An Integrated Analysis of Food Information to Consumers: Problems, Pitfalls, Policies and Progress

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Abstract

The purpose of this paper is to contribute to the discussion on the positive and negative aspects of food information requirements, especially in the light of the acceptance of a new food information regulation (EU) 1169/2011. The methods which are used are legal and literature studies, case studies as well as the provision of supplementary data on the effects of food information requirements on consumer choices, costs and benefits. The field of food information is complex, since it includes legal, socio-psychological as well as economic aspects. The paper describes the major recent changes in food information law and the barriers to competitiveness of the European food industry as a consequence of connected problems and pitfalls. It suggests technical and legal solutions for improvement. The paper especially focuses on the major barriers to innovation: the competition on the package of legal and commercial information, the labelling of novel foodstuffs, (i.e., nanotechnology and gmo), and the authorisation of health claims. It advices to overhaul food information law: to integrate, simplify and to improve its logic.

Keywords*: labelling, food information, gmo, country-of-origin, nanotechnology*

1 Introduction, problem and goal

Uncertainty about and complexity of the content and structure of the required information to be provided on the food package is a major cause for transaction and investment costs to food businesses and public authorities. The regulatory burdens include among others the efforts which are made to bring innovative foods to the market (i.e., foods with superior technical, nutritional or remedial properties). From a public welfare perspective, incremental costs have to be weighted against the perceived extra benefits that users of foodstuffs experience of improved transparency and safety of foodstuffs. Scientifically, the provision of adequate food information requires interdependently regulatory, economic as well as consumer research. This makes the food information field of research complex. Moreover, the available knowledge of the relations between legal (systematic), economic (cost-benefit) and socio-psychological (consumers' perception) parameters which affect adequate provision of food information is scattered. An integrated approach is necessary to improve the understanding of the multiple effects of food information and facilitate the provision of effective policy options to change the European regulatory framework.

The goal of this paper is to assess the problems and pitfalls of food information in an integrated way, especially in the light of the new food information regulation (EU) 1169/2011. The paper will in § 2 review the novelties in the legal requirements of the regulation, as well as address major barriers to innovation in existing food information rules and regulations. Question marks to the appropriateness of the newly designed rules (their completeness, effectiveness and logic) will be placed. In § 3 the lack of appropriateness will be substantiated by means of data and cases including legal, economic and social origins and effects of the regulatory system. Finally, in § 4, policy challenges will be addressed.

2 Food information: changes, policies and pitfalls

In this paragraph we will review some of the major recent changes[1] to and backgrounds of the pre-packed food information system that has been institutionalised on behalf of final consumers (including mass caterers). Food information covers all information which is made available by means of a label, accompanying material, or any other carrier including modern technology (social network media for instance), as well as verbal communication[2]. The scope of food information law has broadened in course of time, especially with the adoption of the food information regulation (EU) 1169/2011 in November 2011 (abbreviated as 'FIR'). In Williamson's classification of social analysis this affects primarily level 2, the institutional level (Williamson, 2000). However, European food information is embedded in the European tradition and culture. Examples are the labelling and legal requirements of gmo, as well as the absolute ban of the use of hormones in the production of beef. Compared to the US, our system of requirements to labelling is different on a multitude of aspects. Ultimately, the system of food information will affect the way contracts are concluded upon (the 'play of the game' in Williamson's words), as consumer's attitudes influence labelling behaviour and *are* affected by it, and the optimisation of resource allocation on a firm and consumer level. Major changes which have been brought about, and which bring the business arena into a state of flux, are addressed.

The FIR repeals or amends several of the more than 100 existing directives and regulations that concern food information provision[3]. In first instance the impression may be that a substantial amount of changes and additions have been made. It should be reminded however, that the same or similar rules have re-appeared in the FIR at a different place or only in a slightly modified form. The general prohibition to mislead is included in the FIR again (Article 7 of the FIR; Article 2 of the present food labelling directive 2000/13/EC, abbreviated as 'FLD'), but actually is virtually superfluous, since such a prohibition already follows from the General Food Law (GFL; (EC) 178/2002). Article 14 (3) GFL specifies that food can be unsafe (and thus may not be put on the market) depending on the information that is provided. While some food information provisions are not necessary, other are not clear or their effectiveness can be doubted. Many have been transposed literally from the present FLD.[4] For instance, derogations from the obligation to reveal the quantity of an ingredient (Article 22 FIR/7 FLD) if this ingredient is included in the name of a foodstuff or is emphasized on the form of a picture, which is included in Article 6 of the FLD, is now to be found in Annex VIII of the FIR.

