

## Summary: Intervention & Options

Department /Agency: <b>FOOD STANDARDS AGENCY</b>	Title: <b>Impact Assessment of EU Proposal for a regulation on novel foods</b>	
Stage: Consultation	Version: Draft 1.0	Date: <b>23 April 2008</b>
Related Publications: Common Assessment Procedure for food additives etc (Common Position); Council document no 16677/07		

Available to view or download at:

[http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm)

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What is the problem under consideration? Why is government intervention necessary?

EU legislation on novel foods (regulation (EC) No 258/97) has been in place for eleven years. This legislation needs to be updated to take account of experience in the operation of the existing regulation and to take account of changes in other areas of EU food law.

What are the policy objectives and the intended effects?

The Commission's proposal is intended to improve the clarity of the existing legislation and to streamline the procedure for obtaining authorisation. In addition some applicants would have the opportunity to benefit from a limited (5 year) period of data protection, in order to protect their investment in innovation. A new simplified procedure is proposed for the authorisation of traditional foods from other parts of the world, where the history of safe use might provide adequate assurance of safety.

What policy options have been considered? Please justify any preferred option.

The European Commission has carried out a public consultation on a range of available options, including retaining the status quo. The Commission has published an Impact Assessment that sets out the rationale for their proposal in each of the major areas where the proposal differs from the current regulation 258/97.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The proposal includes provision for a mandatory review after 5 years

**Ministerial/CEO Sign-off** For consultation stage Impact Assessments:

*I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.*

Signed by the responsible Minister/Chief Executive\*:



Date: 26/4/08.

## Summary: Analysis & Evidence

<b>Policy Option:</b>	<b>Description: Consultation on the Commission's proposal</b>
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<b>COSTS</b>	<b>ANNUAL COSTS</b>		Description and scale of <b>key monetised costs</b> by 'main affected groups' The revision of the existing regulation will require reading and understanding by: <ul style="list-style-type: none"> <li>• Businesses - 1000 x £14.61 x 2hours = £29,200;</li> <li>• Enforcement authorities - 469 x £19.54 x 2hours = £18,300.</li> </ul>
	<b>One-off</b> (Transition)	<b>Yrs</b>	
	£ 9,500	5	
	<b>Average Annual Cost</b> (excluding one-off)		
£ 0		<b>Total Cost (PV)</b>	£ 47,500
Other <b>key non-monetised costs</b> by 'main affected groups'			

<b>BENEFITS</b>	<b>ANNUAL BENEFITS</b>		Description and scale of <b>key monetised benefits</b> by 'main affected groups' Savings to UK companies seeking authorisation for novel products via reduced administrative burden; two dossiers saving £15k each annually.
	<b>One-off</b>	<b>Yrs</b>	
	£ 0	5	
	<b>Average Annual Benefit</b> (excluding one-off)		
£ 30k		<b>Total Benefit (PV)</b>	£ 140,200
Other <b>key non-monetised benefits</b> by 'main affected groups' The proposal is also likely to deliver: reduced barriers to innovation and product times to market; increased consumer choice; and benefits to producers in developing countries.			

Key Assumptions/Sensitivities/Risks

Price Base Year 2007	Time Period Years 5	<b>Net Benefit Range (NPV)</b> £ 80,000 - 100,000	<b>NET BENEFIT (NPV Best estimate)</b> £ 92,700
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What is the geographic coverage of the policy/option?	UK/EU			
On what date will the policy be implemented?	12m after adoption			
Which organisation(s) will enforce the policy?	Local authorities			
What is the total annual cost of enforcement for these organisations?	£ 3,700			
Does enforcement comply with Hampton principles?	Yes			
Will implementation go beyond minimum EU requirements?	No			
What is the value of the proposed offsetting measure per year?	£ n/a			
What is the value of changes in greenhouse gas emissions?	£ negligible			
Will the proposal have a significant impact on competition?	No			
Annual cost (£-£) per organisation (excluding one-off)	Micro Zero	Small Zero	Medium Zero	Large Zero
Are any of these organisations exempt?	No	No	N/A	N/A

