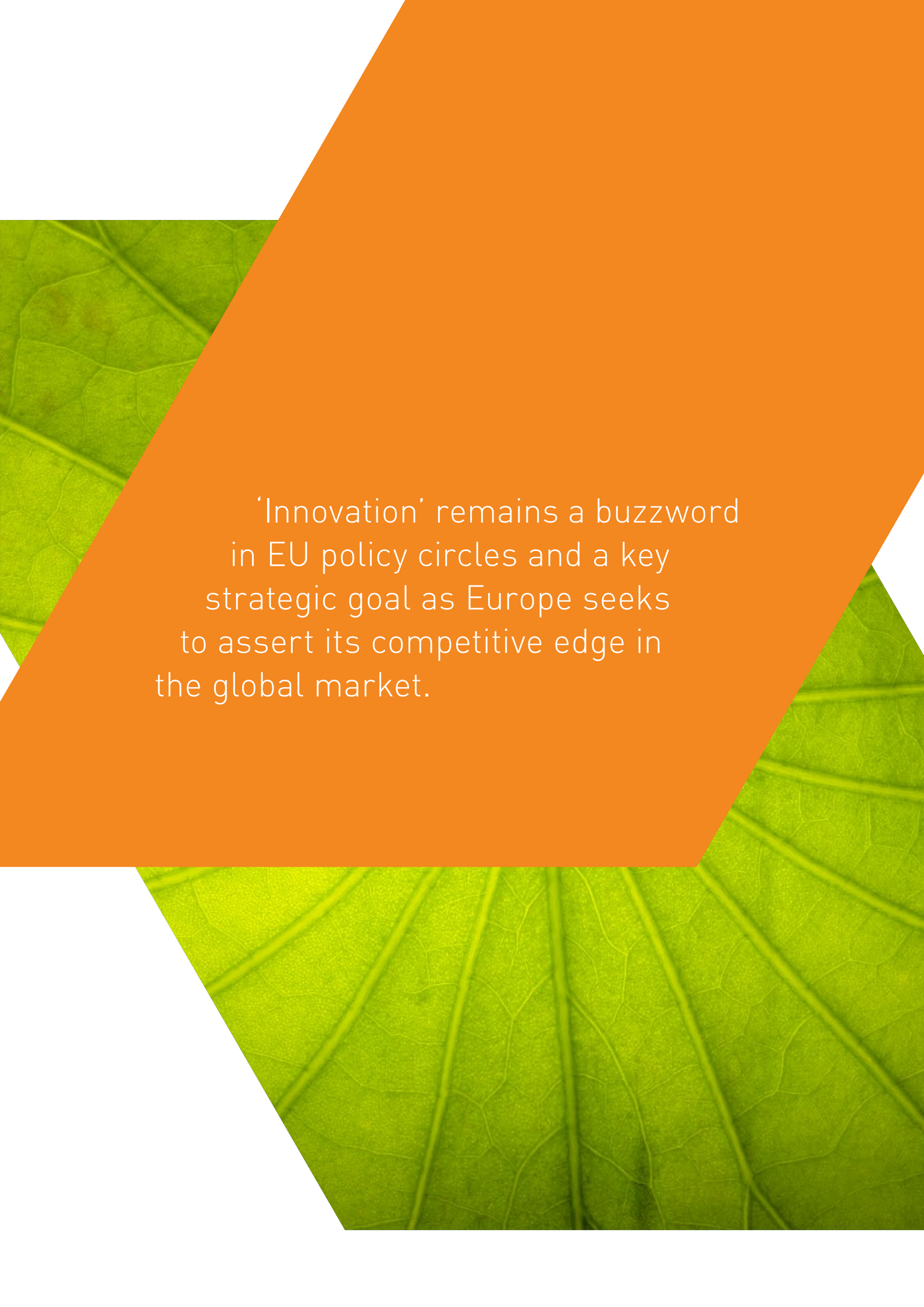
Innovation Dialogue

Can the EU regulatory environment help deliver food innovation?

