

## The legal framework of health claims as indicator for growth and innovation\*

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### 3.2 Impact of regulatory framework on growth of functional foods

Functional products and health claims are a way of differentiating and building a brand in the saturated food market segment without "cannibalising" their own products (Stanford, 2001). Health claims have been found to increase the market share without decreasing the market share of another product category. Foods with health claims are therefore particularly attractive to the food industry due to higher sales margins and a faster growth rate than for conventional products.

The development of functional products and the substantiation of health claims, however, require large financial resources which companies are only willing to invest if there is sufficient legal certainty regarding the permissibility of the composition and health claims. The readiness to develop and include more expensive functional ingredients therefore depends on the possibility to recoup the additional costs by charging higher prices for those products by listing the functional ingredients on the label and by using health claims to differentiate functional foods from their conventional counterparts.

A sound regulatory framework is therefore a prerequisite for the food industry to invest in food innovations and sustainable growth. Legal certainty, predictability, flexibility and clear procedural rules are only a few of the key demands from the food industry. Any process adopted to deal with health claims must therefore be timely and responsive and permit additional claims to be allowed as new scientific evidence emerges to support new claims.

There is consensus that health claims must be based on a clear set of scientific requirements. Several companies observed that if claims were not based on scientific evidence, consumers would lose confidence in functional foods and the industry would suffer. In the USA, health claims became a hot issue in the 1980's, when food marketing strategies began reflecting increased recognition

of the role of nutrition in promoting health. At that time, some of the claims were widely exaggerated and consumers began to doubt their truthfulness. According to a FDA study, consumer confidence in health claims grew considerably in the months following implementation of the Nutritional Labelling and Education Act (FDA, 1998). Adequate protection of confidential data and IP rights has also been found to be a major determinant for a positive regulatory environment. The introduction of product specific claims has been found useful for promoting industry innovation since it protects the necessary investment in human intervention studies to substantiate health claims. Under the FOSHU approval system more than 450 product specific claims have been allowed giving a boost to the functional food segment. This need for data protection is also reflected by the inclusion of product specific claims in most selfregulatory Codes of Practice.

Japan and the USA are two of the countries that have recognized the need for a regulatory framework for health claims ahead of time. Both countries have established their regulatory systems for health claims already at the beginning of the 1990s. They are currently the world leaders in the functional food sector while others without an adequate legal framework have missed out on business opportunities.

A study commissioned by the government of Canada (Stanford, 2001) confirmed that due to the lack of a regulatory system, the development of functional foods in Canada has lagged other markets because of the inability to communicate the benefits of these products to consumers. Many companies might have launched Canadian developed functional foods but were dissuaded by regulatory restrictions and uncertainty. Especially SME felt that they had experienced lost opportunities, lost sales and/or increased costs. The uncertain and restrictive Canadian regulatory environment for functional foods has clearly impeded the emergence of functional foods in the Canadian Market compared to the introduction of these products in other major markets such as the USA or Japan. *Table 6* shows the correlation between the inception date of a regulatory framework and the size of the functional foods market.

Country	Date of Inception	Volume Sales USD (2003)	Market Share % (2003)
Japan	1991	12.5 bn	53.5
USA	1994	5.3 bn	21.9
EU	Expected 2006	5.3 bn	21.9
France	Expected 2006	920 m	3.8
UK	Expected 2006	1.9 bn	8.1
Spain	Expected 2006	1 bn	4.4
Germany	Expected 2006	1.1 bn	4.6
Italy	Expected 2006	436 m	1.8
<b>Total</b>			<b>24.2 bn</b>

**Tab. 6: Size of functional market in various countries and date of inception of a regulatory framework for health claims. Source: Leatherhead, 2003**

### 3.3 Interviews with food companies

The lack of harmonized health claims rules in Europe led to the paradoxical situation that food manufacturers had to develop different product ranges, labels and advertising campaigns for different EU Member States which resulted in significant costs. The inconsistent enforcement added to the uncertainty and risks associated with selling functional products in Europe.