<b>Impact on Admin Burdens Baseline</b> (2005 Prices)				(Increase - Decrease)
Increase	£ 0	Decrease	£ 30k	<b>Net</b> £ -30k

Key: Annual costs and benefits: Constant Prices (Net) Present Value

## Evidence Base (for summary sheets)

### Background to the proposal

The current regulation on novel foods has been in force since 1997 and applies to foods and food ingredients that do not have a significant history of consumption in the European Community before May 1997. The regulation includes a requirement for a review of its operation after 5 years in order to identify possible improvements. In practice, the review has been delayed to take account of other significant developments in EC food law, particularly:

- (a) the adoption of a new regulation on general food law (regulation 178/2002) which provides an overall framework for food legislation and established the European Food Safety Authority; and
- (b) new legislation on genetically modified food and feed (regulation 1829/2003), which removed GM foods from the scope of the novel foods regulation.

In developing its proposal, the European Commission has consulted with a range of stakeholders through various activities undertaken during 2002-2007. The proposal is accompanied by a formal Impact Assessment which is based on responses to a public EU-wide consultation. [http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives\\_en.htm](http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm)

(It should be noted that the majority of respondents to this consultation were food companies and other trade interests. The Commission's overall analysis includes two responses received from consumer interests but these are not highlighted separately in the impact assessment report.)

These consultations identified a number of areas for improvement in the existing regulation and Commission has used this exercise to identify the following objectives for its proposal:

- to avoid the delays that are associated with the current authorisation procedure for novel foods;
- to remove any unjustified barriers to the introduction of traditional foods from non-EU countries that have a history of safe food use in those countries;
- to avoid unnecessary duplication due to the current requirements for different manufacturers to submit applications for the same product;
- to remove the overlap with other EC food law, which current leads to unnecessary duplication in assessments and authorisations
- to update the legal text in order to improve its clarity and to bring it in line with developments in EC food law.

The Commission has therefore proposed to replace regulation 258/97 with a new measure that would meet these objectives by introducing the following major changes:

- **centralising the authorisation procedure for novel foods.** The European Food Safety Authority (EFSA) will carry out the safety assessment on the novel food. The current system requires one Member State to carry out an initial assessment which is then sent to all other Member States for comment – a process that takes a significant period of time, particularly as most dossiers are later referred to EFSA for advice on outstanding concerns raised by the Member States. Once EFSA's opinion is available there is a further delay while the Commission prepares a formal authorisation decision which is voted on by Member States. The centralised process is intended to be more efficient and to result in a streamlined authorisation procedure.
- **introducing a simplified safety assessment system for traditional food from third countries.** This will enable traditional foods to gain an authorisation relatively quickly if

applicant companies are able to demonstrate a history of safe use outside the EU. At present foods that are widely consumed elsewhere in the world have to undergo the same lengthy procedures as completely innovative products.

- **clarifying the definition of a novel food**, including new technologies with an impact on food. This will ensure that technologies not previously used in the food chain will require a premarket safety evaluation. The current provisions have, on occasions, been found to be ambiguous in this regard. The proposal aims to provide a clearer definition and is not intended to apply to a wider range of products than at present.
- **updating the scope of the regulation** in relation to parallel legislation on specific categories of foods. Developments in EC legislation since 1997 have resulted in parallel authorisation procedures being established for ingredients in certain categories of food such as food supplements and medical foods. As a result, a new ingredient can require multiple authorisations before it can be placed on the market. The proposal aims to minimise the overlaps with other legislation.
- **introducing the possibility of data protection.** Under the new proposal, applicants who have invested in new data to demonstrate the suitability of their product can seek a limited (5-year) period of data protection. If authorisation is granted, it would give the applicant the sole right to market the product during this period, using these safety data. Other operators could also apply for authorisation but they would have to provide their own safety data.

## **New costs**

The proposal has the same scope as the existing regulation and maintains the requirement for novel foods to undergo a safety assessment before they can be marketed. The criteria for authorisation are essentially unchanged and it is therefore not expected that the new regulation will impose new ongoing costs on applicants, food operators or enforcement bodies.

