OPPORTUNITIES, PROBLEMS AND PITFALLS OF NUTRITION AND HEALTH CLAIMS

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Abstract: The provision of reliable food information, for instance by printing an authorised nutrition or health claim on a package of food, makes credence dimensions of a food transparent to the consumer. In Europe, prior-to-use authorisation of nutrition and health claims are mandatory and governed by Regulation (EC) 1924/2006. The aim of this paper is to assess the problems and pitfalls of the European claims regime to food businesses. A legal-economic review is performed, supported by case studies. Strategic factors determining whether or not to claim are of a legal-economic kind. Strategic responses include refraining from the use or application of claims, abstaining from innovation, and/or circumvention of the authorisation procedure. Negative social-economic effects make it necessary to improve the present legal structures with respect to their effectiveness while maintaining the balance between public control and individual freedom.

Key words: nutrition claims, health claims, food information, pre-market approval, food law

Introduction

Food businesses and their operators (abbreviated henceforth as FBOs) can obtain a competitive advantage by attaching a claim to their product. Nutrition and health claims[1] therefore represent an incentive for product innovation. Food information can affect consumers' choices in the market (see for instance: Bremmers *et al.,* 2012). Claims can bridge the information gap that exists between the knowledge available to the buyer and the seller's informedness on the intrinsic qualities of a food (Hobbs and Kerr, 2006). The credence character of foods – together with the positive incentives that may be harvested in the market – make the application of legal rules vulnerable to opportunism. For this reason, the use of claims is bound to legal limitations in the Claims Regulation (EC) 1924/2006 (abbreviated as CR). However, a strict regime also contributes to pre-market uncertainty and therefore forms an economic risk to FBOs, meaning that they are unsure whether they will ever be able to harvest the fruits of product innovation. This uncertainty is especially if the burden of scientific substantiation is put on the shoulders of the claiming food businesses. This is notably the case in the EU, and has economic consequences. The institutionalised system of CR affects the way contracts are concluded upon (the 'play of the game') and the allocation of resources (c.f. Williamson, 2000). It is not clear what effect strict authorisation procedures have on the functioning of food markets, the competitiveness of single FBOs or on the European food industry as a whole. Moreover, a negative *ethical* aspect of claim approval is the limit to freedom of speech by food businesses. In the USA, so-called 'qualified health claims' may be allowed (as a result of the Case Pierson – Shalala, 164 F.3d 650, 1999; Fortin 2009: 380). These claims are not – and need not to be – underpinned with full scientific evidence, but are expressed by weighing up supportive and conflicting research. The differences between the EU and the US are possibly rooted in the European reaction to stakeholder scrutiny after the food scares in the middle of the 90's (see for instance: White Paper on Food safety 2000; Knowles and Moody, 2007; Van der Meulen and Van der Velde, 2008). In the end, however, European public authorities have virtually neglected businesses' freedom of speech (Van der Meulen and Van der Zee, 2013).

The aim of this article is to assess the problems and pitfalls of the EU's claims regime for food businesses and to categorise the strategic options FBOs have to deal with it. By elaborating on the impact of claim requirements, lessons may be learned for improving the legal-institutional system. The paper is based on a systematic legal-economic analysis and will include data and cases of accepted and rejected food claims.

[1]According to Article 2(2)(1) of the Claims Regulation (1924/2006) 'claim' means 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.

In the remainder of this paper, the European claims regime will first be addressed. Next, the strategic and economic factors which are to be considered when a claim is made from an FBO-strategic perspective are reviewed. After this, alternative strategic options which are available to FBOs are described. Finally, the conclusions and discussion are presented and a way forward for politicians and scientists is proposed.

Claims in the EU

European food information is influenced by the tradition, culture and the specifics of the institutional environment. Examples are the labelling and legal requirements of GMO, as well as the absolute ban on the use of hormones in the production of beef (see for instance: Herrick, 2005; Heslop, 2006). The specific properties of a food (identity, origin, etc.) that have to be indicated on (pre-packaged) or near (not-prepackaged) foodstuffs enable informed choices, counteract unfair competition and foster the free exchange of goods. The bottom-line is that the consumer should not be misled. The general prohibition to mislead is included in Article 7 of the recently accepted Food Information Regulation (EU) 1169/2011 (abbreviated as FIR). Claims – whether they are nutrition or health claims[2] - should therefore be used in a fair way.

