The EU Regulation on Nutrition and Health Claims: Current and Future Trends

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When considering how to promote health by linking agriculture, food and nutrition, it makes perfect sense to have a closer look at existing legislation in the area of nutrition and health claims made on food products. This is particularly important because what industry is allowed to say about the impact on health of the foods it sells is an essential element in a number of areas, such as consumer awareness, consumer education, product research and development, and research-funding opportunities. After all, why would anyone invest considerable resources to do research, develop and market a particular food product that would be more nutritious or would help mitigate certain disease-risk factors, if the law were to prohibit any commercial communication on those health benefits?

When examining existing legislation on nutrition and health claims made on foods, it is also useful to consider the regulatory framework in the European Union (EU). There are three main reasons for that. Firstly, the EU is certainly one of the most regulated regions in the world, particularly in the food area, and it tries to "export"—or at least promote—its regulatory options to other regions and countries worldwide. Food legislation adopted in the EU tends to inspire regulators in other countries. Secondly, EU food laws, in general, tend to be more restrictive than in other regions. Thirdly, the EU legislation on nutrition and health claims was adopted recently and some of its provisions are still being developed, causing considerable controversy. Therefore, keeping an eye on the developments in the EU in terms of food claims will help promote understanding of what food manufacturers will be able to communicate to consumers in the EU as well as what new regulatory "tools" could potentially be replicated in other countries.

The EU Regulation on Nutrition and Health Claims [Regulation (EC) No 1924/2006], hereafter "the Regulation," has certainly been one of the most controversial pieces of legislation of the last decade in the area of EU food law. Its significant impact—current and future—on the food industry, particularly on functional foods and food supplements, has made its gradual implementation remarkably complex and contentious. In addition, some of its provisions, such as nutrient profiles, have raised such significant opposition from industry that its ongoing implementation has constantly been the subject of extensive press coverage, with a number of tough political and technical debates, since its adoption in December 2006.

Before the adoption of this legislation, various national legal frameworks regulated the use of nutrition and health claims across the EU. Some Member States had strict rules whereas others relied only on very general principles. In certain cases, the differences among national provisions were obstacles to the free movement of food products within the EU market. This situation also created significant distortions of competition on the market. This explains why the food industry itself was one of the main entities asking EU regulators to harmonize legislation in this area.

Scope and Objectives of the Regulation

The Regulation became applicable on July 1, 2007, across all twenty-seven EU Member States. In principle, the same rules are now applicable to all companies selling their products in the EU market, including imported products.

The Regulation applies to all nutrition and health claims made in all "commercial communications." These include not only claims made on product labels, but also claims made in advertising (television, radio, *etc.*), websites, promotional leaflets, on-shelf presentations, *etc*. Any communication on the nutritional or health benefits of a food product made on any commercial entity must comply with the provisions of the Regulation.

When proposing and adopting this legislation, the EU regulators intended to achieve three main objectives:

- To ensure a high level of protection for consumers. This would be achieved through measures aiming at ensuring that all claims are scientifically substantiated, and also through provisions intended to avoid the over-consumption of certain products due to the claims they would make.
- To facilitate consumer choice. A clear set of rules applying across the EU, with strict conditions and specific restrictions would allow consumers to make their purchases knowing that the claims made on the products they would buy are meaningful and scientifically justified.
- To ensure the effective functioning of the internal market. Similarly, the same rules applying to all twenty-seven national markets would lead to equal conditions of competition for the food industry while enabling the free movement of food products across the EU.

To achieve these objectives, the Regulation is based on two key principles:

- All nutrition and health claims must be approved at EU level.
- Certain foods will be prohibited from nutrition and/or health claims.

All Claims Must be Approved at EU Level

The Regulation defines two general types of claims—"nutrition claims" and "health claims"—which are approved through different authorization procedures. Nutrition claims are defined in the Regulation as "any claim suggesting that a food has particular beneficial nutritional properties due to the energy, nutrients, or other substances it contains, contains in reduced or increased proportions or does not contain." Health claims are defined as "any claim suggesting that a relationship exists between a food category, a food or one of its constituents and health."

