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Functional foods: regulation and innovations in the EU

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Worldwide consumers are becoming more interested in the relation between food and health. In order to harmonize regulation on foods throughout the EU, the Regulation EC1924/2006 on nutrition and health claims came into force, as a first specific set of EU legal rules dealing with nutrition and health claims. A Union List of EU-wide approved claims is now being developed that creates a level playing-field on which food operators can innovate, backed by legal certainty to ultimately bring benefits to the consumer. This paper assesses the new Regulation and its impact on the functional food innovation process, functional foods being conventional food products with added substances to promote health. Food innovation is perceived as a collective effort of a variety of actors within the context of a network of institutions, whose activities and interactions initiate, import and diffuse new innovations. Both desk research and semi-structured interviews with actors in the Dutch functional food value chain have been performed to explore the impact of the new Regulation. It seems that the new regulatory regime may not only be restrictive but also selective for future functional food innovative activities.

Keywords: EU legislation; nutrition and health claims; functional foods innovations

Introduction

Nowadays, there is a growing interest in the benefits of foods promoting health and reducing the risk of disease, within the food industry and amongst health care professionals, consumers and society in general. One special category of healthy foods is functional foods: "A food can be regarded as functional if it is satisfactorily demonstrated to beneficially affect 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, or reduction of risk of disease" (International Life Sciences Institute 2002, p. 5). A functional food may enhance human health (e.g. reducing cholesterol, hypertension, constipation), but must remain food (e.g. butter Becel ProActiv) and it must demonstrate its effects in amounts that can normally be expected to be consumed in the diet, not as a pill or a capsule, but as part of the normal food pattern (Diplock *et al.* 1999). A healthy diet is becoming increasingly important in the European Union (EU), as the prevalence of common diseases such as obesity, diabetes and cardiovascular disease is rising (Buttriss 2010). Disease prevention by increased consumption of functional foods may induce substantial

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medical costs reduction (Chadwick 2003), which makes functional foods also interesting from a socio-economic perspective.

Health claims of food need to be scientifically substantiated and correctly interpreted by the consumer. Precise and informative food labels can help consumers to make informed food choices and to select the most appropriate foods for a healthy diet (Van Trijp 2009). Because former regulation on health and nutrition claims was insufficient, the use of claims on products has been abused, which has led to confusion about health claims. In order to prevent consumers being misled by unclear information on food products, the EU has formulated new regulation on nutrition and health claims (EC Regulation 1924/2006) to protect and support consumers in their healthier food choices. This new Regulation aims to guarantee that claims are trustworthy and do not misguide consumers. Furthermore, its purpose is to stimulate innovation to produce healthier food products in the food industry (Buttriss and Benelam 2010). Functional food innovations are dependent on continuous advances in nutrition science and the development of innovative technologies by the food industry. Food operators within the entire functional food value chain are involved in functional food innovative activities. A clear and uniform regulatory framework governing functional food innovations may increase the sales of functional food products, for example, when approved health claims are used as marketing tool, improving the competitive position and innovativeness of food manufacturers. Furthermore, it may lead to a scientifically grounded functional food innovation system with products that really benefit consumers, and to a decrease in the previous consumer skepticism owing to the lack of scientific substantiation of many functional food products (Pennings 2012).

Accordingly, the innovation process of functional foods is not an isolated process but an interplay of various actors in a so-called Innovation System, being defined as a "network of institutions in the public and private sectors, whose activities and interactions initiate, import, modify, and diffuse new technologies" (Freeman 1987).

This paper assesses the new EU Regulation 1924/2006 (i.e. new Regulation) on nutrition and health claims and its impact on functional food innovation processes. First, it provides a description of the new Regulation on nutrition and health claims on food products. Then, it briefly presents the food innovation system in general. Based on literature and exploratory interviews, the paper argues that the new regulatory framework imposes large requirements on food operators, which can be an obstacle to food innovation. This provides reasons for food operators to reconsider their role in functional food innovation.

Current regulation on nutrition and health claims made on foods

Before new EU regulation came into force in 2006, each EU Member State had its own regulation concerning health claims on food. Many of them worked with codes for self-regulation (AGNS 2007). Various countries, such as the Netherlands and the UK, developed a voluntary guideline for health claims of foods. The main criterion was that the claim had to be based on generally accepted scientific evidence. Products could be assessed after they entered the market and authorities could not force firms to comply with the guidelines (Buttriss and Benelam 2010). At that time, food manufacturers had to meet very different legislative frameworks concerning approval of functional foods, the nutrition information required on labels and the types of health claims that were allowed. As a result, they had to expend much effort to

