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Symposium on 'The challenge of translating nutrition research into public health nutrition'

Session 4: Challenges facing the food industry in innovating for health Regulatory challenges and opportunities for food innovation

Nino Binns
Nino Binns Consulting, Grange Rath, Drogheda, County Louth, Republic of Ireland

The primary role of the extensive and complex modern food legislation is to protect the consumer. Providing a framework for industry and enabling free trade are secondary aims. In the EU the 2006 Regulation on nutrition and health claims made on foods was adopted in December 2006. This Regulation defines detailed lists of permitted claims with precise conditions, requires foods making claims to meet specific nutrient profiles and requires the submission of a dossier for approval of new health claims. Nutrient profiles and an initial list of existing health claims will not be agreed until January 2009 and January 2010 respectively. The uncertainty about profiles and the initial list of claims as well as the prescriptive nature of the Regulation will have a major impact, some negative but some positive, on food innovation. Worldwide legislation on nutrition and health claims continues to develop. The current paper also provides an outline of some other key pieces of European legislation that affect food innovation. However, currently, all this legislation remains in development and up-to-date information can be sought from the reference material provided.

Food regulation: Health claims: Nutrition claims

The primary role of modern food legislation is to protect the consumer. Providing a framework for industry and enabling free trade are secondary aims. Food legislation is extensive and complex and is variable around the world, such that it is a challenge for food manufacturers and distributors to sell products in the same packaging across a wide range of countries. The current paper provides a summary of some key pieces of recent European legislation that impact food innovation; however, currently, all this legislation remains in development and reference should be made to the relevant websites cited. The paper also makes brief reference to equivalent legislation in other parts of the world, but these rules may also be in evolution over the coming years.

Historical aspects

Although there was some early rudimentary law in the Middle Ages, the industrial revolution brought with it plenty of opportunities for unscrupulous purveyors of all manner of foods and potions that carried the wildest of claims. Bread was whitened with alum, mashed potatoes extended with plaster of Paris, pipe clay and even sawdust and bitter substances such as strychnine used in beer to save on the cost of hops. Confectionery was sometimes coloured with Pb, Cu and Hg compounds or gamboge, a yellow gum that was a violent emetic and irritant[1].

It was analytical chemists and medical doctors outraged by these practices that led to the English Adulteration of Food and Drink Act of 1860, which was devised to protect the public from these unsafe products; it required that food should not be sold that was 'injurious to health' and not of 'the nature, substance or quality intended'[2]. Scientists active in other countries such as the USA and Canada helped to see similar laws introduced in the late 19th or early 20th century. Laws on adulteration were generally followed by provisions to protect the consumer from misleading information on labels and in advertising. The

Abbreviations: EFSA, European Food Safety Authority.

Corresponding author: Dr Nino Binns, fax +353 41 983 4644, email nino.binns@nbconsulting.eu

fundamentals of these early laws have remained the basis of food law ever since.

Regulations continued to develop and the science base of regulation grew, especially in the USA where science is paramount. In the EU free trade was the most prominent issue and legislation was gradually harmonised to allow for a 'single European market'. This approach did not always work, but the famous Cassis de Dijon case in 1979[3] resulted in the concept of 'mutual recognition'. During the BSE crisis of 1997 the European Parliament issued a notice of censure on the European Commission. This action led not only to a restructuring of the European Commission but also to a new approach to food law that emphasised consumer protection and to the formation of a new European Food Safety Authority (EFSA)[4].

The vast majority of legislation that now affects food (taken to mean food and beverages) in the EU is made in Brussels. The approach is one of 'farm to fork' and the Directorate General for Health and Consumer Protection cites its mission as 'The EU integrated approach to food safety aims to assure a high level of food safety, animal health, animal welfare and plant health within the EU through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market'. The EFSA is responsible for evaluating the science (risk assessment) and also communicating the science (risk communication), but the European Commission and the member states are the risk managers who decide how to develop and apply the laws to protect the consumer. If the science is not clear they can opt for the 'precautionary principle'[4].

Other countries with well-developed food law are Canada, USA, Australia and New Zealand and Japan, and along with the EU these countries tend to determine the direction that other countries take, depending on their nearest neighbours or their main trading partners. Most countries or regions around the world have legislation based on these leaders or, in the case of developing countries, on the Codex Alimentarius Commission (a joint body of the FAO and the WHO). Variation in food law around the world does lead to trade barriers despite the efforts of the Codex Alimentarius Commission and the World Trade Organization. Regional cooperation occurs in, for example, North and South America and in south-east Asia.

