Briefing paper

Economic impact assessment of the way in which the EU novel foods regulatory approval procedures affect the EU food sector

For the Confederation of the Food and Drink Industries of the European Union (CIAA) & the Platform for Ingredients in Europe (PIE)

by

Graham Brookes

GBC Ltd

July 2007

Table of contents

Executive summary and conclusions

This report presents the findings of an economic impact analysis of the EU's Novel Foods Regulation.

Overview of the EU market (section 3)

1. The EU food and drink sector has the largest turnover of manufacturing sectors in the EU (nearly 14% of the total). Within the sector, Small, Medium Enterprises (SMEs) dominate, accounting for over 99% of the total number of companies, generating nearly half of total turnover and employing over 60% of the workforce.

2. The average level of research and development (R&D) intensity in the EU (0.24%) is below comparable levels of R&D expenditure in competitor countries, although the level of R&D expenditure as a % of total output in the leading 20 EU food and drink companies was comparable with the rates amongst the leading non EU food and drink companies (a range of 1.3% to 4.6% for the leading six companies).

3. In terms of innovation type, out of the five main categories (pleasure, health, fitness, convenience and ethics), the leading innovation categories in the EU market are pleasure, convenience and health. Although it is difficult to put novel foods into these categories (reflecting the broad definition of a novel food), the majority of authorised novel products probably fall into the categories of health and fitness.

Impact of regulation on the decision to launch a new product (section 4)

4. The primary criteria determining whether a novel product is brought to market is whether the company undertaking the R&D is reasonably confident that a new product will earn a reasonable rate of return relative to the cost of investment. In general, food companies are looking for internal rates of return on their investment within a range of 20% to 25%. In terms of gross returns, the typical target for a new product is 35%.

5. The decision to launch a new 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) products that better meet consumer wants, without acting as a dis-incentive to industry to bring forward products to the market.

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

   - Efficient and transparent procedures;
   - A consistent and minimal 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.

Time to authorise novel foods (section 4.2.1)

7. The average time taken to authorise the sale of novel foods in the EU market since 1997 has been 35 months (range 16-60 months). This is considerably longer than the authorisation time in most other countries.

Cost of bringing a novel product to market & meeting regulatory requirements (section 4.2.2)

8. The cost of bringing a novel food to market (inclusive of R&D costs) varies considerably. At a global level it falls within the range of €4 million to €15.4 million. Within this total, the cost associated with meeting regulatory requirements (for safety, efficacy, etc studies - that are fairly common to most markets) is between €0.3 million and €4 million.

9. The considerable additional time taken to authorise novel foods in the EU (see 7. above) adds to the cost of meeting regulatory requirements (by between €0.3 million and €0.75 million per novel food application).

Impact of delays in authorising novel foods on the attractiveness of bringing products to the EU market (section 4.2.2)

10. If approval of novel food products occurs within 6 months of an application, food companies would typically expect to earn gross returns (after costs) over the lifetime of the product (budgeted for an average life of 15 years) of between about €3.2 million and €9.9 million (average €6.7 million). The internal rate of return earned on these investments would typically be 24%-25% (against a target of 20%-25%).

11. When approval of novel food products is delayed to 2.5 to 3 years (as has occurred in the EU), gross returns (after costs) over the lifetime of the product fall significantly. The expected gross returns would fall by between €1.75 million and €6.18 million (average (€4 million) per product resulting in a lower internal rate of return of 17%-18%. As this rate of return is below the target rate and closer to the discount rate[1] of 15%, the time delay in authorisation significantly reduces the relative attractiveness of investment.

12. If the time delay in authorisation is extended to five years (as has occurred for some novel foods and ingredients in the EU), the discounted level of gross returns (for the average novel product example above) becomes negative, with the internal rate of return at 14.6%, below the discount rate. At this level of return, the investment to bring the product to market is questionable. Therefore where there is expectation of significant delays in the EU authorisation process for novel foods, it acts as a major dis-incentive to bringing a novel product to the EU market.

Rewarding innovation and data protection issues (section 4.2.3)

13. Under the current Novel Foods regulation, companies, other than the original applicant can obtain authorisation to market similar novel products almost immediately after a

[1] The discount rate (applied to future income streams) represents the next best alternative earning potential for investment funds and hence is a baseline for determining whether investments takes place. The rate takes into account factors such as risk and cost of borrowing

novel food is first authorised for sale in the EU. This allows companies that are 'second' to the market to 'free ride' on the back of the original market entrant (and notifier) because the second to market companies avoid some of the costs associated with seeking authorisation. Companies 'second to market' are also not subject to the same time delays as original notifiers in terms of planning market entry.

14. The current EU Novel Foods authorisation procedures provide an economic incentive for companies to be second to market rather than 'innovator' companies that apply for an original novel food product authorisation. Based on typical expected (discounted) gross margins returns (see above) for original notifying companies relative to expected market shares of competitor companies entering the market soon after authorisation, the internal rates of return earned by companies 'second' to the market can typically be higher than the rates earned by the original notifier (20% to 21%, for the second to market company relative to 17% to 18% for the original notifier).

15. If the novel foods authorisation procedures provided for some form of privileged (exclusive) access to the market (relating to safety, efficacy, etc data supplied to support novel food applications), for example via the provision of exclusive access to the market for three years immediately post authorisation, or 'second to market' companies were required to financially compensate the original notifier for access to data, this would increase the incentive to food companies to bring novel products to the EU market. Based on the examples referred to above (see 14 above and section 4.2.3) the internal rates of return earned by original notifiers would probably be higher than those earned by companies second to market. This would improve the incentive for companies to innovate and bring products to the EU market rather than waiting for others to bring products forward for authorisation.

Uncertainty issues (section 4.2.4)

16. Uncertainty impacts on the attractiveness or otherwise of a market (and hence on the scope for new products or ingredients being bought to the EU market) in two main ways:

a) *Legal uncertainty as 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).* This can result in an additional cost burden (eg, legal costs, for which CIAA/PIE members provided examples of annual costs incurred of €5,000 to €20,000) or loss of sales in specific member states (where there are differing member state authority interpretations of a product's status as a novel food or not) or the EU as a whole (eg, if a product with a history of sale in the EU has its status questioned and may have to be withdrawn until it has been 'authorised' under the novel food regulation). Examples provided by CIAA/PIE members identified potential losses of sales in individual member state markets, or at the EU level, to the annual value of between €3 and €18 million.

b) *Uncertainty about the process and time taken for deciding on a novel food/ingredient authorisation.* Bringing a product to market takes time to plan and execute. Therefore uncertainty relating to when a novel product authorisation will be granted can add risk and result in costs that might otherwise have not been incurred. Examples provided by

CIAA/PIE members where unforeseen delays in the authorisation process resulted in unrecoverable costs being incurred were within the range of €2 million to €3 million.

Concluding comments

Average levels of R&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&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.

This report identified three impacts of the current EU Novel Foods regulation that contribute to explaining why food companies tend to attach a lower priority to the EU market for novel product development relative to other markets (eg, the US).

Firstly, the risk of delays of an average of three years (in some cases taking as long as five years) in obtaining approval, has made some investments of marginal value and significantly diminished the economic incentive to bring products to the EU market.

Secondly, the current approval mechanism encourages companies to be followers to the market rather than innovators; followers to market experience lower costs and risks than novel food innovators and hence can easily earn higher rates of return than innovators.

Thirdly, uncertainty about the timing of approval or the legal status of novel products exacerbates risks and adds cost, further diminishing the economic incentive to bring products to the EU market.

If the EU Novel Foods regulation is to better create an environment that encourages novel product innovation, each of these deficiencies should be addressed. The time taken to approve/authorise a novel food should be reduced, incentives (eg, exclusive access to markets or compensation for data provision) to encourage innovation should be considered and uncertainties (relating to approval procedures and timing and legal uncertainties) minimised.

1 Introduction

The European Commission is currently reviewing the Novel Foods Regulation (EC No 258/97), has undertaken an impact assessment and put forward options for possible changes to the regulation.

As part of their response to this review process, the EU food industry, as represented by the Confederation of the Food and Drink Industries of the European Union (CIAA) and the Platform for Ingredients in Europe (PIE), requested an independent assessment of the economic impact of the Novel Foods Regulation. This document presents the findings of this impact assessment[2].

1.1 Objectives

The primary objective for this report was to contribute to the EU food industry's analysis of the Commission's options for change to the Novel Foods Regulation. More specifically, it was to:

- Analyse the current authorisation process;
- Assess the economic impact of the existing regulation;
- Examine the key features of an 'innovation and economic activity' friendly regulatory framework and how this affects economic activities relative to the existing regulatory framework.

1.2 Report structure and approach

This report is largely based on desk research and analysis, drawing on both publicly available information and data provided by members of the CIAA and PIE. In addition, informal discussions/interviews were held with representatives of the EU food industry and bodies representing them.

The report, after this introduction is structured as follows:

- Section 2: a summary of the original Novel Foods Regulation (EC 258/97) and its objectives;
- Section 3: an overview of the EU market for food products;
- Section 4: economic analysis of the impact of the Novel Foods Regulation on innovation in the food industry.

[2] The material presented in this report is the independent views of the author – it is a standard condition for all work undertaken that all reports are independently and objectively compiled without influence from the funding sponsors (except for the provision of information to assist the analysis)

2 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 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);
- Food and ingredients produced from new production techniques (eg, high pressure fruit 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;
- Preventing consumers from being misled;
- Protecting consumers from products that may be nutritionally disadvantageous.

