drugs, and health from disease, by externalizing the clinical from its 'box' of mechanisms. Functional foods have no patients, but consumers (cfr. Mol, 2008). Consumers' experience of well-being is 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). Figure 3.2 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.

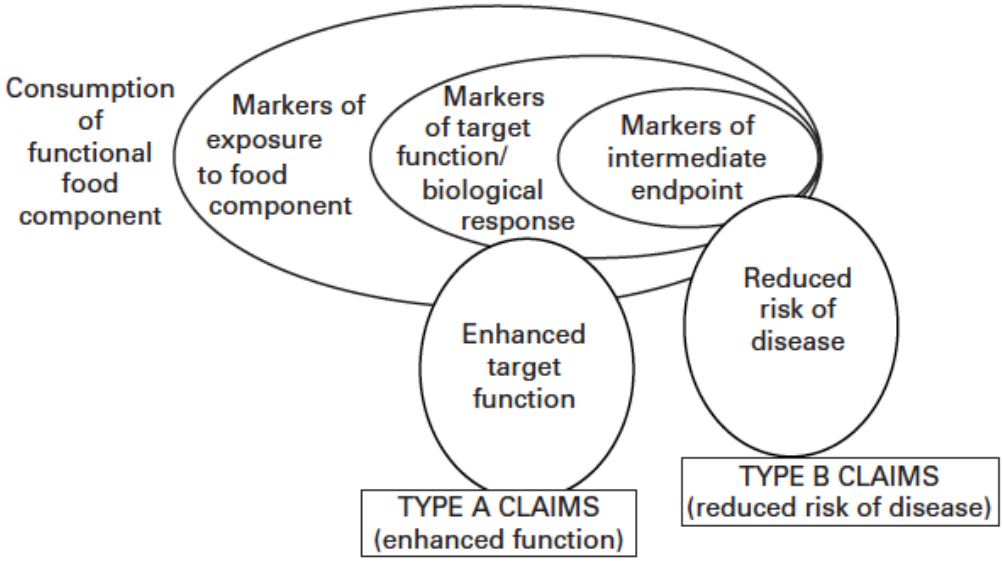

Figure 3.2: The human body as a point of articulation between components and claims (Reproduced from Diplock et al., 1999, p.25)

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 the object itself can also at a certain point contradict a claim or hypothesis. In *Laboratory Life*, Bruno Latour and Steve Woolgar (1986) show 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 be 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, which represents a considerable investment and the taking of risks. Functional food (science) uses the risks taken by other researchers; it starts from recognized objects and makes 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 out. This is not pejorative per se, but it enables us to distinguish the 'technical' from the scientific in the way that Isabelle Stengers proposed: '(T)o treat technique as distinct is crucial if we

are to resist the effects of fascination associated with discourse about the inexorable technoscientific redefinition of the world.' (Stengers, 2011, p.340). The scientific and the technical do not automatically imply each other, and distinguishing them draws attention to the specific conditions their interaction requires.

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[17].

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. Moreover, rational pharmacology imagines a future where clinical trials themselves are no longer necessary (Pignarre, 2004, p.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 as contributing 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[18]. 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:

