Economic Impact Assessment of the European Union (EU)'s Nutrition & Health Claims Regulation on the EU food supplement sector and market

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For the European Health Claims Alliance (EHCA) by

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This paper presents the findings of an independent economic impact assessment of the European Union (EU) Regulation EC/1924/2006 (on Nutrition and Health Claims) on the EU food supplement sector and market

Many in the EU food supplement sector perceive that the negative opinions given to date on health claims for 'other substances' by the European Food Safety Authority (EFSA) are often unjustified because they relate to products/substances that have been legally sold with health claims in national markets for many years, without being challenged under national legislation (eg, relating to misleading advertising).

It was commissioned by the European Health Claims Alliance[1] (EHCA) to investigate the consequences of the current approach by which health claims are assessed by EFSA in a way that is likely to result in, the approval of most vitamin and mineral food supplement health claims, but prohibition of 95% of all health claims for 'other substance' (non vitamin and mineral containing) food supplements when the legal decisions are adopted.

The impact assessment is based largely on the findings of a survey of companies producing and marketing food supplements, and was designed to investigate the mainly economic consequences.

The main conclusions are:

Current impact

1. To date, the authorisation process for health claims has not yet had a significant sector level impact primarily because none of the 'general function' (Article 13.1) claims on which EFSA has given opinions have yet been formally allowed or prohibited by legal decision.

2. Levels of business uncertainty have, however, already increased. Some companies have already incurred costs of adjustment associated with negative opinions/assessments by EFSA[2] (an average of □126,700 expenditure/company) and levels of research/development and new product development are 'on hold' in some businesses.

3. Resources invested by the sector in preparatory work to compile the entries of the Article 13.1 list for submission to the European Commission amounted to a cost of between □4.51 million and □7.65 million.

4. In comparison, the overall cost of submitting an Article 13.5 or Article 14 health claim application (inclusive of a human clinical trial) is likely to be in the region of □0.26 million to □1 million plus per application.

Projected impact under the assumption that most (95%) of the 'other substances' health claims will be prohibited

5. The majority of the food supplement sector expect the economic impacts to be substantial and largely negative[3]:

   - There is expectation that the 'other substances' part[4] of the EU market for food supplements may decrease in size by about 25% (□645 million at the ex-production facility level or □1,031 million at retail level) and result in a 30% loss of gross profitability (€242 million);

   - Additional costs associated with, for example, stock and packaging write offs and changes, would likely add □291 million resulting in total short term losses equal to two-thirds of annual gross profits in the 'other substances' market and 41% of total gross profits in the broader market, including vitamins and minerals;

   - Employment generation is expected to fall by about 13,300 full time equivalents (FTEs), equal to 18% of total employment in the 'other substances' part of the sector (this excludes employment impacts in the retail sector);

   - Levels of net profitability are expected to fall substantially for companies with relatively high levels of dependency on 'other substances' sales. This is likely to threaten the viability of a number of businesses, most of which are small-medium enterprises (SMEs);

   - There is expectation in most companies that the costs of bringing and sustaining a product in the market will increase significantly, raising the barriers to entry in the market;

   - Research and development expenditure, levels of innovation and new product development are expected by most companies to decrease;

   - The majority of companies perceive that EU consumers will lose out from decreased choice, less competition in the market and potentially higher prices;

   - The relative market share of products originating outside the EU and supplied via the internet or mail order is expected to increase, because such products would not be subject to the requirements of the EU Nutrition and Health Claims Regulation in their country of origin and therefore would be free to continue to use health claims, denied to EU suppliers, and be easily accessible to EU consumers.

3 A small minority of businesses in the sector differ in their views, perceiving that long term (more than three years) positive impacts will arise with a market of fewer, higher average quality products which delivers improved levels of profitability for those remaining in the market

4 Which accounts for 45%-50% of the total market (which includes vitamins and minerals)

Overall conclusions

6. If the many negative Article 13.1 health claim opinions, so far made by EFSA, are followed by the European Commission and lead to decisions not to allow these claims, most businesses in the food supplement sector expect substantial, mostly negative, economic impacts. There is expectation that the 'other substances' part of the EU market for food supplements may decrease significantly in size, resulting in important reductions in profitability and employment levels. Barriers to entry are expected to increase, levels of innovation will fall, third country suppliers will increase their EU market share and the viability of many EU businesses (notably SMEs) would be threatened. Consumers would also lose out from reduced choice and possibly higher prices.

7. If the economic impacts highlighted above occur, the EU Regulation on Nutrition and Health Claims will fail to achieve most of its key economic-related objectives, notably relating to stimulating research and development, protecting innovation, encouraging SMEs, facilitating fair competition and achieving a high level of consumer protection. In addition, levels of income and employment generation within the EU would likely be lower than they might otherwise have been in the absence of this Regulation.

8. This impact assessment does not cover the full impacts and consequences for consumers or address impacts on research institutions, enforcement authorities and other stakeholders. It is therefore recommended that if a comprehensive socio-economic impact assessment of the implementation of the Nutrition and Health Claims Regulation is to be conducted[5] (eg, by the European Commission), these aspects should be included.

5 The author is not aware of any such assessment having been undertaken and published to date

General summary and conclusions

This paper presents the findings of an independent impact assessment of Regulation EC/1924/2006 (on Nutrition and Health Claims) on the EU food supplement sector and market.

Scope of the assessment and methodology

This impact assessment was commissioned by the European Health Claims Alliance (EHCA) to investigate the consequences of the current approach by which health claims are assessed by EFSA in a way that is likely to result in, the approval of most vitamin and mineral food supplement health claims, but prohibition of 95% of all health claims for 'other substance' (non vitamin and mineral containing food supplements) when the legal decisions are adopted.

The impact assessment covers the various aspects of the three different procedures of the Regulation to approve or prohibit health claims:

- The Article 13.1 procedures covering 'general function' claims which are authorised on the basis of generally accepted scientific evidence and do not require an application under the formal procedures for Article 13.5 and Article 14 claims (see below);
- The Article 13.5 authorisation procedures for health claims which are based on new or emerging science or contain a request for the protection of proprietary data. These require an application for authorisation;
- The Article 14 authorisation procedures for claims relating to the reduction of a risk factor in the development of a disease and claims relating to children's development and health. These also require an application for authorisation.

It is based largely on the findings of a survey of companies producing and marketing food supplements (in the period April-July 2010), and was designed to investigate the mainly economic consequences. Given the spread of survey responses across different sizes of business, the number of EU Member State markets covered and, more importantly, the share of total EU market sales accounted for by the survey respondents (equal to just under 18% of the total EU market for food supplements), the author considers that the survey results are reasonably representative of the total EU food supplement industry and market.

Overview of the EU market for food supplements (section 3)

The market for food supplements includes products that contain a wide range of substances with nutritional or physiological effects. The products broadly fall into two main groups: vitamins/minerals and 'other substances' (including herbs and plants, and extracts of these and a number of specific food components with health effects (eg, Coenzyme Q10, lycopene, lutein)).

The world market for food supplements is estimated to be worth between about □45 billion and □50 billion in 2009[6] (at retail level). The EU market (at retail level) is valued at between □8.2 billion and □8.6 billion in 2009.

6 Inclusive of vitamins, minerals, botanicals, other substances, tonics and homeopathic remedies

Within the EU market, vitamins and minerals account for the largest share (about 50%-55%: □4.1 billion - □4.73 billion), with the balance (□3.87 billion - □4.1 billion) accounted for by food supplements containing 'other substances'.

The market is serviced by a large number of businesses (about 5,000), most of which are small to medium sized businesses (SMEs). Numbers employed in the sector supplying 'other substances' (2009) are about 70,500 (full time equivalents[7]: FTEs).

Analysis of the current authorisation process for health claims (sections 4.1 and 4.2)

a) Opinions to date

As at May 2010, the total number of Article 13.1 claims with EFSA was 4,637. EFSA began assessment of these claims in early 2008 and the process has been split into batches with two having been published in October 2009 and February 2010. Overall, in both the first and second batches of opinions, almost all (95% plus) of the claims relating to 'other substances' have received a negative opinion.

In relation to Article 13.5 and Article 14 health claims, a total of 299 health claims had been sent to EFSA (at May 2010). 81 opinions (covering 88 claims) have been given. All but one of the Article 13.5 claims so far evaluated have received negative opinions, and only a quarter of the 66 Article 14 claims evaluated have received a positive opinion.

The average time taken to deliver opinions on the 22 Article 13.5 applications has been 4.1 months, within a range of 2 to 8 months. For the Article 14 opinions (total 66), the average time from submission to opinion has been 9.1 months, within a range of 3.5 months to 17 months.

b) Costs of submissions

Many Article 13.1 claims were handled through actions initiated by relevant European level trade associations and their national level Member associations who, in the absence of guidelines from the European Commission and EFSA, developed guidelines and started a concerted action to collect and compile entries for Article 13.1 claims via their members. This co-ordinated, industry associations approach resulted in a list of 776 claims submitted to the Commission via Member State Competent Authorities. Of the remainder of the 4,637 claims, it is assumed that these resulted from individual company submissions to their respective national authorities.

The total administrative cost of submitting the industry list of 776 claims was approximately □2.6 million to □3.83 million[8]. The estimated administrative cost of the other (3,861) company-specific submissions is about €1.91 million to €3.82 million, giving a total cost for all of the Article 13.1 submissions of □4.51 million to □7.65 million. On a per claim basis this is an average cost of □980 to □1,663.

The average administrative cost of making an Article 13.5/Article 14 submission has been about □6,750 (range □6,400 to □8,000). However, this excludes costs associated with conducting human clinical trials to produce proprietary data to support applications.

The cost of conducting a human clinical trial to provide proprietary data to support an Article 13.5/Article 14 health claim application typically costs in the range of □0.25 million to □1 million plus. Given the limited use of data drawn from such trials to date in Article 13.5 and Article 14 applications and the large number of negative opinions relating to such health claims, it is likely that conducting human clinical trials and drawing on the findings will be a key part of future Article 13.5 and Article 14 health claims submissions[9]. Overall, the cost of submitting an Article 13.5 or Article 14 health claim inclusive of a human clinical trial is in the region of □0.26 million to □1 million plus per submission.

c) Impacts to date

From a company perspective, on learning of a negative opinion by EFSA, the short term/interim period course of action can be to:

- Take no action to amend use of health claims on product labelling or associated promotional material/advertising, choosing to wait until after the date of legal decision;
- Take unilateral action to amend labels, promotional literature etc, before any legal date for withdrawal of claims;
- Take action to amend labels, promotional literature etc, because of requests from customers (eg, retailers) further down the supply chain or because of requests by Competent Authorities in some Member States after the issuing of the EFSA opinions.

The impact assessment (industry) survey suggests that a minority of companies have taken unilateral action or been requested to take action by customers to date.

Actions taken include re-formulation of products, label and packaging changes and amending promotional literature, with average costs (where incurred) of about □126,700 (range of □3,000 to □475,000).

As these actions have taken place only in the last 6-9 months, all of the companies who have undertaken these actions indicated it is too early to assess impacts on sales volumes.

A majority of companies with products using health claims that have already received negative EFSA opinions are, nevertheless, waiting for the formal decision by the European Commission to allow or prohibit further use before taking action. This course of action largely reflects the following reasons:

- There are a significant number of products that are promoted/sold with multiple health claims, some of which may have already been given negative opinions and others that await opinions in further batches. Making changes to labels and marketing material is most cost effectively undertaken in one action rather than making amendments per health claim decision;
- Removing health claims from labels and promotional material on a product which competes with a product that can continue to use similar health claim(s) for several more months (ie, that use health claims yet to receive an EFSA opinion) is removing an important tool of marketing and hindering competitiveness in the marketplace.

7 This estimate excludes those employed in the production and supply of vitamins and minerals, and those involved in the majority of retailing (ie, all retailing except direct/online sales)

8 This may understate total costs as it does not include costs of national level association staff in co-ordination roles

9 It should be noted that some Article 13.5/Article 14 submissions with supporting human clinical trial data have also received negative opinions. Hence, simply conducting such trials and submitting the supporting data does not guarantee a positive opinion. This is an issue currently under discussion with EFSA and the European Commission, so that industry can better understand the requirements for data from EFSA before setting up trials

Wider economic impacts of negative evaluations on health claims

The economic impact of negative health claim evaluations has, to date, been limited because the 900 plus Article 13.1 health claims on which EFSA has given opinions have yet to be subject to a legal decision and therefore can continue to be used by companies on labels, promotional material and advertising in accordance with the transition periods of the Regulation. The economic impacts are, therefore, likely to be become more apparent once the legal decisions are taken[10].

