# Briefing paper

## Economic impact assessment of EU food related regulations on research, innovation and competitiveness in the specialty food ingredients sector

For

The Federation of European Specialty Food Ingredients Industries (ELC)

**By**

**Graham Brookes**

**GBC Ltd**

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# Executive summary and conclusions

This report presents the findings of analysis of the impact of EU regulation on innovation in the specialty food ingredient sector.[1]

**Overview of the specialty food ingredients market and sector**

1. Specialty food ingredients typically preserve, texture, emulsify, colour, aid processing and improve the nutritional profile of processed foods. These ingredients range from micro-ingredients like vitamins, minerals and enzymes to macro-nutrients such as specific proteins, fat, carbohydrates, fibres and other substances.

2. In the EU, there are approximately 200 businesses involved in specialty food ingredient production, with the EU market worth about €14 billion. Globally the specialty food ingredients market is worth about €35 billion and the sector employs about 90,000 people. Just under a quarter of the companies are small, medium enterprises (SMEs).

3. Specialty food ingredient companies spend annually between 4% and 6% of their turnover on research and development (within a range of 3% to 8%).

4. A number of specialty food ingredients are classified as novel foods and are often sold with health claims. Examples include healthy-aging products, ingredients that replace dietary fibre or which remove allergenic properties.

5. The time period for undertaking and completing food ingredient research can be considerable. For new food products (eg, novel foods) and new molecules, the total research and development period can be four to ten years. For new formulations, the time period is less, typically 1-3 years.

6. The cost of researching and developing a new ingredient/product can vary considerably depending on whether the new ingredient/product is novel and makes health/nutrition claims. New (novel) food products with health/nutrition claims may cost in the range of €15 million - €20 million, new ingredients with health claims €3 million to €5 million, new ingredients without health claims €2 million to €3 million and new formulations of existing products €0.2 million to €2 million.

7. The average product life of a food ingredient/product is commonly in the range of 5-15 years (some to 20 years). For more simple re-formulations of existing products, the market life may be much shorter (1-3 years).

8. The primary criteria determining whether a new specialty ingredient is brought to market is whether the company undertaking the research and development (R and D) is reasonably confident that a new ingredient will earn a reasonable rate of return relative to the cost of investment. In general, companies are looking for internal rates of return on their investment within a range of 15% to 25%. In terms of gross returns, the typical target

[1] Focusing on the impact of the EU Novel Foods and EU Health Claims Regulations

for a new product is 50%. Some companies also assess new ingredient development projects on a payback basis that they expect to cover all costs within 3 to 5 years.

**Impact of regulation**

9. All businesses in the specialty food ingredient sector consider regulation as important, playing a positive role for ensuring consumer confidence in products. The cost associated with meeting regulation is a necessary and important component of bringing a new ingredient to market. However, regulation is expected to be science-based, have a transparent process, be predictable and show clearly how risk is being assessed. If regulatory systems deliver on all of these expectations, this minimises uncertainty and risks associated with regulation, with the costs of regulation being 'calculable'.

10. The contribution of regulatory costs (eg, the generation of safety data, or clinical trials to demonstrate a health claim) to total costs of research and product development varies. In general, costs associated with meeting regulatory requirements can be up to 50% of the total costs of bringing a product to market.

11. The different nature of regulatory systems operating around the world can have a negative impact on innovation through:

    - Different data requirements;
    - Different interpretations of (the same) data;
    - A lack of clarity and transparency on how interpretations and decisions are made.

    The lack of global 'harmonisation' of regulation is widely perceived to contribute to slowing down the process of bringing products to market in different regions and countries. In particular, the regulatory approval systems in the EU (eg, for novel foods, health claims and also food additives and enzymes) are widely perceived to take longer and have a higher degree of regulatory uncertainty than regulatory approval systems in other countries/regions of the world.

12. The cost of generating data to comply with EU regulatory requirements is estimated to be higher than the requirement for most other markets by between €1 million and €2 million per ingredient.

**Impact of regulation on the decision to launch a new product**

**Time to authorise novel ingredients and health claims**

13. The average time taken to authorise the sale of novel foods/ingredients in the EU market since 1997 has been 36 months (range 16-92 months). The average time for giving approval for health claims has been about 30 months (range 15-54 months). These authorisation times compare with an average of 12-18 months in most other countries.

14. Much of the delay in the EU authorisation process stems from 'comitology' issues after scientific evaluations (Opinions) have been completed by the European Food Safety

Authority (or Member State authorities).[2] These delays can be compounded by requirements for authorisation arising from several regulations where the process of authorisation under one regulation cannot/does not begin until authorisation under another regulation has taken place. In some instances this can lead to the total authorisation process taking up to seven years.

**Impact of delays in authorising novel foods/ingredients on the attractiveness of bringing products to market**

15. If approval of food ingredients classified as novel foods occurs within 12-18 months of an application, specialty food ingredient companies would typically expect to earn an internal rate of return (IRR) on these investments of between 16.1% and 25.8% (average 21.3%) against a target IRR of 15%-25%. In terms of payback[3] this takes about four years (against a target of 3-5 years).

16. If approval of a specialty food ingredient classified as a novel food/ingredient is delayed to three years (as is the average time for novel food approvals in the EU), the internal rate of return falls to between 7.3% and 13.4% (average 10.6%) and the payback takes seven years. Both are outside the target range for returns and payback. Therefore the time delay in authorisation significantly reduces the relative attractiveness of investment.

17. If the time delay in authorisation is extended to five years (as has occurred for some novel foods and ingredients in the EU), the internal rate of return falls to a range of 3.1% and 8.1% (average 5.8%) and the payback is extended to 10 years. At these levels of return, it is highly unlikely that future potential products would be brought to market.

18. The global nature of the specialty food ingredients market means that the asynchronous nature of the authorisation process in different markets complicates the assessment of the impact of regulation on returns. As the EU authorisation process is typically longer than the authorisation process in other markets, the relative importance of the EU market to overall global sales can therefore have a significant impact on global returns. Figure 1 summarises the impact on expected IRR for a globally marketed specialty food ingredient of delays in the EU authorisation process. This suggests that the delays in the EU authorisation process for novel ingredients/products and health claims may have made an important negative contribution to some novel ingredients/products being brought to market. How this ultimately affects the market depends on several factors such as expected global sales, the importance of the EU market relative to other markets, whether target sales can reasonably be expected to be achieved in markets outside the EU and the influence of EU authorisation on regulatory authorities in other countries:

    - If companies perceive they have reasonable scope for achieving target sales outside the EU and the EU is a relatively small part of their target market, they have a financial incentive to seek regulatory approval for novel

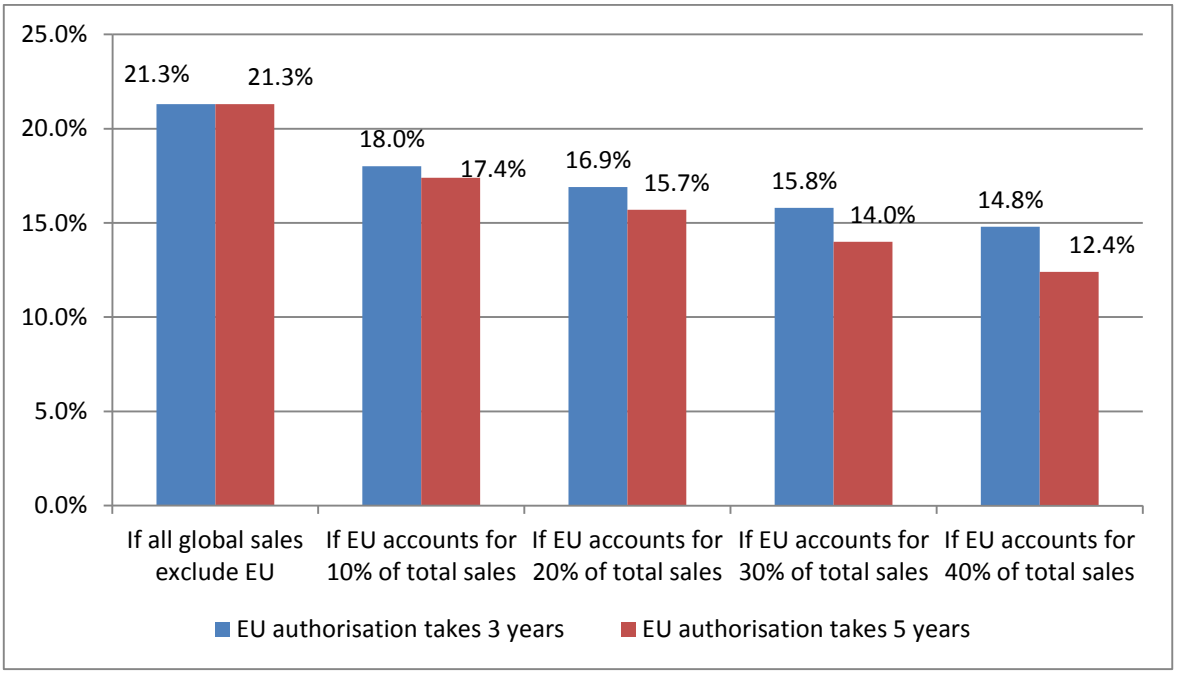
[2] In the case of novel foods/ingredients

[3] When the costs of bringing a product to market, inclusive of research, development and regulatory costs have been re-couped

ingredients/products only in markets outside the EU. In this case, the novel ingredient/product is not brought to the EU market at all, or may be brought to the EU market a few years later, only after successful and profitable sales elsewhere. EU food manufacturers and EU consumers therefore lose out in terms of fewer novel ingredients/products being brought to market compared to other markets;

- Where the EU is expected to be an important part of the global market for a novel ingredient/product, the impact of the longer EU authorisation process may result in novel ingredients/products not being brought to market at the global level because the expected global returns fall below target levels (especially if the EU accounts for 30% to 40% of total expected sales and the EU approval process takes more than three years).

**Figure 1: Impact of the EU's longer authorisation process for novel ingredients/products on global returns (% internal rate of return): average returns basis**




**Uncertainty issues**

Uncertainty has a negative impact on innovation in two main ways:

- *Legal uncertainty:* This relates to the legal status of a product/ingredient - whether it is classified as a novel food or ingredient for the purposes of complying with the Novel Foods Regulation or whether a health claim is likely to be allowed or not. This can have negative economic implications for, or impose additional costs on, companies considering bringing products to markets. It is, however not easily recognised, categorised or quantified. The evidence identified in this study confirms that legal uncertainty is perceived to be greater in respect of the EU regulatory system than the regulatory systems in other countries.

- *Uncertainty about the process and time taken for deciding on a novel food/ingredient authorisation:* Bringing a new ingredient/product to market takes time to plan and execute. Uncertainty relating to when a novel ingredient or health claim authorisation will be granted can add risk and result in costs that might otherwise have not been incurred. For example, having to cancel or delay a product/ingredient launch or having to change labels.

**Impact on competitiveness, employment and consumers**

Innovation is important for businesses if they wish to be profitable and remain competitive because it contributes to the development of improved products and may offer scope for improving productivity/lowering costs of production. This means that innovation-friendly countries and regions tend to have higher levels of income generation, value added and employment than countries and regions that are perceived to be less innovation-friendly.

The longer regulatory authorisation processes for food ingredients and higher levels of 'regulatory uncertainty' in the EU compared to most other countries is contributing to lower rates of return and less willingness in specialty food ingredient businesses to invest in new ingredient development for the EU market. In the long run this has probably resulted in lower levels of investment, value adding and employment in the specialty food ingredient sector located in the EU than would otherwise have occurred if relevant EU regulations were implemented in a more-timely manner and with greater degrees of legal certainty.

The consequences of lower levels of innovation in the EU may have resulted in EU consumers paying higher prices for some foods/ingredients relative to the prices paid for similar products in other markets and there may be fewer new specialty food ingredients and foods available to EU consumers than are available in other markets. EU consumers may be losing out in terms of both the quantity and quality of food ingredients and products available.

**Concluding comments**

The regulatory processes that impact on the development of speciality food ingredients take significantly longer to complete and have a greater degree of uncertainty attached to them in the EU compared to the regulatory processes in most other countries. This has had a negative impact on investment returns and the development of new speciality food ingredient availability in the EU market. In instances where the EU market is considered important to overall (global) sales, this has also had a negative impact on global new ingredient development. As a result, EU consumers may be losing out from decreased choice and 'non availability' of improved products/ingredients, as well as levels of income and employment generation in the EU probably being lower than they might otherwise have been if the regulatory environment had been more innovation-friendly.

If EU regulation of specialty food ingredients is to better create an environment that encourages food ingredient innovation, a number of issues need to be addressed. These include:

- Reducing the time taken to authorise novel ingredients, health claims, enzymes, food additives etc. The EU should be targeting completion of regulatory approval processes within 12-18 months, as occurs in most other countries. A key area where the EU processes need to be improved is related to the 'comitology' processes after scientific opinions have been made. Establishing and adhering to time limits for completion of the 'comitology'

processes for all regulatory approvals has the potential to significantly reduce the authorisation delays;

- It would be helpful if authorisation under different regulations could be undertaken simultaneously rather than currently where there are some instances of the regulatory authorisation process under one regulation not starting until the authorisation under a different regulation has been completed;
- Uncertainty about the timing of approval, the likely legal status of novel ingredients or whether a health claim may be authorised needs to be reduced and minimised.

# 1 Introduction

EU strategy and policy documents (eg, Strategy Europe 2020) refer to commitments to increase European competitiveness but underlines that the '*competitiveness of the European Food industry is weak compared to some of its major competitors*'.

Against this background, there is debate about the effect of EU regulation on the ability of the food industry to innovate and compete. The specialty food ingredients sector is one in which innovation is vital to market development. Therefore, it is not surprising that within this sector, there is concern that various EU regulations and how they are implemented may be having a negative impact on research and development, innovation and competitiveness.