The key principle laid down in the Regulation is that all nutrition or health claims must be approved at the EU level through the applicable procedures and be included in a positive list. Only the claims mentioned in the EU positive lists will be permitted in the EU.

Permitted Nutrition Claims

The Regulation itself includes, in its Annex, a positive list of the permitted nutrition claims (Table 1). Since January 19, 2010, these have been the only permitted nutrition claims in the EU market. All others are prohibited, including certain nutrition claims that have been widely used across the EU until recently, such as "high energy," "cholesterol free," "extra light," "*trans*-fat free" and "high in omega-6 fatty acids."

Table 1. List of permitted nutrition claims in the EU.

Low energy	Source of fiber
Energy reduced	High fiber
Energy free	Source of protein
Low fat	High protein
Fat free	Source of [name of vitamin(s)] and/or [name of mineral(s)]
Low saturated fat	High [name of vitamin(s)] and/or [name of mineral(s)]
Saturated-fat free	Contains [name of the nutrient or other substance]
Low sugar	Increased [name of the nutrient]
Sugar free	Reduced [name of the nutrient]
With no added sugars	Light/lite
Low sodium/salt	Naturally/natural (as a qualifier for other nutrition claim,
Very low sodium/salt	*e.g.* "naturally high in fibre")
Sodium free or salt free	

The Annex to the Regulation includes specific conditions of use that must be complied with in order for a food product to bear a particular nutrition claim. As an example, a claim that a food is "fat free" may be made only if the product contains no more than 0.5 g of fat per 100 g or 100 mL. Also, claims expressed as "X% fat free" are prohibited.

This positive list of permitted nutrition claims may be amended to take into account scientific and technological developments. A first amendment was adopted in February 2010 [Commission Regulation (EU) No 116/2010] with the addition of five more permitted nutrition claims on fatty acids: "source of omega-3 fatty acids"; "high in omega-3 fatty acids"; "high in mono-unsaturated fat"; "high in poly-unsaturated fat"; and "high in unsaturated fat."

As it stands, the Annex on nutrition claims is generally considered to be very restrictive. For example, claims relating to cholesterol ("cholesterol free," "low in cholesterol") are not included, although they were popular with certain consumers. Their inclusion in the positive list had been requested by industry and a number of Member States, but the regulators decided in the end not to authorize them because they were regarded as potentially misleading. It was feared that consumers did not understand the difference between dietary cholesterol and blood cholesterol, and the small impact the former has on the latter. Another example of a "popular" nutrition claim that has not been included in the positive list is "high energy." The fact that this claim, and any claim having the same meaning, is not authorized in the EU has considerable implications on sports foods, for example. A large number of product concepts, such as energy bars, energy gels and sports beverages have been severely affected by this decision.

Certainly, one of the most restrictive aspects of the Regulation, in relation to nutrition claims, is the very limited number of permitted comparative nutrition claims and the conditions applying to them. As it currently stands, the Regulation authorizes only four comparative nutrition claims: "energy-reduced," "increased [name of nutrient]," "reduced [name of nutrient]" and "light/lite." One of the conditions of use for these four claims is that there must be a difference in the content of the nutrient in question of at least 30% between the products being compared. This is clearly a challenge for food manufacturers carrying out reformulation programmes, as reducing the content of certain nutrients by 30% is difficult to achieve and, in certain cases—such as salt reduction—it may even lead to consumer rejection of the new recipe. This restrictive condition, particularly for reduction claims, is seen as a missed opportunity for EU regulators to give an incentive to industry to reformulate their products. By raising the bar too high, the regulators may have discouraged certain companies from improving their product recipes; why would a company reformulate its products at great cost if the law does not allow those efforts to be communicated to consumers? Are reductions in fat, saturated fat, salt or sugar of 15% or 20% really irrelevant?

Permitted Health Claims?

