

## Initial Regulatory Impact Assessment (RIA)

### 1. EU proposal for a regulation on novel foods

- 1.1. The proposal is for a Regulation intended to replace and repeal the current Novel Food Regulation (EC) No 258/97.

### 2. Purpose & intended effect

#### 2.1 The Objectives

- 2.1.1. 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.
- 2.1.2. 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.

#### 2.2. Devolution

- 2.2.1. The EU proposal will apply across all Member States, as does current EU legislation on novel foods. This consultation is taking place in Scotland only. Parallel consultations are taking place in England, Wales and Northern Ireland. The purpose of the consultation is to obtain views on the new proposal, and in particular comments on the key differences between the proposed Regulation and that currently in place.

#### 2.3. Background

- 2.3.1. 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.

2.3.2. 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.)

2.3.3. These consultations identified a number of areas for improvement in the existing regulation and the 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.

2.3.4. 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 that technologies not previously used in the food chain will require a pre-market 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.

2.3.5 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.

2.3.6 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.

2.3.7 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.

2.3.8 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.

## **2.4. Rationale for Government intervention**

2.4.1. 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.

2.4.2 The UK, as Member State, is contributing to preliminary discussions currently taking place at Council Working Party level in Brussels.

## **3. Consultation**

3.1. The purpose of the consultations is to obtain views on the new proposal, and in particular comments on the key differences between this proposal and the current Regulation. This consultation is not being held for a full 12 weeks because it is anticipated that Member States will need to represent their formal positions on this proposal in July. This consultation is taking place in Scotland only. Parallel consultations are taking place in England, Wales and Northern Ireland.

## **4. Options**

4.1. 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.

## **5. Costs and benefits**

### **5.1. Sector and groups affected**

5.1.1. The food industry, principally those businesses investing in innovation or wishing to import foods traditional in other parts of the world but not previously consumed in the EU, enforcement authorities, and consumers.

5.1.2. We consider that the proposal will have no impact on racial, gender or disability equality issues.

5.1.3 There are two possible impacts with regard to sustainable development, 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 authorisation 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.

## 5.2. Costs and Benefits

### Costs

- 5.2.1. 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.**
- 5.2.2. There are 32 local authorities in Scotland, and we have estimated that one officer in each of the 32 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 £1250.
- 5.2.3. 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. This yields an approximate one-off administration cost per company of £29.22. Given the number of enquires the Agency receives annually from companies concerning this area of legislation it is estimated that approximately

100 companies in Scotland will need to invest in understanding the new regulations, thus yielding an approximate one-off administration cost to Scottish firms of £2922. **Consultees in Scotland are invited to provide information on how many companies might need to invest in understanding the new regulations, and on the cost of doing so.**

## **Benefits**

### Streamlined procedures for the assessment and authorisation of novel foods

- 5.2.4. 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).*
- 5.2.5. 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 has 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).
- 5.2.6. 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).
- 5.2.7. 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.

- 5.2.8. 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.
- 5.2.9. Compared with the current system, there would be no change in the burden on enforcement bodies.
- 5.2.10. 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.
- 5.2.11. 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 across the UK 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; none of the companies appear to have been based in Scotland).
- 5.2.12. 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.
- 5.2.13. **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.**

A simplified safety assessment system for traditional food from third countries

- 5.2.14. 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.

- 5.2.15. 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.
- 5.2.16. 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.
- 5.2.17. 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.

#### Clarification of definitions and the scope of the regulation

- 5.2.18. 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.
- 5.2.19. 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.
- 5.2.20. 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.

#### Data protection

- 5.2.21. 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.

- 5.2.22. 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.
- 5.2.23. 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).
- 5.2.24. 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.
- 5.2.25. 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.

### **Small Firms Impact Test**

- 6.1. 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.

### **7. Test Run of Business Forms**

- 7.1 This section will be completed once discussions are further advanced and it is clear whether new or additional forms will be introduced.

### **8. Competition Assessment**

- 8.1. 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.

### **9. Enforcement, sanctions and monitoring**

- 9.1. The current enforcement, sanctions and monitoring system will remain in place. Local authorities will continue to be responsible for enforcing Novel Foods policy.

**10. Implementation and delivery plan**

Note: this section will be completed once discussions are further advanced. The policy will be implemented 12 months after the proposal is adopted.