As a result of this concern, the member companies of the European Specialty Food Ingredients Industries Association (ELC) commissioned an independent assessment of relevant EU regulations on research and development, innovation and competitiveness in this sector. This paper presents the findings of this study.

### *1.1 Objectives*

The primary objective of this study was to assess the effect of EU Regulations on research, development, innovation and competitiveness in the European specialty food ingredients sector.

More specifically the paper covered the following issues:

- An overview of relevant EU regulations: novel foods and health claims;
- Background on the market for specialty food products;
- Research and Development (R and D) conducted in the specialty food ingredients sector: types, timeframe, costs, location, market life of products, criteria used to determine investment, overview of company perspectives on the impact of regulation;
- The EU Novel Foods Regulation: approval process and time to authorise;
- The EU Health Claims Regulation: approval process and time to authorise;
- Impact of authorisation time delays on attractiveness to invest;
- process of new product development: reasons, time and costs involved; life cycle of products, expected returns on investment;
- Impact of regulation on costs, time to market, returns on investment;
- Knock on effects relating to income and employment generation;
- Implications for competitiveness.

### *1.2 Methodology and structure*

The analysis has been undertaken through a combination of desk research and analysis, and the findings of a survey of companies in the European specialty food ingredient sector.

The survey was undertaken in the period April to September 2015 and involved the use of a semi-structured questionnaire. Interviews were undertaken through a combination of e-mail exchanges and telephone interviews.

Responses from a number of companies with head offices, both inside and outside the EU, but all with research facilities in the EU were obtained. The respondent companies account for about 14% of the global and 17% of the EU market (by sales and employment) for specialty ingredients. The author considers that the survey results are probably reasonably representative of the global and EU specialty food ingredients industry and market, although with some bias towards larger companies.

The paper is structured as follows:

- Introduction (this section);
- Section 2: an overview of key EU regulations to be covered in the study;
- Section 3: overview of the European market for specialty food ingredients and research and development in the sector;
- Section 4: economic impact of regulations on innovation in the sector.

### *1.3 Conceptual background: role of regulation*

The nature of regulatory frameworks can influence innovation in both a positive and negative way. The ideal 'innovation-friendly' form of regulation limits the negative impacts of compliance costs and promotes/encourages or provides incentives to innovate. The actual impact of regulation on innovation depends on the extent of compliance costs relative to the incentive effect – if compliance costs are relative low and the incentive is relatively high, innovation is encouraged whilst, if compliance costs are relative high and incentives low, innovation is generally discouraged.

The influence of regulation on innovation can be determined by the nature or type of regulation. Regulation can be classified into a number of categories.[4]

- Economic regulation which tries to overcome market failure;
- Competition regulation: this provides a framework for competition, aiming to maximise competition in markets and minimise barriers to entry to a market;
- Social regulation, which targets the removal of externalities such as pollution and environmental damage;
- Labour and consumer safety regulation which aims to protect the health and safety of consumers and workers;
- Institutional regulation: this covers product liability (which overlaps with health and safety regulation) and the definition of intellectual property rights which are important for encouraging innovation.

In this study, the focus of analysis relates to the latter three categories of regulations as exemplified by the EU regulations on Novel Foods and Health Claims. These two regulations are the focus of analysis in this study.

[4] Bling (2012)

*Evidence to date*

A search of literature examining the impact of regulation on regulation identifies limited analysis. This includes:

- Bassanini and Ernst (2002) found a negative correlation between the intensity of product market regulations and the intensity of R & D expenditure in OECD countries and Swann (2005) found that regulations were both an important source of innovation and a severe obstacle to innovation;
- In relation to the impact of social (environmental) regulation, a majority of studies found a positive correlation between environmental regulations and innovation (eg, Gonzalez, (2009), Popp et al (2007), Lanoie et al (2008);
- There are few studies on the impact of product liability regulation and innovation: Viscusi and Moore (1993) found a positive correlation – in other words a positive influence of liability law on innovation provided the expected liability costs are moderate but once these rise, the impact on innovation is negative;
- Blind (2012) found a positive influence of product and service regulation on innovation in OECD countries. He also found a positive influence of Intellectual Property Rights (IPR) regulations on innovation, backing earlier work by Carlin and Soskice, 2006, and Koch et al, 2004. Blind also found a positive link between legal and regulatory regulation and competitiveness of enterprises and innovation, in line with earlier work by Bassanini and Ernst (2002) and Conway et al (2005);
- Moors E (2012) examined the impact of the EU Health Claims Regulation on innovation, largely based on a survey of companies in the Dutch functional food value added chain. This identified that authorised health claims offered food companies the opportunity to differentiate their products and so reinforce the competitive position of products. However, the high cost of developing and submitting a dossier to support a health claim and the legal uncertainty associated with whether a health claim was likely to be authorised or not was discouraging innovation and new product development, especially amongst smaller businesses;
- Brookes (2007) examined the economic impact of the EU's Novel Foods Regulation drawing significantly on a survey of businesses developing novel foods in the EU. This found that average levels of research and development (R and D) expenditure on food products by companies tend to be lower in the EU compared to average levels in other countries. Also, whilst levels of R and D expenditure amongst the larger EU-based food companies are at levels comparable with the world's largest global food companies, the EU tends not to be the highest priority target market for new (novel) food product development. As a result, EU consumers are losing out from decreased choice and 'non availability' of improved products, as well as levels of income and employment generation in the EU are probably lower than they might otherwise have been if the regulatory environment had been more innovation-friendly.

# 2 Relevant EU regulations

In this study, the focus of attention relates to regulations (in the EU) that impact on novel foods/ingredients and health claims. An over view of these EU regulations is discussed below.

## *2.1 The Novel Foods Regulation (EC No 258/97)*

Novel foods are foods (and ingredients) that were not consumed to a significant degree in the EU before 15 May 1997 and hence do not have a history of food use in the EU before that date. They belong to one of the listed categories in the Novel Foods Regulation[5] can be divided into three broad categories of products:

- Innovative 'new' products and ingredients (eg, phytosterols, coagulated potato protein, D-tagatose, trehalose);
- Traditional foods from third countries (eg, noni juice).

The objectives laid down for the Novel Foods Regulation govern the placing of these products onto the EU market and focus on:

- Facilitating the functioning of the EU's internal market by ensuring that differences between national member state laws on novel foods and food ingredients do not hinder the free movement of foodstuffs within the EU and hence create conditions of unfair competition;
- Protecting public health through ensuring that novel foods and ingredients are subject to a single safety assessment before being allowed to be placed on the EU market, or can be shown to be substantially equivalent to existing foods or ingredients sold on the EU market;
- Protecting consumers from products that may be nutritionally disadvantageous when replacing other foods.

Before being placed on the market, novel foods and ingredients are required to undergo an EU level assessment after which authorisation to market may be given. Under the assessment procedure, the competent authority of a Member State that receives an application is required to make an initial assessment and determine whether or not the product/ingredient should be authorised or whether an additional assessment is required. If the EU Commission or other Member States competent authorities raise no objection, and if no additional assessment (by the European Food Safety Authority (EFSA)) is required, the Member State informs the applicant that the product/ingredient can be placed on the market. If additional assessment is required, or Member States raise objections, the Commission ultimately takes the authorisation decision after EFSA has made an assessment and passed its findings onto the Scientific Committee for Plants, Animals, Food and Feed (SCPAFF) for consideration. The authorisation process is discussed further in section 4.

[5] Article 1 of Regulation 258/97

Five years after the first implementation of the Novel Foods Regulation (in 2002), the EU Commission prepared a discussion document on its implementation.[6] This was followed up with an evaluation report on the Regulation in 2004 and an impact assessment on the Regulation.

The EU Commission then put forward options for change to the Novel Foods Regulation in early 2008 that were not adopted (in 2011), mainly because of disagreements relating to a number of issues, most notably associated with animal cloning. A new proposal for amending the operation of the novel foods regulation was than put forward in 2013 (Com (2013) 894 final) that was based on agreements reached in 2011 (but excluding consideration of animal cloning).

In the words of the proposal, it *'pursues the objectives of the Communication on Smart Regulation in the EU (Com (2010) 543) and of the Europe 2020 Strategy (Com (2010) 2020) with emphasis on simplifying and streamlining the regulatory process, thus reducing the administrative burden and improving the competitiveness of the European food industry, while ensuring the safety of food, maintaining a high level of public health protection and taking global aspects into consideration'.*

With a view to achieving these objectives the Commission proposed to include the use of nanomaterials for food use within the remit of the regulation and to centralise the approval process and remove the 'simplified procedures' based on substantial equivalence. All applications for approval are to be submitted to the EU Commission which then asks EFSA for a scientific opinion. The Commission then considers whether to approve a novel food on the basis of the EFSA opinion, through SCPAFF. To support innovation in the EU food industry, individual authorisations with data protection of proprietary data may be granted for a maximum period of five years. In such cases, specific criteria for the eligibility for data protection will be specified. The concept of substantial equivalence will disappear as the authorisations will become generic in nature (unless data protection is granted). If additional companies wish to seek approval for a similar product during that five year period, they would be free to do so but only if they make a full application that utilises their own data or find an agreement with the owner of the proprietary data so that they can use this data.

These proposed changes were approved in November 2015.

### *2.2 The Regulation on Nutrition and Health Claims*

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.

[6] http://ec.europa.eu/food/biotechnology/novelfood/initiatives_en.htm

There are a number of objectives laid out in the Regulation. These broadly cover the following main issues:[7]

- 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).

[7] 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)

# 3 Background to the European specialty food ingredients market

## *3.1 The European food and drink sector*

In 2013, the food and drink turnover for the EU (28) was €1,244 billion, which represented a 17.1% increase relative to 2012. This is significantly above the annual average increase over the last 10 years of about 4.4%. The sector has the largest turnover of manufacturing sectors in the EU, accounting for 15% of total manufacturing turnover and ahead of the automobile and coke/petroleum products industries (12% and 9.7% respectively of total manufacturing turnover).

In terms of employment, the food and drink sector employed 4.25 million people in 2013, up 0.4% on 2012 employment levels. This accounted for 15% of total manufacturing employment, the largest sectoral share of total employment.

The sector is dominated by small and medium sized enterprises (SMEs).[8] Of the 289,000 companies in the sector, 99.1% (286,000) are SMEs. These companies (SMEs) accounted for just over a half of total sectoral turnover (50.4%) and half of total value added (51.9%) and 36.7% of total employment.

In terms of value added, the gross value added of the EU food and drink sector (2012) €206 billion. This accounted for 12.8% of total EU manufacturing sectors' value added, the highest share of any sector. Lastly, total food and drink expenditure on research and development was equal to 0.27% of food and drink sector output (2012 data).

## *3.2 Trade in food and drink products*

Trade statistics relating to food and drink products for the period 2009-2013[9] (Table 1) show that the EU exported €91.7 billion worth of food and drink in 2013 and imported from third countries €64.1 billion, giving a net trade surplus of €27.6 billion. Since 2009 both the nominal value of imports and exports has increased (by €38 billion for exports and by €13.3 billion for imports). The sectors with the largest share of exports in 2009-13 were spirits, wines and food preparations.

**Table 1: EU trade in food and drink products 2009-2013 (million euros)**

| | 2009 | 2010 | 2011 | 2012 | 2013 |
|---|---|---|---|---|---|
| Exports | 53.7 | 65.3 | 76.1 | 86.2 | 91.7 |
| Imports | 50.8 | 55.5 | 63.0 | 63.2 | 64.1 |
| Balance | *2.9* | *9.8* | *13.1* | *23.0* | *27.6* |

Source: Food Drink Europe – Data and trends of the European food and drink industry 2014/15

[8] Companies with an annual turnover of less than €50 million and employing less than 250 employees

[9] Source: Eurostat

### *3.3 Research, development and innovation – food industry level*

In 2013, the amount spent of research and development (R and D) by the world's largest 59 food and drink manufacturers was €8.6 billion.[10] Within this, 16 were based[11] in the EU, with these companies accounting for €2.6 billion of this total R and D spend in 2013.

The intensity of R&D, expressed as a % of industry output in the EU food and drink industry was 0.27% in 2011. This was below comparable levels of R&D expenditure in competitor countries, where for example the respective R&D intensity levels were 0.73%, 0.57% and 0.36% respectively for Japan (2009 data), USA (2010 data) and Korea.

In terms of innovation by sector, the dairy sector, followed by ready-meals, soft drinks, savoury frozen products and biscuits were the largest innovators (in terms of the % share of total food innovations in Europe.[12]

Categorising innovation by type or trends is difficult, although in the World Innovation Panorama (2015) innovation is categorised into 15 drivers corresponding to five consumer expectations associated with pleasure, health, fitness, convenience and ethics. In the EU market, the leading innovation categories in 2015 were reported to be pleasure, health and convenience which accounted for approximately 57%, 18% and 18% respectively of total innovation.

### *3.4 The European specialty food ingredients sector*

Specialty food ingredients typically preserve, texture, emulsify, colour, aid processing and improve the nutritional profile of processed foods, and are to some extent, present in all processed foods. They aim to offer technological or functional benefits to foods aiming to contribute towards the delivery of tasty, safe, healthy, affordable, high quality, sustainably produced foods. These ingredients range from micro-ingredients like vitamins, minerals and enzymes to macro-nutrients such as specific proteins, fat, carbohydrates, fibres and other substances.

In the EU, there are approximately 200 businesses involved in specialty food ingredient production,[13] with the EU market for specialty ingredients worth about €14 billion. Globally the specialty food ingredients market is worth about €35 billion and the sector employs about 90,000 people. Just under a quarter of the companies (in ELC) are SMEs.