Contrary to the situation for nutrition claims, the Regulation itself does not include a positive list of permitted health claims. However, it lays down specific provisions requiring the establishment of such positive lists, as well as describing the corresponding

authorization procedures that must be followed to obtain authorization for different types of health claims.

The Regulation classifies health claims in three broad categories, to each of which different authorization procedures apply:

- Nutrient-function claims, which include all claims referring to the growth, development or the functions of the body (*e.g.* "calcium helps maintain strong teeth and bones"), as well as psychological and behavioral claims (*e.g.* "substance X helps improve concentration and memory"), and slimming and satiety claims *(e.g.* "substance Y helps you want to eat less/lose weight").
- Reduction-of-disease-risk claims, which "state, suggest or imply 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" (*e.g.* "substance Z has been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease").
- Claims referring to children's development and health. The Regulation itself does not provide a definition for this category of health claims. However, guidance on the implementation of the Regulation (Guidance on the Implementation of Regulation No 1924/2006, 2007) was adopted at a later stage, which clarified that this particular type of health claim would include: a) those solely referring to the development and health of children, and where the scientific substantiation is valid only for children, *i.e.* the scientific substantiation should result from studies conducted with children; b) those used on products intended exclusively for children, like follow-on formulae and cereal-based baby foods.

Obtaining authorization for health claims and their subsequent inclusion in a positive list is possible through two different authorization processes that are currently operational in parallel.

Process 1—The Authorization Procedure for Nutrient-Function Claims that were Submitted for Approval by January 2008

The Regulation established an authorization procedure for nutrient-function claims, whereby the Member States had to send to the European Commission, before the end of January 2008, their national lists of proposed health claims. These lists included the proposed conditions of use for each claim, the proposed wordings and lists of scientific references substantiating the claims. The Commission compiled these national lists and sent them to the European Food Safety Authority (EFSA) for a scientific evaluation, before establishing a Community list of permitted health claims. The Regulation clarifies that until this list is established, claims submitted for approval through this procedure will be allowed to remain on the market until a final decision is adopted on them.

The Commission was probably expecting a few hundred health claims to be tabled for adoption. However, the twenty-seven EU Member States submitted a total of 43,420. The process for collecting these claims differed from one country to another. For example,

one Member State submitted more than 10,000 claims, which had been proposed by its national food industry, whereas another Member State submitted only nine, which were the only ones that had officially been approved in the past by the national authorities. However, a considerable number of the claims submitted were essentially duplicates, as the same claims were often submitted by the same applicants in the different Member States where the claims were being used. With some time and effort, the Commission was able to reduce the list of proposed claims to 4,637, by removing duplicates and deleting entries that were incomplete or inappropriate.

EFSA is now evaluating the scientific basis for these 4,637 proposed health claims. Because the number of claims to be assessed remains quite high, EFSA will publish the results of its assessment in several batches. To date, only two batches have been published, covering fewer than 1,000 claims (Table 2). However, they indicate what should be expected from future evaluations, and what types of claims are likely to be approved or rejected in the EU. Already, impact on the market is becoming clear, particularly for sectors such as probiotics, antioxidants and botanicals. The first EFSA evaluations were mostly negative (66% for the first batch, 98% for the second) with rejections of most claims submitted on probiotic bacteria/microorganisms, antioxidants, plant extracts/botanicals, and claims on carbohydrate glycemic index/response. The higher rate of positive evaluations in the first batch can be explained by the fact that these correspond essentially to claims for vitamins and minerals for which there has long been scientific consensus.

Table 2. EFSA evaluations of nutrient-function claims (to date)—Article 13.3.