2.1 Water

In the FLD, (added) water to a maximum of 5% is exempted from being included as an ingredient in the list of ingredients (Article 6 (4) FLD). This exemption 'does not apply' anymore to meat, meat preparations, unprocessed fishery products and unprocessed bivalve molluscs (Annex VII – Indication and Designation of Ingredients, Part A, point 1). 'Does not apply' should, just like in the FLD, be interpreted that the amount of water has not to be

1 As for now the FLD is still mandatory, or actually the inclusion of labelling requirements in national law of the Member States on the basis of Directive 2000/13/EC.

2 For instance cry-outs on a market or an oral presentation of the food on the plate by the restaurant holder.

3 The Food Labelling Directive 2000/13/EC (abbreviated as FLD) is repealed, as well as among other 90/496/EC (Nutrition labelling). Some other are amended.

4 'Additives' for instance which are used as processing aids and do not have a function in the final product, are not considered to be additives (implicating that they do not have to be specified in the ingredient list with their category name and/or e-number). This is a lack of logic since an 'additive' which is not an additive is not an additive at all.

considered as an ingredient at all. It is strange that this exemption is included in Part A as its heading is "*Specific provisions concerning the indication of ingredients by descending order of weight*", which only refers to the *order* of indicating ingredients, not whether ingredients should be indicated or not.

2.2 Nano

The application in food ingredients of engineered nanotechnology will in future have to be indicated in the ingredient list of foodstuffs. The concept is disputed because it is almost impossible to find a suitable delimitation since "as used today, the term nanotechnology usually refers to a broad collection of mostly disconnected fields".[5] It is not simply the nano-size that is important, but also the novel properties of engineered substances. Taniguchi (1974) has early introduced the concept of nanotechnology, and explicitly referred to size as a decisive criteria, but since then its scope has altered (Whatmore, 1999). Substances/devices for which the size is critical to performance or behaviour (technical novelty criteria) is of importance, but also whether the phenomena which are brought about enable new applications (the 'commercial novelty' criteria). Applications of nanotechnology have enormous potential in the food and packaging industry, but are not without danger. The development of novel nano-applications makes it therefore necessary to regulate these in the legal framework (Chowdry, 2010; Mehta, 2004). Political barriers to adjust the novel foods rlegislation have led the idea to adjust the FIR and oblige food business processors to indicate engineered nanotechnology with the word 'nano' between brackets after each ingredient that is 'engineered' on a nano-scale. Surprisingly the package itself, which is potentially a major source of 'nano-hazard' (intelligent packages including nano-materials, etc.), has not been taken into consideration. In this context it should be noted that 'pre-packed food' is defined as consisting of a food *and* its package (Article 2 (2) – e FIR).

2.3 Allergens

Not only have allergens to be included in the list of ingredients, they also in future will have to be highlighted in it (with bold or italic letter for instance; Article 21 (1) b of the FIR). Allergens will have to be printed, just like all ingredients, with a font size of at least 1.2 mm[6]. New also is the requirement that mass caterers are obliged to provide information on the presence of allergenic substances in offered food, even if this food is not pre-packed anymore (Article 44 (1) FIR). Member States may decide how this information will be provided (Article 44 (2) FIR). The Codex 25%-rule with respect to composite ingredients is not at all applicable to European allergen information (see: Kjelkevik *et al.*, 1997).

2.4 Country-of-origin (or provenance)

Up until now, the country-of-origin had to be indicated if absence of such information would mislead the consumer "to a material degree" (Article 3 (8) of the FLD). Apart from the fact that an improvement has been made in skipping the quoted words in the FIR (see Article 26 (2) –a), the scope of country-of-origin-labelling (cool) has broadened considerably. Cool is upon till now mandatory in the case the labelling of beef. This requirement is directly related to the BSE-crisis (see in this respect Regulation (EC) 1760/2000). In future, certain kind of

[5] Further background information is available for instance via the Center for Responsible Nanotechnology: http://www.crnano.org/whatis.htm.