arrange the marketing of their product properly in each Member State (Caduff and Bernauer 2006, Bech-Larsen and Scholderer 2007). There was a growing concern that the variation in claims among the Member States would lead to misleading claims and barriers to trade (Buttriss 2010). In order to prevent consumers being provided with unclear or false information on food products, the European Commission started to develop new strict regulation concerning the requests of claims made on food products. Their first attempt in 2001 led to a situation in which all product-related statements about the prevention, treatment or cure of human diseases were forbidden. The second step proposal from the EC on nutrition and health claims made on foods included dietary supplements in 2003. In December 2006 the "Regulation (EC) No 1924/2006 on nutrition and health claims made on foods" was approved by the European Parliament and Council and adopted in the European Union, including the obligation to prove a claim on its scientific benefit to human health. It was the first specific set of EU legal rules dealing with nutrition and health claims. The main objectives of this new Regulation were: "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 food sector" (Buttris 2007). The new EU Regulation replaced all the previous regulation in the EU Member States, and the criteria for health claims on foods and the labeling became the same in each EU Member State.

Accordingly, the main goal of the new Regulation was to harmonize the different health claim regulations of the EU Member States, replacing the national regulation concerning health claims on food in order to provide a high level of consumer protection. It aims to develop an approved list of EU-wide claims, which creates a level playing field on which food manufacturers can compete and innovate, backed by legal certainty, to ultimately bring benefits to the consumer. The Regulation makes approval claims open to use by all food operators. Claims based on proprietary data are reserved for the exclusive use of the owner of the data for 5 years unless, in the intervening period, they are independently substantiated on the basis of data from alternative sources (Binns and Howlett 2009).

The new EU Regulation is obligatory for all the new and existing health claims on products. It implies that manufacturers have to substantiate the health and nutrition claims on new and existing food products, before a product enters the market.

What types of claims are discerned in the new Regulation? The Regulation defines *claims* as: "any message or representation, which is not mandatory under Community or national Legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has a particular characteristics" (EC 2006, Article 2.2.1). The Regulation defines three different claims (EC 2006, Article 2.4–2.6):

(1) *Nutrition claim* – any claim that states, suggests or implies that a food has particular beneficial nutritional properties owing to the energy (caloric value) it provides, provides at reduced or increased rate, or does not provide, and/or the nutrients or other substances it contains, contains in reduced or increased proportions, or does not contain.
(2) *Health claim* – any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

(3) *Reduction of disease risk claim* – any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents, significantly reduces a risk factor in the development of a human disease.

Food manufacturers have to send their food claims to national competent authorities of the European Food and Safety Authority (EFSA). At EU level, the EFSA is the risk assessment authority, providing independent scientific advice on food safety. EFSA is responsible for the assessment of the scientific evidence to support health claims. It delivers scientific opinions on the health claims submitted. The European Commission (EC) (DG Health and Consumers) discusses the recommendation and takes the final decision whether to accept or reject a claim. Furthermore, the EC is responsible for guaranteeing that the claim will be well understood by consumers (Buttriss and Benelam 2010).

Health claims could be divided into Article 13 and Article 14 claims. Article 13 health claims refer to: (1) the role of a nutrient or other substance in growth, development and the functions of the body; (2) behavioral or psychological functions; and (3) slimming, weight control, increased sensation of satiety or reduction in available energy from the diet (Buttriss and Benelam 2010, p. S9). If the Article 13 claims are supported by "generally accepted" scientific evidence (Article 13.1) and considered to be well understood by the majority of consumers, it is not necessary to compile a full dossier to gain authorization. A list of such claims is now being prepared. However, Article 13 claims based on newly developed scientific evidence (Article 13.5, "new science") must be authorized via submission of a dossier of evidence for examination by the EFSA (Buttris and Benelam 2010).

Article 14 health claims are those specifically referring to reduction of disease risk or to children's development and health. These must go through an authorization process on a case-by-case basis. Food manufacturers must submit a dossier with full details of the food/constituent and substantial scientific evidence verifying the claim. A systematic and transparent review of human studies data is mandatory, addressing the relationship between the food/constituent and health effect. Data from animal and *in vitro* studies may only be included as supporting evidence (Kiely *et al*. 2010, p. S103). Disease-specific functional claims on foods are now allowed if scientifically proven. Medicinal claims about preventing, treating or curing a disease are not allowed under the Regulation (Buttriss 2010).

Successful claims will be included in the community register of nutrition and health claims, which will be made available for manufacturers to use throughout the EU, with the exception of health claims based on proprietary data (Kiely *et al*. 2010). Decisions are being published in batches. The first batch of EFSA opinions was published in October 2009, a second and third batch in 2010 and further two batches were expected in 2011. The European Commission intends to present its draft Article 13.1 "Union list" of health claims that are permitted in the EU for adoption by the Standing Committee in December 2011. Whether the Standing Committee will directly adopt the text is as yet uncertain (NPI 2011).