	Batch number	
	1	2
Publication date	October 1, 2009	February 25, 2010
Number of claims processed	523	416
Substances involved	Vitamins & minerals Dietary fibers Fatty acids Probiotic bacteria Other (chewing gum, plant extracts, etc.)	Antioxidants Carbohydrates glycemic index/Response Probiotics/microorganisms Botanicals and herbals Substances linked to joints health Other (honey, stearic acid, guar gum, *etc*.)
Positive evaluations	33%	2%
Negative evaluations	66%	98%

Approximately 3,250 additional nutrient-function claims await evaluation. Based on these EFSA evaluations, the EU regulator will then need to officially approve or reject the proposed claims, and include the approved ones in a positive list. Due to the considerable number that remains to be evaluated, the authorization process is expected to take until 2012. Although it is difficult to predict how many claims are likely to be approved in the end, one can guess that, based on the current trend of the EFSA evaluations, the final list of permitted claims will comprise a few hundred rather than a few thousand. And some very popular claims currently on markets worldwide may not be included.

Process 2—The Authorization Procedures for Nutrient-Function Claims Submitted for Approval after January 2008, for Reduction of Disease-Risk Claims and for Claims referring to Children's Development and Health.

In addition to the authorization procedure described above, the Regulation provides the possibility of obtaining authorizations for other types of health claims on the basis of individual application dossiers, *i.e.* reduction of disease-risk claims and claims referring to children's development and health. This applies also to "new" nutrient-function claims that were not submitted via a Member State before the end of January 2008. These application dossiers will also be scientifically evaluated by EFSA, and the claims will subsequently be approved or rejected by the European Commission. Approximately 250 individual claim-application dossiers have been submitted so far (some of which have been withdrawn), of which eleven have been officially authorized (Tables 3a, b) and forty-five officially rejected. Approximately 170 additional applications currently await evaluation.

As is illustrated in Table 4, around 80% of the individual claim applications assessed by EFSA received a negative opinion. This confirms the strict evaluation standards being applied by EFSA to evaluate the scientific evidence being put forward by applicants to substantiate their proposed claims.

The outcomes so far of the two authorization processes mentioned above clearly illustrate that the scientific bases being tabled by applicants to justify their claims are not meeting the standards being applied by the EFSA to evaluate their quality. As EFSA is evaluating the evidence submitted in both processes using the same criteria, it is not surprising that recurring reasons are being given for negative evaluations in both processes. These are, essentially:

- weakness of the scientific evidence submitted, and
- insufficient characterization of the substance for which the claim is made.

A number of proposed claims were made for broad categories of foods ("dairy products," "fruits," "fruits and vegetables") which typically include many products with a range of nutritional compositions and impacts on health. For example, EFSA considers that it cannot approve claims relating to "dairy products" because this category includes many types of foods, from Camembert cheese to fat-free yoghurts. Also, the studies submitted were focused only on certain dairy products. In EFSA's terms, the substance—"dairy products"—is not sufficiently characterized to allow validation of the scientific evidence submitted.

TABLE 3A. HEALTH CLAIMS OFFICIALLY AUTHORIZED (TO JUNE 2010), BASED ON INDIVIDUAL APPLICATION DOSSIERS—ARTICLES 13.5 AND 14.

Health claims referring to the reduction of a risk factor in the development of a disease [Article 14(1)(a)]

Nutrient/substance/food	Claim	Conditions/restrictions of use
Plant sterols/plant stanol esters	Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of 1.5–2.4 g plant sterols/stanols. Reference to the magnitude of the effect may be made only for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the entire range "7 to 10 %" and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.
Plant sterols: sterols extracted from plants, free or esterified with food-grade fatty acids.	Plant sterols have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of at least 2 g plant sterols. Information to the consumer that the beneficial effect is obtained with a daily intake of 1.5–2.4 g plant sterols. Reference to the magnitude of the effect may be made only for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the entire range "7 to 10%" and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.
Plant stanol esters	Plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.	Information to the consumer that the beneficial effect is obtained with a daily intake of 1.5–2.4 g plant stanols. Reference to the magnitude of the effect may be made only for foods within the following categories: yellow fat spreads, dairy products, mayonnaise and salad dressings. When referring to the magnitude of the effect, the entire range "7 to 10 %" and the duration to obtain the effect "in 2 to 3 weeks" must be communicated to the consumer.
Chewing gum sweetened with 100% xylitol	Chewing gum sweetened with 100% xylitol has been shown to reduce dental plaque. High content/level of dental plaque is a risk factor in the development of caries in children.	Information to the consumer that the beneficial effect is obtained with a consumption of 2–3g of chewing gum sweetened with 100% xylitol at least three times per day after the meals.