Legislation today

Current legislation has evolved to control most aspects of food production, formulation and marketing. Food and beverage innovation clearly is affected by any part of the legislation and also by related areas such as that governing packaging. The current paper is necessarily very selective and does not catalogue all applicable legislation. It only considers the impact of a limited number of specific regulations on food innovation for health. Many other pieces of legislation apply to food, e.g. rules about hygiene and specific compositional rules that are not mentioned here. A more comprehensive catalogue of the applicable legislation is available through the Directorate General for Health and Consumer Protection website[5] and the various national agency websites.

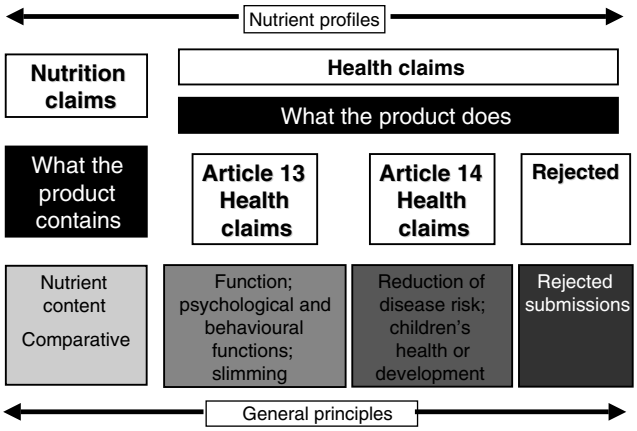

Fig. 1. Schematic summary of the EC Regulation no. 1924/2006 on nutrition and health claims made on foods[6].

The European Commission Regulation on nutrition and health claims made on foods[6,7] (that will be gradually implemented up to 2010 and beyond) is the current focus of attention as this legislation requires considerable investment in clinical studies for those companies wanting to innovate in the food claims area. Also reviewed are the plans to update the rules about novel foods and processes and the imminent rules that will govern the levels of vitamins and minerals that can be added to foods and food supplements. These two pieces of legislation affect formulation and, in the case of the novel food regulation, as with the Regulation on nutrition and health claims made on foods, an impact on time from concept to market is very likely.

So, will the increasing burden of legislation stifle or promote innovation? It remains to be seen; but the food industry has to be innovative to maintain their consumers' interest and so it will find new ways to work within the constraints of food law and continue to find opportunities to benefit consumers' health.

Regulation of claims

EU

The tenet that all foods and beverages can be part of a healthy diet is still reasonable, but once a food is marketed with specific reference to its health benefits, or even reference to the nutrients or other beneficial substances it contains, then it will be subject to the Regulation on nutrition and health claims made on foods[7]. The Regulation applies to any commercial communication about any food (taken to mean food and beverages) whether sold in a supermarket or at a restaurant. Commercial communications include the label, advertising, leaflets, websites etc. It is helpful to read the Regulation in conjunction with the guidance from the UK Food Standards Agency[8].

This piece of legislation has been many years in the pipeline and has had a very rough passage through the EU institutions[9]. Previously, nutrition and health claims were regulated at national level, which meant disallowed in

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Table 1. Nutrition claims in the Annex to EC Regulation no. 1924/2006[7]

	'no more than' per 100 g or 100 ml		Reduced§ (light)	Increased§	'at least' per 100 g or 100 ml		No added
	Free	Low			Source or contains	High	
Energy	17 kJ (4 kcal)/ 100 ml*	170 kJ (40 kcal)/ 100 g or 80 kJ (20 kcal)/100 ml†	<30%	n/a	n/a	n/a	n/a
Fat	0·5 g	3 g or 1·5 g (1·8 g/100 ml semi-skimmed milk)	<30%	n/a	n/a	n/a	n/a
Saturated fat (+ *trans*-fatty acids)	0·1 g	1·5 g/100 g or 0·75 g/100 ml (<10% energy)	<30%	n/a	n/a	n/a	n/a
PUFA, MUFA, 'omega' fatty acids	n/a	n/a	<30%	>30%	n/a	n/a	n/a
Cholesterol	n/a	n/a	?	n/a	n/a	n/a	n/a
Carbohydrate	n/a	n/a	<30%	n/a	n/a	n/a	n/a
Sugars	0·g	5 g/100 g or 2·5 g/100 ml	<30%	n/a	n/a	n/a	Defined
Protein	n/a	n/a	<30%	>30%	12% energy	20% energy	n/a
Fibre	n/a	n/a	<30%	>30%	3 g/100 g or 1·5 g/417 kJ (100 kcal)	6 g/100 g or 3 g/417 kJ (100 kcal)	n/a
Vitamins and minerals	n/a	n/a	<10%	>30%	15% RDA	30% RDA	n/a
Salt	0·0125 g	0·3 g‡	<25%	n/a	n/a	n/a	n/a
Other substances	n/a	n/a	n/a	n/a	Significant amount‖	n/a	n/a

n/a, not applicable.
*Limit 1·7 kJ (0·4 kcal) per portion for table-top sweeteners with equivalent sweetening properties to 6 g sucrose (approximately one teaspoon).
†Limit 17 kJ (4 kcal) per portion for table-top sweeteners with equivalent sweetening properties to 6 g sucrose (approximately one teaspoon).
‡Very low is 0·1 g.
§In comparison with a market range. May change to 25%. Increased must also meet conditions of 'source'.
‖As defined in Annex to Directive 90/496/EEC[51].