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 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 Food and Animal Health (SCFAH) for consideration. The operation of the authorisation procedure is discussed further in section 4.

In 2002, five years after implementation of the Novel Foods Regulation, the EU Commission prepared a discussion document on its implementation[3]. It received 40 comments on this discussion document from stakeholders and subsequently produced an evaluation report on the Novel Foods Regulation in 2004. The EU Commission then produced an impact assessment on

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

the operation of the Novel Foods Regulation together with options for possible changes to the Regulation. The main issues with potential social and economic impacts identified in the evaluation and consultations included:

- For traditional products not on the EU market before 1997, but for which there is information on safe use outside the EU, the application of safety assessment requirements in the Novel Foods Regulation (that are applied to new innovative foods and ingredients) are perceived to be an unjustified barrier to trade for these traditional products;
- The safety assessment and product authorisation procedure takes too long, duplicates work and delays authorisation;
- The authorisation procedure only addresses the applicant, so that others can only market the same food after notifying the Commission through a separate authorisation procedure;
- Assessing and authorising the same substances with different legal frameworks causes repetition and creates additional administrative burden;
- The general implementation of the Regulation needs to be improved;
- There is need for legal clarification and updating because there are some misinterpretations about the definition of novel foods and the scope of the regulation, there is a need to ensure a horizontal approach to the application of new technologies, to update the legal text of the Regulation and develop provisions concerning the determination of the novelty of products, and the labelling provisions could be simplified.

In the light of these issues, the Commission put forward options for change to the Novel Foods Regulation (258/97) citing the following objectives for the proposed changes:

- Ensuring food safety, protecting human health and securing the functioning of the internal market for food by streamlining the authorisation procedure, developing a more adjusted safety assessment system and clarifying the definition of novel food, including new technologies with an impact on food, and the scope of the regulation;
- Improving the efficiency and application of the system and the implementation of the regulation;
- Empowering consumers by informing them about food;
- Achieving legal clarity by making any necessary changes and updating the legislation.

These objectives were linked to the Commission's strategic objectives and principles of Better Regulation, improving the implementation of regulations, facilitating innovation, fostering entrepreneurship and investments (especially in relation to small, medium enterprises), and taking into account economic prosperity, social equity, environmental protection and international responsibilities.

With a view to achieving these objectives the Commission proposed changes to the existing legislation including:

a) *Measures that during the consultations were identified as having a major impact, and for which policy actions (intended to amend and replace provisions already in place under regulation 258/97) are suggested*. For these the Commission has undertaken an impact assessment. The major policy actions identified are:

- Adjusted safety assessment and management for traditional food from third countries;
- Safety assessment and authorisation procedure;
- Authorisation decision;
- Submission of application for several food uses.

b) Measure that are required to bring the legal text into line with other EU policies and legislation

- Making use of the food definition in the General Food Law and abandoning the categories of describing foods;
- Maintaining a horizontal approach to new technologies with impact on food;
- Setting out definitions or criteria for significant human consumption as food, traditional food from third countries and history of safe use;
- Developing current practice on deciding if something counts as novel food by a resolution procedure and publishing the result;
- Introducing deadlines;
- Defining the role of EFSA;
- Updating and formulating provisions on confidentiality and public consultation;
- Simplifying labelling provisions;
- Updating rules for issuing guidance documents;
- Creating a register of novel foods.

It is important to note the recognition in the objectives of the original regulation and for the proposed changes of the importance of facilitating trade and the functioning of the single market. This is further emphasised through the provisions for facilitating innovation and fostering entrepreneurship and investments, especially in relation to small, medium enterprises.

The objectives also emphasise the importance of safety and protecting human health as having the highest priority over all other objectives.

These objectives are highly informative in the context of the Commission's suggested options for changes to the Novel Foods Regulation and the way in which novel foods and ingredients are authorised because they provide benchmarks against which:

- an assessment of whether the original objectives have been attained can be performed;
- an assessment can be made as to whether the legislative changes proposed by the Commission will address any failures in the current mechanisms to achieve the objectives.

The analysis undertaken for this study and presented in the following sections aims to provide insights into these two aspects, with particular emphasis on how the regulation has impacted on novel food product innovation. It is, however important to recognise that this analysis is not a critique of the Commission's impact assessment or the suggested options for change. Its primary

aim is, as indicated in section 1.2, is to examine and analyse the economic impact of the existing regulation and to provide insights into how changes might be made to optimise the scope for delivering more innovation, enhanced economic activity, better operation of the single market and reducing barriers to entry in the sector.

3 Background to the European novel foods market

3.1 The European food and drink sector

In 2005, the food and drink turnover for the EU (25) was €836 billion, which represented a 2.6% increase relative to 2004 and which slightly exceeded the trend observed over the past 10-15 years (an average 1.8% per annum rate of growth[4]).

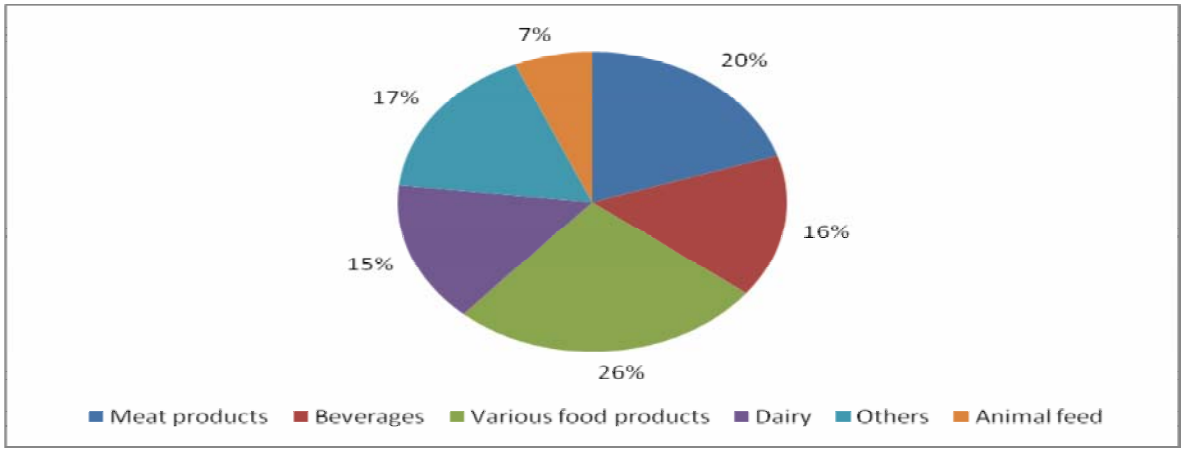
The sector has the largest turnover of manufacturing sectors in the EU, accounting for 13.6% of total manufacturing turnover and ahead of the automobile and chemical industries (12.4% and 10.4% respectively of total manufacturing turnover).

3.2 The European food and drink market

EU household expenditure on food and drink (non alcoholic beverages) accounted for 12.4% of total household expenditure in 2005 (a declining share, having been between 14% and 15% ten years ago). The proportion of expenditure spent on food and drink does, however vary by member state with, for example most of the new member states (post 2004) showing average household expenditure levels on food and drink of over 15% (over 20% in Latvia and Lithuania) compared to, for example under 10% in the UK and Ireland.

A breakdown of the main sectors by turnover is shown in Figure 1. This shows that the category 'various food products' is the largest sector (26% of turnover), comprising sub-sectors such as bakery, pastry, chocolate and confectionery products, sugar, tea, coffee, pasta and baby food. The meat, beverages, and dairy products sectors are also important accounting for 20%, 15.5% and 15.3% respectively of total food and drink sector turnover in 2005.

Figure 1: Distribution of EU food industry turnover by sector 2005



Source: CIAA data & trends 2006

[4] Source: CIAA Data & Trends 2006

3.3 Number and type of companies in the sector

The sector comprises a diverse range of companies. Small Medium Enterprises (SMEs) dominate, accounting for over 99% of the total number of companies. These 282,600 SME companies generate 47.8 % of food and drink turnover and employ 61.3% of the sector workforce. Large companies (that employ more than 250 people) make up 0.9% of the number of companies but account for 52.2% of the total sector turnover and 38.7% of the workforce.

3.4 Research, development and innovation

In 2005, the amount spent of research and development (R&D) by the largest 20 food and drink manufacturers in the EU was €1,790 million[5]. Over half of this amount was accounted for by one company, Unilever (€953 million).

The intensity of R&D, expressed as a % of industry output in the EU food and drink industry was 0.24% in 2004. However, across the leading 20 food and drink companies the R&D level as a % of output varied within a range of 0.6% to 7.1%.

The average level of R&D intensity in the EU (0.24%) was below comparable levels of R&D expenditure in competitor countries, where for example the respective R&D intensity levels were 0.35%, 0.4% and 1.21% for the US, Australia and Japan. Nevertheless, the level of R&D expenditure as a % of total output in the leading 20 EU food and drink companies was comparable with the rates amongst the leading non EU food and drink companies (a range of 1.3% to 4.6% for the leading six companies).