Table 3b. More health claims officially authorized (to June 2010), based on individual application dossiers—Articles 13.5 and 14.

Health claims referring to children's development and health [Article 14(1)(b)]		
Nutrient/substance/food	**Claim**	**Conditions/restrictions of use**
α-linolenic acid (ALA) & linoleic acid (LA), essential fatty acids	Essential fatty acids are needed for normal growth and development of children.	Information to the consumer that the beneficial effect is obtained with a daily intake of 2 g of α-linolenic acid (ALA) and a daily intake of 10 g of linoleic acid (LA).
Calcium and vitamin D	Calcium and vitamin D are needed for normal growth and development of bone in children.	The claim can be used only for food which is at least a source of calcium and vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN(S)] AND/OR [NAME OF MINERAL(S)] as listed in the Annex to Regulation 1924/2006.
Calcium	Calcium is needed for normal growth and development of bone in children.	The claim can be used only for food which is at least a source of calcium as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation 1924/2006.
Vitamin D	Vitamin D is needed for normal growth and development of bone in children.	The claim can be used only for food which is at least a source of vitamin D as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation 1924/2006.
Phosphorus	Phosphorus is needed for the normal growth and development of bone in children.	The claim can be used only for food which is at least a source of phosphorus as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation 1924/2006.
Protein	Protein is needed for normal growth and development of bone in children.	The claim can be used only for food which is at least a source of protein as referred to in the claim SOURCE OF PROTEIN as listed in the Annex to Regulation 1924/2006.
Health claims based on newly developed scientific evidence [Article 13(5)]		
Water-soluble tomato concentrate (WSTC I and II)	Water-soluble tomato concentrate (WSTC) I and II helps maintain normal platelet aggregation, which contributes to healthy blood flow.	Information to the consumer that the beneficial effect is obtained with a daily consumption of 3 g WSTC I or 150 mg WSTC II in up to 250 mL of either fruit juices, flavored drinks or yogurt drinks (unless heavily pasteurized).

Table 4. EFSA evaluations of individual claims application dossiers (to June 2010).

Type of claim	Favorable	Favorable with limited conditions	Issues raised	Total
New functional claims (Article 13.5)	1	–	21	22
Reduction of disease risk claims (Article 14)	5	–	10	15
Claims referring to children's development and health (Article 14)	6	6	36	48
Total	12 (14%)	6 (7%)	67 (79%)	85 (100%)

Another key lesson learned in recent years is that companies tend to be overoptimistic about the quality of their research and the strength of their application dossiers. Most applications were negatively evaluated by EFSA because the scientific evidence submitted did not include human-intervention studies. It was hoped by many that EFSA could be persuaded to, in certain cases, refer to a grading of the available evidence to evaluate whether the data submitted supported the claims—"convincingly," "possibly," "probably," or "insufficiently"—but EFSA refuses to be persuaded and strictly applies its gold standard: human-intervention studies are a must to obtain a positive evaluation. Commission Regulation (EC) No 353/2008 clearly lays down, hierarchically, the levels of data that should ideally be included in an application dossier:

- Human data
  - — Human-intervention studies, randomized controlled studies, other randomized studies (non-controlled), controlled (non-randomized) studies, other intervention studies.
  - — Human observational studies, cohort studies, case-control studies, cross-sectional studies, other observational studies such as case reports.
  - — Other human studies dealing with the mechanisms by which the food could be responsible for the claimed effect, including the studies on bioavailability.
- Non-human data
  - — Animal data including studies of aspects related to absorption, distribution, metabolism, excretion of the food, mechanistic studies, and other studies.
  - — *Ex vivo* or *in vitro* data based on either human or animal biological samples related to mechanisms of action by which the food could be responsible for the claimed effect, and other non-human studies.