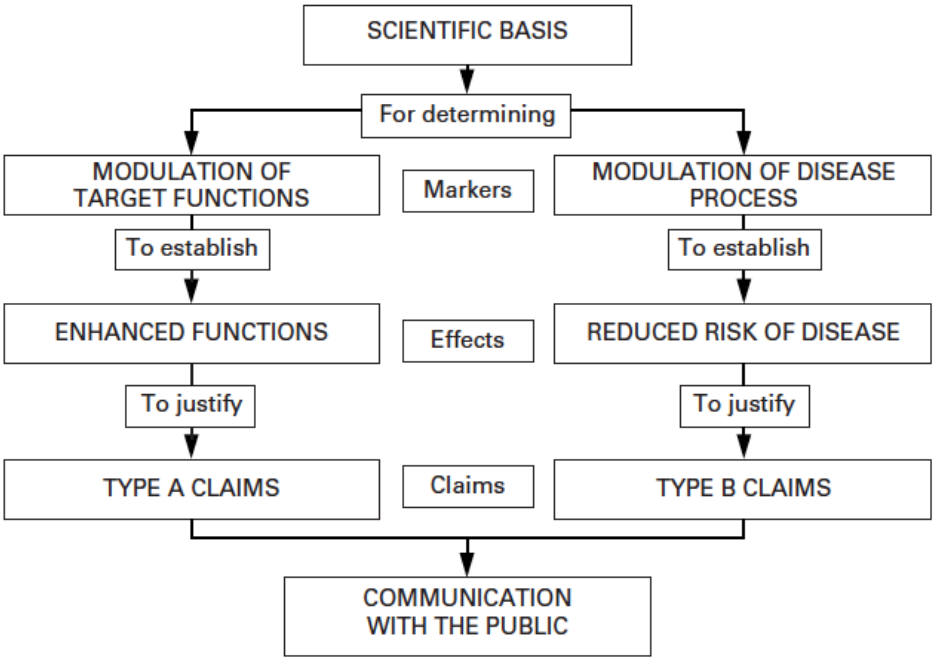

Figure 3.3: A functional food roadmap to product development and regulatory science (Reproduced from Diplock et al., 1999, p.25)

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. The European Commission's proposal for a health claims regulation in 2003 (four years after the publication of the Consensus Document in 1999) took up these categories and cites FUFOSE as 'valuable work' (European Commission, 2003, p.9). In that same proposal, the Commission interpreted the legal prohibition on medicinal (or 'disease-related') claims on food as going too far, and as not in keeping with new technological developments (2003, p.2). This made disease *risk reduction* claims possible. That way, they avoid connecting a food ingredient to disease as a clinical outcome, while still making a therapeutic claim. Avoiding that confusion also fits the food industry's agenda to create a market niche out of 'health'.

FUFOSE's follow-up project, conveniently called PASSCLAIM – 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[19]. PASSCLAIM is the acronym of: ***P****rocess for the* ***A****ssessment of* ***S****cientific* ***S****upport for* ***Claim****s on* foods, and it is one step closer to policymaking – or rather, the 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 now briefly turn to this project.

PASSCLAIM: calibrating the balance before weighing

Like FUFOSE, PASSCLAIM is based on a strategic programme geared to establishing scientific consensus about the criteria of 'sound science'. Published in the European Journal of Nutrition (Aggett et al., 2005), the 'process for the assessment of scientific support for claims on foods' – or PASSCLAIM project - gathers expert groups around pre-established body functions. Indeed, ILSI itself, as we have seen above, has been subdivided into thematic 'task forces'. The themes are set by food companies that are members of the organization[20]. Even more explicitly than in FUFOSE, the PASSCLAIM project, as the acronym indicates, is a strategic programme to deliver a science base to policymakers when a European regulation is under 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 has decided to regulate[21], welcomed such input, and the framework programmes were there to generate policy-relevant inputs[22]. A total of six 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 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 the 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 studies, to define 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 (Timmermans and Berg, 2003), 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 well 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 [sic], 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 a human diet. At the same time, nearly all confounding variables stem from the human diet. 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 clinic must be detached from the body and markers made to stand for the clinic. 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.

Re-engaging imagination

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 witness* (Stengers, 2006) 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 expert judgement. Evidence-based Nutrition, present in FUFOSE and PASSCLAIM, and explicitly championed as opposed to evidence-based medicine in more recent papers (e.g. Biesalski et al., 2011), is a conceptual apparatus to invent both a new type of product and an expert to evaluate it.