[6] The font size has been heavily disputed. Ultimately a minimal font size of 1.2 mm has been accepted, although exceptions (for instance depending on the available package surface) remain. In any case, allergens have to bear a font size of 1.2 mm.

meat have been added to this requirement– listed in Annex XI of the FIR – the application of which depends on the adoption of implementing acts by the Commission (swine, sheep, goat, poultry under CN Code Nr. 2010). Depending on these implementing acts, the scope could further be broadened to include other kind of meat, but also milk, unprocessed foods, single ingredient products, or ingredients representing more than 50% of a foodstuff. The requirements contribute considerably to the regulatory burdens of especially SMEs.

2.5 Nutrition declaration

Last to be mentioned here, but not the only major change and certainly not the least, is the nutrition declaration that will be *mandatory* for almost all foodstuffs (but some exceptions remain – like alcoholic beverages with an alcohol percentage > 1.2% vol.), where at present only in case of a nutrition claim such information has to be provided. In many cases nutrition declaration is already carried out on a voluntary basis. The nutrition declaration encompasses the energy value of a foodstuff plus its content of certain nutrients: fat, saturates, carbohydrate, sugars, protein and salt (exceptions are applicable, depending on the type of foodstuff and space on the package package). These may be supplemented with an indication of mono-unsaturates, poly-unsaturates, polyols, starch, fibre and an indication of vitamins or minerals (Annex XIII of the FIR, Part A). Fibre has moved from obligatory in the FLD to voluntary information in the FIR. Trans-fats have no explicit place in the nutrition labelling yet, pending further research and supplementary rules from the Commission.
Long transition periods up to five years have been granted because the redesign of package information will require investments, especially for those companies that do not have any experience with a nutrition declaration. Disputed has been, and still is, the way of *presenting* the information. In some countries, like England and Germany, traffic light symbols are used to designate the intake as compared to the daily advisable portion. It still is allowed to do so, but it is not regarded as an alternative for labelling in tabular form per 100 g/ml of a foodstuff[7].

2.6 Omissions: claims and gmo

Not only changes have been made in the present system of obligatory food information requirements, also omissions and missed chances should be mentioned: the revision of the labelling of gmo and of health claims.
If authorised, health claims are in many cases combined with obligatory nutrition information that substantiates this claim. Specific labelling requirements with respect to gmo are included in the gmo regulation package, of which for foodstuffs Regulation (EC) 1829/2003 is the most important, in combination with the general requirement that no gmo should intentionally be released to the environment without previous risk assessment (Directive (EC) 2001/18).

With reference to the mentioned problems and omissions, we will further address the following hypotheses with respect to key deficiencies and omissions of present information regulation.
Hypothesis 1: Information requirements on food ingredients lack logic and contribute to transaction costs of food business operators as well as of consumers.
Hypothesis 2: Present food information requirements with respect to gmo are contra-productive and impede on the innovation capabilities of food business operators

[7] This tabular form may be omitted depending on the size of the package.

Hypothesis 3: Present food information requirements with respect to health claims are contra-productive and impede on innovation capabilities of food business operators.

3 Disputed food information

This section provides examples of disputed regulation within the context of the formulated hypotheses. We will particularly focus on the effects of information on consumer choices, as well as on the economic consequences. Prohibitions and/or obligations to give information on a label aims to protect the consumer from digesting foods that are unsafe. The consumer comes first, the rights of industry are second in line, as is expressed vividly in Article 37 of the FIR: "voluntary information shall not be displayed to the detriment of the space available for mandatory food information". So consumer and business interests may conflict.
An abundant amount of studies have focused on the propensity to invest in novel technologies, consumer's behaviour with respect to their acceptance, and the connected role of the regulatory authorities in the institutional framework. Resource allocation (i.e., maximisation of welfare) via food businesses is initiated by human (consumer, managerial) behaviour, that itself can be explained from calculative propensities on the one side (like controllability, attitude) as well as by 'subjective norms' (Ajzen, 1991). Subjective norms are in turn legitimized in the social environment, which comprises 'culture' as a key determinant (compare: Hofstede *et al.*, 2010). Culture (the level of embeddedness in Williamson's framework; Williamson, 2000) is a major determinant for the institutional level, that hosts the formal the legal system. This provides the playing field for contracting and resource allocation. We are especially interested in the key variables culture, attitude (the 'intrinsic payoff' between perceived positive and negative consequences of action) and costs and benefits (the 'external payoff' of consumer/managerial action) which follow from this exposition. With reference to the hypotheses, three problem areas are addressed: ingredient labelling, gmo, and claims.