According to Article 2 of Regulation (EC) 178/2002, 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Point (e) of Article 2 excludes medicinal products from its scope. Medicinal products include products presented as having the property of preventing, treating or curing a human disease. Moreover, it is in general forbidden (besides exceptions) to attribute the property of preventing, treating or curing a human disease to any food, nor is it allowed to refer to such properties (referred to as 'medicinal claims').

Claims (1) can only be made if authorised and (2) authorisation is only granted after scientific substantiation of a submitted claim. Despite the fact that there is a general prohibition on making claims with respect to the prevention, treatment or cure of a disease, it is allowed to make claims of disease risk reduction and claims referring to children's development and health under specific approval conditions (so called Article 14-claims). Generic health claims (such as: 'calcium is good for a healthy bone structure'; Article 13(1) claims) are authorised via milder procedures, but nevertheless pre-market approval is- required.

Strategic factors

Strategic factors in considering whether 'to claim or not to claim' (Food Valley, 2010) are legal and economic of a kind. These are interrelated, as compliance to legal requirements induces costs as well as benefits for FBOs. Strategic considerations may be related to: (see: among other: Food Valley, 2010; also extensively in Bremmers *et al*., 2013):

- food information consequences;
- claims application procedural barriers;
- consequences of claims violation;
- legal uncertainty.

Food information consequences

The consequence of using a claim is *compulsory nutrition information* on the food packaging (Article 7 CR; in this context see also: Capacci *et al.,* 2011). The nutrition declaration provides information on the energy value of a foodstuff as well as on its key nutrients (Annex XIII of the FIR, Part A). In the near future, this factor will lose its significance as a nutrition declaration will be *mandatory* for almost all foodstuffs[3]. Moreover, in many cases, businesses already print the nutrition declaration on the food packaging on a voluntary basis.

Claim application procedures

Claim application procedures are complex, and their outcomes uncertain. The applicable procedure depends on the type of claim that is requested - nutrition or health - health claims are in turn subdivided into Articles 13 and 14 type claims. All types require substantiation with generally accepted scientific evidence (for a more extensive description, see Povel and Van der Meulen, 2007). More specific criteria for allowable scientific evidence are not included in the Regulation itself. The general principles are included in guidance documents which lack legal status[4]. Scientific evidence is to be evaluated in an objective way and generally only intervention studies on healthy humans carried out professionally are accepted, which contributes to the perceived uncertainty of applicants. A further factor influencing the uncertainty of the outcome is the fact that the process may not be free of political interdependencies. Scientific evidence is verified under the responsibility of an EFSA panel that consists of assigned scientists from the Member States. It is the European Commission (hereinafter: the Commission) that takes the final decision. The complexity and uncertainties connected to the authorisation procedures contain risks to such an extent that small and medium-sized companies cannot easily permit themselves to enter the process.

Compliance and boundary violation

Health claims are bounded by the general prohibition to suggest that a foodstuff has a direct effect on a disease. There remains discussion remains as to what exactly this implicates in terms of food information. If a claim is made with respect to a food reducing a risk factor for a disease, this

[2]For definitions see Article 2 of the CR.

[3]Some exceptions remain – such as alcoholic beverages with an alcohol percentage > 1.2%/ vol.

[4]See in this respect http://www.efsa.europa.eu/en/efsajournal/doc/2170.pdf

is considered acceptable by the Commission (Article 14(1)(a) of the CR). The borderline between an allowed health claim and a forbidden medicinal claim is diffuse (see Klaus, 2005 for more detail). Even the border between a health claim for a food and a presentation that turns a product into a medicine is diffuse. For instance, is garlic in capsule form – to which positive attributes are assigned pertaining to digestion – a medicine or a food? (see: 'garlic' case C-319/05). Violating the CR by suggesting curing properties could implicate that the 'food' is regarded as 'medicine', with the consequence that the product must be removed from the market immediately and fines paid[5].