However, it is clear now that most of the studies mentioned above will be useful in an application dossier only if submitted as supporting evidence for well designed human-intervention studies, without which there is very little chance of success. There is no grading of the available evidence.

A good illustration of the strict evaluation criteria being used by EFSA is provided by its opinion on an application for a reduction-of-disease-risk claim on cranberry juice (European Food Safety Authority, 2009a). The proposed claim was: "[the product] helps reduce the risk of urinary tract infection in women by inhibiting the adhesion of certain bacteria in the urinary tract". EFSA concluded that the evidence submitted by the applicant was insufficient to establish a cause-effect relationship between the consumption of the product in question and the claimed effect. Although the application dossier contained a number of human studies, they were dismissed by EFSA for the following reasons:

- Six human studies were judged of limited relevance because the claim targeted healthy women (aged 16 and above), whereas the studies were carried out on unhealthy subjects (patients suffering from neurogenic bladder) and children.
- In an additional human study the daily dose of the active substance consumed was approximately six times higher than the use levels proposed for the claim.
- Although five other human-intervention studies were considered pertinent to the claimed effect, EFSA criticized the two key randomized, placebo-controlled trials. The first one for its short duration and lack of statistical power, the second one for the lack of adequate randomization and high drop-out rate.
- The other three pertinent human studies were also criticized by EFSA due to significant limitations, including the use of different cranberry formulations (matrixes) from that in the application, poor study design, as well as high drop-out rates in some of the studies.
- It is also noteworthy that EFSA did not consider meta-analyses and previous opinions by national food-safety authorities (on the same/similar claim) as relevant evidence.

Interestingly, although EFSA recognized a proven *in vitro* inhibitory effect on adhesion of *E. coli* to mucosal cells, it concluded nevertheless that the evidence submitted did not establish that the anti-adherence effects shown *in vitro* are predictive of the occurrence of a clinically relevant bacterial anti-adherence effect within the urinary tract under the conditions of use proposed for the claim. This claim was rejected by the European Commission in November 2009 (Commission Regulation (EC) No 1167/2009).

Based on the EFSA evaluations so far, as well as on EFSA's guidance for the preparation of claim-application dossiers (European Food Safety Authority, 2007, 2009b), one can list key criteria that potential applicants should use to assess the strength of their application dossier (EAS, 2010):

- Is the food or food constituent sufficiently characterized to the extent that it can be verified that the food or food constituent is the subject of the studies performed and therefore responsible for the claimed effect?

- Are the studies carried out with the food or food constituent that is the subject of the claimed effect?
- Are human studies available with appropriate outcome measures in relation to the claimed effect?
- Are the conditions under which the food or food constituent is tested in the human studies representative for the proposed conditions of use for the claim (level of intake, pattern of consumption, *etc*.)?
- Are the human studies or study group representative of the proposed target of the claim? Can the study results be extrapolated to the target population of the claim?
- Is a rationale available to explain how studies in animals or *in vitro* support the claimed effect in humans?

However, these criteria were "officially" disclosed only after a considerable number of applications had already been submitted (Processes 1 and 2 above). EFSA's evaluation criteria became clearer after its first detailed opinions had been published. For example, the level of characterization that EFSA requires for microorganisms (probiotics) was clearly stipulated only after EFSA had already evaluated (negatively) a considerable number of claims on probiotics.

Needless to say, the extremely high rate of negative claim evaluations by EFSA, and the expected subsequent rejection by the European Commission of the vast majority of the claims submitted for approval, were not greeted with joy by the food industry in the EU. Consequences for the food market will be considerable, particularly in the area of functional foods, food supplements and botanicals. Based on the EFSA evaluations so far, it is fair to say that the mass rejections of most claims on antioxidants, probiotic bacteria/microorganisms, botanicals/plant extracts, joint health and glycemic index/response are likely to lead to serious difficulties for those markets. It is essential that makers of functional foods and supplements be able to communicate the beneficial effects of their products on the body or health. Not being able to do so means the end of such product concepts. It could also mean that fewer funds will be available for research in those areas, particularly if companies feel that regulators are unlikely to allow any commercial communications for those substances. These EFSA evaluations could, therefore, be the beginning of the end for certain functional-food markets in the EU.