3.1 Controversies in generic labelling requirements

Previously we exemplified that the FIR has modified the system of ingredient labelling in a number of instances.

added water

A business practice, especially in the production of poultry, is to tumble the food in salty water so that it gains weight. As stated, new in the FIR is an exemption of the 5%-rule for some meat, poultry and fish products (see § 2). In practice added water – added for technical and/or opportunistic reasons- can range from 0% - 50%; so there is every reason to address malpractices, especially when consumers are misled. However, to our understanding the simple information that water has been added to such products is far from specific enough to influence consumers in a substantial way, as practically all businesses apply the same technical strategy[8]. In case of large quantities of added water it therefore still depends on the 'forensic' qualities of national authorities to enforce proper labelling information on the package.

[8] In principle a quantity indication of an ingredient is not necessary, unless the consumer is misled; the requirement to include water in the list of ingredients is included in Annex VII, part A.

nanotechnology

As already stated, the application of engineered nanotechnology will have to be indicated on the package next to each ingredient with the designation '(nano)'. This message is not intended for a specific consumer group, like is the case with allergens; rather, it is a generic message addressed to the 'average consumer'[9]. The question is *why* such information is prescribed at this moment in time. At present, the 'average consumer' is not very familiar with the concept of 'engineered nanotechnology' (Lee *et al.*, 2005). The indication itself may suggest that he/she is taking a serious risk by consuming the food, like is his/her impression of gmo. Empirical studies on consumer responses to novel food technologies by Frewer *et al.* (2011) reveal that a perception of 'unnaturalness' *alone* does not instigate public rejection of a food. The indication 'nano' may spur the food business processors to high levels of hazard analysis and risk management. But this is not the primary aim of food information law. The indication may come up to the 'right to know' of consumers, but where *are* these consumers that 'wish to know'? The requirement may trigger a negative attitude to the technology before it even has found solid ground in food business applications. Similarities may occur with the public rejection of gmo-food in Europe, where the European consumer has a profound perception of risk, combined with a low perception of potential benefits (Frewer *et al.* 2011; Pidgeon *et al*., 2005; Mehta, 2004). In the American situation this might be just the other way around (compare: Loureiro and Hine, 2004). In principle, engineered nanotechnology in foodstuffs or ingredients belongs to the domain of novel foods, but has not found its place there due to political disputes about how to change this piece of legislation. The fact that the indication 'nano' has to be included in the list of ingredients comes therefore to a surprise. As stated, the fact that "nano" has to be indicated in the list of ingredients might affect consumer's attitude towards the inclination that such ingredients are intrinsically hazardous, while scientific evidence on acute hazards cannot yet be substantiated.

country-of-origin labelling (cool)

Region-related product characteristics have a strong credence character. Labelling can help the consumer to differentiate products on the basis of its origin. The impacts of credence attributes on consumer choices appear to be product-specific and region-specific. A study in the EU by Verbeke and Roosen (2009) investigates the potential for market differentiation of fresh meat and fresh fish by means of a country-of-origin label, as well of quality and traceability information. It appears that -in general- quality marks (like 'best-before' indications) are more appealing to consumers than origin labels, and these more than traceability requirements. For beef, Roosen *et al.* (2003) concluded that consumers value origin labelling of beef more than private brands. Loureiro and Umberger (2007), applying choice experiments to US consumers, found that for beef the country-of-origin indication, traceability and tenderness are ranked lower than the official safety assurance by American authorities (USDA). Consumers that wish to distinguish themselves appear to be more aware of the origin of products than other. Also, ethnic ties enhance the awareness in specific consumer groups to the country-of-origin (Chand and Tung, 2011; Heslop, 2006)[10]. Country-of-origin labelling may be a disguised trade barrier, indicating superior quality or food safety

[9] See: Leible (2010) on the typology of the European consumer in food law.