### *3.5 Research, development and innovation in the European specialty food ingredients sector*

For specialty food ingredient companies, research, development and innovation are essentially a process of undertaking research to find a new ingredient or substance, a new ingredient formulation or new scientific proof for a health or nutritional benefit. This then leads to new processes or applications in, or related to food products.

[10] Source: 2014 EU Industrial R and D Investment Scoreboard, JRC
[11] Location of headquarters
[12] Source: XTC World Innovation Panorama 2015
[13] As represented by the Federation of European Specialty Food Ingredient Industries (ELC)

Ultimately the process is about the development of new processes and products that improve on existing processes and products and better meet (changing) customer requirements - customers being food companies, who themselves need to better meet the changing requirements of end consumers.

The research part of the process is where fundamental research into new substances, processes and formulations takes place along with the identification of clinical (impact) evidence. The development phase then focuses more on finding formulations to make an ingredient more applicable and appropriate for customers' target products and markets (eg, delivering a specific health impact or benefit).

Each company has a slightly different perspective on what constitutes research and development and/or innovation.

How companies organise their research and development varies and is organised according to different competences (eg, formulation, chemistry, nutrition and analysis), with different research centres or bases specialising in different competences. These are usually organised in one or more of the regional locations of the EU, the USA and Asia (mostly China). The development phase is where products, formulations etc are developed and adapted to suit customer and market requirements. This is also where the research and development phase becomes more regionally focused (and at locations outside the main research centres referred to above, for example, Brazil, India), although many products may also have global market applications, rather than being region-specific in nature. Most companies also utilise external researchers (eg, universities). The use of external researchers is typically for fundamental research and the conducting of independent clinical (nutrition) trials but may also extend to assistance with data generation for regulatory dossier preparation, application work and market research.

In terms of the companies present in the EU market for specialty food ingredients, they spend annually between 4% and 6% of their turnover on research and development (within a range of 3% to 8%).

The introduction of products and ingredients classified as specialty food ingredients in the EU mostly fall into the health category of innovation referred to in sub-section 3.3. Examples include:

- 'Healthy ageing' products such as calcium and vitamin D enriched dairy products;
- Ingredients that replace or enhance dietary fibre content of foods;
- Ingredients that remove allergenic properties such as approaches that use prebiotics, probiotics and alternative protein sources;
- Micronutrients with diverse health benefits.

A number of these are classified as novel foods or ingredients within the EU (Table 2).

**Table 2: Novel food authorisations (to July 2015)**

| Company | Product/ingredient |
|---|---|
| Belovo | Phospholipides from egg yolks |
| Unilever | Phytosterols in yellow fat spreads |

| | |
|---|---|
| Bioresso | Trehalose |
| Danone | High pressure pasteurization for fruit products |
| Purocur | Dextran from bacteria in bakery products |
| Avebe | Coagulated potato protein & hydrolysates |
| Morinda | Noni juice |
| Omega Tech/Mortox Bioscience | Oil rich in DHA (from micro algae) |
| Danisco | Salatrim |
| ADM | Phytosterols & phytostanols in various products |
| Pharmaconsult Oy | Phytosterols & phytostanols in various products |
| Unilever | Phytosterols in yoghurts |
| Teriaka | Phytosterols & phytostanols in various products |
| Novartis | Phytosterols & phytostanols in yoghurts |
| Cargill | Isomaltulose |
| Sudzucker | Isomaltulose |
| Pharmaconsult Oy | Phytosterols & phytostanols in bakery products (subsequently changed to rye bread only) |
| Karl Fazer | Phytosterols & phytostanols in bakery products (subsequently changed to rye bread only) |
| Laboratores Pharmascience | Maize germ oil high in unsaponifiable matter |
| Laboratores Pharmascience | Rapeseed oil high in unsaponifiable matter |
| Vitatene antibiotics | Lycopene from blakeslea trispora |
| ADM | Diacylglycerol oil in oils, fats, spreads, bakery products and yoghurts |
| Enzymotec | Oil enriched with phytosterols and phytostanols |
| Teriaka | Rice drink enriched with phytostanols |
| Wacher Chemie | Alpha-cyclodextrin |
| Croda Chemicals | Refined echium oil |
| Unilever | Allanblackia seed oil use in fat spreads |
| Phytotrade Africa | Baobab dried fruit pulp |
| Suntory | Arachidonia acid rich oil from mortieralla alpins |
| Morinda | Leaves of morinda citrifolin |
| Unilever | Ice structure protein type III HPLC 12 |
| NattoPharma | Vitamin K2 from bacillus subtilis natto |
| BASF | Synthetic lycopene in sunflower oil suspension |
| LycoRed | Lycopene oleoresin in tomatoes |
| Vitatene Antibiotics | CWD lycopene from blakeslea trispora |
| DSM | Lycopene from blakeslea trispora (synthetic lycopene) |
| Neptune Technologies | Lipid extract from Antarctic krill euphausa superba |
| Nutrinova | Additional uses for DHA rich algal oil from micro-algae ulkernia sp |
| Martek Biosciences | DHA rich algal oil from schizochytrium sp |
| Viridis | Leaf extract from Lucerne |
| BNL Foods | Chia seed: whole and ground |
| Tahitian Noni International | Puree and concentrate of fruits of morinda citrifollia |
| Akzo Chemical | Ferric sodium EDTA |
| Nestec | Ferrous ammonium phosphate |
| GlycaNova | Mycellal extract of shitake mushroom |
| Kitozyme | Chitin-glucan from aspergillus niger |
| Senmi Ekisu | Sardine peptide |

| | |
|---|---|
| Nutrition 21 | Chromium picolinate |
| Glycanova | Beta gluten rich mycelial extract of shitake mushroom |
| National Starch | Phosphated maize oil |
| CBC Japan | Fermented black bean extract |
| Enzymotec | Soy phosphatidylserine rich phospholipids |
| Kaneka Pharma | Flavanoids from glycyrrhiza glabra |
| Bioethera | Yeast beta-glucans |
| Revolymer | Novel chewing gum |
| Wacher Chemie | Gamma-cyclodextrin |
| DMV International | Lactoferrin |
| Ajinomoto | Dihydrocapslate |
| DMV International | Bovine lactoferrin |
| Chia Company | Chia seed extended use |
| DSM | Synthetic zeaxanthin |
| BioIberica | Rooster comb extract |
| Miyarisan Pharma | Closridum butyricum |
| Reading University | Methyl vinyl ether-maleic anhydride copolymer |
| Functional Products Trading | Chia oil |
| Helm AG | Rapeseed protein |
| Kyowa Hakko | Citicoline |
| Lallemand | UV-treated bakers yeast |
| Nestec | Coriander seed oil |
| Gnosis | S-methlytetrahydrofolic acid |
| DSM | Oil of micro algae schizochytrium sp |
| DSM | Extension of use for DHA and EPA rich oil from algae schizochytrium sp |

Source: Official journal of the European Communities

### *3.6 Timeframe and cost of research and development*

The time period for undertaking and completing food ingredient research can be considerable. For new food products (eg, novel foods) and new molecules, the total research and development period can be in the range of four to ten years, based on 2-5 years for research and 2-5 years for product development (including time for regulatory approval).[14] For new formulations, the time period is less, typically 1-3 years.

The cost of researching and developing a new ingredient/product can vary considerably depending on whether the new ingredient/product is novel and makes health/nutrition claims. New (novel) food products with health/nutrition claims may cost in the range of €15 million to €20 million, new ingredients with health claims €3 million to €5 million, new ingredients without health claims €2 million to €3 million and new formulations of existing products €0.2 million to €2 million.

A significant part of the overall cost derives from regulatory requirements, notably the generation of safety data. This is particularly important for new products and ingredients where up to 50% of the total costs referred to above can be associated with meeting regulatory requirements. The high costs of research and development also reflect the nature of the activity in which many

[14] Assumed to take 12-18 months – for further discussion see section 3.9

potential ingredients are rejected at an early stage of research. The costs of this research ultimately have to be covered by returns generated from the relatively few ingredients that do eventually come to market.

### *3.7 Ingredient/product market life*

The average product life of food ingredient/product varies. For a new product or ingredient, it is commonly in the range of 5-15 years (some to 20 years). For more simple re-formulations of existing products, the market life may be much shorter (1-3 years). How long a product may last in a market depends on several factors such as market trends, competition from similar products, lifestyles and (changing) demands of consumers and decisions of food product companies concerning the renewal/extension of their product lines. Regulation can also affect the product life of a product as changes in regulatory requirements may add costs to continued production and marketing of a product (eg, re-formulation), making its continued presence in a market less viable.

### *3.8 Criteria used to determine whether to bring products to market*

Companies investing in specialty food ingredients look at a number of criteria when making investment decisions and deciding whether new ingredients are brought to market.

The primary criteria determining whether a new specialty food ingredient (which may be classified as a novel food and/or uses a health or nutrition claim or be classified as an additive) is brought to market is whether the company undertaking the associated research and development is reasonably confident that a new ingredient/product discovery will earn a reasonable rate of return relative to the cost of investment. This is influenced and determined by several factors including:

a) Market size and potential for growth. This relates to potential interest from food companies and their end consumers - the extent to which food companies may be interested in buying a new/novel ingredient and whether this can improve the nature of food products so that consumers using the new/enhanced product consider it offers improvements relative to existing products (eg, in being healthier, cheaper, easier to use/cook with). In a global context, the more attractive markets for the development of new ingredients tend to be countries and regions with the largest consumer populations with reasonable levels of disposable income (or countries where disposable incomes are increasing rapidly);
b) The expected sales and profitability of a new ingredient relative to existing ingredients/products and/or expected competitor new ingredients that may also come to the market during the ingredient/product's lifetime;
c) Costs of research and development;
d) The costs of launching, marketing and supporting a new ingredient or novel ingredient/product;
e) Time to market;
f) Risks (eg, of market expectation being less than expected, nature of competition);
g) Internal capacity and knowledge;
h) Strategic fit of market and products to overall company strategy;

i) Regulatory costs and risk: The likelihood of registration approval being granted and the associated costs of getting a product through a registration or approval process. Within this, uncertainty on timing/whether approval is granted can play an important role (see section 3.10);
j) Can the new ingredient/product be protected via patents, exclusive (time limited) access to markets based on regulatory approval systems that offer data protection and whether or not a new ingredient may infringe on other intellectual property protection.

### *3.9 Expected rate of investment return or pay back*

This varies by product, market and company but typically, new products/ingredients are expected to deliver internal rates of return of between 15% and 20%, although some companies may accept a rate of return of between 10% and 15% for some products. Some companies also assess new ingredient development projects on the basis that they are expected to cover all costs within 3 to 5 years.

### *3.10 Impact of regulation on food ingredient investment and innovation: ingredient company perspectives*

All businesses in the specialty food ingredient sector consider regulation as important, playing a positive role for ensuring consumer confidence in products. The costs associated with meeting such regulation can therefore be a necessary and important component of bringing a new ingredient to market.

Regulation is, however expected to be science-based, have a transparent process, be predictable and show clearly how risk is being assessed. If regulatory systems deliver on all of these expectations, this minimises uncertainty and risks associated with regulation with the costs of regulation being 'calculable'.

The contribution of regulatory costs (eg, the generation of safety data, or clinical trials to demonstrate a health claim) to total costs of research and product development varies. In general, costs associated with meeting regulatory requirements can be up to 50% of the total costs of bringing a product to market (eg, €10 million out a total of €20 million for a new/novel ingredient/product).

The different nature of regulatory systems operating around the world also impacts on innovation. As most specialty ingredient companies operate in a number of markets around the world (their main customers, food companies also operate on a global basis) there is a recognition and need to obtain regulatory approval in a number of key markets if a new ingredient is to be successfully marketed. In general, the type of data required to meet regulatory requirements in different markets is similar, although in some instances, notably associated with health and functional claims, there are some differences. For example, in the EU and Canada, selling a product with a health claim requires the generation of clinical trials data to demonstrate the health claim. Whilst a similar requirement exists in the US regulatory system, it is possible for some claims that are classified as health claims in the EU and Canada to be classified as structural functional claims in the US – structural function claims do not need to be supported by clinical trials data and therefore the time and costs associated with regulatory approval in the US can, on average, be less than the equivalents in the EU (and Canada). Overall, the cost of generating data

to comply with EU is perceived by industry to be higher than the requirement for the US market by between €1 million and €2 million per ingredient.

Such specific differences in data requirements between markets are, however, not the only potential negative impact of different regulatory systems on ingredient innovation. A lack of regulatory clarity or certainty is also widely considered to be a major negative factor on innovation and bringing products to particular markets. This arises from the different interpretations that regulatory authorities make of, what is essentially the same data and the lack of transparency in how interpretations are made. Therefore, the regulatory environment can influence whether new product developments and applications are focused in one region or another. The more uncertain and longer it takes to progress through one country's regulatory system relative to others may influence decisions, especially as it is time delays/uncertainty that adversely affect potential returns from a new ingredient much more than the costs of generating data to meet regulatory requirements. This is examined further in section 4.

Overall, the lack of a global level 'harmonisation' of regulation is widely perceived to contribute to slowing down the process of bringing products to market in different regions and countries of the world. In particular, the regulatory approval systems in the EU (eg, for novel foods, health claims and also food additives and enzymes) are widely perceived to take longer and have a higher degree of regulatory uncertainty than regulatory approval systems in other countries/regions of the world. This can result in some companies choosing to bring new ingredients to markets outside the EU rather than include the EU or at least to focus on non EU markets first before seeking approval in the EU.

# 4 Analysis of the impact of regulation[15] on innovation in the EU specialty food ingredients sector

## *4.1 The impact of regulation on the decision to launch a new specialty ingredient/product: general*

The decision to launch a new ingredient/product in a market can be significantly influenced by the regulatory environment affecting a market. The optimum regulatory environment provides for consumer product safety, protects consumer health and delivers the availability of new (novel) ingredients and products that better meet food manufacturer and consumer wants, without acting as a dis-incentive to industry to bring forward products to the market.