some countries, specifically regulated or subject to prior market approval in others and allowed under general food law and codes of practice in the remainder[4,10] The current piece of legislation is very prescriptive and once it is fully implemented industry will be able to use only nutrition claims in the Annex to the Regulation and health claims appearing in one of the approved lists of claims.

Nutrition claims. The regulation covers both nutrition claims and health claims (Fig. 1). Nutrition claims are:

1. those about nutrients or other physiologically-active substances the food contains, e.g. that the food contains Ca, is a source of protein, high in fibre, rich in vitamins and minerals or contains plant components such as carotenoids or polyphenols;
2. those about nutrients that have been removed or reduced, e.g. reduced fat or sugar-free;
3. those comparing the content or absence of nutrients with another food from the same category.

The list of permitted nutrition claims and the conditions that have to be met for each claim are provided in an Annex to the Regulation and are summarised in Table 1.

Health claims. 'Health claim' is defined as any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. However, the subdivision of the claims in the legal text is unnecessarily complicated (see Fig. 1).

All health claims are required to be based on generally-accepted scientific evidence (discussed later) and well understood by the average consumer (who according to the European Court of Justice 'is reasonably well-informed and reasonably observant and circumspect, taking into account social, cultural and linguistic factors' (see Article 16 of the Regulation[7]).

Health claims are divided in legal terms into two groups:

1. Article 13 claims about the effects of foods or ingredients or nutrients as they relate to growth, development and functions of the body (including weight control and psychological or cognitive effects), e.g. Ca is good for bones, high-fibre diets help weight control, caffeine keeps you alert;
2. Article 14 claims, i.e. claims referring to a reduction in the risk of disease or a disease risk factor (e.g. reduces the risk of osteoporosis, lowers blood cholesterol) or claims referring to children's development and health (e.g. Ca builds strong bones).

The bizarre inclusion of these two latter types within the same Article 14 of the Regulation was as a result of the European Parliament's amendments in the second reading, which were then agreed during the final negotiations between the European institutions. The reason for this decision was that it would mean that claims referring to children's development and health would be automatically rendered illegal unless they had been specifically approved under the same procedures required for reduction of disease risk claims. The procedure involves submitting a dossier to the EFSA for scrutiny of the evidence followed

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Table 2. Summary of the content required by the European Food Safety Authority for inclusion in a dossier for a health claim[21,22]

Characteristics (specification) of the food, constituent or nutrient
A proposal for the wording of the health claim
A comprehensive review of the data from human studies and other supporting studies, including all pertinent scientific data (i.e. published and unpublished, data in favour and not in favour of the claim)
Overall conclusions that weigh the evidence, taking into account the totality of the available scientific data. In particular, the evidence should demonstrate the extent to which:
1. the claimed effect of the food, constituent or nutrient is relevant for human health
2. a cause and effect relationship is established between the consumption of the food, constituent or nutrient and the claimed effect in human subjects
3. the quantity of the food, constituent or nutrient and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet
4. the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended

by approval (or rejection) of the claim by the Standing Committee of Member States.

It should be noted that 'reduction of disease risk claims' are distinct from medicinal claims about the prevention, treatment or cure of disease. Medicinal claims cannot be used on foods unless the food is also approved as a medicine.

However, since the Regulation was adopted the EU institutions have been forced to adopt an amendment[11] to allow a transition for those children's claims that were already on the market, otherwise it would have become illegal overnight in July 2007 to market any food that carried a claim for children, e.g. a dairy product claiming to be beneficial to child bone development. Between July 2007 and February 2008 when the legal text was published such products remained on the market on the basis of a 'gentleman's agreement'.

There are a number of prohibited claims, in addition to those that do not meet the requirements of the legislation or are, for example, misleading. Under nutrition claims it is specifically prohibited to use a claim such as '95% fat free'. For health claims it is forbidden to use claims about the rate or amount of weight loss (e.g. 'Lose 7lbs in 3 days') and to use claims that make reference to the recommendations of individual health professionals. This rule about health professionals was intended to stop 'quackery' and brand endorsements by individuals, but it has also meant confusion for a number of groups, in particular dietitians who may write articles about the health benefits of products. The FSA guidance sheds only partial light on this problem[8].