The first batch comprised over 500 opinions, of which 30% were positive (mainly in relation to vitamins and minerals) (Buttriss 2010). Positive EFSA opinions on Article 14 health claims include plant sterols and cholesterol reduction, xylitol and caries reduction, iron and cognitive development in children, fatty acids and visual development in children, and various claims (e.g. vitamin D) related to bone growth

in children (Buttriss 2010). Owing to the enormous number of potential Article 13.1 claims applications to be assessed (i.e. around 44,000 claims submitted), the finalization of the nutrient profiling procedures and the publication of the Union List of Article 13.1 health claims by the EC is behind schedule (Buttriss 2010). In April 2011 the EFSA issued 442 claims opinions on a range of ingredients, including minerals, probiotics and fatty acids, and it had finalized 80% of its Article 13.1 claims assessment process for all substances (excluding botanicals). Around 600 claims are still in the process and expected to be published in the fifth and sixth batches later in 2011 (NPI 2011).

Under the EC Regulation 1924/2006, to be called a functional food, a food might be expected to have the right to carry a nutrition or health claim on the approved list. Claims that are not on this list will no longer be allowed and will be banned in the short term. Since the new Regulation came into force, there are transition periods for all Article 13 claims on food products already on the market (Buttriss 2010). Right now, the length of the Article 13.1 transition period is uncertain, which is expected to expire at some stage in 2012 after the Union List's adoption (NPI 2011). These transition periods in regulation give food operators time to meet the new criteria concerning nutrition profiles and health claims on foods by product reformulation and innovation.

In the United States, the US Food and Drug Administration (FDA) is responsible for the regulation and supervision on foods and drugs. All food products, including functional foods, are regulated by the Federal Food, Drug and Cosmetic Act. The United States does not have a category of foods that is called "functional foods", like in Europe. The FDA currently uses three sets of legislation documents to determine which claims can be used in labelling for a food or dietary supplement (AGNS 2007):

(1) The Nutrition Labelling and Education Act of 1992 and the Dietary Supplement Health and Education Act of 1994. These Acts give the FDA the authority to approve health claims based on extensive review of the scientific literature.
(2) The Food and Drug Administration Modernization Act of 1997, implying that health claims may be based on an authoritative statement of a scientific body.
(3) The Consumer Health Information for Better Nutrition Initiative of 2003, when the evidence for the desired health claim is not strong enough to pass the significant agreement standard by the first set of regulations.

The United States developed its first Act concerning health claims in the 1990s, about 10 years earlier than the EU. Furthermore, the FDA both assesses the health claims (by means of expert commissions) and makes final decisions regarding market approval, whereas the European procedure involves more entities. The European decision process seems to be more democratic (and bureaucratic) than in the United States, where FDA has all the decision power. Both the EU and the United States allow claims that refer to certain ingredients and their effects on functions and structures in the body. Medical claims are forbidden but the EU allows reduction of risks claims, while the United States only allows nutrient deficiency disease claims. The evidence for health claims must be based on generally accepted scientific evidence. Main difference between the EU and the United States is that the United

States may allow health claims based on authorative statements of a scientific body and may even allow claims that are new and for which a solid body of scientific evidence is not yet available. These kinds of market approvals are not possible in the EU. Furthermore, the criteria for new health claims in the EU are stricter than in the United States, owing to the demand for clinical studies. In the United States, the liberal regulatory framework regarding the use of health claims made it easier for food companies to market their products (Van Zoest 2009, Pennings 2012). Summarizing, the new EU Regulation on functional foods appears to be more restrictive than the current regulation in the United States, with lengthier timelines for market approval, which affects the EU functional food innovation system.

The functional food innovation system

Innovation is not a linear, one-actor process. Innovation is perceived as a collective effort of a variety of actors within the context of an innovation system: a network of institutions, whose activities and interactions initiate, import and diffuse new innovations (Freeman, 1987). As a consequence, all actors influence the final outcome of the innovation process. Actors involved do not possess all the information and they must function under conditions of bounded rationality (Smits and Kuhlmann 2004).

New product development, such as functional foods, represents a science-based innovation trajectory, carried out by a network of interrelated actors with various interests and perspectives, such as food producing companies, universities, intermediary research institutes, authorities, consumers and the supportive infrastructure, including investors and consultancy firms (Figure 1). Cooperation between food companies will become increasingly important, for example in sharing the risks and costs of the research for the health claim dossiers.