In terms of innovation by sector, the dairy sector, followed by water/soft drinks, frozen foodstuffs and biscuits were the largest innovators (in terms of the % share of total innovations worldwide[6] eg, the % of total innovations accounted for by the dairy sector was about 11%). Relating this level of innovation by sector, to the relative importance of different sectors (in terms of turnover: section 3.2 above) shows the largest amount of innovation appears to be in the two most important food and drink sectors in the EU, the dairy and 'other food products' sectors.

Categorising innovation by type or trends is difficult, although in the World Innovation Panorama (2006) innovation is categorised into the five categories of pleasure, health, fitness, convenience and ethics. In the EU market, the leading innovation categories in 2005 were reported to be pleasure, convenience and health which accounted for 43%, 24% and 17.3% of total innovation.

It is not possible to place the introduction of products and ingredients classified as novel products in the EU into these categories because of the broad definition of a novel product (that relates novelty to whether a product was on the EU market before May 1997). The majority of the novel products do, however probably fall into the categories of health and fitness (Table 1).

[5] Source: 2006 EU industrial R&D investment scoreboard, EU Commission DG RTD and DG JRC-IPTS

[6] Source: World innovation panorama 2006, International trends & innovation book, SIAL 2006

Table 1: Novel food authorisations (to March 2007)

Company	Product/ingredient	Date applied for authorisation	Date authorisation granted
Belovo	Phospholipides from egg yolk	23-01-1998	22-02-2000
Unilever	Phytosterols in yellow fat spreads	22-05-1998	24-07-2000
Bioresso	Trehalose	25-05-2000	25-09-2001
Danone	High pressure pasteurization for fruit products	03-12-1998	23-05-2001
Purocur	Dextran from leuconostoc mesenteroides	02-04-1999	30-01-2001
Avebe	Coagulated potato proteins & hydrolysates	25-05-2000	15-02-2002
Morinda	Noni juice	25-04-2000	12-06-2003
Mortox Bioscience	Oil rich in DHA (from micro algae)	13-02-2001	12-06-2003
Danisco	Salatrim	28-06-1999	13-12-2003
ADM	Phytosterols & phytostanols in various products	02-11-2001	31-03-2004
Pharmaconsult Oy	Phytosterols & phytostanols in various products	24-09-2001	31-03-2004
Unilever	Phytosterols in yoghurts	06-08-2002	31-03-2004
Tenaka	Phytosterols & phytostanols in various products	15-05-2001	31-03-2004
Novartis	Phytosterols & phytostanols in milk-based products	-7-09-2000	12-11-2004
Cargill	Isomaltulose	30-10-2003	04-04-2005
Sudzucker	Isomaltulose	04-03-2004	25-09-2005
Pharmaconsult Oy	Phytosterols & phytostanols in bakery products (subsequently changed to rye bread only)	24-09-2001	24-01-2006
Karl Fazer	Phytosterols & phytostanols in bakery products (subsequently changed to rye bread only)	21-09-2000	24-01-2006
Laboratores Pharmascience	Maize germ oil high in unsaponifiable matter	24-10-2001	24-10-2006
Laboratores Pharmascience	Rapeseed oil high in unsaponifiable matter	24-10-2001	24-10-2006
Vitatene antibiotics	Lycopene from blakeslea trispora	30-10-2003	23-10-2006
ADM	Diacylglycerol oil in oils, fats, spreads, bakery products and yoghurts	17-04-2002	23-10-2006

Source: Official journal of the European Communities

3.5 Trade in food and drink products

Trade statistics relating to food and drink products for the period 2003-2005[7] (Table 2) show that the EU exported €47.6 billion worth food and drink in 2005 and imported from third countries €43.1 billion, giving a net trade surplus of €4.5 billion. Since 2003 both the nominal value of

[7] Source: Eurostat

imports and exports has increased (by €4 billion for exports and by €5.58 billion for imports). The sectors with the largest share of exports in 2005-06 were spirits, wines and food preparations.

Table 2: EU trade in food and drink products 2003-2005 (million euros)

	2003	2004	2005
Exports	43,497	45,153	47,567
Imports	37,492	40,817	43,075
Balance	*6,005*	*4,336*	*4,492*

Source: CIAA Data & Trends 2006

3.6 Criteria used to determine whether to bring products to market

The primary criteria determining whether a novel food or ingredient is bought to market in the EU is whether the company undertaking the associated research and development is reasonably confident that a new product discovery will earn a reasonable rate of return relative to the cost of investment. In general, food companies investing in novel foods and ingredients are looking for internal rates of return on their investment within a range of 20% to 25%, and preferably in the upper half of this range[8]. In deciding whether to first bring a product forward for development and then for registration for use in the EU, companies have to assess factors such as:

- The extent to which consumers may be interested in buying a product that is novel or containing a novel ingredient. *Is the novel product an improvement on existing products?* Clearly, within a global context, the more attractive markets for the development of new novel foods and ingredients tend to be countries and regions with the largest consumer populations with reasonable levels of disposable income (eg, USA, Japan, EU);
- The likelihood of consumers using a novel product (or product containing a novel ingredient) because of its technical improvements relative to existing products, and its price;
- The expected sales and profitability of a new product relative to existing products and/or expected competitor new novel products and ingredients that may also come to the market during the product's expected lifetime;
- The likelihood of registration approval being granted and the associated costs of getting a product through a registration or approval process;
- The costs of launching, marketing and supporting a new novel product and/or ingredient, including post market monitoring.

Once a novel food or ingredient has passed through the regulatory approval process and has been marketed in the main target markets and countries (eg, US, Japan), subsequent decisions about marketing the food/ingredient in additional countries (eg, EU) are largely determined by the marginal expected profitability that might be derived from sales in this market relative to the marginal costs involved in seeking registration (eg, the research costs associated with generating additional data required, dossier preparation, etc).

[8] Whilst the absolute amount of revenue and profit earned is important to companies, it is the rate of return on an investment that is the crucial factor influencing investment. This measure makes it easier to assess the relative merits of different investment opportunities

4 Analysis of the impact of the novel foods regulation on innovation in the EU food sector

4.1 The impact of regulation on the decision to launch a new product: general

The decision to launch a new 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) products that better meet consumer wants, without acting as a dis-incentive to industry to bring forward products to the market.

As such, the regulatory approval process will inevitably impose some costs on industry seeking to bring 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) then the regulatory system acts as an economic dis-incentive to industry to bring products to the market (for which consumers lose out on in terms of non availability of improved 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.

4.2 The impact of regulation on the decision to launch a new product: the EU Novel Foods regulation

As indicated above, the optimum regulatory approval environment is reasonable and proportionate. The EU's Novel Foods regulation has been in force for ten 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 a Commission discussion paper to bring about some possible changes to the regulation. Following this consultation the Commission produced an evaluation of the Regulation which put forward options for change to the regulation.

The Commission's review and suggestions for change (see section 2) 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.

From the industry perspective, this review and 'proposal for change' phase represents an opportunity to highlight the key aspects of a regulatory framework that will optimise the scope for novel products being bought 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 minimal 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.

As such, the primary aim of the sub-sections below is to highlight and illustrate the impact of having a reasonable, efficient, transparent and proportionate regulatory approval mechanism and how the current regulatory mechanisms and some of the options suggested for changes to the regulation have, and may deliver economic and market inefficiencies and act as dis-incentives to industry to innovate and bring forward products to the EU market.

4.2.1 The current approval process: time to authorise a novel product or ingredient

Under the current legislative arrangements for approving novel foods and ingredients in the EU, new novel foods and ingredients are bought forward for regulatory approval via what are known as *'rapporteur'* member states which effectively 'act as the agent of the EU Commission'. Companies seeking regulatory approval for a new novel food or ingredient present their dossiers supporting the request for regulatory approval to the *rapporteur* member state which undertakes the evaluation, before issuing a report to the EU Commission which then passes on the report to other member state authorities. If the *rapporteur* member state gives a positive initial assessment, other member states have 60 days in which to respond with possible reasoned objections. Depending on the nature of these, further information/clarification may be made to the applicant and/or the dossier may be passed onto the European Food Safety Authority (EFSA) for further assessment and ultimate deliberation. If the EFSA subsequently makes a positive assessment, the dossier is passed back to the Commission which passes it to the Standing Committee on Food & Animal Health (SCFAH) for issuing a formal approval.

Since May 1997 (up to March 2007) there have been 61 full applications[9] 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 March 2007, twenty six of these applications remain under review, twenty two have been authorised, five refused authorisation and eight have been withdrawn by the applicant. In relation to the twenty two that have been authorised, the UK has been the *rapporteur* member state for six of the (subsequently approved) applications, with others dispersed across countries such as the Netherlands, Belgium, Finland, France and Germany (Table 3).

Table 3: *Rapporteur* member state for subsequently approved novel foods and ingredients 1997-2007

Rapporteur member state	Number
UK	6
Belgium	4

[9] Excluding GM foods

Finland	4
Netherlands	4
France	3
Germany	1
Total	**22**

Source: EU Commission (March 2007)

The average time taken for a novel food/ingredient to complete the process of authorisation over the last ten years has been 35 months (within a range of 16-60 months: Table 4). The considerable time interval between application and subsequent approval largely reflects the fact that 21 of the 22 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 SCFAH.

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 60 months after submission of the dossier to the *rapporteur* member state (Table 4).

Table 4: Novel food authorisations (to March 2007): 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
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
Tenaka	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 products (subsequently changed to rye bread only)	56	21-09-2000	24-01-2006
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
Average		**35**		

Source: Official journal of the European Communities

A comparison of the average time taken to approve novel products in other countries (Table 5) 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[10].