10 Likely to occur in early 2011, resulting in some claims (for which negative opinions have been given by EFSA) having to be withdrawn from use from the summer of 2011, with the balance of claims with negative opinions having to be withdrawn over 2011 and 2012

Short term cost and profit implications

Using the basis of the EFSA opinions given to date (that most claims relating to vitamin and minerals would receive a positive opinion, whilst almost all claims relating to 'other substances' would receive a negative opinion), the impact assessment (industry) survey identified a number of likely economic impacts (Table 1). This shows total estimated short term (1-2 years) costs aggregated to the industry level (market for 'other substances') of □291.36 million. Added to this is an average loss of sales equal to about a quarter of existing sales of these products, which is a loss of sales equal to □644.68 million (at the ex-production facility level) or □1,031 million at retail level.

In terms of gross profit on these lost sales, this amounts to about €242 million (equal to 30% of the total gross profit earned in the 'other substance' market and 19% of total gross profit in the wider market inclusive of vitamins and minerals).

Action	Costs to survey respondents (million euros)	Aggregated costs at the industry level (million euros)	Comments
Stock write offs	17.65	72.30	Average costs equal to 3% of annual sales of botanicals and other products (range zero to 14%)
Packaging write offs	2.73	11.22	Average costs equal to 0.6% of annual sales of botanicals and other products (range zero to 2.9%)
Trade stock recall & disposal	17.02	69.93	Average costs equal to 2.7% of annual sales of botanicals and other products (range zero to 24%)
Packaging changes	3.63	14.92	Average costs equal to 0.6% of annual sales of botanicals and other products (range zero to 21%)
Product re-formulation	7.18	29.49	Average costs equal to 1.1% of annual sales of botanicals and other products (range zero to 4.2%)
Marketing and promotional activity changes	18.21	74.84	Average costs equal to 2.9% of annual sales of botanicals and other products (range zero to 10.5%)
Training	5.40	22.17	Average costs equal to 0.9% of annual sales of botanicals and other products (range zero to 7.9%)
Legal costs	Possible cost - not known	Possible cost - not known	
Financial charges	Possible cost - not known	Possible cost - not known	
Total of above costs	**71.77**	**294.87**	
Loss of sales (at factory gate level)	**156.32**	**642.34**	**Average equal to 24.9% of annual sales of botanicals and other products (range zero to 90%)**
Loss of gross profits	**58.96**	**242.27**	**Average loss equal to 30% of total gross profits on botanicals and other substances and 19% of total gross profits on all product sales**

Table 1: Perceived likely short term impacts of no longer being able to use health claims and associated costs

The significance of the perceived short term costs arising from no longer being able to use health claims on packaging, marketing material, advertising, etc and the loss of gross profits is highlighted when these costs are related to annual levels of gross profitability. Across the companies surveyed, these estimated costs and loss of gross profits are equal to 21% of total sales of 'other substances' and 14% of total sales of all products including vitamins and minerals. In terms of gross profits, the combination of additional costs and lost profits are equal to 67% of the annual gross profit on 'other substance' sales and 41% of annual gross profits on sales of all products (inclusive of vitamins and minerals).

Impact on net profitability
Most companies with a major part of their business related to the supply of food supplements containing 'other substances' foresee significant losses to net profitability (eg, -50% to -90%), with some moving into loss-making, threatening the future existence of their businesses.

Impact on employment
The total number of full-time job equivalents (FTEs) perceived to be under threat is about 13,300, or 18% of the total FTEs in the 'other substances' sector. This excludes thousands of retailers and given small, specialist health food shops, chemists and pharmacies are leading outlets for these products, any potential negative impact on total sales is likely to have a significant negative impact on employment in the retail sector.

Impact on returns on investment, innovation and new product development
A majority of companies believe that returns on investment will fall and some have already stopped undertaking research and new product development in the light of the outcome of EFSA opinions.

This reflects widely held views in the sector that there is lack of information, transparency and guidance on how EFSA undertakes its evaluations, data requirements to adequately support claims and how/what to do in human clinical trials to deliver adequate data to support claims.

The main reasons for the negative views on returns to investment and reduced innovation/ new product development stem from the perception that the costs of bringing products to market will increase as a result of not being able to use health claims. These costs are perceived to increase because of a need to conduct human clinical trials to produce data that has a better chance of being accepted by EFSA[11] (costs between □0.25 million and □1million plus per trial) and/or a need to invest more resources into promotional and advertising activities.

Examining the impact of either this level of increase in the cost of bringing a new product to market or from an average expected 25% loss of sales, from the perspective of cash flows over the average expected lifecycle of a typical product (7 years), supports these impact assessment (industry) survey responses. The internal rate of return on a product would, at best, fall below the level which is commonly considered to be reasonable on new product investments (10% to 20%), and would, if costs rose significantly result in negative internal rates of return. In addition, the likely consequences of significantly increasing the costs of bringing new products to market, are sales and gross profit per product would have to increase fivefold and/or prices would have to rise, if sufficient (target) levels of returns on investment are to be realised. The net result is a market in which there are fewer products selling at higher prices than in the current market.

11 Though with no guarantee of success

Location of business activities and relative importance of the EU
Whilst few companies perceive they will re-locate current business activities outside the EU, most perceive that the relative importance of the EU market to their businesses is expected to decrease in the future.

Overall size of market
Almost all companies expect the size of the EU market for food supplements to decrease as a result of no longer being able to use health claims to support sales of most 'other substances'. The expected level of decline in market size varied from -10% to -50%, with an average across all of the survey respondents of about -25%. A very small minority of companies do, however, perceive that, in the long run, there will be a larger market for food supplements[12].

Range of products available to consumers
Most companies perceive that the range of products available to consumers will fall because of declining sales making the viability of a number of products marginal and/or moving into loss-making. Higher expected costs of bringing products to market (see above) will discourage new product development and reduce the profitability of many existing products, especially if additional expenditure on advertising and promotion is required to 'replace' the use of health claims in promotional activities.

Price of products to consumers
A majority of companies perceive that average prices will increase because there will be fewer products and less competition in the market[13]. Also, the expected higher costs of bringing products to market will necessitate a combination of higher average sales volumes and higher prices/profit margins to cover costs and deliver sufficient returns on investment.

Origin of products available to consumers and relative importance of imports from outside the EU
The relative importance and market share of products originating outside the EU is expected to increase. Such products, largely sold over the internet and/or via mail order directly to consumers, would, in their country of origin, not be subject to the requirements of the EU Nutrition and Health Claims Regulation and therefore would be free to continue to use health claims, denied to EU suppliers of 'other substances/products' and be easily available for purchase by EU consumers.

Overall, with expected increases in the average cost of bringing products to the EU market, this is perceived, by some, to likely result in raising the barriers to entry into the market, making it more difficult for SMEs to enter and/or remain in the marketplace. Hence, the origin of products is expected to increasingly become concentrated in the hands of fewer, larger companies.

12 This minority view sees a decreased number of companies in the market, selling fewer products with a higher average quality. This in turn is expected to lead to longer term customer confidence and loyalty in products/brands driving sales upwards

13 Additionally, more products may end up being sold as pharmaceuticals only rather than food supplements

Economic impacts and the objectives of the Nutrition and Health Claims Regulation

In assessing the impact of the EU Regulation on Nutrition and Health Claims, it is important to review the impact of the legislation against the underlying objectives. The analysis presented in this economic impact assessment provides pointers towards such an evaluation in the following ways:

Objectives: to achieve a high level of consumer protection and ensure consumers are not misled – consumers will be able to rely on clearer, more accurate information, enabling them to be properly informed on the food they choose
Aspects relating to whether these objectives are being delivered are beyond the terms of reference for this work as they fall outside the scope of an economic impact assessment (notably relating to whether claims are clear and accurate). Nevertheless, it should be noted that a majority of companies in the food supplement sector perceive that the current thrust of health claim opinions made by EFSA, which points to most health claims on 'other substances' being prohibited, will result in fewer products on the EU market, leading to increased expenditure on brand/product advertising and a greater share of the EU market being serviced by third country suppliers.

If these outcomes occur, it is possible that increased advertising/promotional expenditure may focus on use of more vague/less clear messages to consumers and hence result in less informed choices for consumers.

There may be fewer choices of products and an increasing proportion of these may originate[14] outside the EU and therefore be able to avoid the requirements of EU legislation. An alternative perspective is, however, held by a very small minority of businesses that whilst there will be fewer products available in the long term, consumers may benefit from higher average quality of products and more informed choices because unsubstantiated health claims will be dis-allowed.

Objective: to increase legal security for economic operators
The evidence identified in the impact assessment (industry) survey suggests that most companies in the EU food supplement sector perceive that the lack of clarity and transparency about the data requirements and processes involved in the claims assessment process operated to date have **increased legal uncertainty rather than legal security.**

Objective: to improve the free movement of goods within the internal market and ensure fair competition in the area of foods through the provision of clear and harmonised rules
The principle of operating a single EU level approval mechanism for health claims should contribute towards facilitating free movement of products and contribute to fairer competition. However, the way in which Article 13.1 health claims are being handled (in batches) and the resulting diverging enforcement at Member State level, is perceived by many companies, to be hindering the competitive position of some products (on which claims opinions have been published) relative to others (similar products using different health claims that await opinions).

14 And be purchased outside the EU via, for example, the internet for personal importation

In addition, the expectation that the costs of bringing new products to market will increase significantly[15] will increase the barriers to entry in the market and reduce competition. This is certain to disproportionately affect SMEs relative to larger companies.

Objective: to promote, encourage and protect innovation in the area of foods
The evidence presented in this report shows that the current operation of the Regulation (in which the vast majority of health claims on 'other substances' have received negative opinions) has already contributed to greater levels of uncertainty in the sector and resulted in some companies stopping research and development activities.

The widely held expectation in the food supplement sector is that if all of the negative EFSA opinions so far made on health claims for 'other substances' are ratified, this will reduce returns on investment, make research and development less attractive and lead to fewer products on the EU market. As such, innovation levels are expected to decrease in most businesses.

The recognition in the Regulation of the importance of SMEs in maintaining quality and preservation of different dietary habits across the EU is effectively an objective to encourage the development of SMEs in this market.
The findings summarised above suggest that both the current implementation of the Regulation and the likely impact of a the large volume of negative health claim opinions on 'other substances' is/will raise barriers to entry in the sector and reduce levels of competition. This is likely to impact on SMEs more than larger businesses.

Concluding comments

The EU Regulation for health claims has not yet had a significant sector level economic impact primarily because none of the Article 13.1 health claims on which EFSA has given opinions have yet to be the subject of a legal decision and therefore can largely continue to be used. The economic impacts are, therefore, likely to become more apparent once legal decisions are taken.

If the many negative Article 13.1 health claim opinions, so far made by EFSA (considered by many in the food supplement sector to be unjustified), are followed by the European Commission and lead to decisions not to allow these claims, most businesses in the food supplement sector expect the economic impacts to be substantial and largely negative. There is expectation that the 'other substances' part of the EU market for food supplements may decrease in size by about a quarter, resulting in significant reductions in profitability. Income and employment generation in the EU food supplement sector is expected to fall and be at a lower level than otherwise if the regulatory environment was more innovation-friendly, barriers to entry are expected to increase, levels of innovation will fall, third country suppliers will increase their EU market share and the viability of many EU businesses (notably SMEs) would be threatened.

Consumers are expected to also lose out from decreased choice and less competition in the market.

15 Due to conducting human clinical trials to produce data to substantiate claims, the time needed to obtain authorisation and/or increased expenditure on promotion

If the economic impacts highlighted above occur, the EU Regulation on Nutrition and Health Claims will fail to achieve most of its key economic-related objectives, notably relating to stimulating research and development, protecting innovation, encouraging SMEs, facilitating fair competition and achieving a high level of consumer protection. In addition, levels of income and employment generation within the EU would likely be lower than they might otherwise have been in the absence of this Regulation.

Lastly, it should be noted that this impact assessment does not cover the full impacts and consequences for consumers or address impacts on research institutions, enforcement authorities and other stakeholders. It is therefore recommended that if a comprehensive socio-economic impact assessment of the implementation of the Nutrition and Health Claims Regulation is to be conducted[16] (eg, by the European Commission), these aspects should be included.

