

EXECUTIVE NOTE

THE FOODSTUFFS SUITABLE FOR PEOPLE INTOLERANT TO GLUTEN (SCOTLAND) REGULATIONS 2010 SSI 2010/355

1. The above instrument was made by the Scottish Ministers in exercise of the powers conferred by sections 16(1)(e), 17(2), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990 and all other powers enabling them to do so. This instrument is subject to negative resolution procedure.

Policy Objectives

2. The purpose of the instrument is to provide execution and enforcement provisions in Scotland for Commission Regulation (EC) No. 41/2009 which introduces compositional and labelling requirements for food claiming suitability for people intolerant to gluten (coeliac disease).
3. The objective of Commission Regulation (EC) No. 41/2009 is to improve the long term health of people with coeliac disease. The Regulation harmonises the rules throughout the EU on the use of the claims 'gluten-free' and 'very low gluten'. Standardising the level of gluten for these claims will enable people with coeliac disease to identify those foods that are suitable for their dietary needs. It will also reduce consumer confusion through consistent labelling practice and will improve consumer choice.
4. The instrument also takes advantage of the derogation in Article 10(2) of Commission Directive 2009/39/EC, the framework Directive for foods for **particular nutritional** use (parnut foods) to allow gluten-free foods for particular nutritional use to be sold non pre-packed in Scotland.

Policy Background

5. Commission Directive 2009/39/EC provides a regulatory framework for parnut foods. A parnuts food is a food which, owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption and is sold in such a way as to indicate its suitability for its claimed nutritional use. Examples of parnut foods include; infant formulae, follow-on formulae and medical foods. Article 4.1 (a) of Directive 2009/39/EC envisages rules for foods that have been specifically formulated and/or manufactured to be gluten-free. Commission Regulation (EC) No. 41/2009 addresses that requirement by setting out compositional and labelling requirements for such foods. Article 2.2 of Commission Directive 2009/39/EC provides the scope to allow normal foods and other Parnuts foods that are naturally gluten-free to be labelled using the same claims as Parnut foods. Commission Regulation (EC) No.41/2009 applies this provision to lay down compositional criteria that normal foods will have to meet in order to make the claim 'gluten-free'.

6. Approximately 1% of the UK population have an intolerance to gluten and therefore must avoid the dietary intake of cereals containing gluten such as wheat, rye and barley. The food industry has developed a range of products to fulfil this need, which have been marketed using a range of terms such as 'suitable for coeliacs' or 'gluten-free'. However, the levels in these products have not been regulated and can vary greatly. This has made it difficult for people with coeliac disease to make informed choices and to manage their health condition effectively.
7. Scottish Government action is required to make an instrument to provide for the execution and enforcement of Commission Regulation (EC) No. 41/2009 to control the use of these claims and improve consumer safety.

Consultation

8. Article 9 of EC Regulation 178/2002, laying down the principles and requirements of food law, requires open and transparent public consultation on the revision of food law, save in respect of measures made in circumstances of urgency. These Regulations were not made in circumstances of urgency and therefore full public consultation was undertaken as follows.
9. The Food Standards Agency in Scotland consulted publicly with a total of 347 organisations and individuals in July 2008 during the EU negotiations and in November 2009 on the draft instrument, guidance notes and the Regulatory Impact Assessment. Stakeholders included the food industry, consumer groups and enforcement authorities. (see Annex A to this Executive Note) The documents were also made available on the Food Standards Agency website. Within government, the Food Standards Agency in Scotland consulted with the Scottish Government and the Scottish Government Health Officials. A total of 2 responses were received from stakeholders in Scotland from the 2008 consultation and 4 responses from the 2009 consultation. Parallel consultations were undertaken in England, Wales and Northern Ireland.
10. Responses to the consultation across all four countries indicated general support for the consumer protection measures in the proposal. However, the catering industry highlighted concerns that many businesses will not be able to comply with the new Regulation due to the high risk of cross contamination in the catering sector, and will be prevented from supplying helpful information to customers with coeliac disease. The Food Standards Agency has worked closely with the catering industry and Coeliac UK to address these concerns and ensure that businesses who are unable to meet the compositional criteria can supply certain information to consumers on a voluntary basis and within the regulatory requirements. This will take the form of factual statements about the foods that do not contain gluten-containing ingredients and for which gluten cross contamination is controlled and minimised.
11. The Food standards Agency has produced guidance on compliance and best practice for industry and enforcement officers, which is available on the Agency website.