EU specialty food ingredients
formerly ELC

specialtyfoodingredients.eu



‘Innovation’ remains a buzzword in EU policy circles and a key strategic goal as Europe seeks to assert its competitive edge in the global market.

Looking beyond the rhetoric, what are the challenges for innovators in the food industry and what role can European regulators play in stimulating innovation? The EU Specialty Food Ingredients commissioned the economist Graham Brookes to undertake an in-depth study on innovation in the food ingredients market. A summary of his findings – that draw on interviews with food ingredient companies – can be found below. The full report *Economic Impact Assessment of EU Food Related Regulations on Research, Innovation and -Competitiveness in the Specialty Food Ingredients Sector* is available at:

www.specialtyfoodingredients.eu/uploads/news_documents/Brookes_innovation_report_June_2016.pdf

THE EU FOOD INGREDIENT SECTOR TODAY

Around 200 businesses are involved in the EU speciality food ingredient market, today worth around €16 billion. The EU, therefore, has a significant share of the global market valued at €40 billion and employing 90,000 people. Just under a quarter of the companies involved in the sector are small or medium enterprises.

WHAT IS THE COST OF INNOVATION?

Innovative companies typically spend between 4% and 6% of their annual turnover on research and development, although some may spend as much as 8 percent. The total research and development (R&D) period for a new molecule or food product is 4 to 10 years. For a new formulation of an existing ingredient, the time period is typically 1-3 years.

Research and development costs can vary considerably. A new ingredient can typically cost €2-3 million to develop, with a further cost of €1-3 million required if the ingredient is to be marketed with a health claim. For a novel food making a health claim, the costs are in the range of €15-20 million.

TO INNOVATE OR NOT TO INNOVATE?

An R&D strategy in a given market involves an evaluation as to whether 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 for a new product is 50%. Alternatively, some companies evaluate new ingredient development projects on a payback basis, namely they expect to cover all costs within 3 to 5 years.

WHAT IS THE IMPACT OF REGULATION?

Innovation decisions are inherently risky given a number of unknown factors, including the outcome of prospective research, market uptake for any new product and the behaviour of competitors. One particularly important consideration for any company assessing the viability of investment in innovation is the anticipated return on this investment. This is determined, to a significant extent, by the time taken for a new product to come to market. Regulatory procedures – both how they are designed and how they are implemented in practice –are therefore of utmost importance to a company's innovation strategy.

HOW SIGNIFICANT ARE EFFICIENT PROCEDURES TO MARKET SUCCESS?

Interviewed companies identify two aspects of the regulatory system that influence decisions on innovation:

1. ACTUAL TIME TO MARKET
2. UNCERTAINTY

1.