Table 5: Comparison of novel food approval process times (for yellow fat spreads containing phytosterols)

Country	Approval time (months)
EU	31
USA	3
Japan	18
Australia	14
Switzerland	14
Brazil	1

Source: Unilever

4.2.2 Impact of authorisation time delays on the attractiveness to invest & innovate in novel foods

In order to identify the impact of the approval mechanism on the European food and food ingredient industries, the CIAA and PIE were asked, in 2007, 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 products/ingredients if they had received approval within a relatively short period of time (eg, 3-6 months as has typically occurred in the USA and Australia)

[10] 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 directly comparable

compared to the longer approval process in the EU (an average of 35 months). It also considers the cost of bringing products to market.

The analysis presented below is based on information provided by five member companies of the CIAA/PIE. In order to protect company-specific data confidentiality, the data has been aggregated and the analysis presented is therefore based on an average (mean) together with 'high' and 'low' ranges. Additional, detailed information is presented in Appendix 1.

The primary value to the food industry of having a reliable and relatively quick process for approving a novel product or ingredient 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) product investment.

This can be illustrated by examining representative product life cycles for a new/novel 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 below are based on expected and targeted (representative) revenue flows for the novel products authorised. The data used is therefore considered representative of the average and a range of revenue flows for novel food products and ingredients currently sold in the European markets.

a) *Product life cycle returns using an approval mechanism with a relatively short procedure (up to six months)*

Figures 2 to 4 illustrate the average gross income or margin (cash) flow for three new (novel) products with a typical (average) expected life cycle of 15 years. Key points to note are:

- Expected sales revenue (over 15 years and in current monetary terms) for the products fall within a fairly broad range of between €65 million and €204 million (average €138 million). The expected gross margin over this 15 year period (in current monetary terms) was in the range of between €23 million and €71 million (average €48 million);
- Where products are given regulatory approval for release onto markets within 6 months, the discounted gross returns (discounted at 15%[11]) were between €7.17 million and €25.33 million (average €16.49 million). After consideration of the costs[12] of bringing these

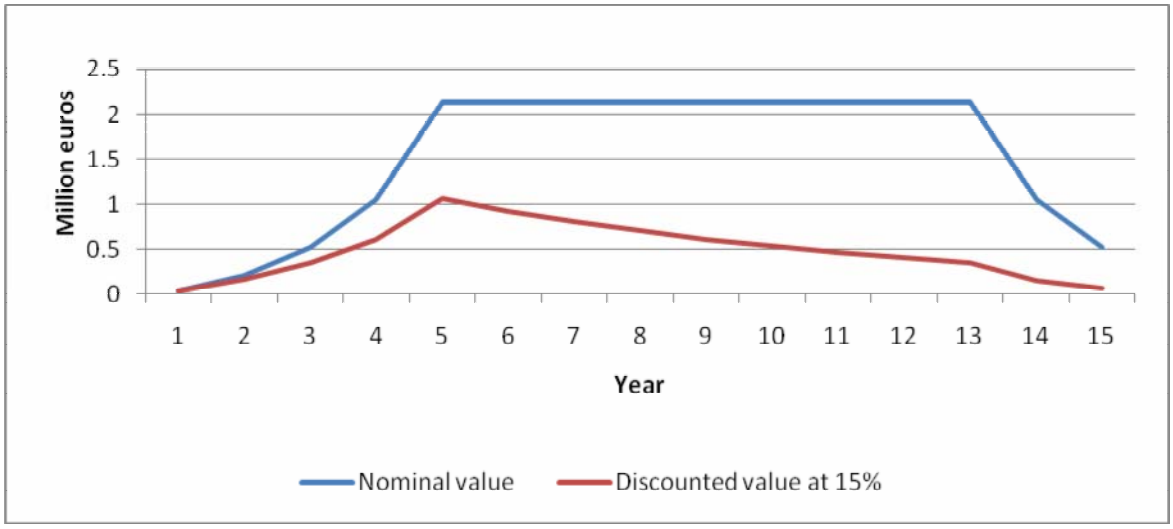
[11] The gross margin returns are standard expected return on sales revenue after production costs (excluding marketing, stewardship, research and development). The expected gross margin return for new products is 35%. In relation to discounting of revenue and income streams (for factors such as the 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. For further explanation of discount rates see footnote 1

[12] The average cost of developing a new product and bringing to the global market was €9.75 million (range €4 to €15.4 million) on a global basis. Within this, costs associated with meeting regulatory approval requirements that are fairly generic to leading markets (eg, US, Japan and the EU) were in the range of €0.9 million to €4 million. The delays inherent in the EU approval process are estimated to add between €0.3 and €0.75 million to overall (global) regulatory compliance costs

products to market are taken into consideration, the discounted gross margin returns were between €3.17 million and €9.93 million (average €6.74 million);

- The internal rate of return on the respective investments (against a target of 20% to 25% which is commonplace in the food industry) was between 24% and 25% (ie, in the target range).

Figure 2: Product life cycle gross margin returns flow with a relatively short approval process (up to 6 months): low end of range of sales and gross returns range



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

Figure 3: Product life cycle gross margin returns flow with a relatively short approval process (up to 6 months): average of sales and gross returns range

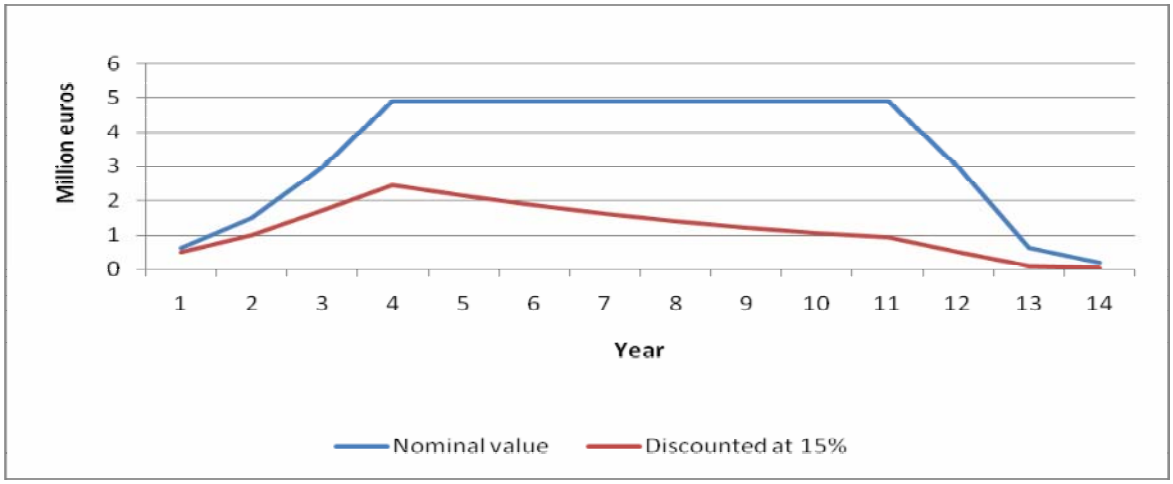
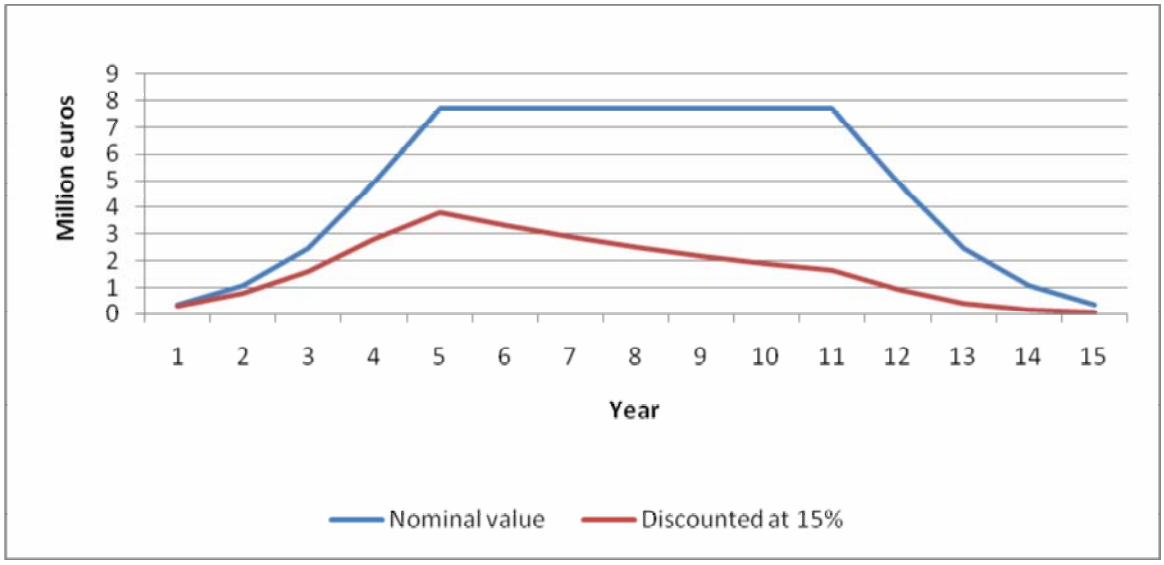