[10] This is 'the individual's emotional attachment to shared identity' (Chand and Tung, 2011).

without scientific evidence, to the detriment of international competitors. Potentially, it is a source for disputes within the WTO (see in this respect: Hobbs and Kerr, 2006). Moreover, several studies confirmed the potential of ethnocentrism in consumer choice[11].
While the labelling benefits for non-red-meat products are doubtful, the transaction costs are manifest: investments in new labelling requirements, the task to distinguish origin in domestic-nondomestic, etc. The counter-arguments to a broadening of the scope of cool may well outperform the pro-arguments, whereas the arguments in favour may be just a cover-up for opportunistic motives vested in the protection of home markets.

3.2 GMO: friend or foe?

The way foods based on genetic modification techniques are treated in labelling is profoundly different in the US compared with Europe. In Europe, for food containing or consisting of GMOs, as well as food produced *from* or containing ingredients produced *from* GMOs, authorisation, supervision and labelling applies on the basis of regulation 1829/2003/EC. Labelling (a message like 'contains…') is exempted in case presence of gmo is unintentional and does not exceed a threshold of 0.9%. Whether the presence of such material in specific cases is intentional or not is open for dispute. In the Bablok case (C-442/09, 6 Sept. 2011) a bee keeper with this name and colleagues were accused of trespassing the gmo labelling and authorisation requirements, because of the processing and sales of honey that included pollen derived by the bees from a maize field planted with gm-Bt maize. Despite the fact that the pollen had lost their reproductive capacity (and so actually gmo's were absent in the final product honey), and despite the fact that one could argue that the material had come into the honey unintentionally, the bee keepers were said to have trespassed the authorisation and labelling requirements in Regulation (EC) 1829/2003.
The case of gmo-labelling and authorisation to the market highlights a profound disparity between the American and European cultural antecedents, which are reflected in the institutional settings. Labelling is, as Herrick (2005) states, 'one of the most effective allegories to illustrate the differences between the EU and US cultures of GM'. Notably, the food law overhaul that was induced by the BSE-crisis halfway the 90-ies of the previous century has changed our regulatory system from 'supply-driven' (US) to 'demand-driven' (EU). The differences between the regions is best exemplified by pointing at the application of the producer-friendly principle of 'substantial equivalence' in the US: foods that are gmo-derived but with respect to their chemical and nutritional properties equivalent to their conventional counterparts, are not subjected to an inquiry about their safety, they are GRAS: 'generally accepted as safe'[12].
Culture is, according to Hofstede *et al.* (2010), the 'collective programming of the mind which distinguishes the members of one group or category of people from another'. Risk perception with respect to gmo may be culturally embedded. As to Geert Hofstede (1993), uncertainty avoidance is one of the four categories to classify cultural differences between nations[13]. Differences in risk perception materialize in differences in labelling requirements and the interpretation of precaution in food regulation. If culturally determined risk avoidance is the only factor involved, it is puzzling why the opposition towards GM has been

[11] An recent overview of research on the topic is included in Lim *et al.*, 2011.
[12] In Europe there is a long road that leads to authorisation, or not (GMO compass.org, website, downloaded 20-05-2010.
[13] The precautionary principle origins from environmental law but has been interpreted in many different ways and is included in the General Food Law (Article 5).

fierce in the UK and virtually absent in the US, while uncertainty avoidance as well as long-term orientation for these nations are close to each other (Hofstede, 2010, Index scores of 2001). Communication channels, lobbying activities, as well as the structure of the 'contract social' between industry, the citizen and government are explanatory factors as well. While legitimate rights of food business processors are not explicitly recognized in the European GFL, at the same time – round the turn of centuries- the consumer has been made the focal point of all legal action, albeit at the cost of innovation.
Turning to governance and resource allocation, it can be stated that the gmo-regulations have had a negative impact on economic activity, especially reducing the innovative power compared to the USA. While 95% of all soya in the US is derived from gm-plants (and the monarch butterfly that was at the beginning of the gmo-'crisis', still flies its rounds), the European production mainly allows gmo in feed and food produced 'with' gmo. Persisting deeply vested consumer concerns may not easily change. With this, the political gmo-agenda for the next decennia has been frozen.