Many food companies also have science-based collaborations with universities and intermediaries (e.g. research institutes) to conduct clinical studies for their health

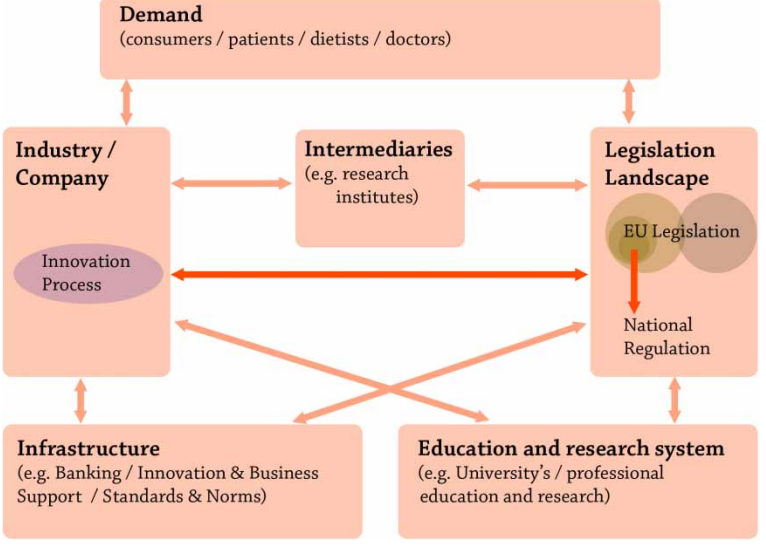

Figure 1. System of innovation. Reproduced with permission from Benthem (2007).

claim dossiers, and to gain rapid access to new scientific and technological knowledge and to benefit from economies of scale in joint R&D. Universities are a strong research partner, as functional food research is an expanding area at universities.

Needs and preferences of consumers not only become visible in the end stage of new product development, but often are articulated throughout the innovation process in, for example, research agendas of firms, wishes of retailers and experiential knowledge of consumers (e.g. Moors *et al*. 2008). Customers are expected to be an increasingly important cooperation partner for functional food operators because of their need for more extensive knowledge and information exchange related to the health claims, if functional food contains specific ingredients. Suppliers often arrange the health claim dossiers together with an ingredient. Often suppliers and customers work together to develop new applications of the functional ingredient.

Most companies are in dialogue with the authorities, mainly the European government, for additional information about EU Regulation EC 1924/2006. The majority of their questions are about the criteria and the procedures for health claims on foods. In the future, even more intense contacts between the European government and functional food manufacturers about the new regulation are expected, when the approved claims list becomes available and the EFSA has assessed all the Article 14 health claims. The industry associations are often used as a forum for discussion and for new information and updates about the new EU regulation. The industry associations on European level (e.g. the Confederation of the Food and Drink Industries of the EU (CIAA, since 2011 called FoodDrinkEurope) represent many functional food companies in their discussions with the EC and the EFSA.

In addition to various partners, a supportive infrastructure is a precondition for functional foods innovations to take place. Development of EU funding proposals in support of research into functional foods is a possibility, for example within the European Technology Platform "Food for Life", which was launched in 2005 as part of the European Food Industry's input into the EU Seventh Framework Programme (FP7). Furthermore, functional foods may be part of the activity "From Fork to Farm; Food, Health and Well-being" of the Food, Agriculture, Fisheries and Biotech Theme within FP7, running from 2007 to 2013 (Binns 2009). Figure 1 visualizes the food innovation process and the EU regulation in the context of the innovation system.

The systems of innovation approach provides the framework within which governments form and implement policies to influence the innovation process. They play an important role in the development and control of regulation. Regulation can guide or control innovation processes in terms of setting rules or standards for products and processes. These standards are meant to improve the performance, quality and safety of products and processes (Tassey 2000). Sometimes they are driving convergence (Lindler 2008). Braun and Wield (1994) showed that regulation can affect technological innovation positively by providing a surrogate market. Sometimes, the purpose is to create greater clarity and uniformity among competing technologies or methods (Wiener 2004). The goal of the new Regulation EC 1924/2006 is to harmonize individual Member States' regulations on nutrition and health claims made on foods and to ensure a high level of protection for consumers.

The creation of standards, such as a Union List of approved claims, decreases uncertainty for firms, since the new EU Regulation is obligatory for all new and

existing health claims on products and takes place before a product enters the market (EFSA 2007). Furthermore, clearer procedures would lead to less variation of requirements and a decrease in costs in the development stage. Additionally, transparency is important. More transparent claims approval procedures, adjusted to specific category of food products, could lead to more efficient and less time-consuming approval procedures (Mathioudakis 1999). Uncertainty will be reduced because companies can better oversee regulatory trajectory in the early stages of innovation process (Menrad 2004). However, being in transition, the new Regulation has not always been clear, which might impede the innovation process of health-improving functional food products (Coppens *et al*. 2006). Therefore, it is interesting to study how this new regulatory framework governs innovations in the functional food sector.

Methods

In order to study the impact of the new EU Regulation on functional food innovations, the innovative activities within the Dutch functional food value chain have been selected as an illustrative case study. In fact, the Netherlands has a long tradition in agriculture and food, for example in dairy products, and is leading in the foods and beverages industry in the EU (Innova 2008). Several multinationals, such as Numico and Danone, and many smaller food operators are situated in the Netherlands. The analysis draws on a variety of data sources.