The regulatory approval process will inevitably impose some costs on industry seeking to bring ingredients/products to the market. The question for policy-makers is whether the regulatory approval process can, nevertheless, provide a favourable climate for innovation. Should the regulatory environment impose an unreasonable or disproportionate burden on industry (this includes the perception of unreasonable and disproportionate burden and uncertainty about the outcome of regulatory decisions) then the regulatory system acts as an economic dis-incentive to industry to bring ingredients/products to the market (for which consumers lose out on in terms of non availability of improved ingredients/products, and reduced choice), contributes to creating a barrier to entry in the market (ie, is bad for competition) and may have an adverse impact on the creation of income and employment in the EU.

From the industry perspective, there remains a need to continue to highlight the key aspects of a regulatory framework that will optimise the scope for specialty food ingredients/products being brought to the EU market place, enhancing consumer choice and contributing to the generation of income and employment in the EU.

The key features of a regulatory environment that industry desires are:

- Efficient and transparent procedures;
- A consistent and predictable timeframe for the approval process to be completed;
- The creation of an environment that rewards innovation and the opportunity to recoup the costs of research, development and complying with the regulations;
- Legal certainty concerning the legal status of novel products and ingredients so that the benefits of the single European market can be attained.

## *4.2 The EU Novel Foods regulation: approval process and time to authorise a novel product or ingredient*

The EU's Novel Foods regulation has been in force for eighteen years and hence has been in place sufficiently long enough for assessment of its impact. In fact, after five years of operation the EU Commission began stakeholder consultations on possible changes to the regulation. The EU Commission then put forward options for change to the Novel Foods Regulation in early 2008 that

[15] Focusing on novel foods and health claims regulations

were not adopted (in 2011), mainly because of disagreements relating to a number of issues, most notably associated with animal cloning. A new proposal for amending the novel foods regulation was than put forward in 2013 (Com (2013) 894 final) that was based on agreements reached in 2011 (but excluding consideration of animal cloning).

The Commission's proposals for change recognise a number of inadequacies in the current functioning of the regulation that may be imposing burdens on industry and hence adversely affecting the efficient operation of the EU market for novel foods and ingredients. Nevertheless, some seven years after first being proposed, the changes have only recently been approved (November 2015) and are yet to be implemented. The regulatory environment affecting innovation to date, has therefore been the one applicable from 1997.

Under the past and soon to be dis-continued legislative arrangements for approving novel foods and ingredients in the EU, new novel foods and ingredients have been brought forward for regulatory approval via what are known as *'rapporteur'* member states which effectively 'acted as the agent of the EU Commission'. Companies seeking regulatory approval for a new novel food or ingredient presented their dossiers supporting the request for regulatory approval to the *rapporteur* member state which undertook the evaluation, before issuing a report to the EU Commission which then passed on the report to other member state authorities. If the *rapporteur* member state gave a positive initial assessment, other member states had 60 days in which to respond with possible reasoned objections. Depending on the nature of these, further information/clarification may have been made to the applicant and/or the dossier may have been passed onto the European Food Safety Authority (EFSA) for further assessment and ultimate deliberation. If the EFSA subsequently made a positive assessment, the dossier was passed back to the Commission which passes it to the Standing Committee on Plants, Animals, Food and Feed (SCPAFF) for issuing a formal approval.

Since May 1997 (up to July 2015) there have been 161 full applications[16] for approval of novel foods and ingredients. Most of these have related to food ingredients although a few applications have related to 'exotic' products (eg, Noni juice).

As at July 2015, 57 of these applications remain under review, 72 have been authorised, 6 refused authorisation and 26 have been withdrawn by the applicants. In relation to the 72 that have been authorised, the UK has been the *rapporteur* member state for 41% of the total, followed by the Netherlands, Belgium, Finland and Ireland with 17%, 13%, 10% and 10% of total authorisations respectively.

The average time taken for a novel food/ingredient to complete the process of authorisation since 2000 has been 36 months (within a range of 16-92 months: Table 3). The considerable time interval between application and subsequent approval largely reflects the fact that many authorised products have been subject to 'reasoned objections' by member state authorities after initial reporting by a *rapporteur* member state that have then necessitated re-assessment by EFSA and deliberation by the SCPAFF.

[16] Excluding GM foods

The shortest time taken for a novel food/ingredient to be authorised for sale in the EU was 16 months after submission of the dossier to the *rapporteur* member state and the longest time taken for a novel food/ingredient to be authorised for sale in the EU was 102 months after submission of the dossier to the *rapporteur* member state (Table 3).

**Table 3: Novel food authorisations (to July 2015): time to authorise**

| Company | Product/ingredient | Time taken to authorise (months) | Date applied for authorisation | Date authorisation granted |
|---|---|---|---|---|
| Belovo | Phospholipides from egg yolks | 25 | 23-01-1998 | 22-02-2000 |
| Unilever | Phytosterols in yellow fat spreads | 26 | 22-05-1998 | 24-07-2000 |
| Bioresso | Trehalose | 16 | 25-05-2000 | 25-09-2001 |
| Danone | High pressure pasteurization for fruit products | 29 | 03-12-1998 | 23-05-2001 |
| Purocur | Dextran from bacteria in bakery products | 21 | 02-04-1999 | 30-01-2001 |
| Avebe | Coagulated potato protein & hydrolysates | 21 | 25-05-2000 | 15-02-2002 |
| Morinda | Noni juice | 26 | 25-04-2000 | 12-06-2003 |
| Omega Tech/Mortox Bioscience | Oil rich in DHA (from micro algae) | 28 | 13-02-2001 | 12-06-2003 |
| Danisco | Salatrim | 53 | 28-06-1999 | 13-12-2003 |
| ADM | Phytosterols & phytostanols in various products | 28 | 02-11-2001 | 31-03-2004 |
| Pharmaconsult Oy | Phytosterols & phytostanols in various products | 30 | 24-09-2001 | 31-03-2004 |
| Unilever | Phytosterols in yoghurts | 19 | 06-08-2002 | 31-03-2004 |
| Teriaka | Phytosterols & phytostanols in various products | 34 | 15-05-2001 | 31-03-2004 |
| Novartis | Phytosterols & phytostanols in yoghurts | 30 | -7-09-2000 | 12-11-2004 |
| Cargill | Isomaltulose | 18 | 30-10-2003 | 04-04-2005 |
| Sudzucker | Isomaltulose | 18 | 04-03-2004 | 25-09-2005 |
| Pharmaconsult Oy | Phytosterols & phytostanols in bakery products (subsequently changed to rye bread only) | 56 | 24-09-2001 | 24-01-2006 |
| Karl Fazer | Phytosterols & phytostanols in bakery | 56 | 21-09-2000 | 24-01-2006 |

| | | | | |
|---|---|---|---|---|
| | products (subsequently changed to rye bread only) | | | |
| Laboratores Pharmascience | Maize germ oil high in unsaponifiable matter | 60 | 24-10-2001 | 24-10-2006 |
| Laboratores Pharmascience | Rapeseed oil high in unsaponifiable matter | 60 | 24-10-2001 | 24-10-2006 |
| Vitatene antibiotics | Lycopene from blakeslea trispora | 36 | 30-10-2003 | 23-10-2006 |
| ADM | Diacylglycerol oil in oils, fats, spreads, bakery products and yoghurts | 54 | 17-04-2002 | 23-10-2006 |
| Enzymotec | Oil enriched with phytosterols and phytostanols | 24 | 04-05-2005 | 15-05-2007 |
| Teriaka | Rice drink enriched with phytostanols | 39 | 12-10-2004 | 11-01-2008 |
| Wacher Chemie | Alpha-cyclodextrin | 44 | 19-10-2004 | 05-06-2008 |
| Croda Chemicals | Refined echium oil | 23 | 11-08-2006 | 08-07-2008 |
| Unilever | Allanblackia seed oil use in fat spreads | 47 | 30-08-2004 | 09-07-2008 |
| Phytotrade Africa | Baobab dried fruit pulp | 23 | 09-08-2006 | 11-07-2008 |
| Suntory | Arachidonia acid rich oil from mortieralla alpins | 102 | 18-06-1999 | 12-12-2008 |
| Morinda | Leaves of morinda citrifolin | 49 | 10-11-2004 | 31-12-2008 |
| Unilever | Ice structure protein type III HPLC 12 | 34 | 15-06-2006 | 25-04-2009 |
| NattoPharma | Vitamin K2 from bacillus subtilis natto | 40 | 20-12-2006 | 22-04-2009 |
| BASF | Synthetic lycopene in sunflower oil suspension | 42 | 19-10-2005 | 28-04-2009 |
| LycoRed | Lycopene oleoresin in tomatoes | 23 | 24-05-2007 | 30-04-2009 |
| Vitatene Antibiotics | CWD lycopene from blakeslea trispora | 21 | 30-08-2007 | 05-05-2009 |
| DSM | Lycopene from blakeslea trispora (synthetic lycopene) | 10 | 18-07-2008 | 01-05-2009 |
| Neptune Technologies | Lipid extract from Antarctic krill euphausa superba | 36 | 02-10-2006 | 13-10-2009 |
| Nutrinova | Additional uses for DHA rich algal oil from micro-algae ulkernia sp | 59 | 15-11-2004 | 28-10-2009 |

| | | | | |
|---|---|---|---|---|
| Martek Biosciences | DHA rich algal oil from schizochytrium sp | 21 | 14-01-2008 | 23-10-2009 |
| Viridis | Leaf extract from Lucerne | 35 | 12-10-2006 | 11-11-2009 |
| BNL Foods | Chia seed: whole and ground | 41 | 30-06-2003 | 11-11-2009 |
| Tahitian Noni International | Puree and concentrate of fruits of morinda citrifollia | 49 | 20-03-2006 | 23-04-2010 |
| Akzo Chemical | Ferric sodium EDTA | 47 | 04-07-2006 | 14-06-2010 |
| Nestec | Ferrous ammonium phosphate | 24 | 21-10-2008 | 25-11-2010 |
| GlycaNova | Mycellal extract of shitake mushroom | 37 | 19-12-2007 | 02-02-2011 |
| Kitozyme | Chitin-glucan from aspergillus niger | 37 | 15-01-2008 | 03-02-2011 |
| Senmi Ekisu | Sardine peptide | 33 | 12-05-2008 | 05-02-2011 |
| Nutrition 21 | Chromium picolinate | 25 | 06-04-2009 | 27-05-2011 |
| Glycanova | Beta gluten rich mycelial extract of shitake mushroom | 38 | 19-12-2007 | 03-02-2011 |
| National Starch | Phosphated maize oil | 72 | 23-08-2005 | 08-082011 |
| CBC Japan | Fermented black bean extract | 37 | 08-07-2008 | 10-08-2011 |
| Enzymotec | Soy phosphatidylserine rich phospholipids | 22 | 01-10-2009 | 15-08-2011 |
| Kaneka Pharma | Flavanoids from glycyrrhiza glabra | 49 | 30-10-2007 | 26-11-2011 |
| Bioethera | Yeast beta-glucans | 26 | 23-09-2009 | 26-11-2011 |
| Revolymer | Novel chewing gum | 45 | 11-03-2008 | 21-12-2011 |
| Wacher Chemie | Gamma-cyclodextrin | 28 | 26-02-2010 | 05-06-2012 |
| DMV International | Lactoferrin | 20 | 02-03-2011 | 27-11-2012 |
| Ajinomoto | Dihydrocapslate | 27 | 06-08-2010 | 27-11-2012 |
| DMV International | Bovine lactoferrin | 43 | 02-03-2009 | 27-11-2012 |
| Chia Company | Chia seed extended use | 21 | 14-04-2011 | 24-01-2013 |
| DSM | Synthetic zeaxanthin | 92 | 01-06-2004 | 24-01-2013 |
| BioIberica | Rooster comb extract | 34 | 09-02-2011 | 03-12-2013 |
| Miyarisan Pharma | Closridum butyricum | 34 | 02-02-2012 | 16-12-2014 |
| Reading University | Methyl vinyl ether-maleic anhydride copolymer | 54 | 30-06-2008 | 13-12-2014 |
| Functional Products Trading | Chia oil | 25 | 29-11-2012 | 10-12-2014 |
| Helm AG | Rapeseed protein | 24 | 25-06-2012 | 01-07-2014 |
| Kyowa Hakko | Citicoline | 28 | 29-03-2012 | 03-07-2014 |
| Lallemand | UV-treated bakers yeast | 26 | 04-05-2012 | 26-06-2014 |
| Nestec | Coriander seed oil | 32 | 21-07-2011 | 21-03-2014 |

| | | | | |
|---|---|---|---|---|
| Gnosis | S-methlytetrahydrofolic acid | 32 | 28-07-2011 | 21-03-2014 |
| DSM | Oil of micro algae schizochytrium sp | 20 | 31-08-2013 | 02-04-2015 |
| DSM | Extension of use for DHA and EPA rich oil from algae schizochytrium sp | 17 | 26-11-2013 | 02-04-2015 |
| **Average** | | **36** | | |

Source: Official journal of the European Communities

A comparison of the average time taken to approve novel products in other countries (Table 4) shows that the EU takes, on average, the longest time for novel food to complete the approval process, taking considerably longer than most other countries.[17]

**Table 4: Comparison of novel food approval process times: EU and other countries (selective products/ingredients of ELC members)**

| Novel food/ingredient | Time taken (months) for regulatory approval: EU | Time taken (months) for regulatory approval: other countries |
|---|---|---|
| Yellow fat spreads containing phytosterols | 31 | 1-23 |
| Lycopene from blakeslea trispora | 10-36 | 1-12 |
| Oil of micro algae schizochytrium sp | 20 | 8-19 |

Notes:

1. Yellow fat spreads containing phytosterols: other countries – Australia, Brazil, Canada, China, Japan, Switzerland and USA
2. Lycopene from blakeslea trispora: other countries China, Singapore, Philippines and Taiwan
3. Oil of micro algae schizochytrium sp: other countries Canada and the USA

### *4.3 The EU Health Claims regulation: time to authorise a speciality ingredient with a health claim*

The EU's Health Claims 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.