Existing guidance on the provision of allergen information for non pre-packed foods will also be amended to provide advice on how to minimise cross contamination with gluten containing ingredients.

Financial Implications

12. The impact of the instrument on businesses, charities and voluntary bodies has been assessed and the costs of this measure in Scotland are estimated to be around £96,800. There may be some additional reformulation and re-labelling costs but these should be absorbed into normal business practice. It is not expected that the instrument will disproportionately impact on small businesses. The costs to Local Authorities Food Enforcement are considered to be minimal. To facilitate the introduction of the changes the Food Standards Agency negotiated a 3 year transition period for the Regulation. The Agency is introducing the Instrument now to give businesses early warning of the changes. Industry has indicated that this approach is helpful.
13. The EU Regulation has been interpreted as flexibly as possible to allow catering businesses, who are unable to meet conditions for a 'gluten-free' claim, to continue to supply helpful information to consumers with coeliac disease. This should give these consumers more confidence to eat out and encourage further market growth of this sector.
14. Coeliac UK is the principal charity representing people with coeliac disease in the UK. The Regulation will impact on their activities. Coeliac UK has indicated significant one off costs of legal advice, communication with their members and changes to its Food and Drink Directory. They do not expect any significant ongoing costs.

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Annex A

List of Stakeholders

Aberdeen City Council
Aberdeen Scotch Meat Ltd
Aberdeen University
Aberdeenshire Council
Adam Smith College
ADAS Scotland
AG BARR (Finlays NMW)
AIC Ltd
Andy Race (Fish Merchants) Ltd
Angus Council
Aquascot Ltd
Argyll & Bute Council
Association of Deer Management groups
Association of Scottish Shellfish Growers
Ayrshire & Arran Health Board
Barratlantic Ltd
Baxters of Fochabers
Bell Bakers Limited
Berits & Brown Ltd
BHJ Protein Foods UK Ltd
Bickiepegs
Biodynamic Agricultural Association
Black of Dunoon (Bakers) Ltd
BMA Scotland
Bramik Foods Ltd
British Egg Industry Council
British Goat Society
British Hospitality Association
British Nutrition Foundation
British Poultry Council
British Soft Drinks Association
British Trout Association
Brooks-Carter Clinic
Brookside Products Ltd
Brown Brothers Ltd.
Buchanans (Scotland) Ltd
Burgon (Eyemouth) Ltd.
C J Lang & Son Ltd
Calder Millerfield Ltd
Cardowan Creameries Ltd
Care Commission
Carrie Ruxton
Castle MacLellan Foods
Centre for Public Health Nutrition Research

Charcuterie Continental
Charles Tennant & Co Ltd
Children In Scotland
Chilled Food Association
Chris Fenn
City of Edinburgh Council
Clackmannanshire Council
Co-operative Group (CWS) Ltd
Coca Cola Enterprises Ltd
Coeliac UK
Coldstorage and Distribution Federation
Comhairle Nan Eilean Siar
Consumer Focus Scotland
COSLA
Crannog Seafood Company
Cream oGalloway
Cumbrian Seafoods Ltd
Dairy UK - Scotland
Dawnfresh Seafoods
Deans of Huntly
Deeside Natural Mineral Water
Dem lane Ltd
DEVRO Plc.
Diageo
Direct & Care Services
DSM Nutritional Products (UK) Ltd
Dumfries & Galloway Council
Dunblane & Stirling Districts Beekeepers Ass.
Dundee City Council
Dundee College
Dundonnell Smoked Salmon
East Ayrshire Council
East Dunbartonshire Council
East Lothian Council
East Renfrewshire Council
Eastwood Beekeepers Association
Edinburgh Community Food Initiative
Edinburgh Smoked Salmon Company (1992) Ltd.
Edinburgh Tea & Coffee Company Ltd
European Parliament
Falkirk Council
Falkirk Royal Infirmary
Federation of Small Businesses
FG Associates
Fife Council
First Milk Cheese Company
First Milk Ltd
Food & Drink Federation
Food Additives & Ingredients Association
Food Certification Scotland Ltd