Developing the list of claims. The list of claims allowed under Article 13 is being developed rather differently from Article 14 claims, for which a dossier must be submitted to the EFSA. The twenty-seven member states of the EU were required to provide a national list of claims and following collation by the European Commission and review by the EFSA the Regulation calls for a list to be published by January 2010. By May 2008 the European Commission was said to be juggling approximately 35 000 claims before removal of all the duplication. The final list sent to the EFSA contained >3000 after removal of duplicates, claims lacking conditions of use (e.g. level of required intake) and claims considered to be Article 14 or medicinal claims.

There must surely be a lesson here for regulators in terms of procedures written in legislation. The food industry did much to try to assist the process and adopted a systematic approach to the evaluation and presentation of information on claims[12,13] that led to a manageable list of <800 health relationships. A number of companies added to this list at national level, but adoption of the core industry list by the European Commission at EU level followed by direct input from either member state government agencies or individual companies would in hindsight have represented a much more practical approach.

Assessment of science. As noted earlier, all claims must be based on generally-accepted scientific evidence. It is the task of the EFSA Panel on Dietetic Products, Nutrition and Allergies to assess the evidence.

There has been plenty of previous work on the substantiation of claims for the EFSA to draw upon, and indeed a meeting convened by the EFSA in November 2006 included presentations on work by US Food and Drug Administration[14–16], by Health Canada[17] by Food Standards Australia New Zealand, by academic, government and industry scientists working with the International Life Sciences Institute Europe[18,19] and by scientists working with national voluntary codes such as the Joint Health Claims Initiative in the UK[20].

Industry wanting to gain approval for a new claim under Article 13 or Article 14 must submit a dossier to the EFSA. The requirements for the content of the dossier are set out in detail on the EFSA website[21,22] and include templates and specific advice on different sections of the dossier. Information required for the applications is summarised in Table 2.

The relationship between a food or food component and health can be demonstrated by a number of different types of studies, but those in human subjects will always carry greater weight than animal and *in vitro* studies. As a result of the scientific uncertainties in extrapolating non-human data to human subjects, data from studies in animals or model systems will be viewed only as supporting evidence, e.g. to explain the mechanism underlying the claimed effect.

Looking at studies on human subjects, the randomised placebo-controlled double-blind intervention study is always assumed to provide the strongest evidence and epidemiological and observational data are generally accorded a lower weighting of evidence. However, it is not always possible to conduct intervention studies with foods and food components, so that in some cases epidemiological

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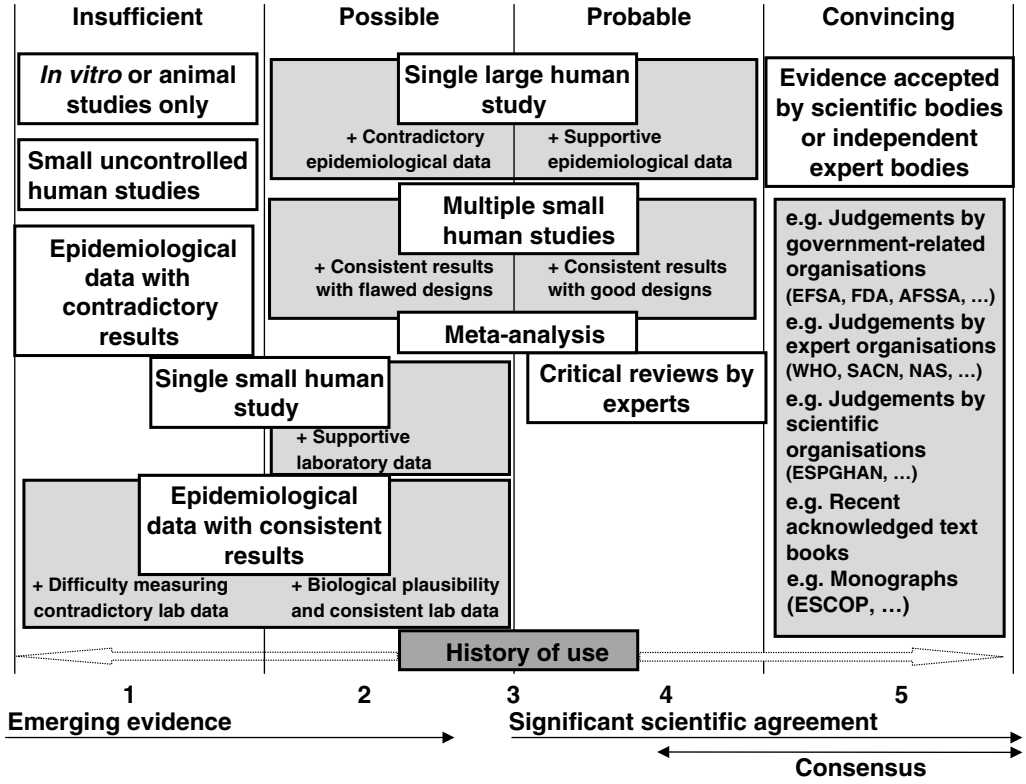