Companies described innovative products that they had introduced successfully in their country of origin, but were unable to introduce in other European markets either because of significantly different compositional standards or because they were prevented from communicating the specific health benefits to the public. In order to obtain an appreciation of the impact of the EU Commission Proposal on growth and innovation, interviews with key players of food industry were carried out including eleven of the largest food manufacturers (CIAA, 2002), three SME's and major food industry association and food consultants. The majority of the MNEs were subsidiaries of parent companies located either in the USA or in Europe. Given the timing of the preparation of the questionnaires subsequent changes of the Commission Proposal by the EP and Council could not be taken into account.

While the majority of the interviewed companies welcomed a harmonised framework for nutrition and health claims in Europe which would facilitate the internal market, they expressed concern that the new proposal could have a negative impact on the competitiveness of European companies. In particular, the introduction of nutrient profiles and the lengthy pre-approval procedure for innovative claims was a matter of concern given that the regulatory environment constitutes an important factor in winning the intra company competition of Research & Development, manufacturing and export capability.

Companies expressed concerns that it would be very difficult to build up a business model on products that are not sold in the domestic market since it is much more difficult to introduce a new product into a foreign country due to a lack of reliable market research, added promotional costs and risk of import restrictions. Furthermore, acceptance of health claims by foreign regulators is more difficult, if health claims are not approved in the country of origin.

Most companies found that the envisaged regulatory framework would be stricter than in most Member States and compared to other jurisdictions. These restrictions would very likely hamper growth and competitiveness of the functional food market. Given the costly approval procedure and the high level of substantiation required, SME would be excluded from making health claims in the future.