16 The author is not aware of any such assessment having been undertaken and published to date

1 Introduction

1.1 Background

Regulation EC/1924/2006, on Nutrition and Health Claims lays down rules relating to the use of nutritional and health claims in the European Union (EU). It contains different procedures covering different types of claims. The most important category of claims for use on food supplements are the 'general function claims' (also called Article 13.1 claims because they are covered by Articles 13.1-13.3 of the Regulation) that are based on generally accepted scientific data. The European Food Safety Authority (EFSA), charged with the scientific assessment of claims, has published to date, two batches of opinions relating to these Article 13.1 claims, respectively in October 2009 and February 2010. In these batches, most claims for vitamins and minerals have received positive opinions, but almost all non vitamin and mineral substances (hereafter referred to as 'other substances') such as probiotics, fatty acids, other bioactive ingredients and botanicals received negative opinions.

Based on these EFSA opinions, the European Commission and Member States will take decisions whether or not to allow these claims. In the case of negative decisions, companies making such claims will be required to stop using the claims within six months. On the basis of the first two 'batches' of Article 13.1 health claim opinions, and if this current 'scientific approach' is applied to the pipeline of other claims in the assessment process (ie, awaiting opinions), this has the potential to affect over 95% of all non vitamin and mineral containing food supplements sold in the EU. In total, these 'other substances' account for a substantial part (45%-50%) of the total EU food supplement market, a sector that is also dominated by small and medium-sized enterprises (SMEs).

To assist in identifying the potential extent and magnitude of the impact of the current approach for assessing the health claims substantiation, the European Health Claims Alliance (EHCA) commissioned an independent economic impact assessment. This paper presents the findings of this assessment.

1.2 Objectives

The primary objective was to independently assess the economic effect and wider consequences (existing and potential) of Regulation EC/1924/2006 on the EU food supplement sector and market. The study was to examine the impact of the current approach for claims assessment (and assume that the same scientific approach is applied to the pipeline of other claims still in the assessment process) on the EU market for food supplements, with particular focus on the impact of negative opinions for non vitamin and mineral containing supplements.

More specifically, the economic assessment covers the following issues:

- Costs associated with submitting claims;
- Costs arising from negative opinions;
- Impact of negative opinions/assessments on sales, availability of products, prices;
- Potential 'knock on' effects of negative opinions/assessments on income and employment generation in the EU within the food supplement sector;
- Impact on research and development, product innovation in the EU, returns on investment;
- Possible implications for competition and consumer choice in the EU market for food supplements.

1.3 Methodology

The analysis has been undertaken through a combination of desk research and analysis, and the findings of a targeted survey[17] of companies in the European food supplement sector.

The survey was undertaken in the period April to July 2010 and involved the use of a semi-structured questionnaire (see appendix 1). Interviews were undertaken through a combination of email exchanges, telephone and personal interviews.

A total of 30 responses to the survey were received by the end of July 2010, covering companies with head offices in seven EU Member States which market products in almost all EU Member States, including larger Member States markets such as France, Germany, Italy, Poland, Spain and the UK, as well as smaller Member States like Belgium, the Netherlands, Czech Republic and Finland. The mix of respondents also included some of the larger players in the sector (at national and international levels) and small businesses. More specifically, the split of responses was approximately 40% from companies with total annual sales turnovers of under □10 million, 20% from companies with annual turnovers of between □10 million and □20 million, 25% from companies with annual turnover of between □20 million and □100 million and the balance of 15% from companies with annual turnovers in excess of □100 million. Overall, the respondent companies accounted for an estimated 17.6% of the total EU market for food supplements[18] and 25% of the EU market for 'other substances'[19] Given the spread of survey responses across different sizes of business, the number of EU Member State markets covered and, more importantly, the share of total EU market sales accounted for by the survey respondents, the author considers that the survey results are reasonably representative of the total EU food supplement industry and market.

The paper is structured as follows:

Introduction (this section)
Section 2: overview of the EU Regulation on Nutrition and Health Claims
Section 3: overview of the European market for food supplements
Section 4: economic impact of the Health Claims Regulation.

17 Targeted to cover a mix of companies across size and type of business and coverage of the different markets across the EU

18 See section 3 for further information on the market

19 The product groupings most likely to be affected by EFSA negative opinions on health claims

2 The Regulation on Nutrition and Health Claims

2.1 Objectives

Regulation (EC) No 1924/2006 on nutrition and health claims lays down (harmonised) rules for the use of nutrition and health claims. A 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 constituent parts and health'.

Before this EU harmonisation was adopted, nutrition and health claims were regulated at the national level. The EU Regulation provides uniform rules in all Member States and organises an EU level claims approval process.

There are a number of objectives laid out in the Regulation. These broadly cover the following main issues[20]:

- To achieve a high level of consumer protection;
- To ensure that consumers are not misled by unsubstantiated, exaggerated or untruthful claims – consumers will be able to rely on clearer and more accurate information on food labels, enabling them to be properly informed on the food they choose;
- To increase legal security for economic operators;
- To improve the free movement of goods within the internal market and ensure fair competition in the area of foods through the provision of clear, harmonised rules;
- To promote, encourage and protect innovation in the area of foods.

The Regulation also recognises the importance of small and medium enterprises (SMEs) in maintaining quality and preservation of different dietary habits across the EU (Recital 33 of the Explanatory Memorandum)).

These objectives are highly informative in the context of this economic impact assessment because they provide benchmarks for an assessment of whether the original objectives are being attained.

Much of the analysis undertaken for this study and presented in the following sections aims to provide insights into this aspect.

2.2 Overview of the current health claims authorisation process

The Regulation provides for different types of health claims. These comprise:

- Health claims describing or referring to the role of a nutrient or other substance in growth, development and the functions of the body;
- Health claims that refer to psychological and behavioural functions;
- Health claims and claims relating to slimming and weight control.

20 These are presented in full within the detailed legal text of the Regulation. This is a summary based on a combination of the original explanatory memorandum of the Regulation (Com 2003/0424 – COD 2003/0165) and the Commission's 'Questions and Answers on Health and Nutrition Claims' (Memo 06/200 of 16 May 2006)

These three categories are commonly referred to as 'general function claims', where they are based on generally accepted scientific evidence and well understood by the average consumer. They are also referred to as Article 13.1 claims, as they are regulated by Articles 13.1-13.3 of the Regulation.

When health claims are based upon newly developed scientific evidence or include a request for the protection of proprietary data, they are regulated by Article 13.5 of the Regulation. These claims are commonly referred to as Article 13.5 claims.

- Health claims referring to the reduction of a risk factor in the development of a disease;
- Health claims relating to children's development and health.

These latter two categories of health claims are covered by Article 14 of the Regulation and are therefore commonly referred to as Article 14 claims.

2.2.1 Article 13.1 claims (general function claims)

Article 13.1 claims are mostly referred to as general function health claims. These are authorised on the basis of generally accepted scientific evidence and do not require an individual application for authorisation as applies to Article 14 (and Article 13.5) authorisations (see below).

A key rationale for having such a generic list of 'general function' claims approved on the basis of generally accepted scientific evidence was to enable SMEs to make use of such claims without having to submit an application via the full authorisation process. Member States were charged with the role of co-ordinating and submitting these 'general function' claims to the European Commission by 31st January 2008.

Member States submitted a total of over 44,000 such claims by the 31st January 2008 deadline, which were consolidated by the European Commission into 4,185 claims for forwarding onto EFSA for evaluation during 2008.

About 2,000 of these claims were sent back by EFSA to the Commission and Member States for additional clarification in June 2009. Of these, about 300 claims were subsequently withdrawn and no additional clarification was provided for about another 620. Additional claims were also sent to EFSA in March 2010 (452, mostly botanicals), making a total of 4,637 current claims (at May 2010).

The EFSA scientific opinions relating to the Article 13.1 claims are being published in batches, with the formal authorisation procedures for these opinions to follow each batch. The first batch of EFSA opinions (94 opinions relating to 523 Article 13.1 claims) was published on 1st October 2009. A second batch of 31 opinions (on 416 Article 13.1 claims) was published on 25th February 2010. Further opinions on over 800 Article 13.1 claims are expected in October 2010, with the balance of Article 13.1 claims expected into 2011.

In the first batch of EFSA opinions, about one third of the opinions are positive and two thirds negative. Most of the positive opinions relate to vitamins and minerals plus a few for other substances (eg, sugar-free chewing gum and maintenance of dental health, some plant sterols and maintenance of cholesterol levels and substances like lactase enzyme and contribution to lactose breakdown).

In the second batch of EFSA opinions, most claims were also negative. Overall, in both the first and second batches of opinions, almost all (95% plus) of claims relating to 'other substance' (non vitamin and mineral) claims have been rejected. More specifically:

- No single probiotic bacteria for digestive and immune health has yet been approved;
- There have been 'group' rejections of large numbers of substances with claims relating to antioxidant effects, joint health benefits and blood glucose and glycemic index effects.

The EFSA first batch of opinions is scheduled for authorisation decisions at the next meeting of the Standing Committee for the Food Chain and Animal Health in October 2010. If the decisions are adopted at that meeting, the formal adoption takes places some three months later, after finalisation of the scrutiny process of the European Parliament (ie, likely in January 2011).

More relevantly, all the rejected claims would then no longer be allowed to be used after a six month transition period from the decision date published in the Official Journal (anticipated in January 2011).

It should, however, be noted that the legal basis for a batch-wise adoption of decisions on the EFSA Opinions is disputed in legal opinions obtained by industry.

2.2.2 Article 13.5 and Article 14 claims

Article 13.5 health claims are those based on newly developed scientific evidence or health claims that include a request for the protection of proprietary data. Article 14 claims are claims relating to the reduction of a risk factor in the development of a disease and claims relating to children's development and health.

These claims require individual submissions of dossiers (applications for authorisation) to support the claims and undergo individual evaluations by EFSA.

As at May 2010, a total of 299 health claims in these categories (265 Article 14 claims and 34 Article 13.5 claims) had been sent to EFSA. 43 of these were subsequently withdrawn and 81 (covering 88 claims) opinions have been published. Within these opinions, all but one of the Article 13.5 claims was rejected, and only a quarter of the 66 Article 14 claims received positive opinions. A further 168 claims have not yet completed the evaluation process.

3 Overview of the EU market for food supplements

Food supplements are foods regulated by Directive 2002/46/EC and intended to complement the diet with vitamins, minerals and other substances with a physiological effect.

The market for food supplements is both broad and diverse in nature. It includes food supplements that comprise or contain a wide range of substances with nutritional or physiological effects, some of which are also used in products classified as medicines in certain Member States, reflecting different (Member State) interpretation of the boundary/borderline between food and medicine and the lack of harmonisation of substance definition and classification. These products are sold via a variety of distribution and sales channels including health stores, pharmacies, supermarkets, health practitioners, direct sales and internet-based sales. As a result of this diversity, the availability of detailed market data is limited and subject to wide variation according to definitions of products and channels of use (eg, inclusive or exclusive of usage as medicines).

In terms of categorisation and coverage, food supplements broadly fall into two main groups:

- Food supplements containing mainly vitamins and minerals;
- Food supplements containing mainly 'other substances': these are botanical and other physiological active substances. This category includes algae, fungi, herbs and plants, and extracts of these. Commonly consumed examples of botanicals include aloe, echinacea, garlic, ginkgo, ginseng, green tea, garcinia and St Johns Wort. It also includes what Directive 2002/46/EC and Regulation 1925/2006/EC classify as 'other' bio-active substances (ie, any substance with a nutritional or physiological effect that is not a vitamin or mineral). These can be further disaggregated into a number of sub-categories including amino acids, enzymes (eg, lactase), pre and pro-biotics (eg, inulin, yeasts, bifidobacterium), essential fatty acids (eg, evening primrose oil, flax seed oil) and a number of specific substances such as coenzyme Q10, glucosamine, lycopene and lutein. Overall, there are in excess of 400 substances used in many thousands of products in this market category.

In the sub-sections below, the market data presented draws on (and extrapolates from) a combination of market research 'type' reports and data from publicly available sources (eg, European Commission reports), private market research reports and industry level/association data.

3.1 Size of the global and European market

The world market for food supplements is estimated to be worth between about □45 billion and □50 billion in 2009[21] (at retail level). The EU market is valued at between □8.2 billion and □8.6 billion in 2009[22].

Within the EU market, vitamins and minerals account for the largest share (about 50%-55%: □4.1 billion - □4.73 billion), with the balance (□3.87 billion - □4.1 billion) accounted for by food supplements classified as 'other substances'. Information on the relative size of different sub-markets within this broad classification is, however, very limited.