Figure 4: Product life cycle gross margin returns flow with a relatively short approval process (up to 6 months): high end of range of sales and gross returns range



b) Product life cycle returns using an approval mechanism with a longer time period (2.5 to 3 years)

Figures 5 to 7 illustrate the average gross income or margin (cash) flow for three new (novel) products when the authorisation time is delayed to 2.5-3 years. The main differences relative to the returns when the authorisation time is only 6 months are:

- the discounted gross returns (discounted at 15%) were between €5.42 million and €19.15 million (average €12.47 million). After consideration of the costs of bringing these products to market are taken into consideration, the discounted gross margin returns were between €1.42 million and €3.75 million (average €2.72 million);
- The time delay in authorisation results in a decrease in the discounted gross returns of between €1.75 million and €6.18 million (average €4.02 million);
- The internal rate of return on the respective investments falls to 17%-18%, which is below the target rate of return and closer to the discount rate of 15%. Hence, the time delay in authorisation significantly reduces the relative attractiveness of investment;
- If the time delay in authorisation is extended to five years (as has occurred for some novel foods and ingredients in the EU: Table 4), the discounted level of gross returns (for the average novel product example above) becomes negative (-€0.32 million), with the internal rate of return at 14.65, below the discount rate. At this level of return the investment to bring the product to market is questionable as the 'next best' alternative for the investment funds is higher. This suggests that the delays in the EU authorisation process for novel foods may have made an important contribution to some novel products not being bought to the EU market. It is, for example, interesting to note that the novel process of high pressure preparation of fruit products that sought authorisation for use as a novel 'product' in 1998, and which took 2.5 years to be authorised, was not subsequently 'bought to market'. Whilst a variety of factors influenced the rationale for not bringing products using this process to market in the EU, the delay in authorisation probably played a role in this decision.

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

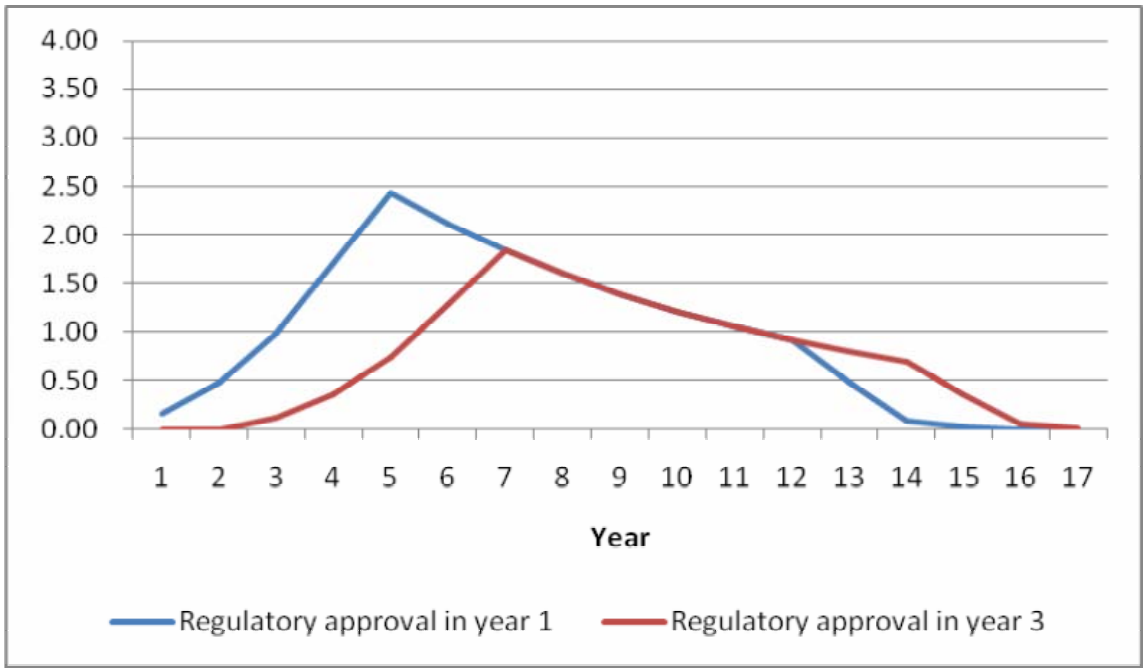


Figure 6: Discounted gross returns: low sales and returns range for different regulatory approval time periods (million euros)

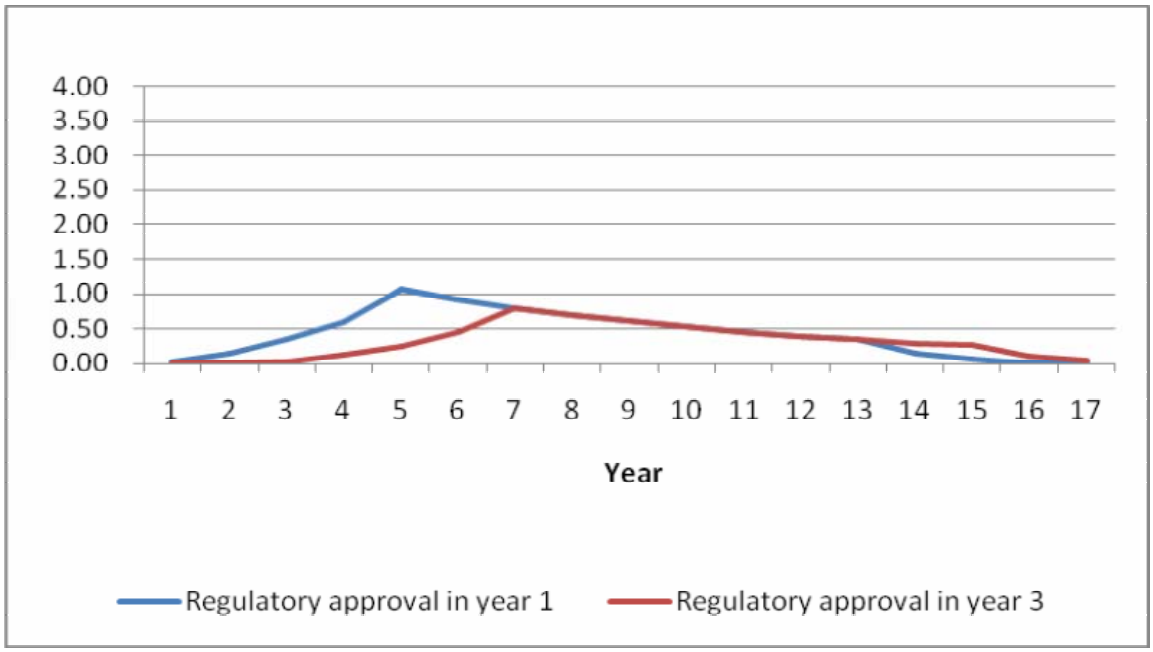
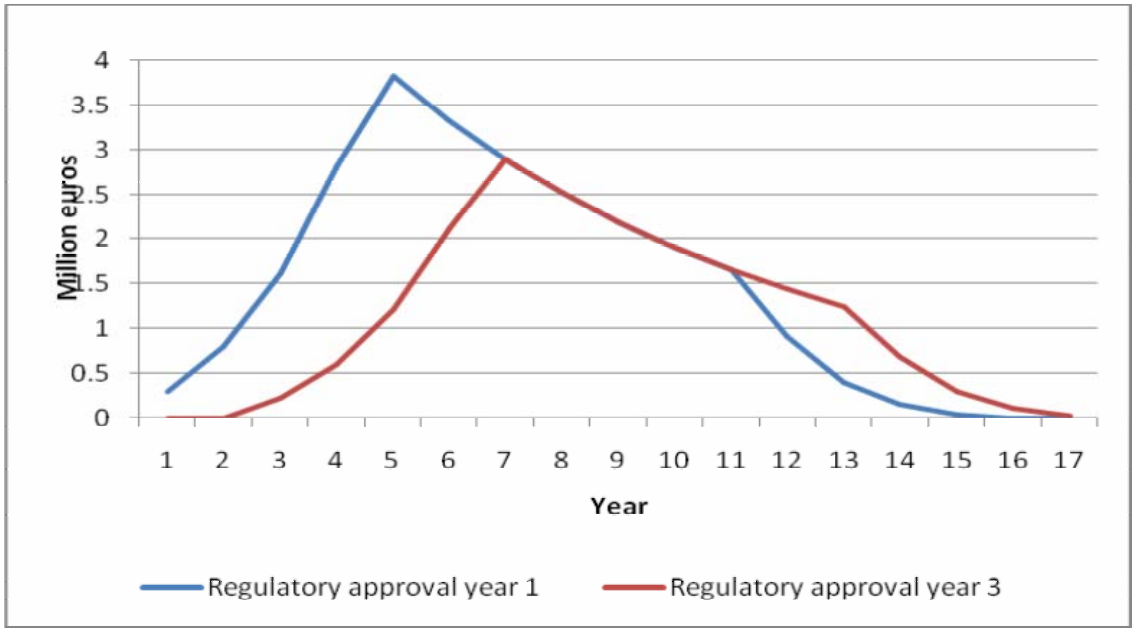


Figure 7: Discounted gross returns: high sales and returns range for different regulatory approval time periods (million euros)



4.2.3 Creating an environment that rewards innovation: data protection issues and re-couping R& D costs

Under the existing Novel Foods regulation, the authorisation decision to permit the sale of a novel food or ingredient on the EU market is addressed only to the applicant company. However, other companies can sell similar products once they have complied with the additional administrative procedure of making a formal notification to the Commission (often referred to as a generic authorisation for a product substantially equivalent to the originally authorised novel food or ingredient (on the basis of scientific evidence)).