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.

[17] The author does, however recognise that due to different criteria used and procedures operated in various countries to approve novel foods, the time taken to approve novel foods between countries are not necessarily directly comparable

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 and health claims relating to children's development and health are covered by Article 14 of the Regulation and are therefore commonly referred to as Article 14 claims.

*a) Article 13.1 claims (general function claims)*

Article 13.1 claims (general function health claims) 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 together with lists of references substantiating each claim 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 claims.

The EFSA scientific opinions relating to the Article 13.1 claims were 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. The Commission subsequently, in September 2010, announced that the list of Article 13.1 claims would be adopted in two steps covering firstly, health claims for all food categories, foods and constituents of food other than botanicals and secondly, health claims for 'botanical substances'. The first of these two steps focusing on the non botanicals established a list of permitted health claims for non botanicals in 2012 (Regulation 432/2012 further amended by Regulations 536/2013 and 1018/2013). This authorised 236 health claims and rejected 1,876 claims.

Most of the authorisations 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).

*b) 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 August 2015, a total of 178 health claim decisions in these categories have been made (Table 5). Within these decisions, all but seven of the Article 13.5 claims were rejected, and less than a quarter of the Article 14 claims received approvals.

**Table 5: Article 13.5 and Article 14 health claim decisions by EU Commission (to 7 August 2015)**

| | **Accepted** | **Rejected** |
|---|---|---|
| Article 13.5 | 7 (5 with data protection and 2 without) | 92 |
| Article 14.1 (a) | 14 | 20 |
| Article 14.1 (b) | 11 | 39 |
| **Total** | **32** | **151** |

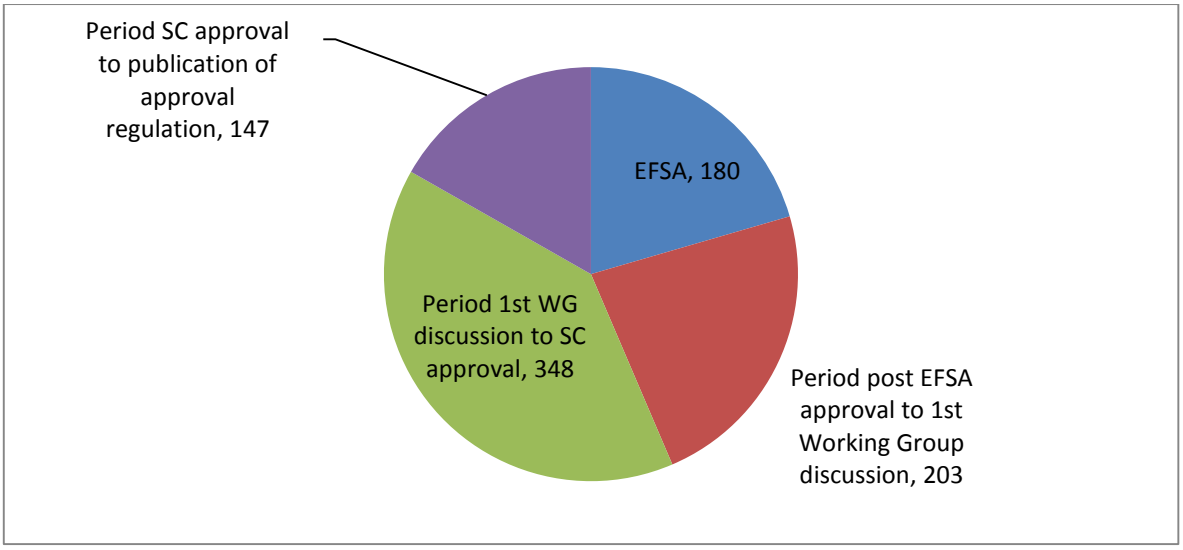
Source: DG Sante

Under the current legislative arrangements for approving health claims in the EU, companies seeking regulatory approval for a food product/ingredient with a health claim under article 13.5 or 14.1 present their dossiers supporting the request for regulatory approval to their relevant national regulatory authorities who then pass this on to EFSA. EFSA then undertakes the evaluation, before issuing its assessment report (opinion) to the EU Commission. A working Group of representatives from all member states and Commission officials examine the findings and prepare a draft decision which is then passed to the SCPAFF. The SCPAFF then discusses and votes to approve or reject the authorisation to use the health claim. After a favourable decision from SCPAFF, there is no further scrutiny of decisions for Article 13.5 claims. For Article 14 claims, the European Parliament and the Council have the right of further scrutiny on the Commission's (SCPAFF) decisions.

EFSA is required to deliver its opinion within five months and if supplementary information is requested from the applicant, EFSA has an additional 1-2 months for the evaluation (1 month for article 13.5 applications and 2 months for article 14.1 applications). There are, however, no time limit requirements placed on the Working Group and Standing Committee to complete their assessments and approvals.

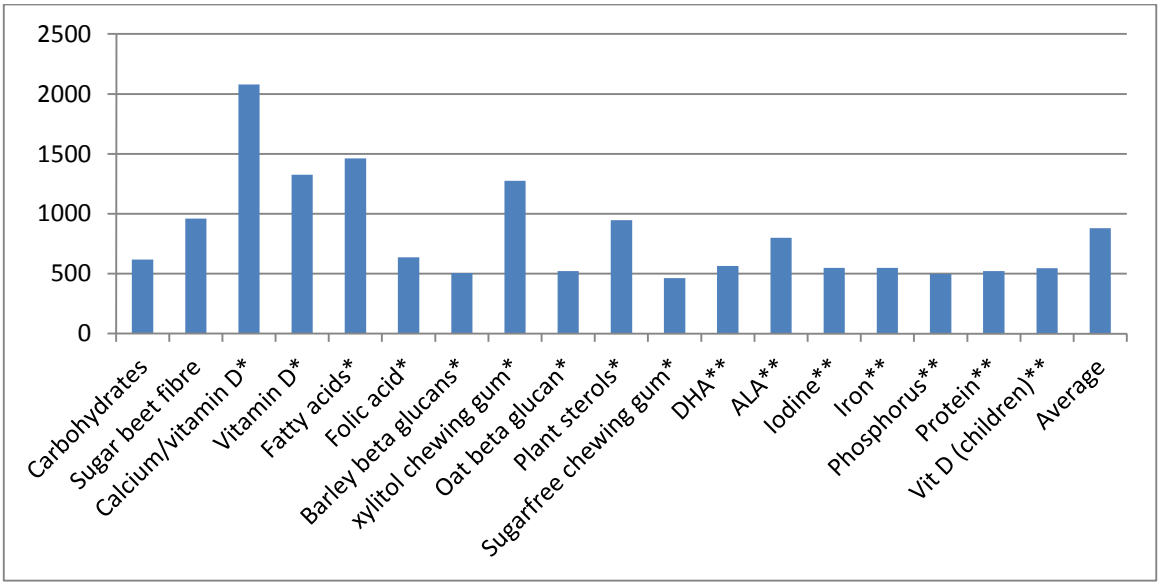
The average total time for giving approval for health claims has been about 2.5 years (Figure 2). The range of time taken to approve health claims is between 15 months and four and a half years (Figure 3).

**Figure 2: Average time taken to approve Article 13.5 and Article 14.1 health claims (days) in the EU (to September 2015)**




Source: derived from DG Sante

**Figure 3: Average time taken to approve Article 13.5 and Article 14.1 health claims (days) in the EU (to September 2015) by type of claim**




Source: derived from DG Sante
Notes: No asterisk = article 13.5, * = article 14.1a, ** = article 14.1b

EFSA usually completes its assessments within the time limits required, with the delays in approval being mainly after the delivery of the scientific opinion by EFSA. Eighty per cent of the total time taken from application to approval of health claims is taken up by post-EFSA Opinion deliberations, with an average of 7 months time elapsing before the Working Group holds its first discussions on the scientific opinions issued by EFSA. The average time then taken from first

discussions in the Working Group to voting in SCPAFF is a year. An insight into some of the delays in the process of approval is provided below in the overview of the approval process for health claims associated with two claims; one for vitamin D, an article 14.1a claim which took a total of 49 months before being approved and one for native chicory inulin, an article 13.5 claim which took a total of 20 months for approval (Table 6 and Table 7).

**Table 6: Vitamin D (article 14.1a) health claim:[18] approval timing schedule**

| Activity/action | Date | Comments |
|---|---|---|
| Submission received by EFSA | 13-10-2010 | EFSA evaluation starts on 15-11-2010 |
| EFSA requests additional (missing) data from applicant | 21-01-2011 | Clock stops |
| Applicant submits missing data | 26-05-2011 | Scientific evaluation procedures formally start |
| EFSA Opinion published | 30-09-2011 | |
| Working Group on nutrition and health claims first meeting examining EFSA Opinion | 12-11-2011 | Dis-agreements amongst members of Working Group on conditions of use and how these relate to maximum recommended daily allowances set at member state levels. Also agreement stalled by waiting for EFSA Opinion on safety of vitamin D and tolerable upper intake limits (Commission asked EFSA to re-evaluate in December 2010) |
| EFSA Opinion on safety of vitamin D and tolerable upper intake limits | 26/06/2012 | Revision of tolerable upper intake limit (UL) from 50 ug/day to 100 ug/day for adults |
| SCPAFF votes a favourable Opinion on the health claim with conditions of use | 13-06-2014 | Discussion on the wording and conditions of use of the health claim |
| Publication of authorisation for use of the health claim | 17-11-2014 | Even though the health claim was authorised, the existence of some national maximum limits in food supplements that are lower than the minimum required to deliver this health claim in some member states (for food supplements containing these substances) means that the health claim cannot be used in these member states |

**Table 7: Native chicory inulin (article 13.5 with protection of proprietary data) health claim:[19] approval timing schedule**

| Activity/action | Date | Comments |
|---|---|---|
| Submission to member state (Belgium) | 16-05-2014 | |
| Transfer of dossier from member state to EFSA | 26-05-2014 | |
| Submission received by EFSA | 06-06-2014 | EFSA evaluation starts on 02-07-2014 |
| EFSA requests additional data from applicant | 11-07-2014 | Clock stops |

[18] Vitamin D helps to reduce the risk of falling associated with postural instability and muscle weakness

[19] Native chicory inulin contributes to normal bowel function by increasing stool frequency

| | | |
|---|---|---|
| Applicant submits missing data | 25-07-2014 | Scientific evaluation procedures re-start and clock starts again |
| EFSA requests additional data from applicant | 23-10-2014 | Clock stops |
| Applicant submits missing data | 04-11-2014 | Scientific evaluation procedures re-start and clock starts again |
| EFSA Opinion published | 09-01-2015 | |
| Working Group on nutrition and health claims first meeting examining EFSA Opinion | 31-03-2015 | |
| SCPAFF votes a favourable Opinion on the health claim | 04-11-2015 | Period from the end of March 2015 includes notification of WTO at the end of June 2015, receipt of a comment from the US at the end of August 2015 and an EU response to this query on 13 October 2015 |
| Publication of authorisation for use of the health claim | 12-12-2015 | Entry into force of Commission Regulation (EU) 2015/2314 on 01-01-2016 |

These examples[20] highlights the impact of comitology delays in which there are no time limit requirements on the Working Group and the Standing Committee to discuss, consider and vote on each of the health claim dossiers and scientific opinions provided by EFSA.

As well as these regulation-specific delays tending to be longer in the EU than most other markets, this can be compounded by requirements for authorisation arising from several regulations, in particular where the process of authorisation under one regulation cannot/does not begin until authorisation under another regulation has taken place. Evidence from the industry survey identified instances where authorisations were first required for novel foods before health claims were to be considered and where approval of enzymes had to take place before a novel ingredient application would be assessed. Where this occurs, the total regulatory delay between starting the process of seeking regulatory approval in the EU to the point at which all relevant authorisations have been given can be between five and seven years.

### *4.4 Impact of authorisation time delays on the attractiveness to invest & innovate in novel ingredients/foods*

In order to identify the impact of the approval mechanisms on the European specialty food ingredient sector, the members of ELC were asked, in 2015, to provide relevant information on how the mechanism has been used. The analysis presented below therefore draws on the findings of this request for information. It examines the value of expected/targeted sales associated with new (novel) ingredients if they had received approval within a relatively short period of time (typically 12-18 months) compared to the longer approval processes in the EU (eg, for novel foods an average of 36 months). It also considers the cost of bringing products to market.

The analysis presented below is based on information provided by member companies of the ELC. Due to the wide variations in the nature of products and their potential markets (sizes) and in order to protect company-specific data confidentiality, the analysis presented is based on an 'average' or

[20] One, a fairly extreme one in terms of time taken for approval compared to the average time of 2.5 years

indicative product example. Additional 'high' and 'low' ranges for sales/revenue assumptions are presented, along with detailed information, in Appendix 1.

The primary value to the food ingredient industry of having a reliable and relatively quick process for approving a novel ingredient or product derives from the opportunity to begin commercial sales at an early date and hence begin to receive revenue against the investment cost of new product research and development as soon as possible. This can have a positive impact on the returns when discounted to take into account risk factors and the time flow of revenue streams and hence influence the relative attractiveness (or otherwise) of a new (novel) ingredient investment.