At the Member State level, the market for 'other substances' shows considerable variation. In 2009, almost three-quarters of the EU 27 market were probably accounted for by Italy, Germany, France and the UK (Table 2).

21 *Inclusive of vitamins, minerals, botanicals, other substances, tonics and homeopathic remedies (Source: IADSA)*

22 *GBC Ltd estimate based on Euromonitor, IADSA and data supplied by various national member state associations*

Country	Approximate 2009 retail value (million euros)
Italy	1,454
Germany	640
UK	390
France	532
Belgium	112
Sweden	110
Denmark	110
Netherlands	60
Czech Republic	80
Finland	80
Others	532
Total	**4,100**

Table 2: Other substances markets by (main) Member State

Source: *GBC estimates based on data supplied from national associations, Euromonitor and IADSA*

The markets within countries also show significant variation:

- Italy: probiotics account for the largest share of the 'other substance' market. Euromonitor estimated that probiotics accounted for 44% of the market for all food supplements in 2005, followed by combination products at 25%. All other product categories probably accounted for less than 10% of the retail value in the total food supplement market in 2005. Whilst more up to date industry estimates are not available, trade association sources estimate that probiotics continue to dominate the 'other substance' segment of the market;
- Germany: Industry level data for 2008 breaks the market down into digestive products (25%), resistance against coughs and colds (48%), sleep and calming (17.2%) and the balance accounted for by skin care. The probiotic and glucosamine markets in 2009 were estimated to be about €64 million and €55 million respectively;
- France: Data from the Syndicate de la Dietetique et des Complements Alimentaires (2009) which covers the market for what this source refers to as 'complementary medicine'[23] breaks this market down into a number of categories, with slimming products accounting for the largest share (23%), followed by tonics (17%), eye health and products to reduce disease risks (8% respectively). Other important categories cited by this source include stress/relaxation (7%), joints/bone products (6%), hair products (6%) and skin products (4%);
- UK: Euromonitor data for 2005 estimated that fish oils had the largest share (40%) followed by combination products (21%). More recent industry association estimates for 2009 suggest a third of the market value is accounted for by vitamin and mineral supplements, with the balance accounted for by 'other substances' (joint health, botanical/herbal and other substances);

23 *Valued at about □604 million in 2009, equal to about 60% of the total French market for vitamins, minerals and other substances/products*

- Other countries: fish oils dominate markets in Denmark and Finland, whilst combination products have the largest shares in Belgium and Austria. In Poland (2008), vitamins and minerals have the largest share (31%), followed by what are classified as digestion supplements (aids to digestion and liver function including probiotics, fibre and weight control products) with 11%. Other significant sub-markets in Poland were eye health, resistance against colds and urinary tract supplements, each with 8% market shares. In the Netherlands, multi vitamins and products high in omega three fatty acids (eg, fish oils) are the largest sub-sectors.

The diversity and significant differences between national markets reflects a combination of reasons. A major factor of influence is tradition in some markets (eg, fish oils in the UK, Denmark and Finland, probiotics in Italy). Regulatory factors also influence the market values presented, as, for example, where a product is considered to be a medicine and required to be sold only through registered outlets like pharmacies.

Drawing on the evidence presented in the impact assessment (industry) survey and aggregating this information to the industry/market level (on the basis that the survey respondents accounted for 24.7% of sales in the EU market for 'other substances'), Table 3 shows estimates of the EU market by key sub-markets for which most negative EFSA opinions have so far been given.

Table 3: EU market for 'other substances' at retail level by key sub-groups: based on survey findings 2010

Source: *impact assessment (industry) survey*

	Survey respondents	Aggregated to industry level
Probiotics	107.76	436.85
Fatty acids	122.53	496.75
Joint health	95.71	388.13
Antioxidants	77.29	313.34
Amino acids	78.58	318.55
Botanicals	377.00	1,528.44
Others	157.34	637.86
Total	**1,016.21**	**4,119.92**

Note: aggregation to industry level based on share of overall market value accounted for the survey respondents (24.7%)

Overall, data on sales in the sector tends to be partial. As a result, the values presented in this sector probably understate the real value of the market.

3.2 Number, types of players and structure in the market (excluding retail level)

The EU market for food supplements is serviced by a large number of businesses. There is a lack of data on the total number of businesses in the sector across the EU, mainly because of its diverse nature and structure (see below). Industry source data suggests that in the five Member States of the Czech Republic, Finland, Italy, Netherlands and the UK, there are about 2,450 companies producing 'other substance' supplements. Inclusive of companies that make vitamin and mineral supplements, the numbers are likely to be higher (eg, in the UK, industry sources estimate that there are about 400 companies involved in the manufacture and supply of vitamins, minerals and 'other substances', of which about 350 trade 'other substances'). Overall, the sector is dominated by small to medium sized businesses, although there are also a few larger national-based and multi-national companies in some Member States.

The total number of businesses in the sector (excluding retailers) is probably about 5,000.

The type of 'players' in the market for food supplements can be divided into the following distinct categories:

- **Manufacturers/suppliers of ingredients.** Most raw material ingredients tend to be manufactured by a small number of manufacturers, some of which may be part of larger groups which both source and manufacture ingredients and supply products to retail and specialist outlets. Some ingredient companies also undertake research and development;
- **Contract manufacturers**. These supply products to brand distributors (often in bulk) and/or packed products for retailer own-label;
- **Product manufacturers and retailers.** There are a limited number of companies that supply and retail food supplements via their own specialist retail outlets, with base production sometimes undertaken by contract manufacturers;
- **Product manufacturers and distributors**. These companies buy in ingredients and manufacture finished supplements/products for distribution and sale to retail outlets;
- **Distributors**. These are either companies that undertake research/development, marketing and sales of products, but out-source production of finished products (often in ready to sell retail packs) or are companies that distribute and sell branded products (often imported) from third parties.

The latter two categories of players in the sector dominate the market for food supplements across Europe. The vast majority of these businesses are small, medium-sized enterprises (SMEs). Whilst these companies market their products via secondary wholesalers, direct to supermarkets, specialist retailers and pharmacies, some are increasingly now selling direct to the public via on-line retailing, mail-order or direct selling.

3.3 Retail channels

The channels through which consumers obtain food supplements are diverse and vary by country. Outlets include pharmacies, specialist retailers, specialist chains, supermarkets, direct mail and internet-based purchases.

In the UK, industry sources estimate that in 2009, about 46% of sales were via large supermarkets and retail chains (grocery and others) and 31% via direct marketing and selling (including internet-based sales). The other main form of retail outlet, with an estimated 19% share, is specialist health food stores (including chains). The balance of sales (4%) is accounted for by practitioners.

In France, just under two-thirds of sales of food supplements were, in 2009, via pharmacies/mega pharmacies. Other important outlets were by supermarkets/hypermarkets and specialist shops (11% and 10% respectively), with the balance of 13% accounted for by other outlets[24]. In Italy, a similar pattern of sales channels occurs, with pharmacies dominating sales, followed by super/hypermarkets, specialist shops and direct/on-line sales.

In Germany, based on data for sales for vitamins and minerals only, pharmacies and chemists dominate with about 85% of total sales, followed by direct mail/internet based sales from pharmacies/chemists (8%). The balance was accounted for by grocery retailers/discount supermarkets (7%).

In the Netherlands, industry sources estimate that the main outlets are chemists[25], health food shops and direct from health advisors/therapists. Internet-based sales are also expanding rapidly. In the Czech Republic, industry sources estimate that in 2009, about 87% of sales were via pharmacies, with the balance via a mix of outlets including supermarkets, specialist shops and direct marketing (including internet).

In Poland, pharmacies have the largest share of sales (64% in 2008), followed a broad category of shops (eg, grocery, garages) and direct sales with 28% of sales and on-line sales which accounted for 8% of sales.

Pharmacies also dominate sales in most other Central and Eastern European countries (eg, accounting for 90% of sales in Romania).

3.4 Competition

Competition in the food supplement market takes several forms. The primary way in which products are sold into this 'self-care and wellness' market is in association with the intended use of the product legally expressed as the product health claim. Thus the use of health claims on labels, in point of sale and other promotional literature, in advertisements and in media articles, is widely considered as key to differentiating products, developing sales and competing in the market.

Within this market, companies compete via the provision of food supplements that they promote as offering better value, performance, utility and convenience to consumers than competitor products and hence will be purchased by consumers.

24 Source: Syndicat de la Dietetique et des Complements Alimentaires

25 Chemists that do not issue prescription medicines - as distinct from pharmacies that issue prescription medicines which have a fairly low share of the market

Competition also occurs through price, branding, advertising, promotion and the provision of consumer information, with, as indicated above, promotional activities tending to be heavily focused on the associated health claims of the products.

Sales of food supplements are also closely related to media coverage of health issues and to manufacturers/distributors and retailers marketing and advertising activities. The leading players in national markets typically devote significant resources to developing brand awareness and to advertising and promotion of their products.

There is strong price competition in the sector due to the increasing number of players entering the sector in recent years, especially the growth of internet-based/on-line retailers (including those based outside the EU who can offer tax-free prices) and from grocery supermarkets.

The nature of competition has also developed increasingly into newer product development, many of which are extensions of existing products and brands. These often combine ingredients to offer consumers the convenience of no longer having to buy several separate supplements.

3.5 Employment

There is very little published data available on employment in the European food supplement sector. This largely reflects the diverse nature of the sector and the considerable overlap between different sub-sectors.

Industry level estimates of the numbers employed in 2009 (limited to the production and supply of 'other substances') in the Czech Republic, Finland, the UK, Netherlands and Italy are 34,930 employees[26]. In addition, there are about 10,000 employees in the sector in France. On the basis that these countries account for about 63% of the total market (by value) for 'other substances' in the EU, and using this as a basis for estimating total employment, this suggests that the sector supplying 'other substances' employs about 70,500 people (full time equivalents).

It should be noted that this estimate excludes those employed in the production and supply of vitamins and minerals, and those involved in the majority of retailing (ie, all retailing except direct/online sales).

26 Excluding those employed at the retail level

3.6 Changes in the market environment

The growing market for food supplements in the EU and its expansion in recent years largely reflects the growing consumer emphasis on 'self-care and wellness'. Frequent media coverage of health issues and increased health consciousness of European citizens have also contributed to the market's development. Nevertheless, in the last two years, economic recession across Europe has tended to slow the rates of growth in the market as consumers choose to consume less or seek more economical options such as internet-based purchases (sometimes tax-free, if supplied from outside the EU, or from EU member states with the lowest levels of tax), or lower priced, grocery retailer private label products.

Within the market:

- Markets targeting women have become increasingly important (eg, 'cosmeceuticals'[27] targeting desires for products that help maintain healthy skin, nails and hair);
- As an ever increasing proportion of European citizens is getting older, the market for products in the joint health category continue to expand;
- Newer markets are developing to meet demand around current/new health issues discussed in media or concerns of citizens such as eye health and tiredness;
- There has been a general broadening of product ranges, offering new combinations or variations of existing products to meet the demand for more convenience. For example multi vitamins with additional ingredients like lutein;
- Additional targeting of products to specific groups (as well as women and the elderly: see above) such as pregnant women and children;
- Levels of competition have increased, notably price competition. This has coincided with increased entry into the sector of grocery retailers with private label supplements and on-line businesses.

27 Products mainly sold without health claims

3.7 Criteria used to determine whether to bring products to market

The primary criterion determining whether a new food supplement is brought to market in a member state market of the EU is whether a company is reasonably confident that a new product/product extension/combination will earn a sufficient rate of return relative to the cost of investment.

In deciding whether to bring a new product to market or to invest in associated research and development, companies have to assess factors such as:

- The extent to which a specific health issue or problem exists and the extent to which a new product may have a beneficial effect and /or represents an improvement on existing products. In general, the more attractive markets for the development of new products tend to be target groups of citizens, issues and member states with the largest populations. As such, this 'market research' phase tends to be the first step in any process of bringing a product to market;
- The likelihood of consumers (in a target group) using a new product because of its beneficial effect, technical improvements, added convenience or perceived value relative to existing products, and its price;
- The ability to be able to communicate the health benefit to the consumer;
- The expected sales and profitability of a new product relative to existing products and/or expected competitor new products that may also come to the market during the product's expected market lifetime;
- The costs of launching, marketing and supporting a product.

The timeframe associated with bringing products to market varies. In general, it can take between about 9 and 21 months to bring a new product to market, depending on whether (health claim) supporting data from clinical trials/research is considered important to the marketing effort and product launch.