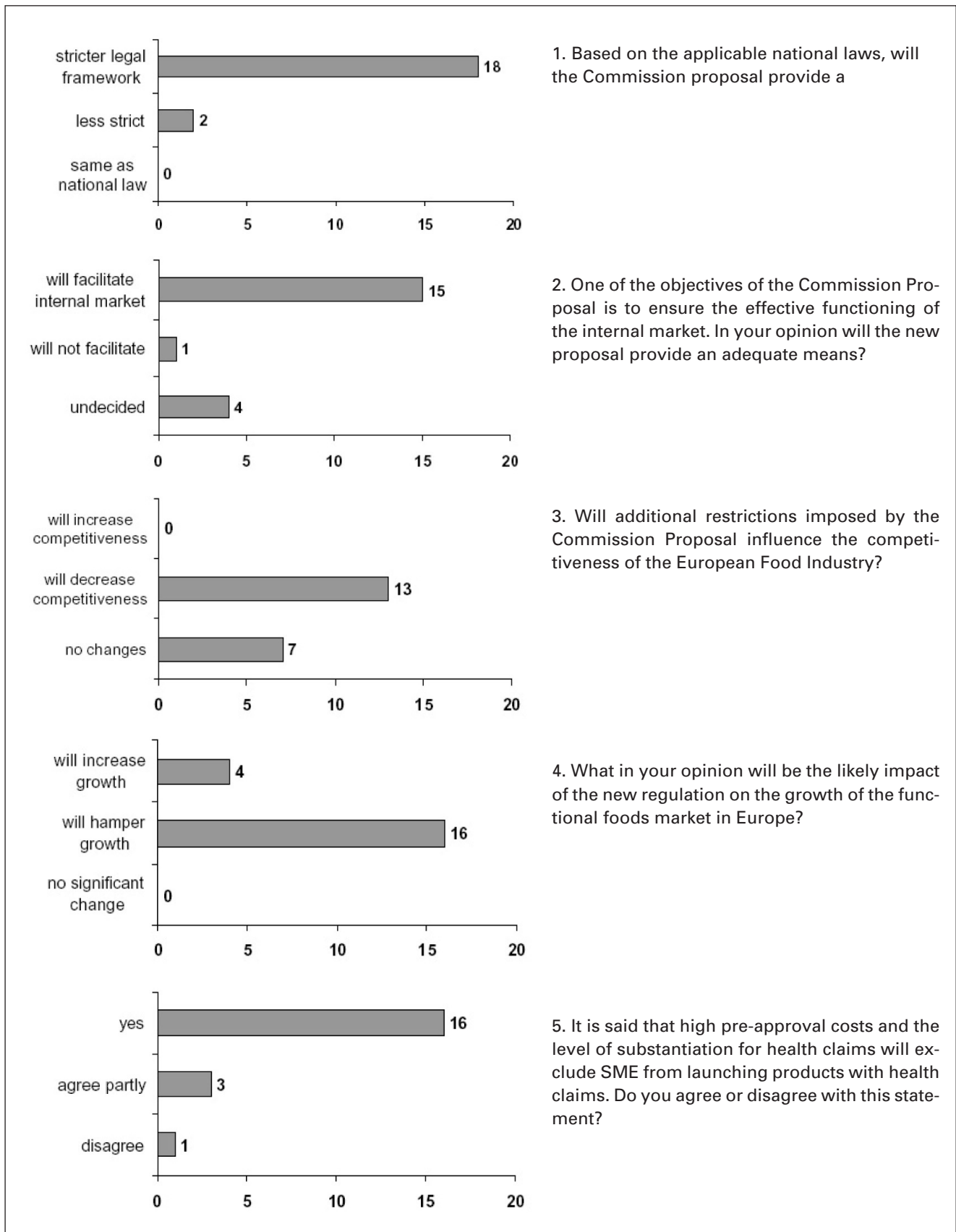
## 4. Discussion

### 4.1 Commission Proposal in line with the new agenda for the Europe of growth and competitiveness?

The European Union can look back on quite remarkable economic and social developments over the last decades. Since the beginning of the 21<sup>st</sup> century, however, Europe's economy is in decline and unemployment figures are on the rise in the majority of the Member States. The gap in terms of growth compared to the USA and Asia is starting to widen. At the same time, economies like India and China are growing four to five times faster than the European Union (Verheugen, 2005). The European Union is therefore confronted with new challenges such as how to foster competitiveness and innovation while maintaining high levels of consumer protection.

The strategy of the year 2000 had the ambitious goal of making the European Union the most competitive economy in the world by 2010. But so far the EU has not fulfilled the objectives in terms of economic growth, investment in research or generation of employment. In March 2005, the Heads of State and governments of the Member States endorsed a major proposal from the European Commission (European Commission, 2005) to set up a new strategy to ensure that Europe remains an attractive location for investment, work and research. Competitiveness is therefore key to the renewed Lisbon Agenda.

This new strategy also includes the "Better Regulation Initiative" which is directly linked to competitiveness. This initiative recognizes the challenge of creating incentives for business, cutting unnecessary costs and removing obstacles to innovation. Furthermore, it addresses the need of a systematic impact assessment before any regulatory initiative is adopted. Should voluntary commitments or other tools deliver



**Tab. 7: Illustrative answers from Food Industry (sample size = 20) regarding the impact of Commission Proposal on Nutrition and Health Claims (COM (2003) 424 final).**

the same results, then those should be the preferred approach. A positive regulatory environment is therefore considered as one of the key determinants of competitiveness and growth.

All the above must be viewed against the current Commission Proposal for Nutrition and Health Claims which is far from creating a level playing field for European companies, legal certainty and predictability. On the contrary both food and advertising industry strongly expressed their concerns that the current proposal would hamper growth and innovation.

In particular, the following provisions have been criticised for their lack of legal and scientific basis (in chronological order):

- no exclusion of existing trademarks or brand name from the scope of the Proposal (Art 1)
- nutrient profiles (Art 4)
- prohibition of certain claims even if scientifically substantiated (Art 11)
- lengthy and costly pre-approval procedure (Art 14 -17)
- wording of the claim in all Community languages (Art 14)
- inadequate data protection and confidentiality clause (Art 15 and 19)

The focus of the discussion in EP and Council, however, has been the restriction of nutrition and health claims through the introduction of nutrient profiles. Only food or food categories in line with nutrient profiles (yet to be set by the Commission within 24 months of entry into effect of the Regulation) would be allowed to bear nutrition or health claims.