3.3 To claim or not to claim, that's the question

Consumers' choices are affected by coercive public policies towards acceptance of novel foods. It may make investors reluctant to take the risk of applying for market authorisation. What is true for acceptance of gmo, or hormone use in the production of beef, may also be true with respect to claims on a food package. These can be discerned in nutrition, health, and 'reduction of disease risk' claims, which are made on foods to be provided 'as such' to the final consumer (including the mass-caterers). Claims do in principle not address business-to-business activities. The claims Regulation (EC) 1924/2006, applicable from 1st July 2007 on, is a specific law, complementing the FIR. Claims have to be approved before they can be made. Approved claims are included in positive lists, provided by the Commission, after consultation of the SCFCAH, EFSA and stakeholders. A specific regulation to the claims regulation and food information regulation is – on top of this – the regulation concerning foodstuffs for particular nutritional uses (like baby food or weight controllers).
Claims indicating that a food cures, prevents or treats a disease are not allowed. However, the borderline between a health claim and a medicinal claim is blurred. This already follows from the definition for 'claim': '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 particular characteristics'. For instance, one can ask oneself whether garlic is a medicine or a food? (ECJ: Commission vs Germany, 2007)
Claims that are regulated in (EC) 1924/2006 are meant only for commercial communications in the labelling, presentation or advertising of foodstuffs. A nutrition claim pronounces the nutritional benefits of a food as to the energy or nutrient content or other substances contained in it. In general, nutrition claims are authorised more easily than health claims, as the nutritional content of a foodstuff can be measured more easily. For instance, whether a product is a source of fibre and a nutrition claim 'high fibre'' can be made depends on whether it contains at least 6 g of fibre per 100 g or at least 3 g of fibre per 100 kcal. A claim like 'light' (or 'lite') is based on the reduction of a nutrient with at least 30% compared to similar products (Annex I to Regulation (EC) 1924/2006).
A health claim suggests or implies that there is a relationship between the consumption of a foodstuff and human health. Procedures to get a claim accepted are precious and prolong the time–to-market substantially, where business practice is that the dynamics of markets

have increased considerably in the last decennia. Moreover, there is a sincere risk that a claim will not be accepted (and all costs have been made in vain), while at the same time the potential benefits after acceptance remain uncertain. A health claim can only be underpinned with experiments with humans; animal experiments are not accepted as evidence by EFSA[14]. Health claims can be listed into categories. Functional health claims are those which refer to the role of a nutrient or substance in the growth, development and the functions of the body (other than children's development and health, psychological and behavioural functions as well as to slimming or weight control; Article 13 (1) of Regulation 1924/2006). For this category, the Commission composes a list, and Member States can provide inputs. Member States submitted a total of around 44000 functional health claims, of which after elimination of all the double entries 4500 remained and upon till now about 2700[15] have been evaluated (botanicals, i.e. herbs, have been put on hold[16]).
Two kinds of other health claims have to follow individual authorisation procedures: 'Reduction of disease risk' claims and those with respect to children's development and health. For the authorisation of all kind of health claims, scientific substantiation has to be provided by the applicant (Article 15 (3) of Regulation 1924/2006). Moreover, the wording of the health claim is important, in combination with supplementary mandatory information to be allowed to label it (like the statement indicating the importance of a varied and balanced diet and a healthy lifestyle, (Article 10 (2) -a). The number of these kind of claims that have been authorised upon till now is very limited. The register of health claims at the website of DG Sanco holds only 19 accepted health claims till 15th January 2012. Case studies may reveal the reasons why the majority of applications have not been accepted yet. Two of these are addressed in the following pages.

The Danadol ® case

Danone requested the Commission for permission to use a health claim, with reference to Article 14(1) - a of Regulation 1924/2006, worded as: "Danadol ® reduces LDL-cholesterol by 10% in 3 weeks, and the reduction is maintained with daily consumption. High blood cholesterol is one of the main risk factors in the development of (coronary) heart disease". The application procedure had to be followed in concordance with Articles 15-17 of the Regulation. This includes an application that is sent to the competent authority of the Member State, which will inform EFSA, which in turn will inform the Member States and the Commission, and will provide an opinion within 5 months, or will ask the applicant for supplementary information. For evaluating this, another two months can be granted. Next, the report including the opinion is sent to the Member States, the applicant and the Commission, as well as is published in the EFSA-journal. In the context of this claim, it was ascertained that elevated low-density lipoprotein (LDL) blood cholesterol is a risk factor for coronary heart disease (CHD). The target population of Danadol ® is adults with mildly raised cholesterol levels. After studying 23 publications, 19 controlled human studies, 1 uncontrolled human study, 3 meta-analyses on the effect of phytosterols on LDL-cholesterol and two unpublished meta-analyses, a favourable opinion was stated: "a biological significant LDL-cholesterol lowering effect can be achieved by a daily intake of 1.6 g