This can be illustrated by examining representative product life cycles for a new/novel ingredient/product, its revenue and cost streams and how changes in the time taken to gain regulatory approval impacts on the returns derived and the profitability/attractiveness of an investment. As indicated above, the reader should note that the revenue streams presented in the analysis are based on indicative average or representative revenue flows for the novel ingredients/products authorised for sale in a number of markets around the world.

### 4.4.1 Global product life cycle returns using approval mechanisms with a relatively short procedure (12-18 months)

Figure 4 illustrates the average gross income or margin (cash) flow for a new (novel) ingredient/product with a range of income flows and with a typical (average) expected life cycle of 10 years. Key points to note are:

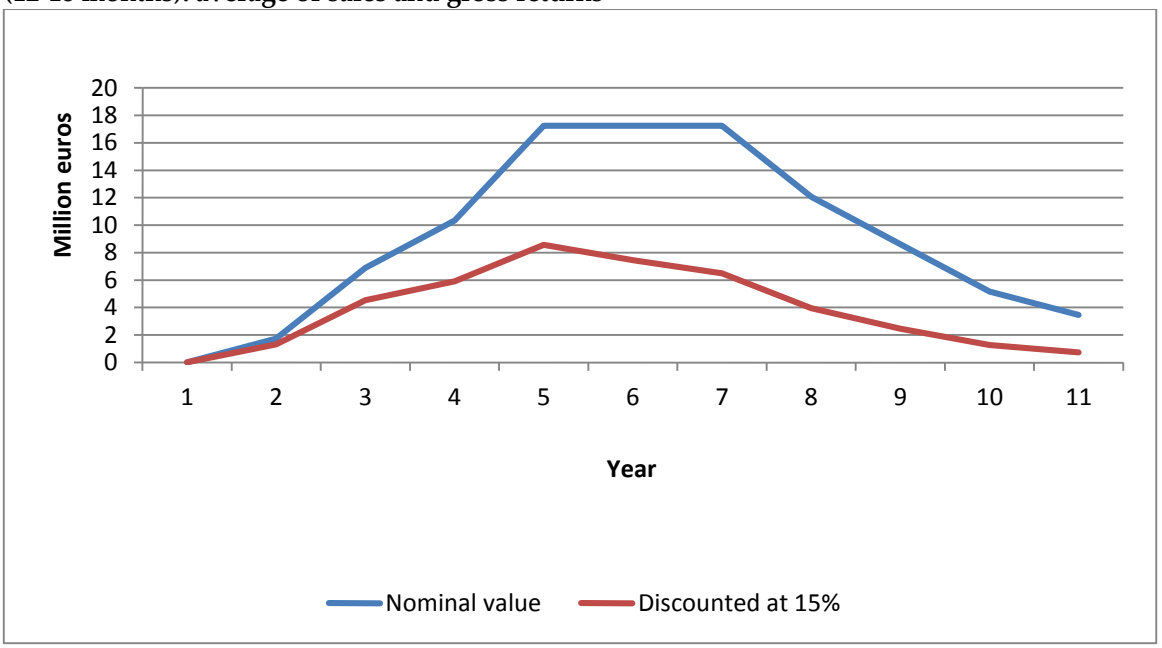
- Expected sales revenue (over 10 years and in current monetary terms) are €200 million with the expected gross margin (in current monetary terms) of €100 million;
- Where products are given regulatory approval for release onto markets within a timeframe of 12-18 months, the discounted gross return (discounted at 15%[21]) is €42.7 million. After consideration of the costs[22] of bringing this product to market are taken into consideration, the discounted gross margin return is €27.7 million;
- The internal rate of return on the investment (against a target of 15%-25% which is commonplace in the food industry) is 21.3%. In terms of payback,[23] this takes about four years relative to a typical industry target of 3-5 years.

[21] The gross margin returns are standard expected return on sales revenue after production costs (excluding marketing, stewardship, research and development). The expected gross margin return used is 50%. In relation to discounting of revenue and income streams (for factors such as the cost of borrowing and risk) businesses in the food sector commonly discount at rates between 15% and 20%. A discount rate of 15% has been used in this analysis.

[22] The average cost of developing a new product and bringing to the global market was €15 million (range €10 to €20 million) on a global basis. Within this, costs associated with meeting regulatory approval requirements that are fairly generic to leading markets (eg, US and Japan) can account for up to 50% of the total cost of bringing a novel ingredient/food to the global marketplace. As indicated above, the additional nature of some requirements in the EU approval process (relative to requirements in other markets) adds between €1 and €2 million to overall (global) regulatory compliance costs

[23] When the costs of bringing a product to market, including research, development and regulatory costs have been re-couped

**Figure 4: Product life cycle gross margin returns flow with a relatively short approval process (12-18 months): average of sales and gross returns**



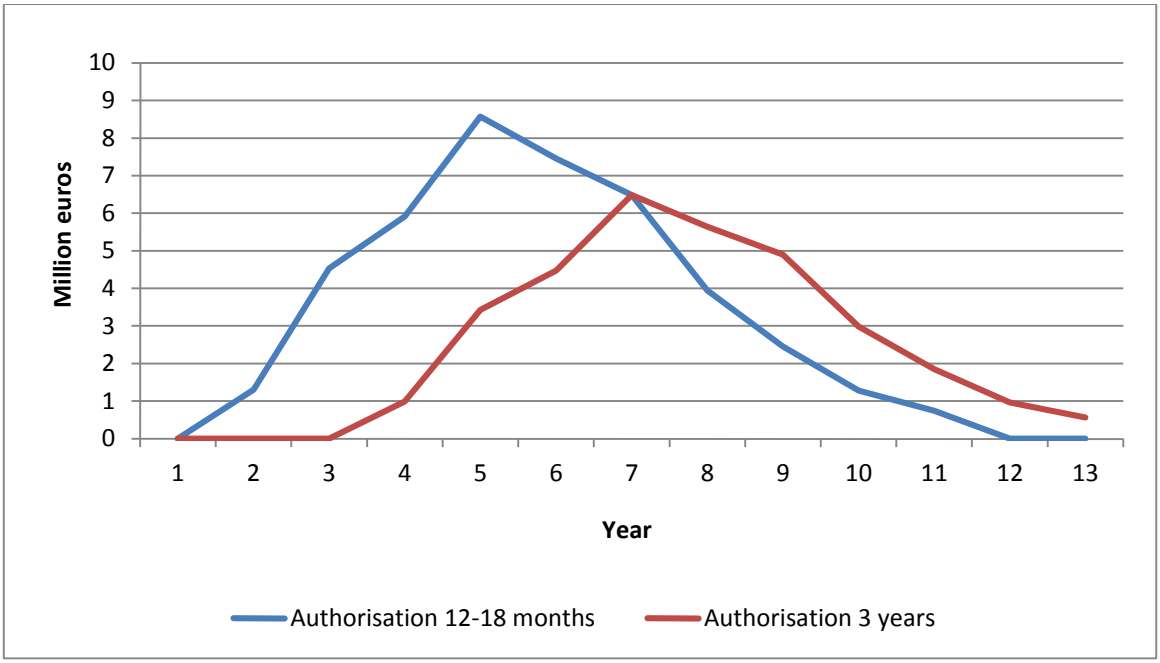

## 4.4.2 Product life cycle returns using an approval mechanism with a longer time period[24]

Figure 5 illustrates the average gross income or margin (cash) flow for the same novel ingredient/product when the authorisation time is delayed to 3 years. The main differences relative to the returns when the authorisation time is only 12-18 months are:

- The discounted gross return (discounted at 15%) is €32.2 million. After consideration of the costs of bringing these products to market are taken into consideration, the discounted gross margin return is €17.3 million;
- The time delay in authorisation results in a decrease in the discounted gross returns of €10.4 million;
- The internal rate of return on the investment falls by more than half to 10.6% below the target range of 15% to 25%. Even if a 'high' sales and returns assumption is used (see appendix 1, the internal rate of return is a very low 7.3%. In terms of payback, the cost of bringing products to markets takes about 7 years to recoup. Hence, an average time delay in authorisation of three years compared to one year reduces the relative attractiveness of investment as the IRR is below the industry average target level and the payback is too long.

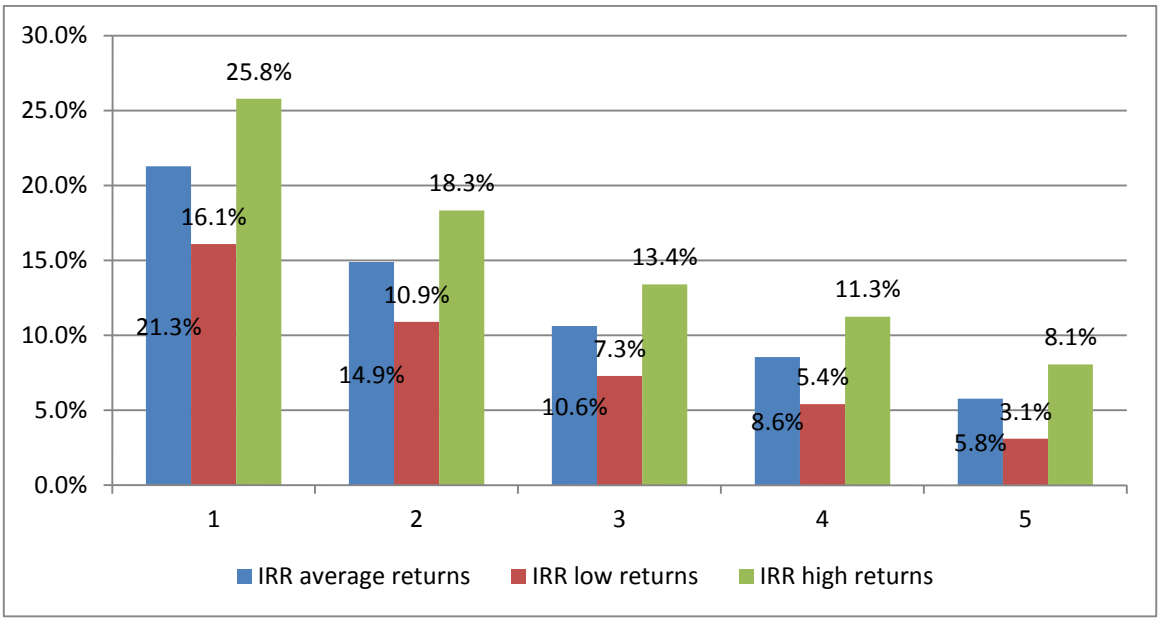
[24] Main example shown is for 3 years - indicative of the average time taken to approve novel foods in the EU since 1997

**Figure 5: Discounted gross returns: average sales and returns range for different regulatory approval time periods (million euros)**




In summary, the impact of delays in authorisation results in significant reductions in the internal rate of return (Figure 6). An average internal rate of return (IRR) of over 21% may be achieved if approval is received in 12-18 months, as applies to novel foods/ingredients in many countries. However, if authorisation was delayed to three years, as is the average for novel foods/ingredients in the EU, the average IRR falls to about 10.6% and if, for example the delay was five years (as might apply if a new ingredient was a novel ingredient which was to be sold in the EU with a health claim and for which the health claim authorisation process did not start until the novel ingredient authorisation had been given), then the IRR falls to 5.8%. Even for a novel ingredient with 'high' expected returns, the IRR with a five year delay in authorisation is only about 8%. These estimated IRR values compare with the target range for IRRs in the sector of between 15% and 20% (some companies may consider bringing a new product/ingredient to market if the IRR is higher than 10%). Similarly, in payback terms, an authorisation delay of three years compared to 12-18 months means that payback takes 7 years compared to 4 years and if authorisation is delayed to 5 years, payback is extended to 10 years, significantly longer than the industry target of 3-5 years.

**Figure 6: Impact of delays (years) in authorisation on internal rate of return**




Note/assumption: average returns basis - total €200 million sales revenue over 10 years' life of product, low returns total €160 million, high returns €240 million

### 4.4.3 The context and impact of the delays in the EU authorisation process for globally marketed specialty food ingredients

Whilst section 4.4.2 above shows the impact on income and returns of general delays in a regulatory authorisation process, the global nature of the specialty food ingredients market means that the asynchronous nature of the authorisation process in different markets complicates the assessment of the impact of regulation on returns.

On the evidence identified in this research, the average time taken to go through the regulatory approval process for novel foods in some of the main global markets (the US, Canada, Japan, Australia/New Zealand, China, Brazil) is 12-18 months. This compares with 3 years in the EU. Similarly in relation to health claims, there is also a disparity, whereby in the EU, the average time to complete the authorisation process is 30 months compared to again an average of 12-18 months in many other countries.[25] Furthermore, there may be instances where the EU delays can be significantly longer than these average delays, for example when a new ingredient requires both novel foods and health claims approval and the health claim approval process is influenced/dependant upon the novel foods approval (eg, where the regulatory authority assessing the health claim is awaiting the safety assessment relating to that ingredient as part of the novel foods approval process), this could result in the total regulatory delay being between 5 and 7 years.