Fig. 2. Levels of evidence in the scientific substantiation of claims. EFSA, European Food Safety Authority; FDA, Food and Drug Administration; AFSSA, Agence Française de Sécurité Sanitaire des Aliments (French Agency for Food Safety); SACN, Scientific Advisory Committee on Nutrition; NAS, National Academy of Sciences; ESPGHAN, European Society for Paediatric Gastroenterology, Hepatology and Nutrition; ESCOP, European Scientific Cooperative on Phytotherapy. (After Richardson[12].)

and observational data are the only type of evidence available to support health claims. Indeed, these studies often form the main source of data on which dietary guidelines are based. A good example is the whole grain and heart health claim, which is approved in the USA, UK and Sweden[23]. Epidemiological and observational studies can provide sufficient evidence if the data are consistent, significant and biologically plausible, especially if supported by appropriate animal and *in vitro* studies. All studies that are available must be reviewed for their quality as well as their relevance to support the claims[19]. Research synopses, such as well-defined systematic reviews, pooled analyses or meta-analyses may also be presented and the EFSA provides guidance on their inclusion.

Grading of evidence. A good deal of groundwork has been done in the past on means to assess evidence for the purposes of public health; evidence has generally been graded as convincing, probable or possible[24,25]. The scientific evidence to support a claim will evolve over time and the Dutch regulatory authorities have adopted this approach in Europe when considering the evaluation of health claims. This approach has been adapted[18] and used to guide industry in the preparation of evidence to support Article 13 claims (see Fig. 2)[12,13]. Evidence is seen as a continuum from emerging evidence to consensus science. Where the line can be drawn to say that the evidence is sufficient to validate a particular claim is a matter of scientific judgement.

Nutrient profiles. The nutrient profile of the overall (habitual) diet is an important determinant of health and the profile of a 'balanced' diet can be defined by science-based recommendations for intakes of energy and nutrients. In current parlance 'nutrient profiling' is the classification of foods for specific purposes based on their nutrient composition. Profiling has been used to identify and encourage the development of 'healthier' foods, e.g. in the Swedish keyhole[26] or the Australian pick-the-tick[27] schemes. The UK took this process a step further and have defined nutrient profiles for foods advertised to children[28] and for 'traffic light' food labelling[29]. The use of nutrient profiles in these cases and in the regulation of nutrition and health claims is rather different. It aims to avoid a situation in which claims could mislead consumers as to the overall nutritional quality of a food product when they are trying to make healthy choices in the context of a balanced diet.

EFSA have stated that in their opinion 'The nutrient profile of the overall (habitual) diet is an important determinant of health and the nutrient profile of a 'balanced' diet is defined by science based recommendations for intakes of energy and nutrients. Because diets are composed of multiple foods, overall dietary balance may be achieved through complementation of foods with different nutrient profiles so that it is not necessary for individual foods to match the nutrient profile of a 'balanced' diet.

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Nevertheless, individual foods might influence the nutrient profile of the overall diet, depending on the nutrient profile of the particular food and its intake'[30].

EFSA have advised that where there is a need for nutrient profiles, they should be based on nutrients of public health concern for the EU population, i.e. saturated fat and Na and dietary fibre and unsaturated fats as well as sugar for some products[30]. They recommend that a profile is set across the board and that exceptions are made as required per category of food, e.g. dairy products might have a higher threshold for saturated fat or Na because they are an important source of Ca; cereals-based foods are an important source of many nutrients yet may have levels of saturates, Na or added sugar that might exceed a generalised profile; non-alcoholic beverages very often contain added sugars yet are important for hydration. The profile could be set per 100 g (or 100 ml) or per 100 kJ (or 100 kcal), but ultimately it will be the European Commission and member states who propose and decide on the profiling system. In general, measures of nutritional quality might be expected to be focused on diets[31] and it will be interesting to see what profiles the European Commission sets and what impact they have. They are due to be set by January 2009 and all food products that make nutrition and health claims will have to comply by January 2011.