Legal Uncertainty

This sub-section refers to the uncertainty in the authorisation process and – after authorisation - the uncertainty in the application of the claim. At the date of writing, 30 nutrition claims and 243 health claims[6] (of which 222 are generic health claims) have been allowed. For 1631 health claims authorisation has been denied, while 2303 health claims are still under consideration (including 2232 claims which are 'on-hold', especially claims referring to foods with plants or plant extracts, so-called 'botanicals'[7]. While a claim is 'on-hold', the respective products may be marketed pending further decision making by the Commission.

Next, the uncertain outcomes of claims procedures are demonstrated through two case studies, one with a positive outcome and one with a negative result.

The Danacol® case

Danone requested the Commission's permission to use a health claim, with reference to Article 14(1) - (a) of Regulation 1924/2006, worded as: "Danacol® 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". 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 Danacol ® 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 EFSA opinion was stated: "a biological significant LDL-cholesterol lowering effect can be achieved by a daily intake of 1.6 g 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 with respect to the health claim was published (Regulation (EU) No 384/2010), however under different conditions/ wording than was applied for. Supposing that EFSA took at least 5 months to provide its opinion, the total time taken until acceptance was 14 months or more. The bureaucratic system of application is the main cause for the delay in this case.

In practice, many claims are found not to satisfy the criteria which are set for substantiated scientific evidence, these being a proven cause-effect relationship (in terms of dose-response, specificity, consistency, strength and biological plausibility), indication of the quantity that has to be consumed to bring about 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 on health which is 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)[8] 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 others, Lactobacillus rhamnosus GG). The claims with respect to two of the mixtures of bacteria strains were rejected by EFSA, due to the lack of valid scientific evidence on 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 did not sufficiently characterise the food for a scientific assessment of this claimed effect and the claim could therefore not be substantiated (EFSA Journal 2011; 9(6): 2167). No 'lactobaccillus'-claims have been validated yet at the time of writing.

Some proposed claims meet difficulties in the authorisation procedure despite the fact that convincing scientific evidence is available. For instance caffeine, chocolates or red wine [9] may have positive effects on health, but positive claims may be considered inappropriate because of other negative (social) side-effects.

From the experience of having a claim accepted or rejected, a learning effect will occur at the FBOs. Strategic responses to the CR-requirements will differ depending on the specific situation an FBO is in, the perceived strategic options, and their feasibility. The main strategic options are addressed in the next section.

[5]In case a product can be classified as 'food' as well as 'medicine' the classification as medicine has legally the advantage.

[6]Data provided by DG Sanco via B. Mathioudakis, workshop EFFL, Brussels, 11 April 2013.

[7]Data obtained from the Head of DG Sanco B. Mathioudakis in a seminar held on 11th April 2013 at the Club of the University Foundation (Brussels), organized by Lexxion Legal Publishers, Berlin/Brussels.

[8]Supplement to the list of claims (Article 13(2) of the Regulation) on the basis of 'newly developed scientific evidence'.

[9]Alcoholic beverages containing > 1.2% alc./vol. are forbidden to carry any claims.

Strategic options

Companies can respond in different ways to the CR-requirements. The options are among other:

- do not apply for a claim;
- do not innovate;
- circumvent the authorisation procedure.

Do not apply

If the probabilities and the effects of claims being accepted (or not) could be assessed with certainty in advance, companies could weigh the favourable and/or unfavourable effects of a claims application. An application will be more profitable if the claim is reserved to a single company and others are excluded. Often, claims are attractive in connection to newly developed ('novel') foods. Newly developed foods have to be submitted to pre-market approval procedures for novel foods/GMO-foods[10], next to the authorisation of proposed claims. The chance of success of an innovation is influenced not only by the claim that can be connected to it, but also by the admittance of a novel food to the market. Even if a claim is authorised, its use is not without risk. The wording of a claim has to equate to the authorised text; however, the exact wording that the Commission has accepted does not have to be used[11]. Using the 'official' wording is often unattractive for marketing reasons, as it might contain scientific expressions that the 'average consumer' does not understand[12]. For marketing purposes, therefore, understandable language is preferred. However, the limits to flexibility in wording might easily be surpassed. The respective products would then be labelled wrongly, have to be relabelled or taken off the market altogether.