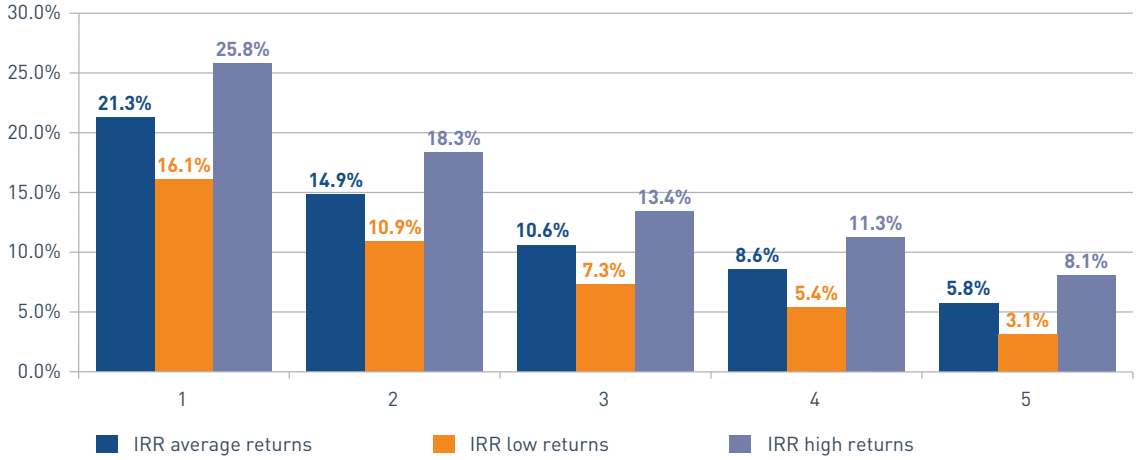
THE TIME TO MARKET: THE COST OF DELAYS

Let us take the example of **novel foods**. The regulatory procedures for authorising new products in many countries typically take 12-18 months. A 12-18 month authorisation procedure, will generally deliver a rate of return of between 16.1% and 25.8% (average 21.3%) within a company's target internal rate of return 15%-25%. In this context, payback – when the costs of bringing product to market, inclusive of research, development and regulatory costs have been recouped – could be completed within four years, again within the target payback time of 3-5 years. Reasonable expectations of arrival to market within these timeframes are conducive to investment in R&D.

The average EU authorisation time (under Regulation (EC) No 258/97) takes 36 months, but has ranged from 16 to 92 months. The average 36 month authorisation period results in an internal rate of return on investment of between 7.3% and 13.4% and a payback period on investment of seven years. An authorisation procedure that extends beyond 36 months further reduces these returns (see Figure 1 – Figure 6 in report). With prospects of a five-year authorisation period (as has occurred for some novel foods and ingredients in the EU), a viable return on investment is highly unlikely. Such a regulatory environment will discourage research-driven companies from pursuing potential new products.

One source of delay in the EU has been the need for an initial Member State assessment, which has generally been challenged by other Member States (through reasoned objections) necessitating further scientific evaluation by the European Food Safety Authority (EFSA).

Figure 1: 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

An additional cause of long authorisation periods identified by the Commission is the EU's internal decision-making process known as "comitology", estimated at amounting to a third of the total authorisation time.[1] While double assessment has been eliminated by the new Novel Food Regulation 2015/2283, the revised comitology procedure is not subject to deadlines. Its operation in practice will be crucial to determining whether the new system can give real incentives for innovation.

Health claims – the possibility to communicate on health-related innovation – may be integral to a company's innovation strategy. The effective operation of health claim approval procedures is therefore another key focal point for innovative companies. In the EU, health claims (regulated under Regulation (EC) No 1924/2006) approvals have thus far raised similar dilemmas for food ingredient manufacturers as novel foods: the approval time for health claims has ranged between 15 months and 4 1/2 years, with an average approval time of 2 1/2 years. Again, analysis of the authorisations shows that 80% of that approval time is taken up by post-EFSA Opinion deliberations. For example, an average of seven months elapses before Working Groups hold their first discussions on scientific opinions issued by EFSA. On average, a further year elapses before voting takes place in the Standing Committee on Plants, Animals, Food and Feed.

Where companies seek both novel food authorisations and health claims authorisations to promote new ingredients, the management of both these procedures – in sequence or in parallel – will further determine the time to market and shape company strategies and investment decisions.

[1] Commission Staff Working document, Impact Assessment for a Regulation Replacing Regulation (EC) No 258/97 on Novel Foods and Novel Food Ingredients (2008).

2.