Based on these timelines, Figures 7-9 show the impact of the longer EU authorisation process on global returns for novel ingredients/products. Key points to note are:

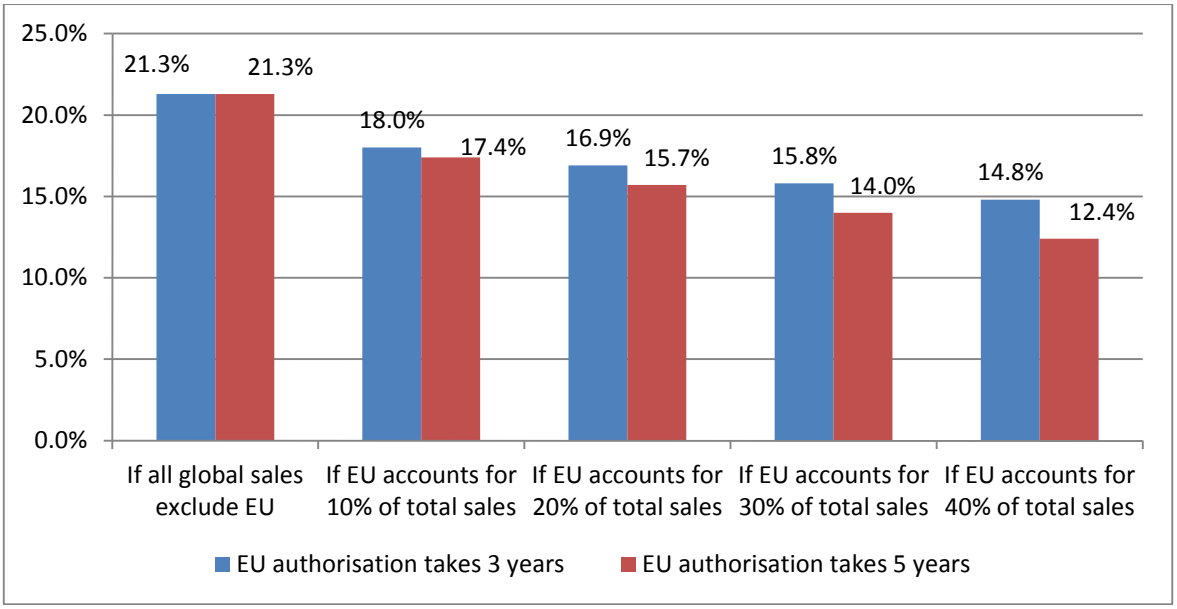
[25] And in the US, if the claim is classified as a structural/functional claim, there is no requirement to seek approval from the authorities

- If a novel ingredient/product with the expected average level of sales and income referred to in section 4.4.2 is sold exclusively in countries where the authorisation process is 12-18 months, the internal rate of return is likely to be about 21%, and therefore within the higher part of the preferred target range of specialty food ingredient companies. If achievement of these sales volumes is, however significantly dependant of sales in the EU market (eg, the EU is expected to account for 40% of total sales), the expected internal rate of return falls to under 15% when the authorisation process takes three years, which is the low end of the preferred IRR range for most companies. If the EU authorisation process takes five years, the IRR falls to 12.4%. At this level of dependence on the EU market and these levels of return, some companies are likely to decide not to bring a new specialty ingredient/product to market (globally) at all or, at best, view the investment as marginal, especially if the authorisation process takes five years;
- Where the novel ingredient/product is expected to have 'low' returns in the global market, investment in bringing this product to market is likely to be viewed as acceptable for some (not all) companies if all expected sales can be realised outside the EU. If the EU is expected to be an important part of the global market (30%-40% of total sales), the decline in the expected internal rate of return to between 8.4% (EU authorisation takes five years) and 10.9% (if the EU authorisation takes three years) is likely to halt all consideration of investment in bringing this ingredient/product to market;
- If the novel ingredient/product is expected to achieve 'high' returns and these can be achieved outside the EU, healthy returns of 25% would be expected. Where the EU is expected to be a significant part of any global market, the expected internal rate of return would fall to between 16%-18% (if the EU authorisation takes five years) and 18%-19% (if the EU authorisation takes three years). This would make investment in bringing such new ingredients to market less attractive and may deter some companies from bringing these products to market.

Overall, this analysis suggests that the delays in the EU authorisation process for novel ingredients/products and health claims may have made an important negative contribution to some novel ingredients/products being brought to market. How this ultimately affects the market depends on several factors such as expected global sales, the importance of the EU market relative to other markets, whether target sales can reasonably be expected to be achieved in markets outside the EU and the influence of EU authorisation on regulatory authorities in other countries:

- If companies perceive they have reasonable scope for achieving target sales outside the EU and the EU is a relatively small part of their target market, they have a financial incentive to seek regulatory approval for novel ingredients/products only in markets outside the EU. In this case, the novel ingredient/product is not brought to the EU market at all, or may be brought to the EU market a few years later only after successful and profitable sales elsewhere. EU food manufacturers and EU consumers therefore lose out in terms of fewer novel ingredients/products being brought to market compared to other markets;
- Where the EU is expected to be an important part of the global market for a novel ingredient/product, the impact of the longer EU authorisation process may result in novel ingredients/products not being brought to market at the global level because the expected global returns fall below target levels.

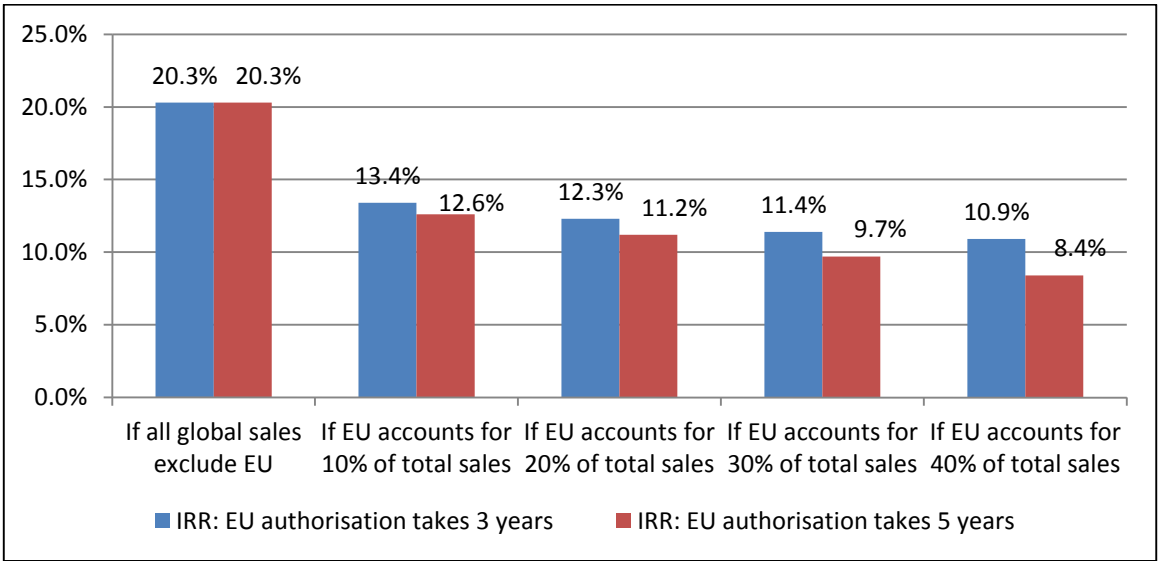
**Figure 7: Impact of the EU's longer authorisation process for novel ingredients/products on global returns (% internal rate of return): average returns basis**




Notes:

1. Target internal rate of return typically 15%-20%
2. Assumptions: EU market authorisations take 3 years and the authorisations in the rest of the world take 12-18 months

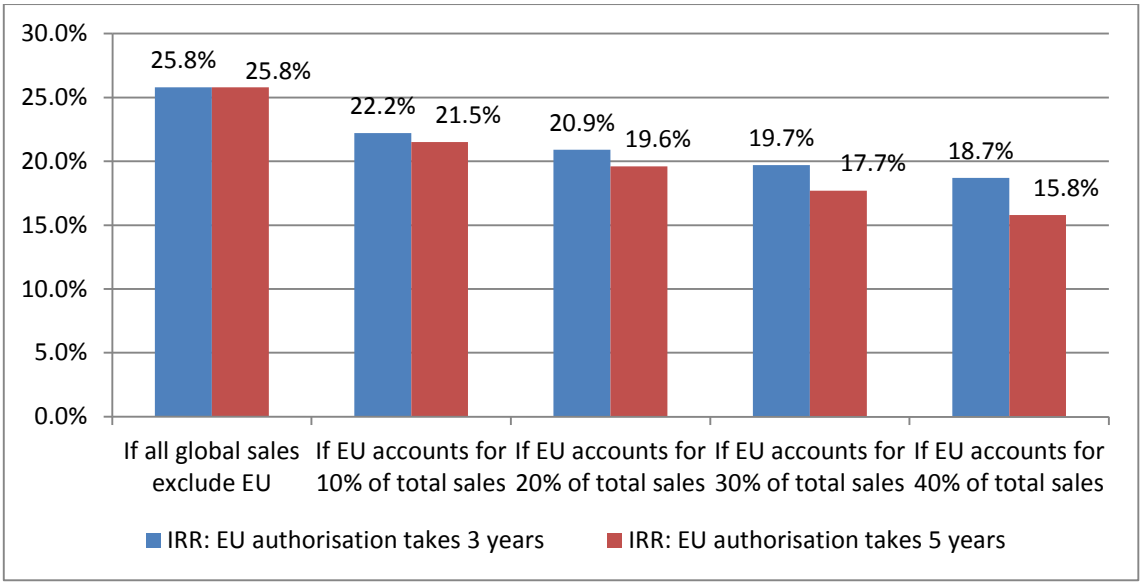
**Figure 8: Impact of the EU's longer authorisation process for novel ingredients/products on global returns (% internal rate of return): low returns basis**




Notes:

1. Target internal rate of return typically 15%-20%
2. Assumptions: EU market authorisations take 3 years and the authorisations in the rest of the world take 12-18 months

**Figure 9: Impact of the EU's longer authorisation process for novel ingredients/products on global returns (% internal rate of return): high returns basis**




Notes:

1. Target internal rate of return typically 15%-20%
2. Assumptions: EU market authorisations take 3 years and the authorisations in the rest of the world take 12-18 months

### 4.4.4 Uncertainty issues

An important 'negative' factor influencing innovation is uncertainty. This has, and continues to, impact on the attractiveness or otherwise of a market and hence on the scope for new products or ingredients being brought to both the EU and global markets in two main ways:

*a) Legal uncertainty*

Legal uncertainty relates to the legal status of a product/ingredient - whether it is classified as a novel food or ingredient for the purposes of complying with the Novel Foods Regulation or whether a health claim is likely to be allowed or not.

Legal status uncertainty can have negative economic implications for, or impose additional costs on, companies considering bringing products to markets. This category of economic cost or dis-incentive to invest or bring novel foods/ingredients (and/or products with health claims), is however not easily recognised, categorised or quantified. The evidence identified in this study confirms that legal uncertainty is perceived to be a negative influence on innovation and confirms the assertions of others (eg, Coppens P (2013), Bremmers H J and Van der Meulen B (2013)). This study also identified that specialty food ingredient companies perceive that there is greater legal uncertainty associated with the EU regulatory system compared to the regulatory systems in other countries.

*b) Uncertainty about the process and time taken for deciding on a novel food/ingredient authorisation*

This relates to uncertainty about how long a decision to authorise a novel food/ingredient will take, how long a health claim will take to be authorised (or rejected) or when a health claim authorisation can be sought or considered by regulatory authorities when it accompanies a novel ingredient.

Companies planning to bring new products to the EU market that are awaiting novel food authorisation have to plan their product launches against a background of potential new entrants to their market very soon after authorisation has been granted. As such, it is in the interests of the notifying company to bring the product to market as soon as possible after authorisation in order to maximise the time the product is on sale before competition enters the market. Also if an ingredient is to be marketed with a health claim, this health claim is often considered to be of great importance for market success - without a health claim, the rationale for consumers being interested in buying a new product/ingredient is likely to be significantly diminished.

Against this background, bringing a product to market takes time to plan and execute. Therefore, uncertainty relating to when/if a novel product authorisation will be granted or a health claim authorised, adds risk and results in costs that might otherwise have not been incurred. For example, a company planning to launch a new ingredient/product has to manufacture the product/ingredient, label it and provide supporting promotional literature directed at customers (which might be food manufacturers and/or end consumers). What should be included on the label?, will a health claim be allowed?, what can be included in promotional literature?. If all these aspects of launching a new ingredient/product are undertaken in anticipation of authorisation and this authorisation is either delayed or not authorised, it may result in unrecoverable costs (eg, having to re-label or postpone launches).

### 4.4.5 Impact on competitiveness, employment and consumers

Innovation is important for businesses if they wish to be profitable and remain competitive because it contributes to the development of improved products and may offer scope for improving productivity/lowering costs of production. Consequently, companies looking to innovate prefer to locate their research, development and marketing focus in regions and markets which they perceive as being more, rather than less innovation-friendly. This means that innovation-friendly countries and regions tend to have higher levels of income generation, value added and employment than countries and regions that are less innovation-friendly.

As indicated above, regulation plays an important role in influencing levels of innovation, where research and development is conducted and which markets are prioritised for new product/ingredient development. The longer regulatory authorisation processes for food ingredients and higher levels of 'regulatory uncertainty' in the EU compared to most other countries is contributing to lower rates of return and less willingness of specialty food ingredient businesses to invest in new ingredient development for the EU market. In the long run this is likely to have resulted in lower levels of investment, value adding and employment in the specialty food ingredient sector located in the EU than would otherwise have occurred if relevant

EU regulations were implemented in a more-timely manner and with greater degrees of legal certainty.

In relation to consumers, there are two ways in which consumers may be affected:

- *Impact on prices paid:* markets which have lower levels of productivity-enhancing new ingredient/product development tend to have higher costs and prices than in other markets. As such, it is possible that EU consumers may be paying higher prices for some foods/ingredients relative to the prices paid for similar products in other markets where productivity enhancing ingredient innovation is more readily applied;
- *Impact on availability and quality of products:* given the analysis above shows that the EU is a less attractive market for selling new ingredients in, it is likely that there are fewer new specialty food ingredients and foods available to EU consumers than are available in other markets. EU consumers may be losing out in terms of both the quantity and quality of food ingredients and products available.