First, an overview of the new Regulation concerning health claims on foods is presented. These data have been obtained via desk research (e.g. scientific articles, books, reports and websites of the EC, EFSA, FDA, ILSI, governments). Second, to complement these data, seven in-depth, semi-structured interviews with key representatives of the Dutch functional food value chain have been conducted. Stein and Rodriguez-Cerezo (2008) discerned only 10 Dutch companies with a functional food in the supermarket in 2004. Because the range of potential interview respondents is confined, we aimed to contact and interview a set of stakeholders that at least covered a large part of the Dutch functional food value chain. Seven organizations were willing to participate in the research. These include: a small supplier of functional ingredients; a specialized supplier of functional ingredients; a small supplier of bakery ingredients; a subcontracting firm; a large manufacturer of specialized food ingredients; a large dairy product manufacturer; and a very large food manufacturer. Organizations involved operated at different stages of the functional food value chain, in the production of ingredients, as an intermediate between ingredient suppliers and final product manufacturers, and as producers of functional foods sold in supermarkets. Respondents include a regulatory affairs officer, a product developer, a group manager, a lead scientist and a sales manager, all having a good overview of the innovative activities and regulatory affairs within their companies, and all being familiar with the new EU Regulation EC 1924/2006. The interviews were audio-taped and transcribed. The interviews were processed on conditions of anonymity.

Topics that have been discussed during the exploratory interviews are related to the building blocks of the Innovation System (Figure 1) as follows: knowledge development and learning processes related to the new Regulation (Industry/ Company, Authorities); substantiation of health claims (Education and Research System, Demand); interactions among firms and public organizations in the value

chain (Industry, Intermediairies); shifts in market strategies (Industry/Company, Supporting Infrastructure); and the relation between new Regulation and innovative output (Authorities, Industry).

Third, the interview data were confirmed and triangulated by desk research (e.g. legislative reports, policy documents, reports and websites related to the European and Dutch food sector and industry associations, scientific articles, press releases, etc.).

Results: regulatory impact on functional food innovations

This section provides the results on the impact of the new Regulation on functional food innovations. First some key characteristics of the European food sector are presented, as the context in which the new Regulation and innovative activities should be set.

The food sector is a stable manufacturing sector operating in a mature European market. Functional foods are part of it. As the largest manufacturing sector in the EU in terms of turnover and employment, the EU food and drink industry had a annual turnover of 945 billion euro (12.9% of total manufacturing sector) in 2009. With 4.1 million employees, the industry serves over 500 million European consumers and many international markets (FoodDrinkEurope 2011). It is a competitive and highly regulated industry. Traditionally R&D investment in the European food and drink industries has been very low compared with other EU industries and other countries' food sectors. R&D investments stagnated at 0.37% of industry output in 2006 (e.g. compared with Japan, 1%; Korea and the United States, 0.5%). (CIAA 2010). Various studies indicate that the reason for this lagging behind in R&D investments in the European functional food market might be the lack of harmonized regulations before 2006 (Gilsenan 2011, Bech-Larsen and Scholderer 2007, Yeung *et al.* 2007, Coppens *et al.* 2006). Other studies have focused on consumer acceptance of functional foods in Europe as a possible explanation of this lagging behind (Verbeke *et al.* 2009, Verbeke 2005, Ares and Gámbaro 2007, Urala and Lähteenmäki 2003, Menrad 2004).

The food supply chain has a complex structure, including a very fragmented market for the producers (with 14.5 million farmers and 310,000 companies in the EU) and a very concentrated market of large retailers. Owing to the high number (99.1%) of small and medium-sized enterprises (SMEs), accounting for 48.2% of total turnover, the EU food and drink industry has an unequal bargaining power when compared with the highly concentrated retail sector (e.g. the three largest retailers having more than 50% market share in majority EU Member States) (CIAA 2010). As a result, food companies have a lower capacity to invest and innovate.

Our research revealed many impacts of the Regulation EC 1924/2006 on functional food innovations. Based on the analysis of the discussed topics during the exploratory expert interviews in the functional foods value chain, and triangulated by data obtained from desk research (Van Zoest 2009), we made several findings. Within the functional food industry high development costs seemed to be an important challenge. Furthermore, the data showed that the companies followed either an early mover or a product follower strategy. Regarding the authorities, legal uncertainty reduced when the EU legislation moved towards harmonization and increased transparency. From the demand side, consumer skepticism regarding functional foods had to be overcome in order to increase

consumer understanding and acceptance. This leads to the following classification, which will be explained in more detail below.

- high development costs;
- early mover or product follower strategy;
- legal uncertainty;
- harmonization;
- transparency;
- consumer understanding.