The inclusion of nutrient profiles into the Commission Proposal has to be seen as a direct response to the publication of the WHO Obesity Report in 2003 (WHO, 2003). Under the panacea of providing consumers with information to make healthier food choices, the Commission introduced nutrition policy into its Proposal. However, will an arbitrary distinction into "good" and "bad" foods solve the issue of obesity or will it unnecessarily restrict trade?

There is scientific consensus that a balanced diet is the key to a healthy nutrition and that the "blacklisting" of products high in fat and salt could lead to an overall reduction of micro-nutrient intakes (Food and Drink Federation, 2004). Negative experience from the USA has shown that nutrient profile and Guideline Daily Amounts (GDA) did not succeed in putting an end to the ever increasing number of overweight and obese people (BLL; 2005).

The Commission's justification in Recital 6 of the Proposal (European Commission, 2003) that consumers would be encouraged to make choices which would directly influence their total intake of individual nutrients in a way which would run counter to scientific advice has yet to be proven.

The introduction of nutrient profiles will have far-reaching consequences for the food industry since companies will no longer be allowed to use their trademarks, brand names or marketing slogans not in line with the current Proposal. Furthermore, there is the inherent risk that they will have to change their international marketing concepts or at least sell different product ranges for Europe and the rest of the world. This will destroy considerable investments and the goodwill of products and brands built up over decades.

Additionally, nutrient profiles would only be set within 24 months after the enactment of the Regulation and the Proposal authorizes the Commission to add restrictions for other foods or categories of foods at its discretion. All of the above prolongs the uncertainty what the new Regulation will be and adds to the lack of predictability of the regulatory process/environment.

The current proposal therefore lacks not only an adequate scientific basis but would also not withstand a proper risk assessment. Given the far-reaching consequences for food industry, advertisers and ultimately consumers, it can be doubted whether the introduction of nutrient profiles is a necessary and proportional means to steer nutritional policy.

Commission President, Mr Barroso, announced on 14 September 2005 to "axe absurd EU laws" if legislation can be better left to Member States, where there is an inadequate assessment on the impact on business or where the measure is seen as "too heavy handed". Mr Barroso went on to say that he would urge his Commission colleagues on 27 September 2005 to withdraw proposals for EU-wide rules in areas such as food labelling, presentation and advertising (Parker et al., 2005). It is therefore to be seen whether Mr Barroso's "deregulation campaign" will also include the Commission Proposal on Nutrition and Health Claims. His announcement will certainly give an impetus to bring in line the Commission Proposal with the renewed Lisbon Strategy of an effective internal market and free and fair trade which will help to prevent trade irritants and solve market access problems which are often caused by the implementation of divergent regulations.

#### **4.2 Health claims as potential trade barrier?**

Health claims regulations can act as a potential trade barrier by preventing the import of foods with health claims that do not conform with the rules of the re-

ceiving country. Since the use of health claims plays a key role in the marketing of functional foods, restrictive health claims regulation can be a decisive factor whether or not to launch a product. The need of a pre-market approval for health claims has also been recognized to impede trade. In January 2003, the European Court of Justice (ECJ) ruled against Austria by declaring the pre-approval procedure as disproportional to the aims pursued since there are less restrictive measures such as an obligation on the manufacturer or distributor of the product in question to furnish evidence of the accuracy of the facts mentioned on the label (ECJ, 2003).

The 1994 Agreement on Technical Barriers to Trade of the WTO (TBT) addresses the discriminatory potential of food labelling and health claims. The Agreement aims at reducing trade barriers in three ways. Firstly, it encourages member countries to formally accept the standards of other countries through "equivalence agreements", secondly, it asks its members to harmonize their national standards with international standards such as Codex Guidelines and thirdly, requests member countries to notify the WTO and member countries about their standards and openly answer other members' questions. Under this Agreement, governments have to prove that the envisaged measures for restricting trade are not disproportionate to the aim pursued and that the measures are the least restrictive to trade (TBT, 1994).