***Consultees are invited to comment on the enforcement costs, to confirm whether or not they would remain the same under the new proposal***

There are approximately 469 local authorities in the UK, and we have estimated that one officer in each of the 469 local authorities is expected to read and understand the Regulations and that it takes them one hour to do so. In addition, we have estimated that that person uses one more hour for dissemination to key staff within the organisation. A reasonable estimate of the cost with respect to the time taken by enforcers to read the guidance is £19.54. This figure is taken from the 2007 ONS ASHE (Annual Survey of Hours and Earnings) figures for a Public Service Professional of £15.03 per hour (median value), which, in-line with the Standard Cost Model, is then up-rated by 30% to account for overheads. This equates to an approximate one-off administration cost to enforcement authorities of £18,300.

A reasonable estimate of the cost with respect to the time taken by businesses to read the guidance is £14.61. This figure is taken from the 2007 ONS ASHE (Annual Survey of Hours and Earnings) figures for Managers in Distribution, Storage and Retailing of £11.24 per hour (median value), which, in-line with the Standard Cost Model, is then up-rated by 30% to account for overheads. Again it is estimated that the reading and understanding of the Regulations will take about one hour with one more hour for dissemination to key staff within each firm. Given the number of enquires the Agency receives annually from companies concerning this area of legislation it is estimated that approximately 1,000 companies will need to invest in understanding the new regulations. Thus yielding an approximate one-off administration cost to firms of £29,200.

## New benefits

### (a) Streamlined procedures for the assessment and authorisation of novel foods

The time taken for decisions to be made on applications submitted under the current regulation has varied from 6 months to more than 4 years. The Commission has calculated that authorisations have, on average, been issued 39 months after the application was submitted. This might be reduced to 18 months under the new proposal. *(Note: the diagram in the Commission's impact assessment anticipates a timescale of 12 months, but is based on decisions being presented for a vote 3 months after completion of the safety assessment. In fact the proposal allows 9 months for this stage of the procedure).*

The cost to an applicant of making a novel food application will vary from case to case, depending on the complexity of the case and the need to generate new data to demonstrate the acceptability of the product. Unilever have estimated that the total cost of obtaining authorisation for their phytosterol ingredient (used in spreads and other products in their Flora pro-activ range) was €25 million, although this figure does not differentiate between costs that resulted specifically from the novel food regulation and costs which would have been incurred in the absence of that regulation (e.g. work required to satisfy general obligations under EC food law, to meet the company's own level of corporate safety assurance or to obtain authorisation in other regions of the world).

Informal enquiries among recent applicants in the UK suggest that the administrative cost of preparing a dossier and taking it through the existing process may be of the order of £20-30k. If the applicant does not already have the data to undertake a formal risk assessment, the cost of the individual studies could range from £10k (for a detailed analysis of the composition of the product) to £150k (for a 90-day feeding study in laboratory rats).

The current authorisation procedure is based on assessments carried out by the relevant authorities in one of the 27 EU Member States, which are then scrutinised by the others. In most cases there are outstanding questions and concerns which, if they cannot be satisfied by further information from the applicant, are referred to EFSA. The proposal would replace this with a single centralised assessment by EFSA, in line with the approach used in other areas of EC food law, such as food additives. This would have the effect of speeding up the process, although the financial cost of assembling data and preparing the initial dossiers would be substantially the same as at present.

Reliance on a single, centralised safety assessment should not detract from the rigour of the safety assessment and it will be essential to ensure that assessments are carried out to a high standard and with the maximum degree of transparency.

Compared with the current system, there would be no change in the burden on enforcement bodies.

The centralised safety assessment will remove some of the burden placed on national authorities and transfer it to EFSA. However, Member States may still want to run their own checks (at least in the early days of the new procedure) and EFSA may wish to draw on expertise from Member States to support its work in this area, for example under the scientific networking system established under Article 36 of regulation 178/2002. The UK currently has a high level of expertise in the novel foods area, through the Advisory Committee on Novel Foods and Processes, and it seems likely that there will be a continued need to apply this expertise in one way or the other. No allowance has therefore been made for financial savings resulting from the transfer of the safety assessments from national level to EFSA.