Do not innovate

Due to a lack of resources and capabilities, SMEs are hindered in their innovation efforts, or might not innovate at all. Once they have entered into the authorisation process, FBOs can be 'locked-in': opting out is no longer wise because of positive future net cash flows, while an overall loss on the total project is already certain due to past negative cash flows. This strategic side-effect is surprising: the aim of European authorities was to *stimulate* innovation through the CR, not to create barriers to innovation.

Circumvent the authorisation procedure

The CR can be circumvented by choosing marketing texts which promote sales without suggesting the reduction of a disease risk factor, for instance by substituting a health claim with a nutrition claim or using a 'hidden claim'' message represented in an alternative text[13].

Conclusions, discussion and way forward

For FBOs, consumers and public authorities, the CR brings uncertainties with it. FBOs have to deal with limited predictability as to whether a claim will be authorised. Even after acceptance, the challenge remains as to how to design a text that on the one hand meets the mandatory legal requirements and on the other hand has enough marketing potential to be able to recover the R&D expenditures and regulatory burdens. For consumers, it may not immediately be clear what a claim means. For instance, he/she may grasp the general notion of relatively low energy-levels contained in a product called "light", but how this is measured goes beyond the knowledge of the 'average consumer'[14]. Also, the average consumer is barely aware of the scientific evidence underlying claim and novel food applications (Frewer *et al.* 2011) or of the efforts made and criteria used by public authorities to make the industry comply. For public authorities, it is difficult to assess whether a given piece of food information stays within the boundaries of the CR. While European food law should bring clarity and uniformity with respect to rights and obligations and serve common goals (free exchange of goods, facilitating informed choices by consumers, and provision of safe foods) the lack of quality within the food law itself as an institutionalised system of rights and obligations jeopardises the attainment of its own goal from the start.

A scientific agenda of tasks can be defined with the aim of improving the legal system, especially the claims regime. In retrospect, an investigation could be made on the stakeholder pressures which were at the source of the present legal system, as it impedes the competitiveness of the industry. Special attention should be paid to the adverse effects of premarket approval on the FBO innovativeness and access to the market. One of the goals of the CR was to create a 'level playing field'. SMEs (the majority of the European food industry by far) lack the financial means and capabilities to successfully engage in novel foods and/or claims authorisation procedures. However, they are the motors of the European food industry (see for instance Wijnands *et al.,* 2007; Poppe *et al.,* 2009). In retrospect, lessons can be learned from the hormone and GMO-disputes at the international level between the EU and

[10]Novel Foods Regulation (EC) 258/97. Novel foods are foods and food ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997. If 'substantial equivalence' exists with present foods, a simplified authorization procedure is applied. Gmo-foods are included in different regulations and are only authorised after a full procedure (see Regulations 1829/1830/1831/2003).

[11]Some countries, like the Netherlands and Belgium, have developed guidelines in this respect. Possibly other countries will do the same exercise, with a different outcome.

[12]For instance a health claim related to eicosapentanoic acid (EPA): "reduces the AA/EPA ratio in blood. A high AA/EPA level is a risk factor in the development of attention difficulties in children with ADHD-like symptoms". EFSA Journal 2013;11(4):3161 [10 pp.]. doi:10.2903/j.efsa.2013.3161.

[13]Like 'one glass a day is as important as a glass of milk'; similar as in the "Monsterbacke" case, 5 Dec. 2012 C I ZR 36711 (Source: presentation A. Meisterernst, Brussels, April 2013).

[14]This is a legal category. On the basis of product liability case law, it is a consumer that is 'reasonably circumspect, taking into account social, cultural and linguistic factors' (among other: Case C210-96 Gut Springenheide). See also Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market.

US, as pre-market approvals might be considered barriers to trade (especially if human health is not at stake and precautionary measures are therefore questionable; see in this context: Bremmers *et al.,* 2011). Last, uncertainties connected to the CR show that legal structure and logic have an impact on business strategies and compliance, as well as to legal content. The CR and related legislation does not meet basic principles of unambiguity, completeness, clearness or coherence. An overhaul of the nutrition and health claims requirements is therefore necessary.

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