Food Industry (North) Development Services
Food Innovation Institute (F2i)
Food Microbiology, Fish Handling and Processing
Food Partners Ltd.
Food Safety Authority of Ireland
Food Training & Consultants Company
Framgord Ltd
G McWilliam (Aberdeen) Ltd
Galloway Lodge Preserves
Glasgow Caledonian University
Glasgow City Council
Glasgow Metropolitan College
Glasgow Scientific Services
Glasgow University Veterinary School
Glenample Estate
Gordon & MacPhail
Gourmets Choice Ltd
Grampian Oat Products
Greenwood Academy
H.R. Bradford (Bakers) Ltd
Hallmark Meat Hygiene Ltd/ AA Duncan & Son
Harbro Group Ltd
Healyliving Award
Health Promotion Service
Health Protection Scotland
Health Services Research Unit
Hebridean Seafare Ltd.
Helen Glass
Highland Council
Highland Drovers Ltd.
Highland Smoked Salmon Ltd
Highland Spring Ltd
Hilton International
HUSH
Hutchison Associates Ltd
Hutchisons Flour
Ian Ham Associates
Independent
Ingram Brothers Ltd.
Institute of Biological & Environmental Services
Inverawe Smokehouses
Inverclyde Council
Island Cheese Co Ltd.
Islay Crab Exports Ltd
J & I smith (Bakers)
J G Ross (Bakers) Ltd
James Rizza & Sons Ltd
James Ross & Son (Ed in) Ltd.
John Hogarth Ltd.
John M Munro Ltd

Jura Fine Foods Ltd
JWC Services Ltd.
Keltic Seafare(Scotland)Ltd.
Kettle Produce Ltd.
Kings College London
Kingdom Bakers Ltd
Klinge Foods Ltd.
Lactalis McLelland Limited
Larder Bytes Ltd
Lerwick Fish Traders Ltd.
Loch Fyne Oysters Ltd
Lothian Health Board
Lothian NHS
M A Mackinnons Marmalade
M Corson
M&D Catering
M.D. Longhorn & Co
MacDonalds Smoked Produce
MacDuff Shellfish
Mackays Ltd
Mackies Of Scotland
MacPhie of Glenbervie Ltd
Macsween of Edinburgh
Marine Harvest (Scotland) Ltd
MatthewAlgie & Co Ltd
McAusland Crawford
Mcintosh Donald
Meat and Livestock Commission
Microgram
Middleton Food Products
Midlothian Council
Mitchells
Moray Seafood Ltd
Mortons Rolls Ltd
Munlochy GM Vigil
Mylnefield Reasearch Services Ltd.
Nairn Beekeepers
Napier University
National Beef Association Scotland
Neogen Europe Ltd.
Neville Craddock Association
Newcastle University
NFU Scotland
NHS Ayrshire & Arran
NHS Borders
NHS Dumfries and Galloway
NHS Fife - Nutrition & Dietic Dept.
NHS Forth Valley
NHS Grampian
NHS Greater Glasgow & Clyde

NHS Health Scotland
NHS Highland
NHS Lanarkshire
NHS Lothian (West Lothian CHCP)
NHS Orkney
NHS Tayside - Directorate of Public Health
Nisha Enterprises Ltd.
Nor-Sea Foods Ltd
Norscot Seafoods Ltd
North Ayrshire Council
North Lanarkshire Council
Oatmeal of Alford
Olrig & District Beekeepers Association.
Orkney Herring Co Ltd
Orkney Islands Council
P & C Morris
Pan Fish Scotland Ltd
Pars Foods Ltd
Paterson Arran Limited
Perth & Kinross Council
Perth College
Pinneys of Scotland LTD
Purem alt Products Ltd.
Quality Meat Scotland
Queen Margaret University College
R.T.Stuart Ltd
Regulatory Solutions
Renfrewshire Council
Resipole Farm
Robert Gordon University
Robert Wisemans Dairies
Rowett Institute
Rowett Research Services
Royal Environmental Health Institute for Scotland
Royal Highland Agricultural Society of Scotland
Royal Highland Education Trust
SAC
Sangs (Banff) Ltd
Scallop Association
Scotch Whisky Association
Scotch Whisky Research Institute
Scotland Excel
Scottish Association of Master Bakers
Scottish Association of Meat Wholesalers
Scottish Beef Cattle Association
Scottish Beer & Pubs Association
Scottish Borders council
Scottish Care Commission
Scottish Chambers of Commerce
Scottish Churches Rural Group