If clinical trials are considered important to a product launch, this process can typically add 9-12 months[28] to the timeframe for product launch (ie, the total time is typically 9-12 months if no clinical trials are required). In addition, if a new product launch is linked to health claims identified in clinical trials, time involved in submitting an Article 13.5/Article 14 health claim, waiting for an opinion and Commission authorisation must be factored into the process. This typically adds 3-12 months (see section 4).

The costs involved in bringing a new product to market also vary. At its simplest level (eg, an extension of an existing product), with no supporting clinical trials, reliance on a general (article 13.1) health claim and limited promotion (limited to some point of sale promotions, media articles etc but excluding TV advertising), the costs of a product launch might be in the range of □80,000-□120,000 (excluding cost of stocks).

If clinical trials to produce supporting data/claims are undertaken this can add typically between □0.25 million and □1 million to costs and if large scale advertising campaigns (eg, on television) are used to support a new product launch this can also add between □0.5 million and □1 million to costs.

28 This is a typical timeframe for a clinical trial, although trials of up to 3 years might be considered

4 Economic Impact of the Regulation

4.1 Analysis of the current authorisation process for general function claims (Articles 13.1-13.3)

4.1.1 The development of the Article 13.1 list

Background

As indicated in section 2.2, 'general function' claims are to be authorised on the basis of generally accepted scientific evidence and do not require an application for authorisation as applies to Article 14 and Article 13.5 health claims.

Member States were charged with the role of co-ordinating and submitting 'general function' claims to the European Commission and given a deadline of 31st January 2008 to complete this exercise.

The organisation and co-ordination of many claims was largely handled through a concerted action initiated by relevant European level trade associations (CIAA, EHPM, ERNA, EBF) and their national level member associations of companies in the food and food supplement sectors.

The approach taken by the trade associations involved:

- In the absence of official guidance, drawing up a common methodology *(Model for the assessment of Article 13.1 health claims in the framework of the EU Nutrition and Health Claims Regulation in relation to the terms of reference)* for submission of the claims (and communicating this to officials in the European Commission and Member States);
- Drawing up a priority list of claims for products/substances that were judged of importance;
- Identifying the health relationship for each of these claims based on generally accepted scientific evidence;
- Identifying companies, groups of companies or associations that would undertake submissions of the entries for each claim/health relationship;
- Assigning companies, groups of companies or associations to compile and submit these entries together with references covering the evidence;
- Evaluation of the claims. The claim details drafted by companies were submitted for initial screening for conformity with the common methodology 'Guidance Model' by an independent scientific expert group organised by the European level associations. Claims entries could then be amended and finalised for submission to Competent Authorities in Member States during January 2008.

At the national level, the submission of claims entries was commonly handled by companies sending in these entries directly, or via their relevant national trade associations to the national authorities. In the absence of guidelines from EFSA/the European Commission on data requirements for submissions, these tended to be drawn up by relevant scientific experts in (or advisors to) the companies and/or national associations[29]. At the end of the co-ordinated, industry associations' approach, a list of 776 claims was finalised for submission to the European Commission via Member State Competent Authorities. In addition, individual companies directly submitted claims to national authorities.

29 Often in consultation with staff in Competent Authorities

As indicated in section 2, the total number of health claims entries originally submitted to the European Commission was in excess of 44,000, many of which were duplicated submissions. Of the finalised consolidated number, 776 of these entries were submitted 'as based on the trade association list', with the balance being individual submissions from different Member States.

Based on the common methodology established by the European trade associations, the data requirements, at the claim level, essentially involved the characterisation of the food/substance, its health (claim)/relationship, a summary of the nature of evidence and a listing of references for this evidence (eg, textbook, monograph, traditional use). It also included examples of how the claim was formulated in practice.

Impact

a) Costs of the trade associations' concerted action

- The time involved in compiling the evidence for a single 'general function' claim was, on average, 2-3 person days, with an associated cost of approximately €2,000-€3,000;
- On the basis that 776 claims made the industry associations' list, this suggests an initial cost of €1.55 million to €2.33 million;
- Added to this cost were the time/costs involved in the development of the common methodology and the organisation, co-ordination and evaluation of the initial claims by appointed industry experts across four associations. These were approximately □0.2 million to □0.25 million per European association, giving a total cost for this aspect of the submissions of €0.8 million to €1 million;
- At the national association level (for those actively involved in the exercise), additional costs involved are estimated to amount to a total of between □0.25 million and □0.5 million[30];
- The total cost of submitting the industry list of 776 claims was therefore approximately □2.6 million to □3.83 million[31].

b) Costs of other Article 13.1 entries

In terms of estimating the total costs involved in submitting all of the Article 13.1 'general function' claims entries, this is more difficult to estimate. It is evident that a large number of the 44,000 original health claims submitted were duplications. Also, as the majority of the claims submitted by individual companies, outside of the European level associations list of 776 claims, were less comprehensive in nature, they probably incurred a lower average cost of preparation than the industry association submissions. Thus, if for example, a lower average cost of claim preparation of □500 to □1,000/claim is assumed and applied to the balance of the 4,600 finalised compiled list of health claim submissions (ie, after deduction of the 776 drawn up via the trade associations), this adds a further cost of about □1.91 million to □3.82 million.

30 Based on a cost estimate of □25,000-□50,000 per association

31 This may understate total costs as it does not include costs of national level association staff in co-ordination roles. It also does not take into account the numerous entries made by more than one company

32 *Using the evidence from the impact assessment (industry) survey grossed up to an industry level on the basis of the share of total market sales accounted for by the survey respondents*

c) **Total cost of Article 13.1 list entries**

- Adding both figures from a) and b) above puts the total costs of submissions at €4.51 million to €7.65 million;
- On a per claim basis this is an average cost of €980 to €1,663;
- Evidence from the impact assessment (industry) survey supports this estimate, with the aggregated[32] costs of staff time and hire of consultants to assist in drafting, evaluating and submitting article 13.1 claims being about □2.53 million.

4.1.2 The consequences of negative EFSA opinions

Background

As indicated above (see section 2)), the vast bulk of Article 13.1 health claims were submitted by the end of January 2008. The process of evaluation by EFSA has been split into batches with two having been made public (94 opinions relating to 523 Article 13.1 claims on 1st October 2009 and 31 opinions on 416 Article 13.1 claims on 25th February 2010). The balance of opinions is expected in further batches, the next announced for October 2010 and others in the course of 2011. At the time of writing (August 2010), no formal legal decisions on these Article 13.1 EFSA opinions have so far been taken and therefore legally all of these health claims continue to fall under the transition periods of the Nutrition and Health Claims Regulation. They can, therefore, continue to be made on product labels and in promotional literature/activities. Furthermore, the European Commission has indicated it will consider discussions on a number of rejected claims (insufficiently characterised probiotics, insufficient claims, claims based on patient studies and claims for botanicals based on traditional use) which means these claims will not immediately be prohibited when the first batch of decisions is taken.

Impact

From a company perspective, on learning of a negative opinion by EFSA, the short term/interim period course of action can be to:

- Take no action to amend use of health claims on product labelling or in associated promotional material/advertising, choosing to wait until after the date of the formal decision;
- Take unilateral action to amend labels, promotional literature etc, before any legal date for withdrawal of claims;
- Take action to amend labels, promotional literature etc, because of requests to do so from customers (eg, retailers) further down the supply chain. Additionally, changes may be (and have been) requested by Competent Authorities in some Member States on the issuing of the EFSA opinions.

Drawing on the evidence from the impact assessment (industry) survey, a minority of companies (a third of the survey respondents) have taken unilateral action or been requested to take action by customers to date. Actions taken include re-formulation of products, label and packaging changes and amending promotional literature, with average costs (where incurred) of about □126,700 (range of □3,000 to □475,000).

A majority of companies with products using health claims that have already received negative EFSA opinions are, nevertheless, waiting for the formal decision by the European Commission to allow or prohibit further use before taking action. This course of action largely reflects the following reasons:

- There are a significant number of products on the market that are promoted/sold with multiple health claims, some of which may have already been given negative opinions and others that await opinions in further batches. Making changes to labels and marketing material is most cost effectively undertaken in one action rather than making amendments per health claim decision;
- Removing health claims from labels and promotional material/advertising on a product which may compete with other products that can continue to use the same health claim(s) for several more months and/or other products that use health claims yet to receive an EFSA opinion is removing an important tool of marketing and effectively hindering competitiveness in the marketplace.

33 *This assessment is based only on the time from date of application submission to date when the Opinion was given as indicated in the published Opinions on the EFSA website*

4.2 Analysis of the current authorisation process for Articles 13.5/14 claims

4.2.1 The development of an application for authorisation under Article 13.5/Article 14

Background

As discussed in section 2.2.2, a total of 299 health claims in these categories had been sent to EFSA, as at May 2010. 43 of these were subsequently withdrawn and 80 (covering 87 claims) opinions have been issued. Within these opinions, all but one of the Article 13.5 claims were rejected, and only a quarter of the 66 Article 14 claims have been accepted.

Looking at the time taken to process Article 13.5 applications, the average time taken to deliver opinions on the 22 applications already given has been 4.1 months, within a range of 2 to 8 months (inclusive of instances where requests for additional information/clarification has been sought by EFSA from an applicant)[33]. For Article 14 applications (total 66), the average time from submission to opinion has been 9.1 months, within a range of 3.5 months to 17 months (inclusive of instances where requests for additional information/clarification has been sought by EFSA from an applicant).

The cost of making an Article 13.5 or Article 14 application varies mainly because of the amount of time/costs involved in putting together an application. A key part of any application is the provision of scientific substantiation data of any claimed health effect. This involves a minimum of completing a detailed literature search and review, together with completing an elaborate template of relevant information and copies of such references. These may include both human and non human-based data and include both published (in peer review journals and other publications) and unpublished data. In addition, proprietary data from product-specific human clinical trials may be commissioned and reported on to support application submissions.

Impact

a) **The costs of developing an Article 13.5/Article 14 application**

Drawing on the evidence from the impact assessment (industry) survey, the average cost of making an application for the small number of companies (13% of the survey respondents) that had made such applications was □6,750 (range □6,400 to □8,000), based largely on staff or consultants time in undertaking literature reviews to support applications.

In addition, two companies in the survey indicated that Article 13.5/Article 14 applications were in preparation and estimates of likely costs involved were higher than the costs incurred to date; in a range of €10,000 to €23,000 per application.

It should be noted these costs exclude any costs associated with conducting human clinical trials to produce proprietary data to support applications (the majority of Article 13.5/Article 14 application submissions on which opinions have so far been given appear to have relied mostly on literature search/review data to support applications rather than proprietary studies).

b) **Costs inclusive of conducting human clinical trials**

The cost of conducting human clinical trials to provide proprietary data to support an Article 13.5/Article 14 health claim application can vary according to the scope and nature of a trial but typically costs are likely to be in the range of □0.25 million to □1 million plus.

Given the limited use of data drawn from such trials to date in Article 13.5 and Article 14 applications and the large number of rejections of such health claims, it is likely that conducting human clinical trials and drawing on the findings will be a key part of Article 13.5 and Article 14 health claims applications in the future[34]. Hence, it is reasonable to assume that the additional costs of clinical research for submitting an Article 13.5 or Article 14 health claim application with a better chance of being accepted/authorised is likely to be in the region of □0.26 million to □1 million plus per submission.

4.2.2 The consequences of a negative EFSA opinion

From a company perspective, the course of action to take, or to consider taking, is similar to that outlined above in section 4.1 for 'general function' claims. Once a decision by the European Commission has been legally adopted, a company selling the product using the now rejected health claim has six months in which to stop using this claim on labels and associated marketing literature/material. Whilst this appears a straightforward course of action to take post decision, the current partial, batched and incomplete process of decision-making relating to Article 13.1 health claims has complicated matters where similar products are sold with health claims based on Article 13.1, Article 13.5 or Article 14 applications.

Thus, in some Member States, the Competent Authorities have allowed some Article 13.5/Article 14 claims to continue to be used (even after negative decisions on these claims), provided the companies affected have established a long term plan to make changes to relevant labels, packaging and promotional material which will be implemented once similar claims addressed via the Article 13.1 claims process have received their formal decision.