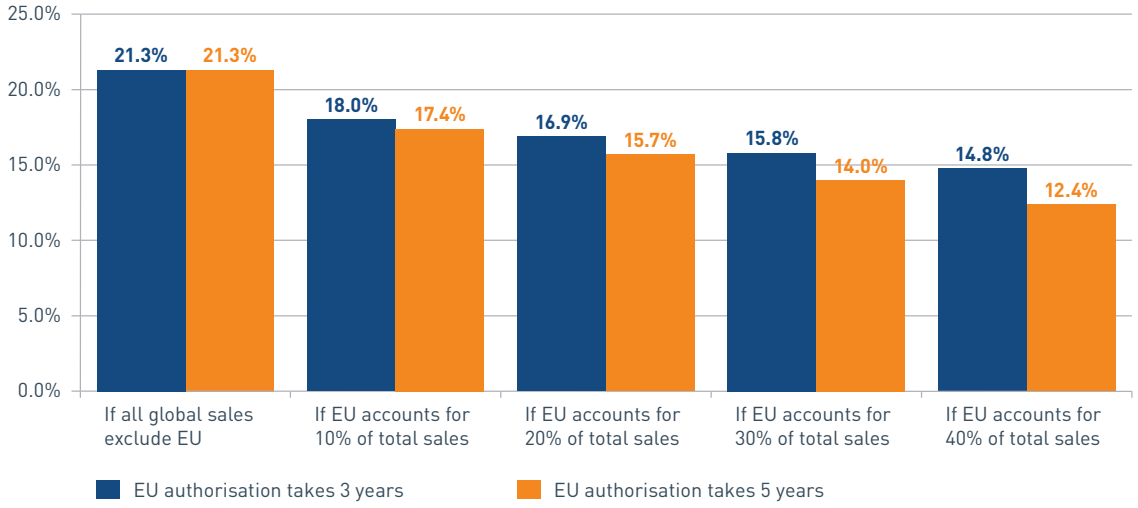
UNCERTAINTY: SHAPING DECISIONS ON INNOVATION

Some delays are to be expected in bringing a product to market. The problem identified by Brookes through interviews with leading ingredient companies is the wide variation in authorisation times in the EU, and therefore a level of uncertainty and unpredictability which is viewed to be systemic. While there are individual cases of more efficient access to market, it is this perception of systemic uncertainty that erodes confidence and discourages investment in innovation. Procedural uncertainty is compounded by legal uncertainty as to the legal status of food ingredients and the need to seek authorisation. While the economic implications of legal uncertainty are difficult to quantify, this study identifies that the EU regulatory system is considered particularly problematic in this respect when compared to regulatory systems in other countries.

The danger of EU exclusion from global innovation strategies

The global nature of the specialty food ingredient market means that a divergence between EU and other regulatory systems has more far-reaching consequences for companies' innovation strategies. As EU procedures are typically longer than the authorisation processes in other markets, delays incurred through the EU's regulatory system may significantly inhibit the company's global returns. In such cases, there will be an additional incentive not to bring innovative products to the EU market, to delay European marketing until other markets have been established or even to not bring a product to the entire global market. As can be seen in Figure 2 (Figure 1 in report), the impact on global returns will depend upon the importance of the EU market share.

Figure 2: Impact of the EU's longer authorisation process for novel ingredients/ products on global returns (%internal rate of return): average returns basis



Where the EU market is a key component of expected global sales, the EU regulatory delays may result in a new innovative product not only being dropped from the EU market, but from any market at all. Overall, this is potentially detrimental to consumers in the EU and beyond and damaging to the competitive position of EU food manufacturers.

HOW TO IMPROVE THE REGULATORY ENVIRONMENT IN THE EU

The Brookes innovation report exposes significant challenges for regulators and industry for creating a regulatory environment that meets the EU's innovation ambitions in the food sector. Both the actual and perceived inefficiencies and uncertainties in EU regulations are discouraging investment in innovation and undermining the competitive position of Europe's food manufacturers.

An improved, innovation-friendly regulatory environment could be created by:

- targeting completion of regulatory approval processes within 12 to 18 months.
- ensuring regulatory approval processes under different pieces of legislation are streamlined i.e. can be completed simultaneously rather than consecutively.
- setting and adhering to deadlines for the completion of comitology procedures.
- fostering greater confidence among innovative companies by improving clarity on both timings and applicability of approval procedures.

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