Scottish Commission for the Regulation of Care
Scottish Crofting Foundation
Scottish Crop Research Institute
Scottish Enterprise Borders
Scottish Environmental Research Centre
Scottish Federation of Meat Traders
Scottish Food & Drink Federation
Scottish Food Enforcement liaison Committee FSSC
Scottish Food Enforcement Officers Association
Scottish Food Guide
Scottish Food Quality Certification Ltd
Scottish Game Dealers & Processors Association
Scottish Government
Scottish Grocers Federation
Scottish Health Food Retailers Association
Scottish Midland Co-op Society
Scottish Newcastle UK
Scottish Organic Producers Association
Scottish Pig Producers Ltd.
Scottish Qualifications Authority
Scottish Rural Property and Business Association.
Scottish Salmon Producers Organisation
Scottish Salmonella Reference Laboratory
Scottish Shellfish Marketing Group Ltd.
Scottish Womens Rural Institutes (SWRI)
Scrabster Seafoods Ltd.
Sea Fish Industry Authority
Seachill
Seafood Scotland
Seafood Shetland
Shetland Catch Ltd
Shetland Farm Dairies Ltd
Shetland Islands Council
Shortbread House of Edinburgh Ltd
SN DRT
Soil Association Certification Ltd
Soil Association Scotland
Solway Veg.
South Ayrshire Council
South Lanarkshire Council
Speyfish Ltd
Speyside Enterprises Ltd
Spicemanns Ltd.
Spitfire Resources
SQA
Stirling Council (Catering & Claeaning)
Strathlomond Mineral Water Co Ltd
Strathmore Foods Ltd.
Summer Isles Foods
SUSTAIN

T & L Food Services Ltd
Tan International Scotland
Tayside Contracts
Tayside Scientific Services
TESCO Stores Ltd
The Applecross Trust
The Association of Meat Inspectors
The British Dietetic Association
The Cheese Company
The Dram buie Liqueur Co.Ltd
The Glenside Group
The Halal Food Authority
The Highland Council
The Infant & Dietetic Foods Association Ltd
The Moray Council
The Really Garlicky Company
The Robert Gordon University
The Royal Society of Edinburgh
The Salmon Net Fishing Association of Scotland
The Scottish Licensed Trade Association
Thomas Tunnock Ltd
Tilquhillie Fine Foods
Tobermory Fish Co.
Tods of Orkney Ltd.
Trading Standards Institute
United Central Bakeries Ltd
United Fish Industries
University of Aberdeen
University of Abertay Dundee
University of Dundee
University of Glasgow
University Of Paisley
University of St Andrews
University of Stirling
University of Strathclyde
V.M.G. Bakery Ltd
Vegetarian Economy & Green Agriculture (VEGA)
Verner Wheelock Associates
Vion
Visit Scotland
Voluntary Health Scotland
Walkers Shortbread Ltd
Wellington Church
West Dunbartonshire Council
West Lothian Council - Domestic Services
Which?
Wicken Fen Wholesome Foods
William Forrest & Son (Paisley) Ltd
William Yule & Son Ltd
Womens Food & Farming Union

Woodhead Brothers Turriff
WTS Forsyth & Son

FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

1. TITLE OF THE PROPOSAL

Commission Regulation (EC) No. 41/2009¹ concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. The execution and enforcement requirements for this EU Regulation will be set out in The Foodstuffs for People Intolerant to Gluten (Scotland) Regulations 2010.