In order to make a health claim a food will have to comply fully with whatever nutrient profile applies. For a nutrition claim the food may fail on one nutrient; however, in that case the 'high' level of the failed nutrient must be stated on the label close to the main claim. To take a hypothetical example: a specialist bread could make a high-fibre nutrition claim if it contains 6 g fibre/100 g even if it fails the profile for Na. However, if the bread is used in a sandwich that fails the profile on Na and saturates it would not be possible to make any fibre claim. Neither the bread nor the sandwich could make a health claim about the bowel benefits of fibre, as to make a health claim all profiles will need to be met. It is assumed that when setting nutrient profiles the European Commission will weigh the benefits of fibre against the risks of Na and will set a pragmatic level.

Asia and Japan

In Asia, and especially in Japan, the approach had been to regulate individual foods that are considered to have functional properties (and thus the claims made on them) on a case-by-case basis. In some countries, notably Japan, Korea, China and Taiwan, there are regulatory systems for such 'functional' foods, the best known being the Japanese Foods for Specified Health Use (FOSHU) system in which individual foods are approved. This system contrasts with the EU system in which it is the health claims that will be approved, with conditions of use that may link it to a food or food component.

USA

In the USA the Department of Agriculture regulates food commodities such as meat and milk and the Food and Drug Administration regulates processed foods under the Federal Food, Drug and Cosmetic Act. Medicines (drugs), foods, dietary supplements, food for special dietary use or medical foods are all subject to separate rules.

The rules around health claims are complex[32]. The US Congress has defined health claims made on foods in the Nutrition Labelling and Education Act of 1990 as a claim on the label or in the labelling of a food that characterises a relationship between a 'nutrient' in that food and a disease or health-related condition. These claims must reach the standard of 'significant scientific agreement'[14]. A 1997 amendment to the Nutrition Labelling and Education Act, the Food and Drug Administration Modernization Act, permits a manufacturer of foods (not dietary supplements) to rely on a health claim or statement from an 'authoritative' scientific body of the US Government or the National Academy of Sciences. In a further development in July 2003 (Better Nutrition Information for Consumer Health Initiative) the Food and Drug Administration issued documents laying out the criteria by which it would evaluate 'qualified health claims' that do not meet the standard of 'significant scientific agreement'[16]. Pre-market approval or notification is required for all health claims and the wording for both the claim and for any required 'qualification' is prescribed.

For the separate legal category of dietary supplements the Dietary Supplement Health and Education Act 1994 governs not only the basic definition and safety standards for dietary supplements but also what structure–function claims are permitted. Structure–function claims on foods are not subject to pre-market approval but must not be misleading[32].

During 2007 the Centre for Food Safety and Nutrition of the FDA consulted on draft guidance on an Evidence-Based Review System for the Scientific Evaluation of Health Claims[33] and they are reputed to be considering a formal regulatory system specific for functional foods.

Canada

In Canada the 2002 amendments to the Food and Drug Regulations allow diet-related health claims on foods for the first time in Canada. Five generic claims were approved based on sound scientific evidence that has established a relationship between certain elements of healthy diets and reduction of risk of certain diseases[34]. Guidance is provided for the preparation of dossiers[35]. Nutrient function (biological role) claims are also permitted but are not subject to pre-market approval[34]. Health Canada, like the US Food and Drug Administration, is considering legislation on functional foods.

Australia and New Zealand

Food Standards Australia New Zealand has been discussing the regulation of nutrition and health claims and setting nutrient profiles for quite some time and have drawn heavily on the UK for their approach to profiles[36]. Three types of claims will be regulated but currently the new food standard appears to be awaiting final approval[36]:

1. nutrition content claims;
2. general-level health claims about the effect of a nutrient or substance in a food on a health function.

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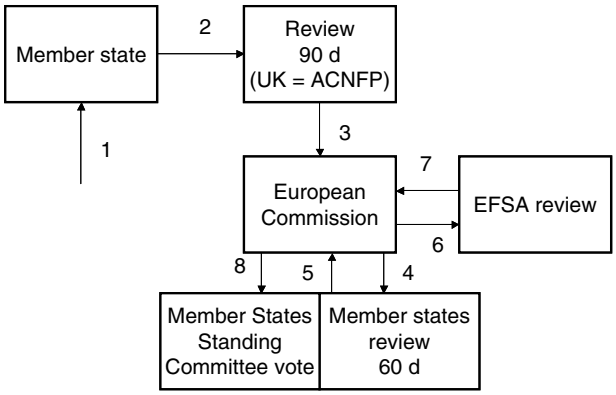

Fig. 3. Schematic summary of procedure (stages 1–8) for approval of novel food under Regulation (EC) no. 258/97[38]. ACNFP, Advisory Committee on Novel Foods and Processes; EFSA, European Food Safety Authority.

There will be a 'model list' of statements. Additional claims can be used but scientific evidence to substantiate such claims must be available on request for enforcement agencies;

3. high-level health claims are those that make reference to a serious disease or biomarker (e.g. blood cholesterol) and these claims will need pre-market approval.