High development costs

The new Regulation influences how the food innovation process is organized, thereby influencing development time and development costs, especially when costly and lengthy clinical trials needs to be done. Several respondents signaled that the cost of substantiating a health claim and building an accurate dossier is a serious hurdle for innovation. One respondent stated that it took 20 million euro on average to develop a good health claim dossier with extensive scientific evidence. The cost of bringing a novel food to the market varies considerably (globally between 4 and 24 million euro, inclusive of R&D costs); there are global regulatory requirements (safety, efficacy studies costing 0.5–4.5 million euro) and EU-specific regulatory costs (i.e. in addition to meeting common requirements of most regulatory systems: 0.3–0.75 million euro; CIAA 2009). The functional ingredient producers play an important role regarding health claims. These companies deliver the ingredients including a health claim and often take care of the health claim dossier. Manufacturers of functional foods for the supermarkets buy these ingredients and add them to their products (e.g. Omega 3 being added to a dairy drink). However, the functional ingredient producers are often SMEs and do not have the resources to submit new health claim dossiers. The new Regulation affects SMEs relatively more than larger companies. As their turnover is low (<2 million euro), the new regulation on claims will have significant impact on the end cost of the product. The costs of health claim dossiers may be too high for SMEs, accounting for $>99\%$ of Europe's food operators, because of their lack of financial resources (FoodDrinkEurope 2011).

Furthermore, the large companies also fear the risk to the image of the established brands, if claims prove not to be supported or product performance falls short of expectations (Binns and Howlett 2009). Therefore, a main problem for functional food manufacturers is the return on investment. Required health claim dossiers imply additional development costs, which are lost if the health claim is not approved. Even if the health claim is approved, the question remains, according to several respondents, whether or not the sales on the relative small European market, compared with the largest and oldest functional food market of Japan, followed by the United States (AGNS 2007), in terms of functional foods consumers, are high enough to earn the investments back. Furthermore, the small specialized supplier of functional ingredients expected that the R&D budget will be allocated differently in the future. Some ingredients may not have market potential without claims. These products might be canceled before reaching the market. The large dairy product manufacturer indicated that they focused on a smaller number of products. As a result, the pipeline was filled with fewer products, but with a stronger market

potential owing to the substantiated evidence for the health claim on these chosen products.

Early mover or product follower strategy

Despite high development cost, products with new health claims remain attractive. They provide an "early mover advantage" to companies that market the product first, which may result in higher sales and market leadership. However, it may be easier to follow the product leader when the specific health claim cannot be protected and generic products might appear very shortly after market launch of an inventive product, according to the large food manufacturer. Since all authorized claims, other than those dependent on protected proprietary data for their substantiation, will be available for everyone to use, generic products are mentioned as a threat to the operator's returns on investment. This makes product imitation more attractive than searching for new health claims. In that case, the product followers use the product leader to collect more information and to observe whether or not the claim is approved and what the market potential of the food product is. This may decrease financial risk. Developing a generic product may imply lower development costs, because the claim may be already on the EU Union List, and there may already be more scientific evidence available. As a result, a decrease of product innovation and an increasing number of product-followers might be expected.

Legal uncertainty

Delays in claim approval procedures of two to three years provide major disincentives to innovate and bring a product to the EU market, as the industry's return on research investment can be marginal. EFSA uses strict approval criteria and only a few dossiers for new health claims (Article 14) got a positive recommendation. At the moment, the proportion of existing health claims that will be banned from the market is still uncertain, pending the final Union List of claims. The proportion of new health claim dossiers that will get a positive recommendation of the EFSA and will be approved by the EC is also uncertain.

Some companies mentioned that after the new Regulation the pipeline was filled with fewer products, but the products had a stronger market potential because the evidence for the claim on these chosen products was more extensive as time and effort were more concentrated. None of the investigated companies raised their R&D expenditures on functional foods. This may be related to the high legal uncertainty currently. Some respondents of both large and small firms stated that they had reconsidered their investments in new health claims owing to the uncertainty about the feasibility of the health claim dossier and the returns on investment. The two large companies interviewed stated that they may not invest, or may less invest in new health claims if the EFSA remains as strict as it is at the moment. The smaller companies stated that they cannot afford these kinds of health claim dossiers anyway and will not develop new claims.

For food operators with products carrying claims that do not meet the nutrient profiles on the Union List, there will be a need to reformulate or remove these products from the market. The problem continues to be that it is not exactly known what the profiles will be, so reformulation has to wait. For new product development this means that nutrient composition is at best a guess until at the very least the

Union List with Article 13.1 claims is available. Food manufacturers call on the Commission to meet the legal obligations of the Claims Regulation without delay to provide legal certainty to operators in the application of claims on their products. Legal uncertainty adds costs and loss of market opportunities (up to 5 million euros in some cases). Or, according to Binns (2009), the intention of nutrient profiling has always been to stimulate innovation of healthier products, and while in the long term this may be the case for uniform EU profiles, some innovation has been put on hold now. The current system favors followers or secondary applications that can avoid regulatory costs and time delays (CIAA 2009). Some companies are changing the recipes of their products. Others have decided to focus more on a smaller product portfolio in order to spend more time and effort in substantiating the health claims with a greater chance of claim approval.