2. PURPOSE AND INTENDED EFFECTS

(i) Objectives

The new EU Commission Regulation puts in place compositional criteria related to the claims ‘gluten-free’ and ‘very low gluten’ for foods which have been specifically manufactured to satisfy the particular nutritional requirements of people who are intolerant to gluten as provided for by Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs for **particular nutritional** uses (partnut foods).

In addition, the EU Regulation also introduces a provision to allow foods that are not specifically prepared for people intolerant to gluten (i.e. those for normal consumption and other partnuts foods) to be labelled as ‘gluten-free’ as long as the foods meet certain compositional requirements in relation to the levels of gluten.

This Regulation, as extended to non pre-packed foods by the domestic Regulations, should ensure that all foods (including non pre-packed food, such as food sold in catering establishments) which are labelled to indicate their suitability for people intolerant to gluten will use harmonised labelling terms. Harmonised labelling will reduce consumer confusion about these products. In addition, the new rules will facilitate better consumer understanding of how much gluten there is in the foods they buy and therefore help to improve the health of these consumers. This Regulation also aligns the EC legislation with the recently agreed Codex international standard for foods targeted at people intolerant to gluten, thereby facilitating international trade.

¹ OJ L 16, 21.1.2009, p.3.

The Regulation is directly applicable in all EU Member States. Provision as to execution and enforcement are being made in national Regulations for Scotland, England, Wales and Northern Ireland.

(ii) Background

Until this Regulation was adopted there were no specific European Community rules on the use of claims to indicate the absence of or the reduced level of gluten in foods and national rules varied widely across the EU. This created uncertainty and potential confusion for people with coeliac disease, which may have impacted negatively on their health. Differences in national provisions may have impeded the free movement of these products and hence created unequal conditions for competition.

The Legal Basis

Article 4.1 (a) of Directive 2009/39/EC on foodstuffs for particular nutritional uses (parnuts foods) envisages rules for foods that have been specially formulated and/or manufactured to be gluten-free. The new Regulation addresses that requirement by setting out compositional and labelling criteria for such foods. In addition, Article 2. 2 of Directive 2009/39/EC provides the scope to allow normal foods and other parnuts foods that are naturally gluten-free to be labelled using the same claim as parnuts foods.

Extension of voluntary 'gluten-free' claims to foods naturally free of gluten

Normal foods and other parnuts foods which are naturally gluten-free and meet the specified compositional criteria should also be able to make voluntary claims, i.e. 'gluten-free' (where the gluten content does not exceed 20mg/kg), to highlight this property. The new Regulation uses the Article 2.2 provision to lay down the compositional criteria that these normal foods would have to meet in order to be able to make a 'gluten-free' claim. This will enable consumers to choose from as wide a range of foods as possible to maintain a low gluten diet.

Extension of the 'very low gluten' claim to other foods

All other foods which contain levels of gluten above 20mg/kg, either because they include gluten containing ingredients or through cross-contamination during processing, should not be able to make a voluntary claim about their levels of gluten. Eating significant amounts of foods with these higher levels of gluten (20-100mg/kg) would be detrimental to the health of people with coeliac disease. In addition, the allergen labelling requirement of Directive 2000/13/EC (as amended) means that the inclusion of gluten containing cereal ingredients in a pre-packed food product will be clearly declared, thereby allowing people with coeliac disease to avoid such products.

Coeliac Disease

People who are intolerant to gluten suffer from a serious autoimmune disorder (coeliac disease) that is triggered by gluten (proteins found in cereals such as wheat, rye and barley). When people with coeliac disease eat foods containing gluten, it causes damage to the lining of the small intestine, which stops the body from absorbing nutrients. A diet free from cereals containing gluten is prescribed for people with coeliac disease and provides the only relief from the symptoms of this condition, which can include stomach pains, diarrhoea, weight loss and, in some cases, malnutrition with attendant consequences e.g. anaemia and osteoporosis. As wheat is

usually found in most types of bread, pasta, pizza, pastry and cakes, a gluten-free diet is not easy to achieve and the absence of such cereals may result in deficiencies of nutrients usually obtained from these sources.