Up to February 2007, there had been 124 of these 'generic' notifications made (Table 6) of which 72 related to the use of products containing phytosterols and 40 related to the sale of noni juice. Whilst the notification procedure represents an additional administrative hurdle that companies are faced with, in practical terms, it allows competitors to the original notifier to enter the market at an early stage following original authorisation of a novel food or ingredient. For example, the majority of the notifications for products containing phytosterols like milk products, yoghurts, spicy sauces, spreads and salad dressings were made within 3-6 months following the original authorisations granted at the end of March 2004.

Table 6: Generic notifications under the novel food regulation 1997- February 2007

Year	Total	Of which phytosterols	Of which noni juice	Of which others
2000	2	0	0	2
2001	0	0	0	0
2002	2	0	0	2

2003	2	0	1	1
2004	33	13	18	2
2005	28	15	10	3
2006	49	39	8	2
2007	8	5	3	0
Total	**124**	**72**	**40**	**12**

Source: CIAA (based on EU Commission database)

In the Commission's draft impact assessment report options for changes to this authorisation procedure are made. These include a) no change to the current mechanism, b) immediate generic authorisation at the time of initial applicant authorisation, c) the provision of generic authorisation made conditional to notifiers providing their own supporting documentation (of, for example relevant health/impact studies) and being able to access the original data in the dossier provided by the original applicant, and d) the establishment of different types of authorisation (some generic and some applicant-linked), so that those applications that were based on considerable investment in research, product development and supporting studies could be applicant-based so as to 'protect' the original applicant's investment.

These options recognise that the Commission is aware of issues relating to data protection and how best to 'reward' innovation, but at the same time maximise the scope for new entrants to the sector and hence to enhance competition. The analysis presented below aims to place the issue of data protection and innovation incentives (or otherwise) into context through further examination of the returns on investment to notifying companies relative to those for 'follower' or secondary applicants/notifiers.

a) Impact of the existing rules for secondary notifiers (allowing notifications immediately after first authorisation) on the incentive to invest and bring novel foods and ingredients to market

As indicated in sections 3.6 and 4.1, the income and profit benefit from sales of a novel food/ingredient is clearly the primary driver influencing the decision to bring a novel product to the EU market. Provided the expected returns are greater than the costs associated with getting the product through the regulatory approval process and are sufficiently large enough to meet target returns on investment, then a novel product/ingredient is likely to be bought to the EU marketplace.

The level of expected return is, however subject to possible erosion, due to the entry into the market of competitors. When competitors (in cases where patent protection is not available, or is insufficiently broad enough to prevent similar products being bought to the marketplace) enter the market, the share of the market taken by them erodes the level of returns and profit taken by the 'first to market'. The level of return to the initial applicant is also potentially further eroded relative to subsequent entrants to the market, if secondary notifiers do not have to invest the level of resources in getting their novel product/ingredient through the notification process as the original applicant has incurred (ie, secondary notifiers are effectively given an economic incentive to wait for another company to be the lead or applicant company for a novel food, if they can access the same data as presented by the applicant company to support their notification at no cost, or are not required to provide similar levels of scientific supporting data).

The way in which the current EU novel food authorisation procedures operate provides a degree of economic incentive for companies to be a secondary 'to market' operator using the notification procedure because they can submit notifications as soon as a novel product has received its authorisation and they are not required to support their notifications with the same degree of information as the original applicant. As such, because the secondary market entrants (notifiers) do not have to commit the same level of financial and human capital resources as the original applicant , or wait 2-3 years after incurring these costs before starting to market produce, they can 'free ride' on the back of the investment made by the main applicant.

Drawing on the data provided by CIAA members (see section 4.2.2 above), Table 7 provides insights into the returns and benefits that the secondary market entrants/notifiers might reasonably expect relative to the original notifier. This shows that in all three examples of markets (for low, high and average sales and returns), the internal rate of return earned by the second market entrant (follower) is higher by about 2% to 4% relative to the internal rate of earned by the original notifier. The secondary market entrant effectively avoids some of the market entry costs (associated with seeking regulatory authorisation). In addition, the secondary market entrant benefits from sales and associated profits at an earlier stage after incurring market entry costs relative to the original notifier because the secondary market entrant avoids the 2.5-3 year wait for authorisation. In essence, the secondary notifying company has gained a 'free rider' gross return and investment benefit equal to an internal rate of return of 2% to 4% relative to the original market entrant.

Table 7: Comparison of internal rates of return for notifiers and second market entrants: current novel foods regulation (%)

Product life cycle sales and gross returns	Original notifier	Second market entrant
Low	17.0	21.1
High	17.9	20.4
Average	18.2	20.0

Note: See Appendix 2 for detailed data and calculations

b) Impact of providing the original notifier with exclusive use/access to the market for 3 years following authorisation as an incentive to invest and bring to market novel foods and ingredients

Under this 'option' secondary market entrants are not permitted to enter the market (ie, are not given authorisation to enter the market) until 3 years after the original authorisation, leaving the entire market to the original applicant. Hence, the original applicant seeking novel product/ingredient authorisation is 'rewarded' for innovation through the provision of exclusive rights to the market for three years.

The impact of adopting this approach is to raise the internal rate of return to the original notifier by between 0.4% (average returns example) and 2.1% (low returns example) making the investment more attractive (Table 8). For the second market entrant the delay in market entry results in reduced internal rates of return (13.8% to 15.5% which represents between a 5% and 6% decrease in the internal rate of return) that are below those of the original notifier (instead of being higher than the internal rate of return earned by the original notifier under the current mechanism).

Table 8: Comparison of internal rates of return for notifiers and second market entrants (%): if original rotifer granted 3 years exclusive market access

Product life cycle sales and gross returns	Original notifier	Second market entrant
Low	19.1	14.7
High	18.4	15.5
Average	18.6	13.8

Note: See Appendix 3 for detailed data and calculations

c) Impact of providing the original notifier with 'data protection compensation' following authorisation as an incentive to invest and bring to market novel foods and ingredients

Under this 'option' secondary market entrants can seek authorisation to market their products as soon as an original authorisation is granted but are required to pay the main notifier a fee for accessing relevant data to support their notification. This is assumed in the analysis below (further details in Appendix 4) to be equal to 50% of a total data generation costs of €0.9 million[13] (ie, the analysis assumes their might be 2 market entrants as well as the original notifier).

Drawing on the information presented above relating to the three ranges of sales and returns data for novel foods supplied by CIAA/PIE members, the impact of adopting this approach is to raise the internal rate of return to the original notifier by between 0.5% (high returns example) and 3.6% (low returns example) making the investment more attractive (Table 9). For the second market entrant the payment of compensation for data access results in reduced internal rates of return (16.5% to 18.7%, a drop of between 2.5% and 4.4% relative to under the current mechanism) that are below those of the original notifier (instead of being higher than the internal rate of return earned by the original notifier under the current mechanism). The rate of return to the secondary market entrant is, however higher than under the scenario where exclusive use of the market for three years is granted to the notifier[14].

Table 9: Comparison of internal rates of return for notifiers and second market entrants (%): if original notifier paid compensation by later market entrants for data access

Product life cycle sales and gross returns	Original notifier	Second market entrant
Low	20.6	18.7
High	18.4	17.0
Average	19.0	16.5

Note: See Appendix 4 for detailed data and calculations

[13] The €0.9 million cost associated with studies required to meet regulatory approval is based on the lower end of the range of regulatory costs for bringing a novel product to market (see section 4.2.2). In the analysis presented this cost is divided between two market entrants (ie, assumes two 'secondary' market entrants)

[14] Although it should be recognised that the returns relating to the data protection example depend upon the amount payable by the second market entrant to the original notifier and the total amount value of compensation received by the original notifier

4.2.4 Uncertainty issues

Uncertainty has, and continues to, impact on the attractiveness or otherwise of a market (and hence on the scope for new products or ingredients being bought to the EU market) in two main ways:

- Legal uncertainty as 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);
- Uncertainty about how long a decision to authorise a novel food/ingredient will take.

These are discussed further below.

a) Legal uncertainty

Legal status uncertainty can have negative economic implications for, or impose additional costs on, companies considering bringing products to the EU market. This category of economic cost or dis-incentive to invest or bring novel foods/ingredients to the EU market, is however not easily recognised, categorised or quantified. Based on discussions with members of CIAA and PIE, examples where legal status uncertainty has had a negative impact on businesses include:

- the burden of additional costs (eg, legal costs associated with clarifying or defending the legal status of a product/ingredient) – members of CIAA/PIE indicated that legal costs associated with product status defence or clarification were in a range of €5,000 to €25,000 in the last year;

- loss (or potential loss) of sales and income within the EU (eg, where member state authorities have different interpretations about the status of a product and hence may not allow sales in that member state unless the product has been granted novel food authorisation at the EU level (even though the product may be legally sold in other member states)). In other words, different member state authority interpretations are adversely affecting the operation of the single market. Examples provided by CIAA/PIE members identified potential losses of sales in individual member state markets, or at the EU level to the annual value of between €3 and €18 million.

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

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 on the market.