In that way the new regulation framework is forcing companies to improve or change existing products or product ideas and design in the early stage of innovation. However, many food companies are not taking any action now. They are waiting for the EFSA and the end of the transition period. When the uncertainty is reduced, companies may start to adapt their strategies, products and processes.

Harmonization and the efficiency of procedures

The aim of the harmonized Regulation EC 1924/2006 was to create bigger market potential, as the product can be brought on the market in all Member States based on the same documentation, and more efficient procedures by decreasing development time and costs. Before this Regulation came into force, food operators needed to negotiate market-by-market to seek approval to market an innovative product with a health claim, and in some cases no health claims were permitted. With the new Regulation, food operators only need one approval that covers all EU Member States. However, non-uniformity can also be advantageous because it gives companies the opportunity to enter the market first in countries with less strict criteria for functional foods.

All the respondents indicated that they had specialists involved in regulation. The information needed was obtained from governments, food industry associations and relevant websites. Most of the companies were already familiar with previous food regulation and the new EU Regulation was regarded as a follow-up step. Many companies continuously monitor the regulatory requirements and integrate the latest requirements in their product development cycles. The large manufacturer of dairy products had changed its intellectual property (IPR) strategy to secure the returns on investment; the other respondents had not changed their IPR policy. The respondent from the specialized supplier of functional ingredients stated that patents do not make any sense for the protection of health claims, because the claims themselves cannot be patented and become public information because they are on the label.

If a company cannot substantiate their health claims, they might leave the functional food market and focus on other food products. Their products might be "selected" away by preferred products with a health claim. Companies whose health claims are no longer approved will have to find alternative ways of marketing their products and advertising health benefits to consumers, with fresh innovative packaging or product label design, new tastes and slogans that fall outside the scope of the EU health claims regulations. Product differentiation could then be

achieved through the inclusion of special ingredients, even without making specific health claims. Claims can be made in different ways, for example, by combining ingredients with approved health claims with other ingredients (NPI 2011).

Summing up, products without scientifically substantiated health claims are selected away. This will make it more difficult for free-riders to market their products (Pennings 2012). In this way, the harmonized EU Regulation itself may become a selection mechanism in innovation.

Transparency

Customers of companies demand ingredients and products with health claims. Health claims offer functional food companies the opportunity to differentiate their products on mass markets, adding value to them, so reinforcing their competitive position. By establishing a Community procedure for evaluation of claims and a register for those assessed to be valid, the Regulation provides an even playing field for all food operators, reducing the possibility for large companies to gain credibility for claims solely from their larger market presence (Binns and Howlett 2009).

The food industry asked for more dialogue and greater guidance for applicants and the EFSA is now organizing scientific stakeholder meetings, an essential step to ensuring applicants know what is expected of them (CIAA 2010). Currently guidance is also being developed on how authorized claims can be used by Member States. This could provide greater clarity and legal certainty for stakeholders, including the consumers.

Industry is not totally reliant on approved health claims and can increase market share by marketing products without claims via smart media offerings (Binns 2009). Some companies apply creative marketing techniques using vague fantasy claims (such as "super fruit"), implying that the product is extra healthy, without claiming anything. In the current regulatory framework, this might occur more often in order to avoid costly and lengthy health claim procedures and to sell products without a health claim, which does not improve the transparency for consumers.

Consumer understanding

The issue of consumer interpretation of nutritional information has received considerable policy interest. In the new EU Regulation the evidence for consumer understanding of nutrition and health claims is a prerequisite in the claim approval process, next to trustworthiness (i.e. scientific substantiation of the claimed benefit). From a consumer protection point of view, this is an important milestone in nutrition and health communication at the European level (Van Trijp 2009). After all, the new Regulation avoids consumers spending unnecessary money on products that do not have an additional effect.

Regarding health-enhancing functional foods, it is important for consumers that the information is easy accessible. Consumers like to obtain the proof of safety and efficacy of an functional food product from an independent scientific organization, such as the EFSA. Furthermore, regarding trustworthiness of claims, there is a consumer need for an independent quality symbol on the packaging. Reliable information about functional food products should be given by general practitioners, dieticians and TV programs about product quality and comparisons (Moors *et al.* 2009).

A food market in which available health claims are scientifically substantiated and effectively communicated to consumers guarantees transparency and informed choice and creates a level playing-field for fair competition among food operators, further stimulating innovations in the food industry (Van Trijp 2009). Successful functional food products are then those that are presented to consumers in a form that meets their perceptions and expectations with regard to traditional food characteristics (i.e. the consumer tendency to prefer naturalness in their food, associating "active" components with risk), and communicates the additional health benefits consumers can expect to obtain in a user-friendly context. The challenge is to re-establish the perceived value of food in general by improving its quality with regard to both taste and nutritional value (Binns 2009). According to Asp (2009), one of the key challenges and opportunities for functional food innovation is to add functionality to traditional foods in such a way that they retain their appeal, and yet deliver added benefits.