Codex

The topic of functional foods was first discussed during the 47th Session of the Executive Committee of the Codex Alimentarius Commission in 2001 when the Asian region proposed work in the area of novel foods (other than those derived from biotechnology), functional foods and foods that were also considered to be at the food–drug interface. However, as Codex already had guidance on nutrition claims, they extended this guidance to include health claims[37] rather than suggesting regulation of functional foods per se. Codex is at an early stage in discussions on the scientific substantiation of claims.

Additional EU legislation

Novel foods

The Regulation on novel foods[38] and processes came into force on 15 May 1997. It covered foods and food ingredients that had not before that date been used for human consumption to a major extent within the European Community. The Regulation included GM foods and foods and food ingredients subject to new processes. The Regulation was intended to catch foods that should be subject to a safety assessment but that were not caught by additives rules. GM foods have been subject to separate legislation from 2003, but taking out all applications for approval of controversial GM foods the statistics[39] for other dossiers make depressing reading. The outcome of seventy-eight applications for EU approval of non-GM organism novel foods between May 1997 and July 2007 is: twenty-eight approved (of which eight were phytosterols); five refused; twelve withdrawn; one was determined to be an additive; one was determined to be not novel; thirty-one still pending, some since 2003. In view of the number of dossiers still pending since 2003, it is no wonder the words 'novel food' strike fear into the heart of most industry members.

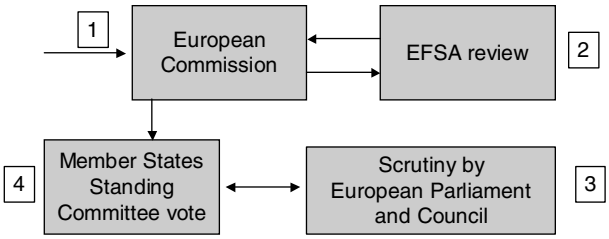

Fig. 4. Schematic summary of proposed new approval process for novel foods[40]. EFSA, European Food Safety Authority.

The procedure (Fig. 3) is long-winded. The scientific assessment for safety is conducted by a single member state within 90 d, but during the 60 d member state consultation stage there are nearly always objections and queries raised that means the dossier ends up being reviewed by the EFSA. However, after the initial time limits of 90 d and 60 d (150 d in total) there are no further time limits either on the EFSA review (that usually occurs fairly promptly) or with the Standing Committee (that has spent literally years on some dossiers, e.g. the phytosterols).

It is a relief that the Regulation is being overhauled[40] and a new Regulation should be in place by the end of 2009. A new approval procedure has been proposed; in fact, it is a common procedure for food additives, food enzymes, food flavourings and sources of food flavourings that will be adopted shortly in the EU[41]. The procedure (Fig. 4) requires a scientific assessment by the EFSA right at the start, cutting 150 d off the procedure. Time limits should be set in the Regulation to ensure timely actions are taken by the EFSA, the European Commission and the Member States Standing Committee. This new approval procedure will reduce the regulatory burden and should thus enhance innovation.

EU: addition of nutrients

A sister regulation published at the same time as the Regulation on nutrition and health claims made on foods governs the addition of vitamins and minerals and (later) other substances to foods[42]. For a number of years there has also been a separate Directive on food supplements[43] (which are in principle regulated as foods). However, both these pieces of legislation provide only a framework and the task of proposing maximum amounts of vitamins and minerals that can be added to foods and supplements is supposed to be completed by the European Commission in January 2009.

The maximum amounts should be based primarily on the tolerable upper intake of nutrients set by the EFSA[44] and on the intake of the nutrient from all dietary sources. The tolerable upper intake is the upper safe daily intake level for each nutrient; however, the European Commission

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Scientific Committee on Food and the EFSA have only been able to set a numerical tolerable upper intake for sixteen of thirty-four nutrients for which an assessment has been made. Nutrient profiles might also be taken into account if the tolerable upper intake is close to the RDA. Setting maximum amounts for addition to foods and supplements can be built on a strong science base and several groups have developed very conservative formulas that take into account the tolerable upper intake, current dietary intake of micronutrients at the 95th centile and energy intake at the 95th centile as well as conservative estimates of market size and growth for fortified foods and food supplements [45–47]. An April 2008 International Life Sciences Institute Europe workshop that brought together pan-European experts on micronutrient intake[48] has led to discussion of a more realistic approach that is being considered by the European Commission.