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

The way in which this uncertainty adversely impacts on businesses is also best illustrated through the example of phytosterols in yoghurts, salad dressings and various products (other than spreads). The launch of products containing phytosterols onto the markets in four EU member state markets was planned by one notifier company to commence two weeks after the date of expected authorisation. In order to prepare for this, product had to be manufactured, labelled and delivered to a reasonable number of retail outlets in each market, advertising and promotional literature had to be organised, booked and prepared and in-store promotions set up. The date of the expected decision to authorise was then delayed resulting in the products launch date being postponed. This resulted in unrecoverable costs for perishable product that had to be destroyed (past its shelf life when the eventual product launch took place) and advertising space booked (and fees incurred) that had to be cancelled but still paid for. In total the non recoverable costs associated with this uncertainty delay were in the range of €2-€3 million.

Overall, these examples highlight how legal and time to authorise uncertainty have a negative impact on returns to companies and consequently reduce the potential returns (for example, in terms of the internal rate of return) for companies considering bringing novel products to the EU market.

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 15 years.

Assumed rate of discount = 15%

Assumed gross margin return 35%

Average (million euros)

Year	Expected sales	Expected gross margin	Discounted value of margin assuming first sale in year one (ie, approval for sale given within 6 months of application)	Expected gross margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)	Discounted value of margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)
0	-9.75	-9.75	-9.75	-9.75	-9.75
1	0.55	0.1925	0.167	0	0
2	1.8	0.63	0.476	0	0
3	4.25	1.4875	0.978	0.1925	0.126
4	8.5	2.975	1.701	0.63	0.360
5	14	4.9	2.436	1.4875	0.739
6	14	4.9	2.118	2.975	1.286
7	14	4.9	1.842	4.9	1.842
8	14	4.9	1.602	4.9	1.602
9	14	4.9	1.393	4.9	1.393
10	14	4.9	1.211	4.9	1.211
11	14	4.9	1.053	4.9	1.053
12	14	4.9	0.916	4.9	0.916
13	8.5	2.975	0.483	4.9	0.796
14	1.8	0.63	0.089	4.9	0.693
15	0.55	0.1925	0.024	2.975	0.366
16				0.63	0.067
17				0.1925	0.018
Total	**137.95**	**48.2825**	**16.49**	**48.2825**	**12.47**
Total after	**128.25**	**38.53**	**6.74**	**38.53**	**2.72**

deducting cost of bringing product to market					
Internal rate of return			**24.32%**		**18.2%**

Low (million euros)

Year	Expected sales	Expected gross margin	Discounted value of margin assuming first sale in year one (ie, approval for sale given within 6 months of application)	Expected gross margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)	Discounted value of margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)
0	-4.0	-4.0	-4.0	-4.0	-4.0
1	0.1	0.035	0.030	0	0
2	0.6	0.21	0.159	0	0
3	1.5	0.525	0.345	0.035	0.023
4	3.0	1.05	0.600	0.21	0.120
5	6.1	2.135	1.061	0.525	0.261
6	6.1	2.135	0.923	1.05	0.454
7	6.1	2.135	0.803	2.135	0.803
8	6.1	2.135	0.698	2.135	0.698
9	6.1	2.135	0.607	2.135	0.607
10	6.1	2.135	0.528	2.135	0.528
11	6.1	2.135	0.459	2.135	0.459
12	6.1	2.135	0.399	2.135	0.399
13	6.1	2.135	0.347	2.135	0.347
14	3.0	1.05	0.148	2.135	0.302
15	1.5	0.525	0.064	2.135	0.262
16				1.05	0.112
17				0.525	0.049
Total	**64.6**	**22.61**	**7.17**	**22.61**	**5.424**
Total after deducting cost of bringing product to market	**60.6**	**18.61**	**3.17**	**18.61**	**1.424**
Internal rate of return			**24.79%**		**17.0%**

High (million euros)

Year	Expected sales	Expected gross margin	Discounted value of margin assuming first sale in year one (ie, approval for sale given within 6 months of application)	Expected gross margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)	Discounted value of margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)
0	-15.4	-15.4	-15.4	-15.4	-15.4
1	1	0.35	0.304	0	0
2	3	1.05	0.794	0	0
3	7	2.45	1.612	0.35	0.230
4	14	4.9	2.802	1.05	0.600
5	22	7.7	3.828	2.45	1.218
6	22	7.7	3.329	4.9	2.118
7	22	7.7	2.895	7.7	2.895
8	22	7.7	2.517	7.7	2.517
9	22	7.7	2.189	7.7	2.189
10	22	7.7	1.903	7.7	1.903
11	22	7.7	1.655	7.7	1.655
12	14	4.9	0.916	7.7	1.439
13	7	2.45	0.398	7.7	1.251
14	3	1.05	0.148	4.9	0.692
15	1	0.35	0.043	2.45	0.301
16				1.05	0.112
17				0.35	0.032
Total	**204**	**71.4**	**25.33**	**71.4**	**19.15**
Total after deducting cost of bringing product to market	**188.6**	**56**	**9.93**	**56**	**3.75**
Internal rate of return			**24.09%**		**17.91%**

Appendix 2: Returns to original notifier relative to secondary market entrants: existing novel foods regulation

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 15 years.

Assumed rate of discount = 15%

Assumed gross margin return 35%

Original sales and gross margin figures for notifier (as used in Appendix 1) used to represent the notifier's share in overall market.

Secondary market entrant assumed to enter within 3-6 months after original authorisation, with secondary market entrant incurring market entry costs equal to 75% of original notifier and taking a market share of 15% in year one of entry, rising to 20% in year two, 25% in year three, 30% in year four and 40% from year five. The secondary market entrant is assumed to operate to the same gross margin return levels and discount rate as the notifier. These relative costs and returns to the secondary market entrant are considered to be reasonably reflective of 'real' market conditions.

Average (million euros)

Year	Original notifier: expected gross margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)	Original notifier: discounted value of margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)	Secondary market entrant: expected gross margin assuming first sale in year of original authorisation	Secondary market entrant: discounted value of margin
0	-9.75	-9.75	0	0
1	0	0	0	0
2	0	0	-7.3125	-7.3125
3	0.1925	0.126	0.034	0.0295
4	0.63	0.360	0.157	0.119
5	1.4875	0.739	0.496	0.326
6	2.975	1.286	1.275	0.723
7	4.9	1.842	3.267	1.624
8	4.9	1.602	3.267	1.412
9	4.9	1.393	3.267	1.228
10	4.9	1.211	3.267	1.068
11	4.9	1.053	3.267	0.929
12	4.9	0.916	3.267	0.807

13	4.9	0.796	3.267	0.702
14	4.9	0.693	3.267	0.611
15	2.975	0.366	1.983	0.322
16	0.63	0.067	0.42	0.059
17	0.1925	0.018	0.128	0.016
Total	**48.2825**	**12.47**	**30.629**	**9.976**
Total after deducting cost of bringing product to market	**38.53**	**2.72**	**23.316**	**2.663**
Internal rate of return		**18.2%**		**20.0%**

Low (million euros)

Year	Original notifier: expected gross margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)	Original notifier: discounted value of margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)	Secondary market entrant: expected gross margin assuming first sale in year of original authorisation	Secondary market entrant: discounted value of margin
0	-4.0		0	0
1	0	0	0	0
2	0	0	-3.0	-3.0
3	0.035	0.023	0.006	0.005
4	0.21	0.120	0.052	0.04
5	0.525	0.261	0.175	0.115
6	1.05	0.454	0.45	0.257
7	2.135	0.803	1.423	0.708
8	2.135	0.698	1.423	0.615
9	2.135	0.607	1.423	0.535
10	2.135	0.528	1.423	0.465
11	2.135	0.459	1.423	0.405
12	2.135	0.399	1.423	0.352
13	2.135	0.347	1.423	0.306
14	2.135	0.302	1.423	0.266
15	2.135	0.262	1.423	0.231
16	1.05	0.112	0.7	0.099
17	0.525	0.049	0.35	0.043
Total	**22.61**	**5.424**	**14.534**	**4.442**
Total after deducting cost of bringing product to	**18.61**	**1.424**	**11.534**	**1.442**

market				
Internal rate of return		**17.0%**		**21.1%**

High (million euros)

Year	Original notifier: expected gross margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)	Original notifier: discounted value of margin assuming first sale in year three (ie, approval for sale given 2.5 to 3 years after application)	Secondary market entrant: expected gross margin assuming first sale in year of original authorisation	Secondary market entrant: discounted value of margin
0	-15.4		0	0
1	0	0	0	0
2	0	0	-11.0	-11.0
3	0.35	0.230	0.062	0.054
4	1.05	0.600	0.263	0.198
5	2.45	1.218	0.817	0.537
6	4.9	2.118	2.1	1.2
7	7.7	2.895	5.13	2.552
8	7.7	2.517	5.13	2.219
9	7.7	2.189	5.13	1.93
10	7.7	1.903	5.13	1.678
11	7.7	1.655	5.13	1.459
12	7.7	1.439	5.13	1.269
13	7.7	1.251	5.13	1.103
14	4.9	0.692	3.27	0.610
15	2.45	0.301	1.63	0.265
16	1.05	0.112	0.7	0.099
17	0.35	0.032	0.23	0.029
Total	**71.4**	**19.15**	**44.98**	**15.2**
Total after deducting cost of bringing product to market	**56**	**3.75**	**33.98**	**4.2**
Internal rate of return		**17.91%**		**20.4%**

Appendix 3: Returns to original notifier relative to secondary market entrants: exclusive use granted to original notifier option

The same three levels of product life cycle and internal rate of return analysis have been used as in Appendix 2. These represent an average (mean) plus two elements of a range (low and high).