Concluding remarks

Food regulation is extensive and complex, especially for functional foods where health claims are involved. Regulation is becoming more detailed and prescriptive, such as the EU Regulation EC 1924/2006 on nutrition and health claims made on foods. This Regulation is obligatory for all new and current health claims on functional food products. The new Regulation is based on the precautionary principle, in which consumer protection has a high priority. By assuring a high level of consumer protection by demanding a high level of scientific substantiation of health claims, the new Regulation has created a research-driven market. The EFSA assesses the health claim dossiers and advises the European Commission, which finally makes the decision. This paper has identified various impacts of this new Regulation on functional foods innovations, such as high development costs, early mover advantage vs product-following strategies, legal uncertainty, harmonization and the efficiency of procedures, transparency and consumer understanding.

Health claims offer functional food companies the opportunity to differentiate their products on mass markets, adding value to their products, and so reinforcing the competitive position of their products. Furthermore, products with a health claim may be sold for a higher price, making health claims commercially attractive. On the other hand, the cost of developing and submitting a health claims dossier to be approved by the EFSA and the EC requires a lot of additional effort, time and resources, which appears to be a core problem for functional food operators. These costs overrule the expected returns on investments on innovative foods with new health claims. The large number of SMEs in the food sector cannot afford these additional efforts and will probably not develop new health claims on foods but accept a product-follower strategy. Furthermore, the number of approved claims determines the competitive landscape that will occur. If EFSA will reject the majority of the claims, the development of functional foods products may decline. If EFSA approves most of the claims, mainly large companies will be able to obtain health claims because they have enough financial resources, giving them a better opportunity to increase their innovation output.

The new EU Regulation had already some influence on existing functional food products: companies have changed their recipes, focused on fewer products or abandoned specific product development projects. However, the majority of

companies have not changed their position and are waiting for the health claim assessment results of the EFSA and the official Article 13.1 Union List of the EC. Meanwhile, an open dialogue between industry and authorities will lead to better state-of-the-art knowledge and understanding by authorities and vice versa regarding health claims. When these results are clear by the end of 2011, there may be a large change in the number of health claims on foods. Existing products might have to leave the market, because they are no longer allowed and new health claims might not be developed because the returns on investments may be too low. This might result in a total collapse of products with health claims on the markets and the development of new health claims. Maybe the current claims will be consolidated or only the strongest health claims and companies with enough resources to pay the high costs of health claim dossiers will be left. Small companies may develop creative marketing techniques and vague claims in order to stay in the market and avoid the lengthy and expensive health claim procedures. In other words, the new regulation policy may not only be "restrictive" but also "selective" for future innovative pathways in interaction with regulatory institutions.

The uncertainty about the health claims criteria should be reduced in the short term. This will enable companies to make a better estimation of the financial risks and the chances of approval. The first way to realize this is to wait and see which claims are approved to draw lessons from the success and failures of health claim submissions. These results give food operators more insight into the time, effort and quality of evidence needed for a health claim dossier. The EFSA may support this process by clearly communicating its criteria to the companies. Another way to reduce the financial risk of firms is to increase the possibilities for protecting health claims, as some parts of the health claim dossiers can be appropriated via IPR. During 2012, the transition period during which companies have been granted time to ensure that their marketing is in accordance with the list of approved health claims will expire and food companies will face the challenge of having to adapt their innovation strategies to benefit from the approved health claims and to develop alternative ways of marketing and advertising to communicate health benefits of products for which claims have not been approved. In this way, the new Regulation has a huge impact on innovation.

As the research population is small, with an emphasis on food operators, the results must be considered as a first, tentative, exploration of the impact of the new Regulation on the Dutch functional food value chain. Nevertheless, functional food operators in other EU countries have to meet the same regulatory requirements. Companies involved in this research cover at least a large part of the Dutch functional food value chain. Furthermore, the interview results have to be interpreted with caution as most of the respondents within the functional food value chain are industrial food operators (manufacturers, suppliers), which could bias the results.

This paper presented preliminary insights into the ability of the EU Regulation on nutrition and health claims to steer complex science and technology, such as the development of functional foods providing healthier food choices for consumers. The future of functional foods is dependent on continuous advances in food and nutrition sciences, technical innovation in the food industry, the regulatory framework and the ability to respond to evolving consumer demands. After all, a better performing European functional food innovation system can increase the health benefits of functional food consumers by a higher diffusion of functional food products in the EU or higher quality products, the consumers being better protected against

misleading products. Furthermore, it contributes to the competitiveness of European functional food firms on the global market, which will have a positive influence on economic activity within the European Union.

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