Certain Foods will be Prohibited from Claims

The first principle established by the Regulation is that all claims must be approved at the EU level. However obtaining the authorization for a particular health claim on a specific substance will not be enough to ensure its use with the food formulation or product concept of choice. A second obstacle needs to be taken into account to determine use of the permitted claim on a specific product: the nutrient profile.

Nutrient Profiling

When drafting its proposal for a regulation on nutrition and health claims, the European Commission feared that indiscriminate use of claims by food manufacturers could lead to

overconsumption of "certain" food products, which could potentially contribute to the rising levels of obesity and diet-related diseases. It was feared also that the use of claims on such less nutritionally balanced products could potentially "mislead consumers when trying to make healthy choices in the context of a balanced diet" (Regulation 1924/2006, Whereas 11). Therefore, as part of the objective of ensuring "a high level of protection for consumers," and with the aim of avoiding the overconsumption of "certain" foods and consumer confusion as to what a balanced diet really is, the EU regulators introduced the concept of nutrient profiles in the claims Regulation. Nutrient profiling will be used as a tool to determine which foods will be "healthy enough" for claims to be made and which foods will be considered "unhealthy" and therefore unsuitable for claims.

This concept has been one of the most controversial provisions of the Regulation, leading to numerous scientific debates, political negotiations and intense lobbying by the food industry as well as by health and consumer non-governmental organizations. The main criticism raised by industry, as well as by a considerable number of nutritionists, against nutrient profiling is that it does not make much sense to classify individual foods as "healthy/good" or "unhealthy/bad." It is acknowledged that the relevant factor in terms of obesity and diet-related diseases is whether the range of foods that is consumed over a certain period of time is sufficiently varied and balanced. This argument was also stressed by EFSA itself, which recognized in its 2008 scientific opinion on the establishment of nutrient profiles that "there is an inherent difficulty in seeking to apply to individual food products nutrient-intake recommendations that are established for the overall diet" (European Food Safety Authority, 2008).

As was requested by the Regulation, the Commission asked EFSA for scientific advice on the development of nutrient profiles. However, the EFSA advice remained very general, consisting essentially of a list of possible options on how profiles could potentially be developed, indicating also the respective advantages and disadvantages of each option. As a consequence, the profiles are being developed mostly on the basis of political negotiations between the Commission and the Member-States experts, rather than on the basis of purely scientific arguments. This explains why the establishment of the profiles has been such a difficult task, and why the Commission was not able to meet the January 2009 deadline required by the Regulation to establish the profiles.

The Commission tabled a first proposal in June 2008, and various texts were then successively discussed until March 2009, at which time the process was put on hold when the political discussions reached a dramatic point: on the one hand, Member-State experts were seriously unhappy with the Commission's proposals and were making too many requests for exemptions for specific products—considered to be of national interest!—and, on the other hand, various services within the Commission itself were unhappy with the proposals being tabled by the service in charge of the negotiations, essentially for legal and economic reasons. So far, the Commission has not tabled any new proposals.

Although the process that will lead to the establishment of nutrient profiles in the EU is currently on hold, the proposals that have been discussed already give a good impression of what they will look like in the end. The Commission is focusing on three key nutrients: saturated fat, sodium and sugars. Different thresholds would be established

for these nutrients. The profiles would consist of generic thresholds for foods in general, expressed per 100 g or 100 mL, as well as specific thresholds for certain food categories that play important roles in the diet (*e.g.* dairy products, cereal products, meat products). Certain foods could be exempted from having to comply with the profiles, such as fruits and vegetables, food supplements, and sugar-free chewing gum. Products containing higher levels of saturated fat, sodium and sugars than the applicable thresholds would be restricted or prohibited from nutrition and/or health claims.