34 It should be noted that some Article 13.5/ Article 14 applications with supporting human clinical trial data have also received negative opinions. Hence, simply conducting such trials and submitting the supporting data does not guarantee a positive outcome. This is an issue currently under discussion with EFSA and the European Commission, so that industry can better understand the requirements for data from EFSA before setting up trials

In some other Member States, the Competent Authorities have, however, taken a less pragmatic view and insisted on the removal of health claims from labels, packaging, etc strictly in line with the provisions of the Regulation. This has resulted in the cancellation of orders until such time as labels etc have been changed[35].

4.3 Wider economic impacts and implications of negative evaluations on health claims

Background

The economic impact of negative health claim evaluations has, to date, been limited (see sections 4.1 and 4.2 above). This largely reflects the fact that the 900 plus Article 13.1 health claims on which EFSA has given opinions have yet to be the subject of a legal decision and therefore can largely continue to be used by companies on labels, promotional material and advertising in accordance with the transition periods of the Regulation.

The economic impacts are, therefore, likely to become more apparent once legal decisions are taken[36]. On the basis of the opinions given to date in the first two batches of EFSA opinions, it is probable that most claims relating to vitamins and minerals may be allowed whilst almost all claims related to 'other substances' will be rejected. Based on this broad categorisation, our impact assessment (industry) survey asked respondents to assess likely economic impacts under the assumption that all 'general function' health claims that are not relating to vitamins and minerals are prohibited[37].

A summary of the key impacts expected is presented below. Readers should note that the aggregation (grossing up) of the survey data impacts to the industry level is based on the market share of total EU market sales accounted for by the survey respondents.

Impacts

As indicated in sections 4.1 and 4.2, once a company is faced with having to withdraw use of a health claim, the following actions are typically required:

- Identify all stocks of product, labels, marketing and promotional material that contain a no longer allowed health claim;
- Notify customers that products supplied may contain labels, point of sale and other marketing material referring to the dis-allowed claim. Due to the wide range of food and food supplements and the range of distribution channels, this potentially involves contacting a significant number of customers in the wholesale, pharmacy and retailing sectors;
- All stocks that contain reference to the disallowed health claim will have to be re-labelled, re-packaged, re-formulated or discarded;
- All labels, marketing and point of sale material that uses a dis-allowed health claim will have to be destroyed;
- Possibly recall products and associated point of sale and marketing material supplied to customers in the wholesale and retail sectors.

35 Reported in the survey by one company – no further information is provided for reasons of confidentiality

36 Likely to occur in early 2011 resulting in the first Article 13.1 claims (for which negative opinions have been given by EFSA) having to be withdrawn from use from the summer of 2011, with the balance of claims with negative opinions having to be withdrawn over 2011 and 2012

37 In other words health claims are no longer permitted for all other substances (eg, probiotics, glucosamine, antioxidants, joint health products, weight management products and botanicals used in foods and food supplements). Sales of these products were to be assumed to be allowed but without any claim on commercial communications literature, labels, advertising and websites

The time, process, impact and costs involved in initiating these actions vary by businesses. More specifically:

- **Product/stock withdrawal and write off.** The volume of products withdrawn from the market (and associated time and costs involved) can vary according to factors such as the range of products sold and marketed/labelled with now dis-allowed health claims and the volume of stocks held that might not be sold to consumers by retail customers within six months. It may also include active recalls in some Member States that have a strict interpretation of the Regulation and will not allow products on the market to be sold after the six month transition period (see below). Given the shelf life of food supplements is typically 2-3 years, this could have significant cost implications. It may also include single ingredient products and/or products with multiple ingredients and claims. Most of the survey respondent companies expect to have to write off some stocks that are not expected to be sold within six months after authorisation/confirmation of health claims no longer being allowed[38];
- **Replacement of withdrawn supplies and supporting marketing/promotional material.** The scope for continuing to supply products to customers is likely to be affected by the speed and associated cost with which labels and promotional material can be re-designed. Some products may also be subject to re-formulation to, for example, remove ingredients for which health claims can no longer be used or to add ingredients for which health claims are allowed. The policy approach of the European Commission to take decisions about health claims in batches may also introduce an additional cost burden for combination products containing ingredients, the claims for which belong to different 'decision batches'. It is, however, not possible to foresee the full extent of likely changes because the final wording of approved claims and the scope of rejected ones only becomes clear at the moment a decision is adopted. Also, claims for one ingredient may belong to different 'decision batches' and will, therefore, be approved or rejected at different times. A minority of survey respondents (36%) indicated that product re-formulation was a likely course of action. These impacts not only add costs, but may affect ability to supply customers with existing contracts (unless customers continue to take supplies during the six months transition period), future continuity of supply and could have negative quality/brand image issues, especially as a key component of marketing (the health claim) can no longer be directly used;
- **Impact of inconsistent responses at Member State authority level.** The responses by Member State authorities to implementation and enforcement of legal decisions taken in batches may vary and consequently, the impact could differ by Member State. For example, if one Member State authority insists that all dis-allowed claims are removed strictly within the six month time period, this may require some products (with multiple health claims) to be subject to re-labelling more than once (if different health claims are subject to evaluation at different times) compared to another Member State where a more pragmatic enforcement approach is taken of not requiring changes to labels for products with multiple claims to be made until the evaluation process for all claims has been completed. As a result the levels of disruption and cost at the company level may vary by Member State;

38 Two of the survey respondents did, however, perceive that they would probably be able to avoid product/stock withdrawal provided customers continued to take existing products for sale in the six month transition period following final legal decision disallowing claims

- **Legal costs.** These may be incurred for breach of contract/non supply and disposal/return of recalled produce;
- **Adverse impact on brands and product/company image.** Brands of products and general reputations/goodwill may be negatively impacted as a result of reporting of claims rejections in the media and enforcement actions by authorities, leading to product recalls and disruption to supplies. This is most tangibly identified through loss of sales and profits. Additional costs incurred may include having to cancel promotional and marketing activities (eg, having to pay for advertising space reserved but not used, preparation of marketing material no longer used) and a number of the survey respondents indicated that they expected these types of cost to occur. Lastly, given the prominence and importance of health claims in the marketing and promotion of products, future sales and profits may well be lower than they might otherwise have been if the health claims had continued to be allowed (see below);
- **Training**. No longer being able to use a health claim as an important part of sales and marketing is likely to require investment of time and costs in re-training of staff both within companies supplying/manufacturing food supplements, and in customers (eg, retailers of these products). Most of the survey respondents expect to have to invest further in staff training to address this issue;
- **Marketing and promotional expenditure.** Overall, this category of expenditure is expected to increase in the vast majority of the survey respondents for two main reasons. Firstly, as indicated above, requirements to review and make changes to websites, product information, catalogues, brochures, point of sale and shelf edge material and all marketing and communication material and media. Secondly, most companies also perceive that no longer being able to use a health claim as a means to promote a product will result in companies seeking to 'compensate' for this loss of a key marketing message through increased expenditure on brand/product advertising and promotional activities;
- **Financial charges.** Where companies incur loss of sales, profits and additional costs associated with making changes to labels, packaging, promotional literature and advertising, and with conducting clinical research, this may result in additional borrowing requirements having to be sought from lenders. This may have been granted on less favourable terms (eg, higher interest rates) than existing borrowing;
- **Staff time.** Dealing with the implications of no longer being able to use a health claim and associated consequences (as summarised above) may involve a considerable input of staff time (including senior management) that would otherwise have been utilised on business activities that aim to develop sales, profits and development of business;
- **Loss of sales and profits.** Disruption to both the supply of products, as well as additional costs incurred and loss of the key marketing/usage message associated with a health claim; as indicated above this may result in important reductions in sales and associated profits for many producers, distributors, suppliers and retailers of food supplements, almost all of whom are SMEs. This aspect was highlighted as an expected consequence of no longer being able to use health claims by almost all of the survey respondents (see below).

Drawing on the findings of the impact assessment (industry) survey, Table 4 summarises the type and typical/average level of costs perceived as likely to occur by suppliers and manufacturers of food supplements associated with dealing with no longer being able to use health claims on products.

As indicated, these cost estimates are based on forward looking estimates cited by companies in the EU food supplement sector who responded to the survey and assumed a likely ban on the use of health claims on 'other substances', but allowed health claims for vitamins and minerals. This shows total estimated short-term costs for the survey respondents of □71.87 million, which aggregated to the industry level (market for 'other substances') gives an estimated cost of €291.36 million.

Added to this are foreseen lost sales, which the survey suggests an average loss of sales equal to about a quarter of existing sales of these products. For the companies responding to the survey this amounted to a □159.02 million loss of sales, aggregated to an industry-wide loss of sales equal to □644.68 million at the ex-production facility level or about □1,031 million at retail level.

In terms of gross profit on these lost sales, this is about €60 million for the survey respondent companies and at the industry level □242 million (equal to 30% of the total gross profit earned in the 'other substances' market and 19% of total gross profit in the wider market inclusive of vitamins and minerals).

The significance of the perceived likely short-term costs arising from no longer being able to use health claims on packaging, marketing material, advertising, etc and the loss of gross profits is highlighted when these costs are related to annual levels of gross profitability. Across the companies surveyed, these estimated costs and loss of gross profits are equal to 21% of total sales of 'other substances' and 14% of total sales of all products. In terms of gross profits, the combination of additional costs and lost profits are equal to 67% of the annual gross profit on 'other substance' sales and 41% of annual gross profits in the broader market inclusive of vitamins and minerals.

Table 4: Perceived likely short term impacts of no longer being able to use health claims and associated costs

Action	Costs to survey respondents (million euros)	Aggregated costs at the industry level (million euros)	Comments
Stock write offs	17.65	71.54	Average costs equal to 3% of annual sales of 'other substances' (range zero to 14%)
Packaging write offs	2.74	11.11	Average costs equal to 0.6% of annual sales of 'other substances' (range zero to 2.9%)
Trade stock recall & disposal	17.02	69.02	Average costs equal to 2.7% of annual sales of 'other substances' (range zero to 24%)
Packaging changes	3.64	14.76	Average costs equal to 0.6% of annual sales of 'other substances' (range zero to 21%)
Product re-formulation	7.21	29.21	Average costs equal to 1.1% of annual sales of 'other substances' (range zero to 4.2%)
Marketing and promotional activity changes	18.21	73.84	Average costs equal to 2.9% of annual sales of 'other substances' (range zero to 10.5%)
Training	5.40	21.88	Average costs equal to 0.9% of annual sales of 'other substances' (range zero to 7.9%)
Legal costs	Possible cost - not known	Possible cost - not known	
Financial charges	Possible cost - not known	Possible cost - not known	
Total of above costs	**71.87**	**291.36**	
Loss of sales (at ex-production facility level)	**159.02**	**644.68**	**Average equal to 25% of annual sales of 'other substances' (range zero to 90%)**
Loss of gross profits	**59.75**	**242.24**	**Average loss equal to 30% of total gross profits on 'other substances' and 19% of total gross profits on all product sales**

Impact on net profitability

About half of the companies responding to the survey provided further assessments on likely impacts on net profitability, both in the short-term (up to 12 months following no longer being able to use health claims on a significant number of products) and in the longer term. Not surprisingly, there was a range of foreseen impacts that were closely related to the relative importance of 'other substances' in total sales and business activities of the respondent companies. Those with a major part of their business related to the supply of 'other substances' foresee significant losses to net profitability (eg, -50% to -90%), with some also perceiving that they would be loss-making, threatening the future existence of their business. For companies where 'other substances' are a less important share of total business activity (eg, accounting for less than 50% of total sales), the potential negative impact on net company profitability is less dramatic (eg, in a range of less than 5% to a 20% loss of net profitability).

Impact on employment

The survey responses relating to possible impact on employment points to a net loss to numbers employed. The total number of full-time job equivalents (FTEs) perceived to be under threat aggregated to the industry level is 13,290 FTEs, or 18% of the total FTEs in the sector. Within the companies surveyed, potential impact on employment varies. Companies that perceive only limited negative impact on sales and business activities, not surprisingly, think that there would be little or no impact on total employment levels. In contrast, the companies perceiving larger potential negative impacts on their business activities/sales foresee potential significant reductions in employment levels of 30% to 50%.

It is, however, important to recognise that these potential employment impacts relate only to the manufacturing, supply and distribution part of the supply chain, and hence exclude retailers. Given that small, specialist health food shops, chemists and pharmacies are prominent outlets for these products, and food supplements account for important shares of their total (retail) sales, any potential negative impact on total sales of these products in Europe will likely have a significant negative impact on employment in the retail sector.