In 2004, the Codex Alimentarius Commission finally adopted Guidelines on the Use of Nutrition and Health Claims (Codex Alimentarius, 2004) which aims at the international harmonization of health claims regulation. However, concerns remain about the potential impact of the guidelines on trade due to the introduction of a clause in the preamble which allows Member States to restrict health claims in line with their nutritional policies. During the discussion of the Guidelines, a number of delegations including the USA had raised concerns against this clause since it would create trade barriers and contradict the objective of international harmonization (Codex Alimentarius, 2001 and 2002). Despite those objections, the clause was incorporated in the preamble of the guidelines. In the meanwhile a number of countries such as Brazil and Argentina have invoked the "nutritional policy excuse" in order to ban certain products from their market without adequate scientific justification. Also the European Union has recognised that different approaches in different EU Member States could result in obstacles to intra Community trade. One of the objectives of the current Commission Proposal was to "improve the free movement of goods within the internal market" (European Commission, 2003).

At the same time, however, the Commission ignores the negative potential of its proposal for international trade. In particular, the Art 4 and 11 as well as the pre-market approval are likely to restrict trade. Furthermore, there are concerns about the inadequacy of the protection of IP rights such as registered trademarks (TRIPS, 1994) which could be construed as prohibited health claims under Art 1 of the Proposal.

## 5. Conclusion

With the emergence and growth of the functional food market, adequate regulation of health claims has gained importance both in Europe and internationally. In most developed countries, the appeal of functional foods and health claims is based on a higher sales margin and a faster growth rate than for conventional products. Health claims have become an ideal means to build and differentiate a brand without "cannibalism". The development of functional foods and substantiation of health claims requires large investments in terms of research and new technologies.

In particular SME can only afford these extra costs if there is sufficient legal certainty that they will be able to recoup their costs by charging higher prices for products with health claims. A sound regulatory framework is therefore prerequisite for the food industry to continue to invest in food innovations and new technologies. This has been confirmed by the growth of markets where regulators have recognized the need for a flexible and industry friendly regulatory framework. Both Japan and the United States have established legal frameworks for health claims already at the beginning of the 90's leading to an unprecedented growth rate in this sector. Other regulators such as Canada have not reacted to this new "trend" in an adequate and timely manner with lost opportunities and sales for companies based in Canada.

The lack of harmonization of rules pertaining to health claims has become an impediment of trade not only between Canada and US but also between the Member States of the European Union. Divergent rules and enforcement procedures in relation to health claims resulted in significant costs for the adaptation of labelling and advertising and - in some cases - even in a ban of products legally sold in other Member States. Consequently, both national and international bodies have aimed at the harmonization of health claims standards. In 2004, the Codex Alimentarius Commission adopted Guidelines on the Use of Nutrition and Health Claims. However, concerns remain about the potential impact of the guidelines on trade due to the introduction of a clause in the preamble which allows member countries to restrict health claims in line with their nutritional policies.

In 2003, the EU Commission presented its highly controversial Proposal for a Regulation of the European Parliament and of the Council on Nutrition and Health Claims Made on Foods. This Proposal has been criticised heavily for being too bureaucratic and unnecessarily burdensome on food industry, in particular SME. A large number of different stakeholders raised concerns about the potentially negative impact of the Proposal on the much needed growth and innovation in Europe. Key criticism focused on the introduction of nutrient profiles (Art 4), the prohibition of certain health claims (Art 11) and the need for a costly and lengthy pre-approval system (Art 14-17).

Whereas Parliament followed the majority of arguments raised by food industry and rejected nutrient profiles and the necessity for pre-approval in its plenary voting of 26 May 2005, Council embraced the concept of nutrient profiles with minor adaptations in its political agreement of 3 June 2005. In the light of the recent announcement by Commission President Mr Barroso to "scrap unnecessarily burdensome laws including food labelling", hope remains that the Commission and Council will bring in line their positions with the Commission's renewed Lisbon Agenda for a "Europe of Growth and Innovation". Only a proposal based on sound science and strict necessity will allow European companies to grow and expand their businesses while at the same time avoid trade irritants with Europe's key trading partners.

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