[14] European food safety authority, legally initiated by the General Food Law in 2002; EFSA advices on the acceptability of a claim to the Commission.
[15] Infromation of H. Verhagen, RIVM, Netherlands, 7/01/2012.
[16] Information by DG Sanco representatives, Brussels, 5/12/2011.

phytosterols added to low fat fermented milk products". However, EFSA only advises, it does not have the final say. In May 2010, that is 9 months after the favourable opinion of EFSA, the Commission Regulation is published (Regulation (EU) No 384/2010) that includes the health claim, however under different conditions/wording than was proposed by Danone. Supposing that EFSA took at least 5 months to provide its opinion, the total time-till-acceptance has been 14 months or more.
The bureaucratic system of application is the main cause for the delay in this case. In practice many claims do not satisfy the criteria which are set for substantiated scientific evidence, which are a specified cause-effect relationship (as to dose-response, specificity, consistency, strength and biological plausibility), the quantity that has to be consumed to cause the effect and pattern of consumption, as well as specificities about the data gathering process (composition of the study group(s), target population, etc.), and of course the specific beneficial effect to health which are suggested (see in this respect: EFSA Journal 2011; 9(6):2233; EFSA guidelines for the submission of health claims).

The LGG-case

Several subsequent claims relate to the positive effects of LGG. Health claims by Valio Ltd were submitted in 2008 based on Article 13(5)[17] of the Regulation, referring to a probiotic LGG ® MAX for the reduction of gastro-intestinal discomfort by means of mixtures of strains of bacteria (among other Lactobacillus rhamnosus GG). The claims with respect to two mixtures of bacteria strains were rejected by EFSA, due to lack of valid scientific evidence of a cause-and-effect relationship (doi:10.2903/j.efsa.2008.853). In 2011 the EFSA-panel again rejected a similar health claim with respect to *Lactobacillus rhamnosus* GG (LGG), and its proclaimed defence against pathogenic gastrointestinal micro-organisms. The scientific evidence that Valio Ltd provided was weighted to be not enough to proof the cause-and-effect relationship between LGG and positive effects of the gastro intestinal system (EFSA Journal 2011; 9(6): 2167). Finally, a claim was submitted with the generic aim of of "gastro-intestinal health". The target population was this time not a specific category of users, but the general population. The claim was rejected on grounds that the "claimed effect is not sufficiently defined", and no further details were provided in the proposed wordings. The EFSA-Panel (i.e., the Panel on Dietetic Products, Nutrition and Allergies) notes that the references addressed several effects, and that it was not possible to establish the effect which is the target for the claim.

In total, since the start of the work of the Commission/EFSA, only 19 health claims have been accepted. Only *one* is based on 13(5) of the Regulation, that gives –as stated- Member States the opportunity to submit health claims to be included in a register.

[17] Supplement to the list of claims (Article 13 (2) of the regulation), with no further authorisation required, on the basis of 'newly developed scientific evidence'.

4 Conclusions

- Hypothesis 1 was stated as: *Information requirements on food ingredients lack logic and contribute to transaction costs of food business operators as well as of consumers.*

From the modifications and requirements with respect to the listing of ingredients and further particulars on added water, gmo and nanotechnology it may be concluded that:

- cultural differences cannot explain to the full extent why gmo-labelling in the US is virtually absent[18], while in the EU a strict regime exists which provides for a de facto ban of foods including or derived from gmo from the market. Consumer attitudes are different, probably because of differential communication of stakeholder groups towards new technologies.
- while a focus on dangers of new technologies might provoke consumer responses towards a virtual ban of novel technologies, such coercive reactions will impede negatively on the innovativeness of the European food industry along two roads: they may trigger policy makers to design restrictive legislation that adds to transaction costs on top of development costs, and may adversely induce consumers to avoid products with particulars that they do not understand (like 'nano').
- the 'added water'-example shows, that much is expected of the interpretation capabilities of the 'average consumer', which has to be aware of an ingredient that he/she would not expect in certain foodstuffs. Indeed, the addition of water, although technically avoidable, solely out of commercial motives might mislead the consumer and should be counteracted. The question is whether this should be done in an indirect way via the labelling or directly via prohibition. Food information can only affect consumers' choices if he/she is *aware* of malpractices. In this case, the un'quid'[19]ded inclusion of the ingredient 'water' in the list of ingredients will probably not influence the attitude of the consumer[20] towards a foodstuff to a material degree, but will add to the costs of food businesses. As said, legal action might better be based on the general prohibition to mislead (Article 14 GFL).