The ILSI consortium claimed that we are at a new frontier in nutrition science, and suggested that a new role for food in public health has become possible. However, the stratagem analysed is not oriented towards new research questions and possibilities in science, but towards ways of *closing down* scientific questions and speculations. ILSI wants to create not only certainty, but a *guarantee* that their methods and concepts will bring certainty with respect to the relation between food ingredients and the human body – a certainty that is translatable to a health claim on a food label. Scientific research arguably also aims to bring more certainty, but the crucial difference with ILSI's evidence-based and consensus-based approach is that scientists will never guarantee that a specific method will bring that certainty. Revising methods and concepts are part and parcel of scientific work and nothing can be guaranteed in advance. Arguably then, the guarantee that ILSI wants to bring for its own corporate, commercial, political and sectorial reasons signals the end of scientific imagination. Does this mean that ILSI is unimaginative? The document I have analysed, full of strategic concepts, seems to point out the opposite. Where to go then, with this concept of 'imagination'?

The theme of this book is the relation between science and imagination or imaginaries in shaping the future. Analysing the ILSI stratagem where imagination is being put to work into specific operational concepts ('shaping the future') has convinced me that more precise conceptual distinctions in the realm of what we call 'imagination' and 'imaginaries' may be needed. This, in relation to a distinction that has been central in this chapter: the distinction between scientific practice on the one hand, and the development of policy-oriented technical concepts, or an *evidence*-base, on the other. This distinction is critical in order to avoid and resist the expectations, rhetoric and intimidations that result from the quick merging of science and technology. This merging obliterates the different relations and exigencies vis-à-vis an object or phenomenon under research, as I have tried to show through my close reading of functional food 'science'. The *shibolleth,* as Latour calls it (1997; 2004), that distinguishes science from – in our case – a technology of demonstration wrapped in the discourse of science, is the following question: 'is the object under research granted the power to redefine the questions that we address to it?' A good scientific experiment then, 'maximizes the occasion for the phenomenon at hand to raise its own questions against the original intentions of the investigator' (Latour, 2004,

p.219). The approach, the exigencies and the consequences of scientific *practice*, then, are very different than the approach that ILSI pursues *in the name of* science. In this conclusion, I suggest that this difference should make us attentive to different forms of 'imagination' or collectively cultivated 'imaginaries'. ILSI, arguably, mobilizes a form of imagination to operationalize the human body as a test site different from the clinical trials for drugs. As we have seen, this working of the imagination operates under a set of very specific constraints that are at once legal, political, technical and commercial. As such, the imagining work relates closely to already existing arrangements that are actively remodelled. Put differently, ILSI *engages* with its object in a very specific way. Common dictionaries define imagination in contrast to reality: imagination is a form of fiction. However, what both scientific practice and evidence-based approaches like ILSI's have in common is that they are geared to *change* reality, thereby operating in the interstices of fiction and reality. What makes them different is the way they engage with the world in order to produce new realities.

If we take 'imagination' to cover very different *modes of engagement* with the world and with specific phenomena and objects, then we might want to become attentive to the forms of imagination that we deploy as social scientists as well. And this stands in direct relation to the status of an analysis like the one in this chapter about the specific strategies of a group like ILSI. Concluding that ILSI is not a scientific consortium but a strategic think tank or lobbying group is hardly surprising.

So, rather than simply denouncing ILSI's claim to science while they are doing something else, I wanted to draw attention to the specificities of what it is they are doing. I wanted to tease out how they engage with their main object: functional foods. ILSI indeed provides the basis for what can be called 'regulatory science' (Irwin et al., 1997) or 'cameral science' (Stengers, 2013), but the texts that I analysed also shed light on an ontological matter: the separation of food from drugs needs conceptual, material, methodological, political and technical *work.* Food ingredients, health claims, the human trial subject, but also drugs and pharmacology are *boundary projects* (Haraway, 1997). Indeed, the division between food and drugs is a historical and ongoing boundary project. Considered that way, it is not helpful to see functional foods as a blurring of the division between food and drugs. Rather, functional