Impact on returns on investment and innovation

The general perspective of those responding to questions about returns to investment and innovation is that if health claims on almost all 'other substances' are no longer allowed this will have a negative impact on returns to investment and innovation. A majority of companies believe that returns on investment will fall, with a few perceiving that returns will fall substantially. Three of the respondent companies indicated that research and new product development activities in these product areas had already stopped in the light of negative opinions given by EFSA to both Article 13.1 claims and to some Article 13.5/Article 14 claims. This reflected lack of information, transparency and guidance relating to how EFSA undertakes its evaluations, data requirements to adequately support claims and how/what to do in human clinical trials to deliver adequate data to support claims.

The main reasons for the negative views on returns to investment and reduced innovation stem from the perception that the costs of bringing products to market will increase as a result of not being able to use health claims. These costs are perceived to likely increase because of probable need to conduct human clinical trials to produce data that is more likely to be accepted by EFSA costing between □0.25 million and □1 million plus per trial and/or a need to invest more resource into promotional and advertising activities. In addition, some cited the increased level of uncertainty in the market arising from negative opinions which was acting as a disincentive to invest.

It should, nevertheless, be noted that a small minority of respondent companies (7%) indicated that they did not perceive that there would be any change to their returns on investment or to their research and development activities and new product development. These companies did, however, tend to be some of the larger businesses (turnovers of □50 million plus) who responded to the survey and/or which have established brands and are used to supporting these brands with significant annual advertising and promotional budgets. One respondent to the questionnaire also went as far as stating that more investment was likely and returns could, in the long term, be higher than currently because if the costs of bringing new products to market increased, it would potentially encourage the development of fewer, higher quality (branded) products in the market. Companies might therefore focus more resources on a more limited and more profitable product range than currently.

Impact on returns to investments: the product life cycle model

In order to better illustrate the impact on innovation in the food supplement market of no longer being able to use health claims and of delays in coming to decisions on health claims, the analysis below examines and draws on the concept of a product life cycle for a new food supplement product, its revenue and cost streams and how changes in the cost of bringing a product to market impacts on the returns derived and the profitability/attractiveness of an investment.

It should be noted that the revenue streams presented in the analysis below are representative (but simplified) revenue flows for an average food supplement product currently sold in European markets. The analysis presented below is based on information provided in the industry survey. Additional, detailed information is presented in Appendix 2.

a) **Product life cycle returns of a typical (average) current food supplement product**
Figure 1 illustrates the gross income or margin (cash) flow for an average food supplement product with a typical (average) expected life cycle of 7 years. Key points to note are:

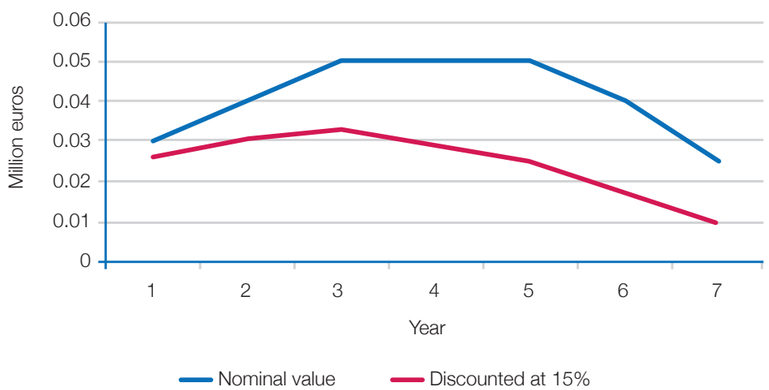
- Expected average sales revenue (over 7 years and in current monetary terms) for the product is □855,000. The expected average gross margin over this 7 year period (in current monetary terms) is €285,000 and discounted at 15% is €169,350;
- After consideration of the costs[39] of bringing the product to market are taken into consideration, the discounted gross margin returns (discounted at 15%[40]) were €69,350;
- The internal rate of return on the investment (against a target of 10% to 20% which is commonplace in the food/dietary supplement sector) was 17.5% (ie, in the target range);
- If the timing of a new product launch was linked to the timing of an authorisation/approval of a related health claim (eg, the average time for an article 14 opinion is 9.1 months), it should be noted that a launch delay of 9-12 months effectively reduces the internal rate of return to 9.3% (borderline at the lower end of the target range).

39 The average cost of developing a new product and bringing to a national/EU market is □100,000. This cost is broadly representative of a new food supplement and includes research, product development and marketing/advertising

40 The gross margin returns are standard expected returns on sales revenue after production costs (excluding marketing, research and development). The expected gross margin return for new products is 50% (based on an average of gross returns in the impact assessment (industry) survey). In relation to discounting of revenue and income streams (for factors such as the cost of borrowing and risk) businesses in the food supplement sector commonly discount at similar rates to businesses in the food sector, namely between 15% and 20%. A discount rate of 15% has been used in this analysis. The discount rate (applied to future income streams) represents the next best alternative earning potential for investment funds and hence is a baseline for determining whether investment takes place. The rate takes into account factors such as risk and cost of borrowing

Figure 1:
Product life cycle gross margin returns representative food supplement product

Note:
nominal value refers to the returns in current monetary terms



b) Product life cycle returns under post health claim rejection scenarios

i) Loss of sales of 25%

Based on the assumption that health claims for all non vitamin and mineral health claims are no longer permitted, the impact assessment (industry) survey produced an estimated/foreseen average loss of sales by respondent companies to be 25%. Using this as a (revised) basis for assessing cash flow and returns (see Appendix 2), the main differences relative to current returns (where health claims are allowed) are:

- Average sales and gross profits fall to €641,250 and €213,750 respectively. The discounted gross returns (discounted at 15%) are □127,010. After the costs of bringing the product to market are taken into consideration, the discounted gross margin returns are €27,010;
- The internal rate of return on the investment falls to 7.7%, which is below the target rate of return. Hence, the loss of sales and profit of 25% reduces the relative attractiveness of investment and discourages the bringing of a new product to market.

ii) Increase in costs of bringing a new product to market

On the basis that a health claim is a key component of product marketing, and in the light of probably no longer being able to use an Article 13.1 health claim for 'other substances', one route to trying to secure a useable health claim is to seek authorisation via an Article 13.5/Article 14 health claim. As indicated above (see section 4.2), this is increasingly likely to require data, based on human clinical trials, if a health claim is to stand a better chance of being authorised and hence would potentially add significantly to the cost of bringing a product to market. If the cost of bringing a new product to market included conducting human clinical trials with costs of about □400,000 (ie, total costs of bringing a product to market of □500,000), the internal rate of return (assuming the same sales and gross profit levels as occurred beforehand) would be negative (-20.3%: see Appendix 2). Clearly, if the typical cost of bringing a product to market increased to about □0.5 million[41], no new product with a sales and gross profit profile akin to the average profile presented above would be brought to the market. In order to achieve a similar level of internal rate of return as the current (baseline) average product (17.5%), sales and gross profits per product would have to increase fivefold.

The likely consequences of significantly increasing the costs of bringing new food supplement products to market (via running human clinical trials and/or increasing expenditure on brand/product advertising) clearly shows that sales and gross profit per product would have to increase significantly, if target levels of returns on investment are to be realised. This would, as the impact assessment (industry) survey identified, necessitate significant increases in sales volume per product and/or increases in the level of gross profit per product (via price increases). The likely net result is a market in which there are fewer products selling at higher prices than in the current market.

41 This cost reflects having to conduct human clinical trials to produce supporting data for an article 13.5/Article 14 health claim. Alternatively, it may reflect increased expenditure on brand/product advertising/promotion; one of the other activities that companies indicated would likely have to increase if health claims were no longer allowed

Location of business activities and relative importance of the EU

The majority of companies responding to the survey indicated that the impact of disallowing the use of most claims on 'other substances' is unlikely to result in changes to the primary location of their business activities. However, most companies stated that they expected an increased focus and emphasis (especially relating to future business expansion) on non EU markets (eg, Asia, Middle East) as a direct result of expected negative market impacts in the EU. Thus, whilst few companies perceive they will re-locate current business activities outside the EU, the relative importance of the EU market to their businesses is expected to decrease in the future.

New product development

As indicated above (impact on innovation), most of the companies perceive that there will be a decrease in research and development and hence in new product development in the EU market for food supplements. This is expected to arise because of reduced returns and expected higher costs of bringing products to market (higher costs of having to do human clinical trials to substantiate health claims and greater expenditure needed on advertising and promotion).

In addition, some companies indicated that increased uncertainty (see below) existed in the market, as a result of the negative opinions on numerous health claims and this contributed to fewer products being brought to the EU market. A small minority of responding companies did, however, indicate that they did not expect any change to their level and rate of new product development for the EU market.

Overall size of market

Almost all of the survey respondents expect the size of the EU market for food supplements to decrease as a result of no longer being able to use health claims on most 'other substances'. The expected level of decline in market size varied from -10% to -50%, with an average across all of the survey respondents of about -25%.

A small minority of companies (7%) do, however, perceive that the disallowing of many health claims on 'other substances' will, in the long run, lead to a larger market for food supplements because a decreased number of companies in the market will sell fewer products with a higher average quality. This in turn is expected to lead to longer term customer confidence and loyalty in products/brands driving sales upwards. One respondent also indicated that they had removed all health claims from their labels and marketing literature in the last 12 months (on a small number of products), and had not seen any noticeable changes to sales volumes. This company did, however, indicate that expenditure on brand and product advertising had increased during this period.

Range of products available to consumers

Most of the companies responding to the survey perceive that the range of products available to consumers will fall. This reduction in product choice is expected to arise because of declining sales across the market making the viability of a number of products marginal and/or moving into loss-making. Higher expected costs of bringing products to market (see above) will discourage new product development and reduce the profitability of many existing products, especially if additional expenditure on advertising and promotion is required to 'replace' the use of health claims in promotional activities. Some of the respondents provided estimates of the extent to which product availability might be expected to fall, with these being between a 10% and 50% reduction in the number of products available to consumers.

Price of products to consumers

In relation to impact on prices of food supplements to consumers, a majority of companies perceive that average prices will increase. This reflects a view that there will be fewer products and less competition in the market. Also, the expected higher costs of bringing products to market will necessitate a combination of higher levels of average sales volumes and higher prices/profit margins being required to cover costs and deliver sufficient returns on investment.

A minority of company respondents (10%) did, however, perceive that average prices for products were unlikely to change and one respondent thought that there was the possibility of some prices falling. This latter perception assumes no longer being able to use health claims in marketing results in increased company focus on price competition to gain sales/market share.

Origin of products available to consumers and relative importance of imports from outside the EU

A majority of the companies in the survey think that the relative importance and market share of products originating outside the EU will increase. Such products, largely sold over the internet or via mail order directly to consumers, would not be subject to the requirements of the EU Nutrition and Health Claims Regulation in their country of origin and therefore would be free to continue to use health claims, denied EU suppliers of 'other substances'. Some of the survey respondents (40%) believe that an increased market share of products from outside the EU, sold via the internet direct to the consumer and which do not have to comply with EU regulations, potentially increases the scope for poorer average quality products entering the market, to the detriment of consumer protection (and possibly safety).

Lastly, with the widely expected increase in the average cost of bringing products to the EU market, this is perceived, by some (10% of respondents), to likely result in increasing the barriers to entry into the market, making it more difficult for SMEs to enter and/or remain in the marketplace. Hence, the origin of products is expected to increasingly become concentrated in the hands of fewer, larger companies.

4.4 Uncertainty issues

The creation of uncertainty in the market for food supplements was a recurring theme raised by many respondents to the survey. As such, this section explores the issue in more detail, with particular reference to its effect on investment decisions.

Uncertainty has, and continues to, impact on the scope for new food products or ingredients being brought to the EU market in three main ways:

- Uncertainty as to the future legal status of a health claim currently being used as a key part of marketing for a product/ingredient (is it likely to be allowed?, will additional data/clarification be required?);
- Uncertainty about how long a decision to authorise (or prohibit) a health claim currently used with a product/ingredient will take;
- Uncertainty about the data requirements and the process of claims assessment.