The centralised procedure might however reduce the administrative burden on the applicant as they would have to liaise with a single body rather than each individual member state. For the purposes of this Impact Assessment, it has been assumed the current administrative cost per dossier is £30k (see above) and that 50% of this might be saved. An overall saving has been calculated on the basis of 2 applications from UK-based companies per year (the novel food applications that were made during 1997-2007 included 8 from small UK companies and 16 from multinationals – see EU Annex below).

There are no data on which to base an estimate of the financial benefits of enabling a new product to be brought to the market in a shorter time after the dossier is submitted.

***Further evidence of the actual cost of applications made under the novel foods regulation would be welcomed, along with evidence of the potential savings that might be achieved under a more streamlined system. Estimates of the financial benefits resulting from a shorter and predictable timescale for authorisation decision would be particularly useful.***

#### (b) A simplified safety assessment system for traditional food from third countries

There is increasing interest in the introduction of exotic fruits and vegetables on to the EU market from non-EU countries which have not previously exported them to Europe. For example, a group of Andean countries (Colombia, Ecuador and Peru) have estimated that there are about 60 plant species that are traditionally consumed in their region and that could in future be exported to the EU.

The existing novel foods regulation prevents the trade in such products but few applications have been received, apparently because the requirements for authorisation are seen by the exporters as unduly onerous.

The Commission has proposed that such applications should in future be treated separately to other novel food applications, via a notification system that allows products to proceed directly to the market unless a Member State (or EFSA) lodges a reasoned objection to the claim that the product has a history of safe use in a non-EU country.

One possible outcome of introducing this simplified procedure is that a number of foods from non-EU countries will be notified under the new regulation that would not be put forward under the more complex procedures that currently apply. This would result in a wider choice of foods for consumers.

#### (c) Clarification of definitions and the scope of the regulation

The proposal is intended to maintain the same scope as the current regulation, with minor changes to remove the current degree of duplication due to the overlap with other legislation on food supplements etc. The wording has also been amended to reflect the introduction of general EC food law (regulation 178/2002), providing improved clarity.

In addition the proposal provides for implementing measures that will allow criteria to be set for interpreting definitions, particularly the concept of a "significant" history of consumption, which is central to the definition of novel food.

The new wording, and the implementing measures, are intended to provide greater clarity and certainty for food operators who may otherwise be unsure whether a food they intend to market falls within the scope of the regulation and therefore requires approval as a novel food.

#### (d) Data protection

Authorisations issued under the current system are specific to the applicant and any other manufacturer who wishes to market the same product must submit a separate application. In most cases this can be done via a simplified procedure that is based on demonstrating to one of the national authorities that the two products are equivalent. This has led to a large number of "me-too" applications, creating unnecessary administrative burdens on applicants and national authorities.

Under the new proposal, authorisations would be issued on a generic basis, as they are in other areas of EC food law such as food additives.

However, the original applicant may have made a substantial investment in general new or proprietary data. In order to protect this investment and to promote innovation, the Commission

has proposed a data protection system that could be applied in appropriate cases. In qualifying cases, an applicant would be able to benefit from a limited period of protection (5 years) where only they would be able to benefit from the authorisation. Other operators could also apply for authorisation but they would have to provide their own data. This part of the proposal is modelled on the recent regulation on nutrition and health claims (Regulation (EC) No 1924/2006).

This change may provide benefits for the original applicant in cases where they are unable to rely on other systems that provide protection for intellectual property e.g. patents.

Where the data protection system does not apply, generic authorisation would benefit other operators who currently would have to notify their equivalent products under the simplified procedure, since generic authorisations will allow them to proceed directly to market.

## Specific Impact Tests: Checklist

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No



The marketing of novel foods, defined as foods and food ingredients that do not have a significant history of consumption in the European Community before May 1997, is currently regulated under Regulation (EC) No 258/97.

According to this Regulation, novel foods must undergo a pre-market safety assessment before being considered for authorisation. The criteria for authorisation are that the product must not present a danger to health, mislead consumers, or be nutritionally disadvantageous. Where necessary, authorisations may be accompanied by specific conditions of use and labelling requirements.