foods are a concerted, consensus-based and evidence-based project to reinvent and reaffirm that division differently. Many commentators have characterized functional foods as an instance of the medicalization of food. Again, the opposite is true, as the main stake in the functional foods projects is to articulate a difference with medicine. This changes the game for the social researcher too: given distinctions are not suddenly blurring, and indeed distinctions are perhaps not 'given' at all. The difference between food and drugs, their markets, and experts is not a given, but it is *at stake.* This establishes ontological uncertainty as the 'default position', as it were, from which to start thinking, posing questions and engaging different forms of imagination. This resonates with a line of inquiry that runs through the entire work of Michel Foucault. One of his main questions was what *singularizes* things (e.g. Burchell, Gordon and Miller, 1991). Here, we could ask, along with Foucault, what singularizes food and medicine; how are they singularized; how did we come to talk of 'the human body' the way we do in the first place? And even more importantly: what other versions of the human body exist, or *could* exist (i.e. could be imagined and realized)? Imagining boundary projects is inherently political, and the deal is not to denounce that political nature, but to resist the early taming and closing down of important societal matters by the hasty (self-)appointment of experts[23]. Thinking from (and with) ontological uncertainty indeed denaturalizes divisions between the makers of knowledge, recipients of knowledge and a priori limitations on who is concerned by this knowledge. It emphasizes the singularization of problem-frames and the fact that things could have been different and could still be different. Next to critical genealogical analysis, it makes a bet on possible worlds, while being sensitive to the question of who is in charge of imagining those possible worlds. Thinking from ontological uncertainty relates knowledge to power indeed, while at the same time making an appeal to a kind of imagination that seeks to cultivate an appetite for such uncertainties and the speculative horizon of the possible.

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[1] In dialogue, both empirically-inclined thinkers have elaborated a pragmatic and normative theory as to what the practice of science demands from its researchers, thereby redefining what a successful experiment means, other than in methodological and epistemological terms. Their work connects well to that of Bruno Latour, as can be read, for example, in an article that Latour has written on what he calls the 'Stengers-Despret falsification principle' (Latour, 2004). These relations and concepts will be developed and applied through the chapter.
[2] http://www.ilsi.org/Europe/Pages/Who-We-Are.aspx (Accessed 15 January 2014)
[3] Personal interview with ILSI's deputy director in Brussels, 26 August 2011.
[4] Argentina; Brasil; Europe; China (ILSI 'focal point'); India; Japan; Korea; Mexico; North Africa and Gulf
[3] Personal interview with ILSI's deputy director in Brussels, 26 August 2011.
[4] 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.ilsi.org/Pages/GlobalNetwork.aspx
[5] Interview at ILSI, Brussels, 26 November 2010 with FM and FR.
[6] As counted on the ILSI Europe website on 15 January 2014: http://www.ilsi.org/Europe/Pages/Task-Force-List.aspx.
[7] The procedure is briefly explained on the website (see footnote 37).
[8] Ibid.
[9] 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.
[10] Consensus Document, preface.
[11] See for example: Heasman and Mellentin (2001).
[12] See his book Scrinis (2013). For his characterization 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.*
[13] 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.'
[14] 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'.
[15] 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.
[16] Interview at the European Commission, DG Sanco, Brussels, 23 April 2013.
[17] Personal interview at ILSI's Annual Symposium. Brussels, 24 March 2011.
[18] See Pignarre, 2004, 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*.
[19] Interviews at the Belgian Federal Ministry of Health, Brussels, 12 March 2012, and at the Commission's DG Sanco, Brussels, 23 April 2013.
[20] Interviews at ILSI Europe, Brussels 16 November 2010, 26 November 2010, 26 August 2011.
[21] Barry (2001). During the 1980s, the EU went through a reform and expanded its areas of regulation. See e.g. Young (2005, p.105), and the work of lobbyists Guéguen (2007) and Guéguen and Rosberg (2004).
[22] 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.' Aggett et al. (2005, p.3)
[23] This, of course, echoes Bruno Latour's *Politics of nature* (1999), and Callon, Lascoumes and Barthe's *Acting in an uncertain world* (2009). I connect their work to Haraway's commitment, through all of her work, to speculation, fabulation and science-fiction.