Hypothesis 2 is: *Present food information requirements with respect to gmo are contra-productive and impede on the innovation capabilities of food business operators.*

- the present legislation on the authorisation and labelling of gmo-related foodstuffs is coercive. The US takes a completely different standpoint in this respect, which cannot solely be explained by pointing at 'cultural differences'. Consumer attitudes are different, which has been induced by adverse communication of stakeholder groups. While all dangers have been ruled out, the potential benefits evaporate with it.
- it should be admitted that gmo-technology, just like nano-technology can be dangerous to humans and to the natural environment. But the problem is not primarily that a de facto ban from the market has been imposed; the main problem is that – despite the fact that European food regulation is intended to be science-based (White Paper on Food Safety, 2000; GFL) - the discussion is more governed by emotions than by solid scientific evidence.

[18] Not really understandable for Europeans is the fact that in the US gmo-foods may potentially be labeled as 'organic' due to the absence of use of pesticides.

[19] 'Quid' stands in labeling language for 'quantity of ingredient declaration'.

[20] At least, for as far as we know, this has not been scientifically researched.

- in practice, application procedures for the admittance of gmo-related foodstuffs ato the market are bound to be useless from the start. This seriously hampers the development of safe gmo-applications and the competitiveness of the European food industry.

Hypothesis 3 was formulated as: *Present food information requirements with respect to health claims are contra-productive and impede on innovation capabilities of food business operators.*

- a great number of applications have been submitted, and only a staggering 19 health claims have been accepted upon till now. The negative success rate shows that the system does not work; it just *cannot* work because of the prolonged time to market, the low chance of success, and the technical bottleneck vested in the authorizing authorities' available time and means. Food business managers will change in response their attitude towards the submission of health claims and thus towards innovating in new, healthy foods.
- the institutional system of the US towards health claims is completely different; whereas in Europe strong evidence in favor of a claim has to be submitted, the American system is much more business-oriented, and the positive effects of foodstuffs on the human body can be labeled in a more liberal way. The differences in the institutional systems are probably not culturally determined, but related to a sincere fear of negative consumer responses to food scares that origins from the midst of the 90s of the last century, as well as a fear of negative publicity via pressure groups.
- the costs of bringing a product with a health claim to the market are significantly higher in Europe than in the US. Also the success rate is much smaller. The behavioural consequence in business is potentially *avoidance behavior*: if you can't positively proof an effect of claim x (which is difficult because the effect has to be proven for healthy – not: sick !- people), bring the product to the market with claim y, by including approved substance z[21].

5 Discussion

In many cases it is not clear why food information requirements have been vested upon industry at the time or in the format that has been chosen. Some of the described novelties will not alter the attitude of the consumer significantly, or will have an adverse effect on the availability of safe food. Information burdens will negatively influence innovation, as well as provoke increased costs of monitoring and control for the food business operators as well public authorities.

Possible improvements would potentially be made by investigating:

- retrospectively, the motives and pressures in organizational fields which instigated the design of regulatory barriers. For instance, if we understand what mistakes we have made with gmo-admittance, we could learn from that for the authorisation of nanotechnologies in the future;
- the present system of food information, with the aim to improve its logic, transparency and coherence, not just from a consumer's perspective, but using a multi-stakeholder approach, in which food businesses can claim their legitimate rights alongside consumers and othr stakeholder groups;

[21] For instance: add certain vitamins or minerals with acknowledged effects, though they are not a necessary ingredient for the marketed foodstuff.

- the possibilities of integration and development towards a truly science-based food information system, that potentially is not only less costly, but also provides information which are substantiated by evidence, not fear (see in this respect: Cheftel, 2005).

This paper has presented only some of the problems, pitfalls, policies and progress in food information requirements. Certainly, it requires further empirical underpinning. It should be clear however that much work still has to be done, so that an effective and efficient system of provisions is made available to consumers as well as to business operators. The new food information regulation promises in this respect a lot, but offers only limited value-for-money.

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