These are discussed further below.

a) **Legal uncertainty**

Legal status uncertainty can have negative economic implications for, or impose additional costs on, companies considering bringing new food products to the EU market. This category of economic cost or disincentive to invest or bring new products/ingredients to the EU market is, however, not easily recognised, categorised or quantified. Drawing on the survey responses, examples where legal status uncertainty has had a negative impact on businesses include:

- The burden of additional costs (eg, costs associated with clarifying and/or providing additional information and data 'defending' a health claim on which EFSA has given a negative opinion);
- loss (or potential loss) of sales and income within the EU. This has arisen/can arise because of the 'batched' nature of EFSA opinions and subsequent legal decisions. Products with health claims given a negative assessment by EFSA in the first or second batch of EFSA Opinions are/will be required to no longer use these claims on labels and marketing literature at an earlier stage than similar products with (but perhaps slightly different) health claims that will be subject to EFSA opinions at a later date. This creates a marketing advantage for the products subject to later EFSA opinions. This issue can also be re-enforced by actions taken at the Member State level by the relevant authorities for implementing and enforcing the Claims legislation. For example, if authorities in one Member State enforce negative opinions on health claims strictly in line with the requirements of EU legislation (potentially as soon as an EFSA opinion is published), whilst another Member State authority adopts a more pragmatic approach of enforcing negative opinions relating to claims on similar products once all relevant claims have completed the evaluation process.

Alternatively, ingredients/products with health claims given a positive assessment in the 1st or 2nd batch of EFSA opinions may be able to derive a marketing benefit from this legal certainty relative to similar ingredients/products with slightly different health claims that will be given an opinion and legal decision on their health claim at a later date (ie, in a later batch of opinions and decisions).

b) **Uncertainty about time taken for deciding on claims authorisation**
Companies planning to bring new products to the EU market that are awaiting claims authorisation (for Article 13.5 or Article 14 claims) have to plan their product launch against a background of potential competitors/new entrants to their market. As such, it is in the interests of the company filing an Article 13.5/Article 14 health claim to bring the product to market as soon as possible and to get a health claim authorisation in order to maximise sales before competition enters/increases on the market.

However, bringing a product to market takes time to plan and execute. Therefore uncertainty relating to when a claims authorisation will be granted can add risk and result in costs incurred that might otherwise have not been incurred.

The way in which uncertainty relating to the decision taking time adversely impacts on businesses is best illustrated through an example. The launch of product X with a new health claim is likely to be planned for launch onto the markets in perhaps (initially) a few (eg, one or two) EU Member State markets on a date soon after a date of expected authorisation/decision. In order to prepare for this, products have to be manufactured, labelled and delivered to a reasonable number of retail outlets in each market, advertising and promotional literature has to be organised, booked and prepared and in-store promotions set up. If the date of the expected decision on a health claim is then delayed it may result in the product's launch date being postponed because the health claims on labels or marketing material cannot yet be utilised or cannot yet state that the claim has been formally approved.

c) **Uncertainty about data requirements and the process of claims assessment**
Lack of clarity and transparency about the data requirements and processes involved in the claims assessment increases the risk of a negative opinion being issued. In addition, uncertainty about the wording of a claimed effect and its conditions of use, together with accessing decisions increases the risk that labels and marketing literature will have to be withdrawn/amended etc.

This uncertainty can also act as a significant disincentive to undertake research and development into new product development and a majority of the companies interviewed in the course of this research highlighted this uncertainty as having resulted in (or likely to cause) reductions and/or the stopping of research and development activities for new products.

Overall, these examples highlight how uncertainty has a negative impact on returns to companies and consequently reduces the incentive to innovate and bring new products to the EU market.

Appendix 1: Semi structured questionnaire used for the impact assessment (industry) survey

Economic Impact Assessment on Health Claims Legislation

NAME……
COMPANY……

PREFERRED CONTACT DETAILS (telephone, email) if follow up required
……

The Nutrition and Health Claims Regulation categorises health claims as:

- Article 13.1 GENERIC HEALTH CLAIMS which refer to the role of a nutrient or other substance in the growth, development and functions of the body. This category also includes claims referring to psychological and behavioural functions; and to slimming and weight control, reduction in sense of hunger/increase in sense of satiety. To date, EFSA have published two batches of opinions covering over 900 individual claims: these opinions have no current legal status as they are awaiting adoption;
- Article 14 CLAIMS REFERRING TO REDUCTION IN RISK OF DISEASE OR TO CHILDREN'S GROWTH AND DEVELOPMENT. These require individual submission and undergo individual evaluation and EFSA opinions are in the process of being adopted into law.
- Article 13.5 HEALTH CLAIMS BASED ON NEW OR EMERGING SCIENCE OR HEALTH CLAIMS BASED ON PROPRIETARY DATA. These require individual submission and undergo individual evaluation as per Article 14 claims.

In responding to this questionnaire, please assume that:

ALL generic health claims that are NOT relating to essential nutrients including vitamins, minerals and essential fatty acids are prohibited. In other words, health claims are no longer permitted for:

- ALL other substances (eg, probiotics, glucosamine, antioxidants, joint health products, weight management products, luteine, etc)
- Botanicals used in foods and food supplements

Sales of these products should be assumed to be allowed but without any claim on commercial communications literature, labels, advertising, websites etc in the EU

1. RELEVANT COMPANY ACTIVITIES

a) Approximately how many food supplement products (product types and brands but not different pack sizes) in these affected sectors do you sell in the EU?
NOTE If you sell a large range list on a separate sheet of paper

Please list products by product category:

Probiotics/prebiotics
Fatty acids
Joint health
Antioxidants
Amino acids
Botanicals
Others

b) What is the approximate value of annual sales of **these** products per category used in the food and food supplement sectors to your business (please state in terms of ex-factory value terms excluding VAT and relate to the last available financial year you have information on)

Probiotics/prebiotics
Fatty acids
Joint health
Antioxidants
Amino acids
Botanicals
Other

c) What is the approximate share (%) of total company sales accounted for by these 'affected' products (in the last available financial year of trading)?

d) What would you say is a typical profit margin (%) applied to products sold in each of these affected categories – this relates to the typical profit margin applied (eg, sales revenue less direct cost) at your level **before** your customers add their costs and margins

e) How many people do you employ a) in total and b) (approximately) directly relating to the production and marketing of the 'affected' products – please try to answer in terms of full time employed 'equivalents'

2. IMPACT OF EXISTING/CURRENT NEGATIVE GENERIC HEALTH CLAIMS EVALUATIONS BY EFSA

The first tranche of EFSA evaluations rejected hundreds of joint health, probiotic and botanical claims. The 2nd tranche of evaluations rejected mostly antioxidant, joint health and blood-glucose-related claims.

a) As a result of these EFSA evaluations/opinions have you been requested by any customers to make changes to your claims (eg, on labels, promotional literature, to change ingredients in products, withdraw products)?

If yes, please provide additional details about nature of requests, products affected, actions taken and costs involved

Category	Actions taken	Approximate cost (euros)
Probiotics/prebiotics		
Fatty acids		
Joint health		
Antioxidants		
Amino acids		
Botanicals		
Others		

b) As a result of these EFSA evaluations/opinions have you made any changes (or plan to) to your business activities (eg, on labels, promotional literature, to change ingredients in products, withdraw products) that are not as a result of customer requests?

If yes, please provide additional details (eg, actions taken and costs involved?)

Category	Actions taken	Approximate cost (euros)
Probiotics/prebiotics		
Fatty acids		
Joint health		
Antioxidants		
Amino acids		
Botanicals		
Others		

c) Any other impacts (eg, funding company or industry action in response to EFSA Opinions)?

If yes, please provide example or additional information

3. ARTICLE 14/13.5 NON GENERIC CLAIMS

It will also be helpful for the Economic Impact Assessment to identify the costs involved in submitting dossiers for Article 14/13.5 claims. It is recognised that you may consider this a very competitive and commercially sensitive subject to provide information on. Therefore if you would rather not respond to the questions in this section, please feel free to not respond.

a) Have you submitted any (Article 14/13.5) non generic health claims for evaluation by EFSA?

If yes, please an example or examples of dossiers submitted and provide additional information about the product and reason why this category of authorisation was used (as distinct to relying on the Article 13 generic authorisations)

b) For any Article 14/13.5 claims made, please provide estimates of the costs per claim dossier involved from starting the submission to outcome (staff/consultant time, new studies, literature searches, etc)?

4. COSTS OF SUBMITTING ARTICLE 13.1 GENERIC CLAIMS

Were you involved in providing input such as expertise, staff time, data etc for Article 13.1 generic claims (usually submitted via national trade associations)

If yes, please provide further information about your input and an estimate of the associated costs

5. WIDER POTENTIAL IMPACTS OF NEGATIVE GENERIC CLAIMS EVALUATIONS

If it is assumed that all **non vitamin, mineral and essential fatty acid health** claims were disallowed and only 6 months transition is foreseen, how do you see this affecting your business and the wider market?

a) In terms of short term (within 12 months of claims being prohibited) actions needed to be taken (eg, withdrawal of products from markets, re-labelling, etc) and associated costs? A list of some possible actions is listed below to assist you in completion but feel free to add others if required

	Estimated Cost Impact (Euros)	Comments/sub-sector (eg, botanicals, probiotics) and additional information of actions to be taken and why
Annual loss of sales		
Stocks write offsw		
Packaging write offs		
Trade Stock recall & disposal		
Pack changes		
Product re-formulation		
Marketing and promotional activity changes		
Training		
Other costs (please specify)		

b) What impact will the actions detailed above have on:

Overall company profitability (eg, likely loss of xx%)
Employment levels (eg, % change, or number of full time equivalents that might change)
Returns on investment
Location of business activities (eg, inside/outside the EU)
Relative importance of the EU market in future business activity plans
(New) product development for the EU market

c) In terms of the broader EU market for supplements what are your views on the likely impacts in terms of:

Overall size of the market(s) for the product categories affected?
Range of products available for consumers?
Price of products available to consumers?
Origin of products available to consumers?
Sale of products imported by consumers from outside the EU (where the NHCR will not apply
Any other impacts/comments you wish to make?

THANK YOU FOR YOUR TIME AND INPUT

Appendix 2: Product life cycle returns and the internal rate of return

The product life cycle and internal rate of return analysis used are based on average (typical) products sold in the EU market for food supplements. Sales and gross profit figures have been simplified to make comprehension easier.

Expected life of a product is 7 years.

Assumed rate of discount = 15%

Assumed gross margin return 50%

Current market

Year	Expected sales (Euros)	Expected gross margin (Euros)	Discounted value of margin (Euros)
0	-100,000	-100,000	-100,000
1	90,000	30,000	26,087
2	120,000	40,000	30,246
3	150,000	50,000	32,876
4	150,000	50,000	28,588
5	150,000	50,000	24,859
6	120,000	40,000	17,293
7	75,000	25,000	9,398
Total	**855,000**	**285,000**	**169,347**
Total after deducting cost of bringing product to market	**755,000**	**185,000**	**69,347**
Internal rate of return			**17.53%**

Delay of 9 months in bringing a product to market (awaiting claims approval)

Year	Expected sales (Euros)	Expected gross margin (Euros)	Discounted value of margin (Euros)
0	-100,000	-100,000	-100,000
1	0	0	
2	90,000	30,000	22,684
3	120,000	40,000	26,301
4	150,000	50,000	28,588
5	150,000	50,000	24,859
6	150,000	50,000	21,616
7	120,000	40,000	15,037
8	75,000	25,000	8,173
Total	**855,000**	**285,000**	**147,258**
Total after deducting cost of bringing product to market	**755,000**	**185,000**	**47,258**
Internal rate of return			**9.26%**

Sales down 25%

Year	Expected sales (Euros)	Expected gross margin (Euros)	Discounted value of margin (Euros)
0	-100,000	-100,000	-100,000
1	67,500	22,500	19,565
2	90,000	30,000	22,684
3	112,500	37,500	24,657
4	112,500	37,500	21,441
5	112,500	37,500	18,644
6	90,000	30,000	12,970
7	56,250	18,750	7,049
Total	**641,250**	**213,750**	**127,010**
Total after deducting cost of bringing product to market	**541,250**	**113,750**	**27,010**
Internal rate of return			7.29%

Significant increase in cost of bringing a product to market

Year	Expected sales (Euros)	Expected gross margin (Euros)	Discounted value of margin (Euros)
0	-500,000	-500,000	-500,000
1	90,000	30,000	26,087
2	120,000	40,000	30,246
3	150,000	50,000	32,876
4	150,000	50,000	28,588
5	150,000	50,000	24,859
6	120,000	40,000	17,293
7	75,000	25,000	9,398
Total	**855,000**	**285,000**	**169,347**
Total after deducting cost of bringing product to market	**355,000**	**-215,000**	**-330,653**
Internal rate of return			-20.3%
Total if sales volume increased fivefold	4,275,000	1,425,000	922,799
Total if sales volume increased fivefold less cost of bringing product to market	3,775,000	925,000	422,799
Internal rate of return with fivefold increase in sales			16.9%

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