**11. Post-implementation review**

The proposal includes provision for a mandatory review after 5 years.

**12. Summary and Recommendation**

Note: this will be completed after consultation.

**13. Declaration and publication**

Note: this will be completed after consultation.

## **List of Interested Parties**

Aberdeen University  
ADAS Scotland  
AG BARR (Finlays NMW)  
AIC Ltd  
Authorities Buying Consortium  
Berits & Brown Ltd  
BHJ Protein Foods UK Ltd  
Biodynamic Agricultural Association  
BMA Scotland  
British Hospitality Association  
British Nutrition Foundation  
British Soft Drinks Association  
Brooks-Carter Clinic  
Brown Brothers Ltd.  
Cairnton House  
Cardowan Creameries Ltd  
Centre for Public Health Nutrition  
Research  
Children In Scotland  
Chilled Food Association  
Claymore Dairies  
COSLA  
Dairy UK - Scotland  
Diageo  
Direct & Care Services  
Dunblane & Stirling Districts  
Beekeepers Ass.  
Federation of Small Businesses  
FG Associates  
Food Additives & Ingredients  
Association  
Food And Drink Federation  
Food Industry (North) Development  
Services  
Food Innovation Institute (F2i)  
Food Safety Authority of Ireland  
Food Training & Consultants Company  
Glasgow Caledonian University  
Glasgow Metropolitan College  
Glasgow Scientific Services  
Glasgow University Veterinary School  
Hallmark Meat Hygiene Ltd/ AA  
Duncan & Son  
Health & Sport Committee  
Health Promotion Service  
Health Protection Scotland  
Heriot-Watt University  
Hutchison Associates Ltd  
Ian Hain Associates  
IHS Technical Indexes  
Ingram Brothers Ltd.  
Inverclyde Council  
J G Ross (Bakers) Ltd  
JWC Services Ltd.  
Kettle Produce Ltd.  
Klinge Foods Ltd.  
Lossie Seafoods  
M&D Catering  
M.D. Longhorn & Co  
Mackies Of Scotland  
MacPhie of Glenbervie Ltd  
Matthew Algie & Co Ltd  
Meat and Livestock Commission  
Microgram  
Moray Seafood Ltd  
Munlochy GM Vigil  
Napier University  
National Association of Health Stores  
Neogen Europe Ltd.  
Neville Craddock Association  
NFU Scotland  
NHS Ayrshire & Arran  
NHS Borders  
NHS Fife  
NHS Fife - Nutrition & Dietetic Dept.  
NHS Grampian  
NHS Health Scotland  
NHS Highlands  
Orkney Herring Co Ltd  
P & C Morris  
Paterson Arran Limited  
Puremalt Products Ltd.  
Queen Margaret University College  
Regulatory Solutions  
Renfrewshire Council  
Rowett Research Institute  
Rowett Research Services  
Royal Environmental Health Institute  
for Scotland  
Royal Highland Education Trust  
Ruma  
Scotch Whisky Association  
Scotch Whisky Research Institute  
Scottish Agricultural Science Agency  
Scottish Association of Master Bakers  
Scottish Beef Cattle Association  
Scottish Beekeepers Association  
Scottish Chambers of Commerce  
Scottish Churches Rural Group  
Scottish Consumer Council  
Scottish Crop Research Institute  
Scottish Enterprise Grampian  
Scottish Environmental Research  
Centre  
Scottish Food & Drink Federation  
Scottish Food Quality Certification Ltd

Scottish Government  
Scottish Grocers Federation  
Scottish Health Food Retailers  
Association  
Scottish Organic Producers  
Association  
Scottish Pig Producers Ltd.  
Scottish Qualifications Authority  
Soil Association Scotland  
Tayside Scientific Services  
TESCO Stores Ltd  
The British Dietetic Association  
The Halal Food Authority  
The Royal Society of Edinburgh  
United Central Bakeries Ltd  
University of Aberdeen  
University of Dundee  
University of Strathclyde  
Vegetarian Economy & Green  
Agriculture (VEGA)  
Verner Wheelock Associates  
Walkers Shortbread Ltd  
Which?  
Wicken Fen Wholesome Foods  
William Yule & Son Ltd  
Women's Food & Farming Union

122 Consultees

+ Local Authorities