As of March 2008, 73 applications had been made under the 1997 regulation (excluding applications for GM food) of which 16 were from large multinational companies such as Unilever, Cargill and ADM. 8 were from smaller companies based in the UK. The remainder were from smaller companies based in other Member States or from outside the EU.

No data are available on the size of the current or future EU market for novel foods. Overall novel foods play only a minor role in the diet. Phytosterols are probably the most successful of the products authorised under the 1997 regulation, being widely available in a range of products aimed at people who wish to reduce their cholesterol levels. Other authorised novel foods are less widely on the market, being found for example in a limited number of food supplements. In some cases the products may not yet have been introduced onto the market for commercial reasons unrelated to the novel food regulation.

### **Competition Assessment**

The present system is regarded by many food businesses as a barrier to innovation and any improvements to the efficiency and clarity of the procedures (including allowing reasonable returns on investments by means of data protection) are expected to lead to increased innovation and potentially competition, especially if the time to market of new products/ingredients is reduced.

### **Small Firms Impact Test**

Small enterprises are potentially more vulnerable to complex regulatory requirements and by uncertainty in the timescale for decisions on the authorisation of new products, Simplification and increased efficiency of the procedures should therefore increase the ability of small firms to bring novel foods to the EU market.

### **Sustainable development**

There are two possible impacts, related to the introduction of novel foods derived from natural sources.

(a) ingredients could be derived by harvesting scarce natural resources. While trade in products obtained from recognised endangered species would be illegal, a sudden increase in demand could significantly reduce the numbers of a given species if the ingredient is obtained from plant or animals taken from the wild. The proposed criteria for future autorisation of novel foods do not include environmental risk, although some Member States are suggesting that this should be included, in line with food additives legislation that is currently being developed.

(b) the authorisation of traditional foods from countries outside the EU could stimulate the conservation of wild species through horticulture and provide a valuable source of income for farmers in developing countries.

### **Race equality issues**

The proposal does not impose any restrictive compliance to any person from a particular race, gender or with disability

### **Gender equality issues**

The proposal does not impose any restrictive compliance to any person from a particular race, gender or with disability

### **Disability equality issues**

The proposal does not impose any restrictive compliance to any person from a particular race, gender or with disability

## List of Interested Parties

Alford Health	Inside Consulting Group
Alimentar	Kraft Foods EU
Arcadia Biosciences	LACORS
Baker & McKenzie CVBA	Leatherhead Food International
Bioresco	Lipid Nutrition
Bodycote LawLabs	Merton Council
British Frozen Food Federation	National Association of Health Stores
British Heart Foundation	National Consumer Council
British Retail Consortium	National Farmers' Union
British Soft Drinks Association	National Starch Food Innovation
Cadbury Schweppes	Nestle UK Ltd
CA Medica Ltd	New Zealand Food Safety Authority
Campden & Chorleywood Food Research Association	Premier Foods
Cantox Health Sciences	Richmond Scientific Society
Central Science Laboratory	RSPCA
Chartered Institute of Environmental Health	RSPCA
Consumers for Health Choice	S. Black Ltd
Consumer Goods	Tate & Lyle Ingredients (France)
Croda International	Trading Standards Institute
Deans Foods & Belovo	Unilever
Decision News Media	Unilever
Eco Trace	VEGA
Efficas Inc	Waitrose
Englyst Carbohydrates Ltd	Which?
Eurofins Laboratories	Margaret Anderson
European Advisory Service	Prof. John Banks
Exponent International Ltd	Prof. Ralph Blanchfield
Fair Venture Consulting Limited	Andrew Borland
FNLI (Dutch Food Federation)	David Godfrey
Food and Drink Federation	Dr David Jukes
Food Manufacture Magazine	Peter Lapinskas
Gareth Edwards Consultancy	Paul Lawrence
Hampshire County Council	Benny Lee
Health Food Manufacturers' Association	Prof. Anne Murcott
Higher Nature	Dr Eva Novotny
Holland & Barrett UK	Steve Ruckman
Huntingdonshire District Council	Anuj Saha
	Dr Naomi Salmon
	David Webber
	Chris Whitehouse