As was already mentioned, the development of the nutrient profiles has been essentially a political process with difficult negotiations on various points, including:

- What food categories should benefit from adapted thresholds?
- How should these categories be defined?
- What thresholds should apply to these categories?
- What foods should be exempted from the need for profiles?

As EFSA was not asked to develop a profiling system or to propose possible nutrient thresholds for different food categories, this is being done by the Commission and the Member-State experts. Inevitably, these discussions became very political with different thresholds being proposed by different Member States without any apparent scientific justification. For example, in the discussions on the threshold that should be set for sugar in the category "non-alcoholic beverages," some Member States insisted on a level of 5 g, another proposed 8 g, and a few suggested 10 g, without providing any explanations whatsoever to justify why 5, 8 or 10 g would be most appropriate.

It is clear that the food industry is not a strong supporter of nutrient profiling for many reasons, among which is the serious risk that nutrient profiling could hinder innovation—particularly in the area of product reformulations—as it will represent a clear disincentive for the development of healthier products within certain food categories. It will simply not be possible to make any claims at all (not even "reduction" claims) due to the strict thresholds that are being considered. However, although many legal, technical and scientific reasons are being put forward by industry to oppose nutrient profiling, one of the key reasons explaining this opposition has nothing to do with the nutrition and health claims. The main fear is that if a European, harmonized nutrient-profiling system, which would be used to identify "healthy" and "unhealthy" foods, were to be agreed by the Commission and the twenty-seven Member States, it would then be very difficult to resist calls for further restrictions and discriminations against certain food products. Already a number of national and EU-wide campaigns are calling for restrictions, such as color-coded nutrition labelling ("traffic lights"), advertising restrictions and food taxation, that would be based on the future EU profiles.

Conclusion

Although not all of the key provisions of the EU claims Regulation have been implemented yet, it is already possible to see its future impact on the EU market for functional foods, as well as on other related areas of activity such as food and nutrition research. It

is now clear that the full implementation of the claims Regulation will lead to a drastic reduction in the number of nutrition and health claims being used on the EU market. As a result, and taking into account the recent evaluations by EFSA of some of the claim-applications dossiers, it is fair to say that a number of product concepts, some of which have been successful worldwide in past years, will be facing serious challenges. Certain segments of the functional-foods market will be forced to reconsider their product concepts, particularly in the areas of antioxidants, probiotics, low glycemic-index products, and herbal products. The implementation of the Regulation will also lead to considerably less flexibility for food manufacturers and marketers to communicate to consumers the beneficial nutritional and health properties of certain products. Such communications will also be increasingly more standardized and repetitive as companies will need to keep their messages as similar as possible to the approved claims which, in addition, are not necessarily consumer-friendly.

Science will be the determining factor for success. The quality of the scientific evidence submitted to substantiate an application for the authorization of a health claim will be the essential element that will determine whether the application—and the product concept that would use the claim in question—has any chance of being approved. However, it must be stressed that it is EFSA, and EFSA alone, that will ultimately decide whether the data submitted really establish a cause-effect relationship between the substance or food and the claimed benefit. This should be taken into account if one intends to carry out studies to demonstrate the beneficial properties of certain substances. It would be worthwhile taking a closer look at the criteria being applied by EFSA to evaluate claim-application files, particularly with regard to the importance given to well designed human-intervention studies. Finally, the potential future implementation of nutrient profiles is likely to have a devastating effect on a number of functional foods as associated nutrition and/or health claims will be prohibited. This will also have very concrete implications on funding opportunities for research, as no company will want to invest in research if none of its current and future products will be the subject of claims due to their nutritional composition. And, worryingly for industry, when such a tool that will help discriminate between "healthy" and "unhealthy" foods will be agreed at the EU level, the temptation for national and European regulators to use it for other restrictive purposes will be very real.

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