For each the expected life of a product is 15 years.

Assumed rate of discount = 15%

Assumed gross margin return 35%

Original sales and gross margin figures for notifier (as used in Appendix 1) used to represent the notifier's share in overall market.

Secondary market entrant assumed to enter the market 3 years after original authorisation, with secondary market entrant incurring market entry costs equal to 75% of original notifier and taking a market share of 15% in year one of entry (ie, year 4), rising to 20% in year two after entry (year 5), 25% in year three after entry (year 6), 30% in year four after entry (year 7) and 40% from year five after entry (year 8). The secondary market entrant is assumed to operate to the same gross margin return levels and discount rate as the notifier.

Average (million euros)

Year	Original notifier: expected gross margin assuming first sale in year three and taking market share of second market entrant in first 3 years of sales	Original notifier: discounted value of margin	Secondary market entrant: expected gross margin assuming first sale in year 3 after original authorisation	Secondary market entrant: discounted value of margin
0	-9.75	-9.75	-7.3125	-7.3125
1	0	0	0	0
2	0	0	0	0
3	0.226	0.149	0	0
4	0.787	0.45	0.033	0.019
5	1.983	0.986	0.157	0.078
6	2.975	1.286	0.496	0.214
7	4.9	1.842	1.275	0.479
8	4.9	1.602	3.267	1.068
9	4.9	1.393	3.267	0.93
10	4.9	1.211	3.267	0.81
11	4.9	1.053	3.267	0.702
12	4.9	0.916	3.267	0.611
13	4.9	0.796	3.267	0.531

14	4.9	0.693	3.267	0.462
15	2.975	0.366	1.983	0.401
16	0.63	0.067	0.42	0.212
17	0.1925	0.018	0.128	0.039
Total	**48.97**	**12.86**	**30.63**	**6.556**
Total after deducting cost of bringing product to market	**39.22**	**3.108**	**23.32**	**-0.7565**
Internal rate of return		**18.64%**		**13.81%**

Low (million euros)

Year	Original notifier: expected gross margin assuming first sale in year three and taking market share of second market entrant in first 3 years of sales	Original notifier: discounted value of margin	Secondary market entrant: expected gross margin assuming first sale in year 3 after original authorisation	Secondary market entrant: discounted value of margin
0	-4.0	-4.0	-3.0	-3.0
1	0	0	0	0
2	0	0	0	0
3	0.041	0.028	0	0
4	0.262	0.15	0.006	0.004
5	0.7	0.348	0.052	0.026
6	1.05	0.454	0.175	0.076
7	2.135	0.803	0.45	0.169
8	2.135	0.698	1.423	0.465
9	2.135	0.607	1.423	0.405
10	2.135	0.528	1.423	0.352
11	2.135	0.459	1.423	0.306
12	2.135	0.399	1.423	0.266
13	2.135	0.347	1.423	0.231
14	2.135	0.302	1.423	0.201
15	2.135	0.262	1.423	0.175
16	1.05	0.112	0.7	0.152
17	0.525	0.049	0.35	0.065
Total	**22.84**	**5.546**	**13.117**	**2.893**
Total after deducting cost of bringing product to market	**18.84**	**1.546**	**10.117**	**2.593**

Internal rate of return		**19.13%**		**14.72%**

High (million euros)

Year	Original notifier: expected gross margin assuming first sale in year three and taking market share of second market entrant in first 3 years of sales	Original notifier: discounted value of margin	Secondary market entrant: expected gross margin assuming first sale in year 3 after original authorisation	Secondary market entrant: discounted value of margin
0	-15.4	-15.4	-11	-11
1	0	0	0	0
2	0	0	0	0
3	0.412	0.271	0	0
4	1.3125	0.75	0.062	0.041
5	3.267	1.624	0.265	0.15
6	4.9	2.118	0.817	0.406
7	7.7	2.895	2.1	0.908
8	7.7	2.517	5.13	1.93
9	7.7	2.189	5.13	1.678
10	7.7	1.903	5.13	1.459
11	7.7	1.655	5.13	1.269
12	7.7	1.439	5.13	1.103
13	7.7	1.251	5.13	0.959
14	4.9	0.692	3.267	0.462
15	2.45	0.301	1.633	0.201
16	1.05	0.112	0.7	0.075
17	0.35	0.032	0.233	0.022
Total	**72.54**	**19.75**	**39.86**	**10.66**
Total after deducting cost of bringing product to market	**57.14**	**4.35**	**28.86**	**0.007**
Internal rate of return		**18.4%**		**15.5%**

Appendix 4: Returns to original notifier relative to secondary market entrants: data protection fee granted to original notifier option

The same three levels of product life cycle and internal rate of return analysis have been used as in Appendix 2. These represent an average (mean) plus two elements of a range (low and high).

For each the expected life of a product is 15 years.

Assumed rate of discount = 15%

Assumed gross margin return 35%

Original sales and gross margin figures for notifier (as used in Appendix 1) used to represent the notifier's share in overall market.

Secondary market entrant assumed to enter the market after 12 months of original authorisation, with secondary market entrant incurring market entry costs equal to €0.45 million payable to the original market entrant for data to support their notification. The secondary market entrant is assumed to operate to the same gross margin return levels and discount rate as the notifier.

Average (million euros)

Year	Original notifier: expected gross margin assuming first sale in year three and taking market share of second market entrant in first 3 years of sales	Original notifier: discounted value of margin	Secondary market entrant: expected gross margin assuming first sale 12 months after original authorisation	Secondary market entrant: discounted value of margin
0	-9.75	-9.75	0	0
1	0	0	0	0
2	0	0	-7.76	-7.76
3	1.092	0.718	0	0
4	0.63	0.36	0.04	0.025
5	1.487	0.74	0.15	0.1
6	2.975	1.286	0.496	0.283
7	4.9	1.842	1.275	0.634
8	4.9	1.602	3.267	1.41
9	4.9	1.393	3.267	1.228
10	4.9	1.211	3.267	1.067
11	4.9	1.053	3.267	1.929
12	4.9	0.916	3.267	0.807
13	4.9	0.796	3.267	0.702
14	4.9	0.693	3.267	0.610
15	2.975	0.366	1.983	0.531

16	0.63	0.067	0.42	0.28
17	0.1925	0.018	0.128	0.052
Total	**49.18**	**13.06**	**27.36**	**8.664**
Total after deducting cost of bringing product to market	**39.43**	**3.31**	**19.60**	**0.904**
Internal rate of return		**18.96%**		**16.54%**

Low (million euros)

Year	Original notifier: expected gross margin assuming first sale in year three and taking market share of second market entrant in first 3 years of sales	Original notifier: discounted value of margin	Secondary market entrant: expected gross margin assuming first sale 12 months after original authorisation	Secondary market entrant: discounted value of margin
0	-4.0	-4.0	0	0
1	0	0	0	0
2	0	0	-3.45	-3.45
3	0.935	0.615	0	0
4	0.21	0.12	0.006	0.005
5	0.525	0.261	0.175	0.115
6	1.05	0.454	0.45	0.257
7	2.135	0.803	1.423	0.708
8	2.135	0.698	1.423	0.615
9	2.135	0.607	1.423	0.535
10	2.135	0.528	1.423	0.465
11	2.135	0.459	1.423	0.405
12	2.135	0.399	1.423	0.352
13	2.135	0.347	1.423	0.306
14	2.135	0.302	1.423	0.266
15	2.135	0.262	1.423	0.231
16	1.05	0.112	0.7	0.099
17	0.525	0.049	0.35	0.043
Total	**23.51**	**6.02**	**14.49**	**4.402**
Total after deducting cost of bringing product to market	**19.51**	**2.02**	**11.04**	**0.952**
Internal rate of return		**20.6%**		**18.7%**

High (million euros)

Year	Original notifier: expected gross margin assuming first sale in year three and taking market share of second market entrant in first 3 years of sales	Original notifier: discounted value of margin	Secondary market entrant: expected gross margin assuming first sale 12 months after original authorisation	Secondary market entrant: discounted value of margin
0	-15.4	-15.4	0	0
1	0	0	-11	-11
2	0	0	0	0
3	1.25	0.822	0.0618	0.046
4	1.05	0.6	0.262	0.173
5	2.45	1.218	0.817	0.467
6	4.9	2.118	2.1	1.044
7	7.7	2.895	5.13	2.219
8	7.7	2.517	5.13	1.93
9	7.7	2.189	5.13	1.678
10	7.7	1.903	5.13	1.459
11	7.7	1.655	5.13	1.269
12	7.7	1.439	5.13	1.103
13	7.7	1.251	5.13	0.959
14	4.9	0.692	3.267	0.531
15	2.45	0.301	1.633	0.231
16	1.05	0.112	0.7	0.086
17	0.35	0.032	0.233	0.025
Total	**72.3**	**19.75**	**45.00**	**13.22**
Total after deducting cost of bringing product to market	**56.9**	**4.35**	**34.00**	**2.22**
Internal rate of return		**18.4%**		**17.0%**