Impact on industry

Opportunities

The food industry continues to innovate in order to meet the needs of the consumer and there seems to be no decrease in the pace of recent product launches[49], but the companies that survive are those that innovate effectively. Consumers do seem to be increasingly interested in health[50], so the ability to make health claims is considered to be an important marketing tool. In the longer term there are opportunities for all manufacturers and sellers of food to use all but a few of the claims that are included in the lists of claims approved under both Article 13 and Article 14. Of course, the products to which the claims relate will need to meet any conditions of use such as nutrient profiles, levels of claimed ingredients or specific labelling information. The exceptions that will not be open to everyone are those claims that are based on proprietary data (Article 21)[7].

More markets will now be open for products making health claims. Before the EU Regulation on nutrition and health claims made on foods it was necessary to negotiate market-by-market to seek approval to market an innovative product making a health claim, and in some cases no health claims were permitted. Now it will be possible for industry to have one approval that covers twenty-seven EU member states. Furthermore, as several neighbouring countries generally follow EU rules, marketing is likely to be acceptable in European Economic Area territories, Switzerland and, in due course, countries aspiring to EU membership such as Turkey and Ukraine.

The Regulation has also opened up an era of opportunism, of which the industry has rightly made use. The exact wording of the Regulation has meant that new Article 13 claims could be placed on the market right up until the publication of the final list in January 2010. Certainly, the requirement of the Regulation is that claims placed on the market after 19 July 2007 should meet the general requirements of the Regulation (not to mislead, carry the appropriate labelling etc.), but nevertheless new claims that have not been caught by Article 14 are permissible and have been widely exploited.

How many existing claims will be approved is as yet unknown and the difficulty of getting approval for new claims will gradually become evident as the EFSA provides opinions on submitted dossiers. However, consumers do hear about health topics in non-commercial communications in the media. The information will in many cases be much less reliable than the information on a compliant label or advertisement, but nevertheless may drive consumer choice. Thus, the industry is not totally reliant on approved health claims and can market products without claims and may benefit from the relevant media offerings.

Challenges

The biggest challenges for industry are the onerous procedures for approval of health claims and the uncertainty that has prevailed from the publication of the proposed Regulation in July 2003. As noted earlier, despite the uncertainties the use of Article 13 type claims has flourished. However, in the case of individual claims, particularly if they are for a single substance marketed by a small company, the uncertainty of whether or not the claim will be on the final list means that it is very hard to market the substance to food manufacturers. Also, unless the European Commission writes a legal transition period into the formal decision on the Article 13 list, then claims not approved and on the list become illegal overnight on 31 January 2010. This situation makes difficulties not only for those trying to sell innovative ingredients but also for any manufacturer selling foods bearing health claims. Stocks of labels held may range from a few weeks to 1 year, so changing labels to meet new rules is not something that can be achieved overnight.

Those manufacturers who sell foods caught by Article 14 have also had their share of uncertainty. Before the adoption of the Regulation the European Commission had reassured industry that cholesterol-lowering claims, many of which were already on the market, fell under Article 13. A claim would only be considered a disease risk reduction claim if it went on to reference a reduced risk of heart disease. However, after adoption the member states decided that as the definition of a disease risk reduction claim in the legal text is ‘reduction in a disease risk factor’ a claim ‘maintains healthy cholesterol’ would be Article 13 but a claim ‘reduces or lowers cholesterol’ would be regarded as Article 14. Similar constraints apply to blood pressure claims. This situation has led to a flurry of Article 14 applications to EFSA. In the meantime, most if not all markets have allowed the status quo for cholesterol-lowering foods that were on the market and no doubt they will also allow a transition period in the event of any requirement to modify wording of claims.

As noted earlier, those manufacturers marketing foods bearing claims directed at children had a period of unpleasant uncertainty while they waited for the amendment to allow a legal transition for their claims.

The date for publication of nutrient profiles in the EU was set for January 2009. This position has meant that the time between the publication of the proposal in July 2003 and January 2009 when the profiles will be set has been a time of great uncertainty. For products that currently carry

NS Proceedings of the Nutrition Society

claims but do not meet the nutrient profiles there will be a need to reformulate or remove them from the market by January 2011. The problem continues to be that it is not known exactly what the profiles will be, so reformulation has to wait, and for new product development it means that nutrient composition is at best a guess until at the very least a serious draft proposal is sighted. The intention of nutrient profiling has always been to stimulate innovation of healthier products, and while in the long term this intention may be the case for EU profiles, some innovation has no doubt been on hold.

Conclusion

Food legislation is extensive and complex and continues to develop. In some rare cases such as novel food legislation in the EU it is being simplified. However, in most cases it does appear to be becoming more detailed and more prescriptive; a prime example being the EU Regulation on nutrition and health claims made on foods. It remains to be seen whether eventually the Regulation stifles the innovation it was supposed to stimulate.

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