# Appendix 1: Product life cycle returns and the internal rate of return

Three levels of product life cycle and internal rate of return analysis have been used. These represent an average (mean) plus two elements of a range (low and high).

For each, the expected life of a product is 10 years.

Assumed rate of discount = 15%

Assumed gross margin return 50%

**Average (million euros)**

| Year | Expected sales | Expected gross margin | Discounted value of margin assuming first sale in year 1-2 (ie, approval for sale given 12-18 months after application) | Discounted value of margin assuming first sale in year four (ie, approval for sale given 3 years after application) |
|---|---|---|---|---|
| 0 | -15 | -15 | -15 | -15 |
| 1 | 3.45 | 1.72 | 0 | 0 |
| 2 | 13.79 | 6.90 | 1.3037 | 0 |
| 3 | 20.69 | 10.34 | 4.5346 | 0 |
| 4 | 34.48 | 17.24 | 5.9147 | 0.9858 |
| 5 | 34.48 | 17.24 | 8.5720 | 3.4288 |
| 6 | 34.48 | 17.24 | 7.4539 | 4.4723 |
| 7 | 24.14 | 12.07 | 6.4817 | 6.4817 |
| 8 | 17.24 | 8.62 | 3.9454 | 5.6362 |
| 9 | 10.34 | 5.17 | 2.4505 | 4.9011 |
| 10 | 6.90 | 3.45 | 1.2785 | 2.9833 |
| 11 | | | 0.7412 | 1.8530 |
| 12 | | | | 0.9668 |
| 13 | | | | 0.5604 |
| **Total** | **200** | **100** | **42.6762** | **32.2693** |
| **Total after deducting cost of bringing product to market** | **185** | **85** | **27.6762** | **17.2693** |
| **Internal rate of return** | | | **21.28%** | **10.61%** |

**Low (million euros)**

| Year | Expected sales | Expected gross margin | Discounted value of margin assuming first sale in year 1-2 (ie, approval for | Discounted value of margin assuming first sale in year four (ie, approval |
|---|---|---|---|---|

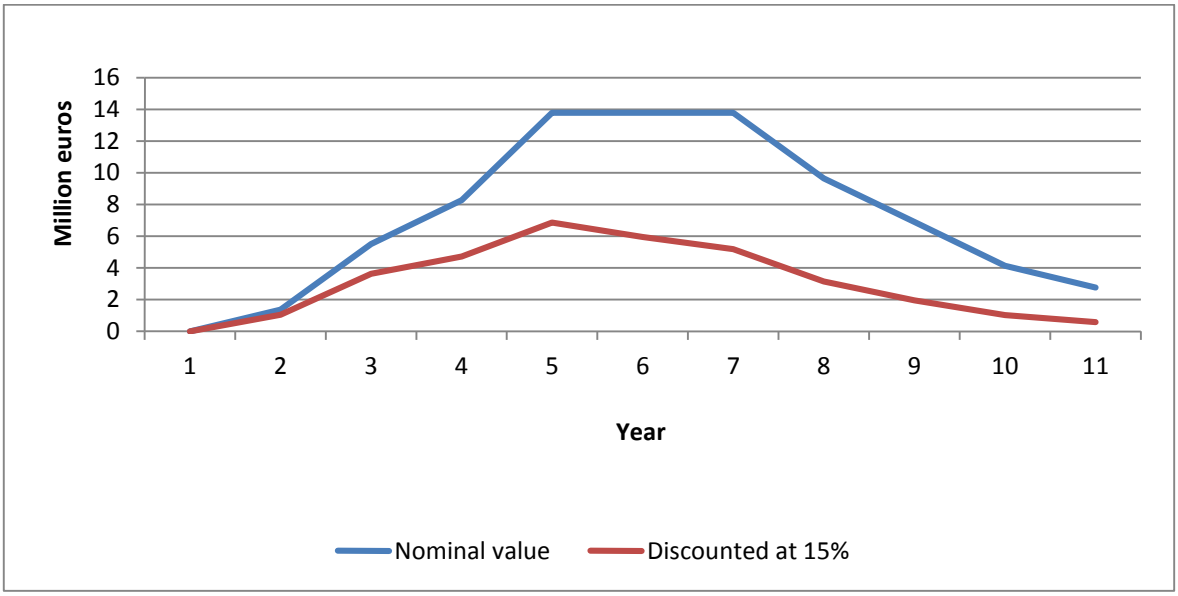
| | | | sale given 12-18 months after application) | for sale given 3 years after application) |
|---|---|---|---|---|
| 0 | -15 | -15 | -15 | -15 |
| 1 | 2.76 | 1,379 | 0 | 0 |
| 2 | 11.03 | 5.517 | 1.043 | 0 |
| 3 | 16.55 | 8.276 | 3.628 | 0 |
| 4 | 27.59 | 13.793 | 4.732 | 0.789 |
| 5 | 27.59 | 13.793 | 6.858 | 2.743 |
| 6 | 27.59 | 13.793 | 5.963 | 3.578 |
| 7 | 19.31 | 9.655 | 5.185 | 5.185 |
| 8 | 13.79 | 6.897 | 3.156 | 4.509 |
| 9 | 8.28 | 4.138 | 1.960 | 3.921 |
| 10 | 5.52 | 2.759 | 1.029 | 2.387 |
| 11 | | | 0.593 | 1.482 |
| 12 | | | | 0.773 |
| 13 | | | | 0.448 |
| **Total** | **160** | **80** | **34.141** | **25.815** |
| **Total after deducting cost of bringing product to market** | **145** | **65** | **19.141** | **10.815** |
| **Internal rate of return** | | | **16.13%** | **7.35%** |

**High (million euros)**

| Year | Expected sales | Expected gross margin | Discounted value of margin assuming first sale in year 1-2 (ie, approval for sale given 12-18 months after application) | Discounted value of margin assuming first sale in year four (ie, approval for sale given 3 years after application) |
|---|---|---|---|---|
| 0 | -15 | -15 | -15 | -15 |
| 1 | 4.14 | 2.069 | 0 | 0 |
| 2 | 16.55 | 8.276 | 1.564 | 0 |
| 3 | 24.83 | 12.414 | 5.442 | 0 |
| 4 | 41.38 | 20.690 | 7.098 | 1.183 |
| 5 | 41.38 | 20.690 | 10.286 | 4.114 |
| 6 | 41.38 | 20.690 | 8.945 | 5.367 |
| 7 | 28.97 | 14.483 | 7.778 | 7.778 |
| 8 | 20.69 | 10.345 | 4.734 | 6.763 |
| 9 | 12.41 | 6.207 | 2.941 | 5.881 |
| 10 | 8.28 | 4.138 | 1.534 | 3.580 |
| 11 | | | 0.889 | 2.223 |
| 12 | | | | 1.160 |
| 13 | | | | 0.672 |
| **Total** | **240** | **120** | **51.211** | **38.723** |

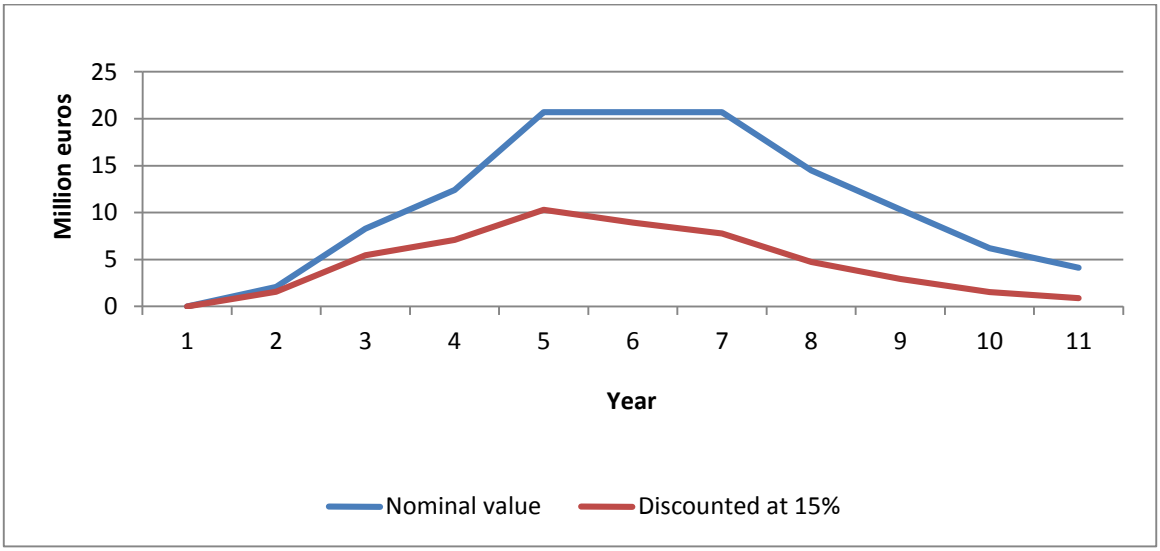
| | | | | |
|---|---|---|---|---|
| **Total after deducting cost of bringing product to market** | | | **36.211** | **23.723** |
| **Internal rate of return** | | | **25.78%** | **13.39%** |

**Product life cycle gross margin returns flow with a relatively short approval process (12-18 months): low end of range of sales and gross returns**

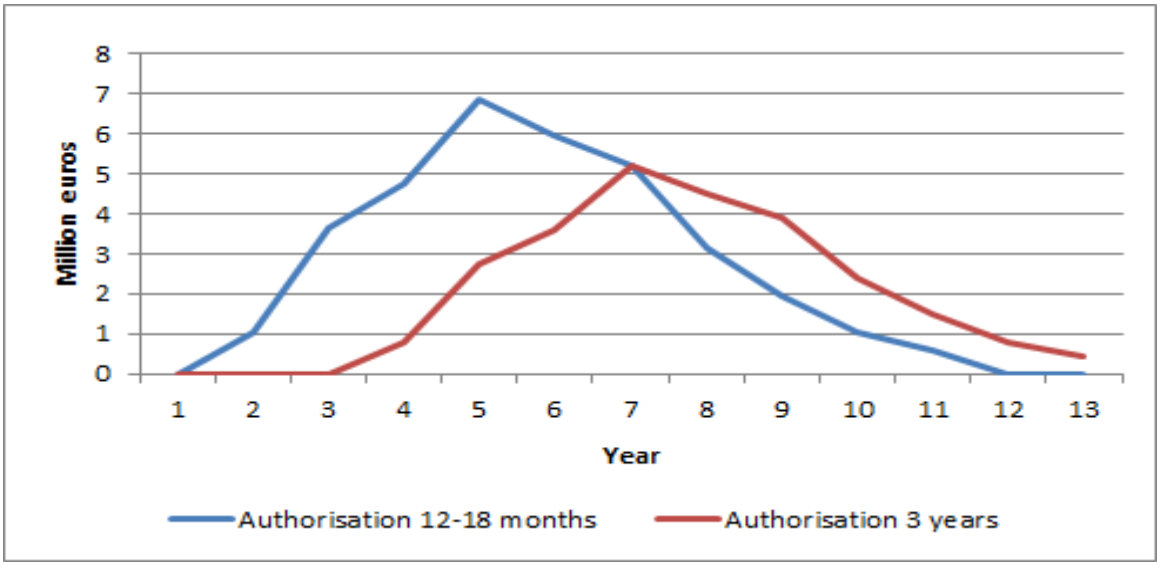



Note: nominal value refers to the returns in current monetary terms

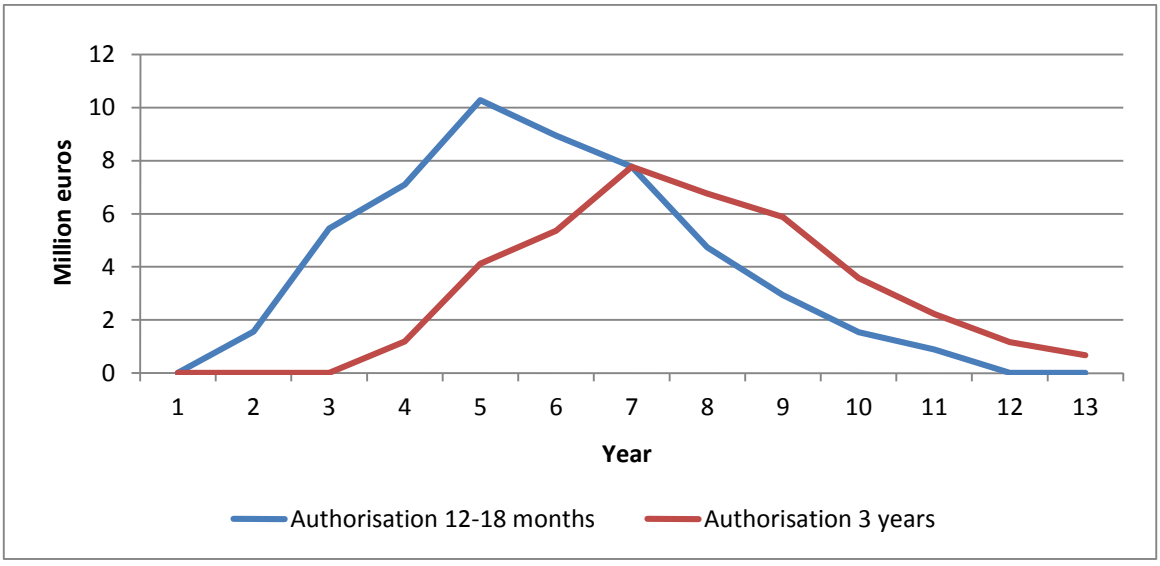
**Product life cycle gross margin returns flow with a relatively short approval process (12-18 months): high end of range of sales and gross returns range**



**Discounted gross returns: low sales and returns range for different regulatory approval time periods (million euros)**




**Discounted gross returns: high sales and returns range for different regulatory approval time periods (million euros)**



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