Coeliac disease and oats

There is also some debate as to whether individuals with coeliac disease can tolerate oats as they contain a protein that is similar to gluten. Recent evidence suggests that most but not all people with coeliac disease can tolerate oats. In the case of individuals who do react to oats, it may be that the oats are contaminated with small amounts of other cereals, such as wheat, because of the conditions under which they are grown, harvested, transported, stored or processed. Some oat products are therefore manufactured using specially sourced oats in which the cross contamination from gluten containing cereals is carefully controlled and kept to a minimum. The level of gluten in such products is typically very low. Special attention is therefore given to claims on oats in the Regulations.

Coeliac sensitivity to gluten

While most people with coeliac disease can tolerate small amounts of gluten in their diet, the sensitivity varies between individuals. Therefore, it is important to enable individual consumers to differentiate between various types of gluten reduced products such that they can make informed choices and manage their condition effectively. This can be achieved through clear criteria for the different sorts of products and unambiguous claims on the labelling of all products specifically manufactured for people with coeliac disease.

The rise of the gluten-free/low gluten market

The food industry has developed a range of products in which the gluten content has been eliminated or reduced. The increase in products marketed as gluten-free is demonstrated clearly in the Mintel report on Food Intolerance (October 2007), which estimates that the value of retail sales of gluten/wheat free foods has increased by 57% between 2004 and 2007. Sales of gluten free products in 2007 are estimated to have been between £60 and £74 million.²

Elimination and reduction of gluten in food

The elimination/reduction of gluten is achieved in a number of different ways. Some products have been reformulated to remove the gluten containing ingredients or to include substitute ingredients i.e. the gluten containing cereal is replaced by a cereal ingredient which does not contain gluten, such as maize or rice flour. Such products tend to have very low levels of gluten, which may be present as a result of cross contamination at some point in the food chain. There are also products that have gluten containing cereals as ingredients, but at very low levels and others that are naturally gluten free. Other products include gluten containing cereals that have been specially processed to remove almost all the gluten (e.g. codex wheat starch) and usually contain a slightly higher residual level of gluten than the substitute products. However, due to technological constraints it is not currently possible to eliminate gluten altogether from all specially formulated foods and in some cases it is necessary

² Mintel estimates sales in 2007 to be £74 million: Mintel (2007) *Food Intolerances and Allergies*.
Euromonitor estimates sales in 2007 to be £60 million: Euromonitor *Health of the Nation*.

to include some wheat starch in order to maintain the consistency and/or texture of the food as it is the gluten which gives bread its chewy texture.

Up until now these products have been marketed using a range of terms such as 'suitable for coeliacs' or 'gluten-free', or through listing them in directories of products suitable for people with coeliac disease. The new Regulation defines two permissible terms, 'gluten-free' and 'very low gluten' and sets associated limits for the amount of gluten allowed in these products. The FSA conducted research to ensure that consumers understood the new labelling terms and how they should be used to make safe food choices to manage their condition. A copy of the report can be found at:

http://www.foodbase.org.uk//admintools/reportdocuments/389-1-687_T07059.pdf

(iii) Rationale for Government Intervention

Approximately 1%³ of the UK population suffers from an intolerance to gluten and as such must avoid the dietary intake of cereals containing gluten. The number of foods marketed to these people is increasing rapidly to fill this need. Formerly, there were no European Community rules to control the use of 'gluten-free' or 'very low gluten' claims on food. Levels of gluten in products making these claims could vary greatly. The new EU Regulation is directly applicable in all EU Member States. Government intervention is required to implement these provisions and to give the necessary powers to enforcement authorities. Implementing the Regulation will assist people with coeliac disease to make healthier, safer, and more informed choices and in doing so contribute to the FSA overall strategic plan to improve food safety.

(iv) EU Position

Following the adoption of the Codex Standard on gluten-free foods, the European Commission published a proposal to align European law with the Codex standards, with the aim of reducing the level of gluten in foods targeted at people with coeliac disease.

The objective of the new Regulation is to harmonise the Community rules on the use of claims highlighting the absence of gluten (gluten-free) or the reduction of gluten (very low gluten). Standardising the levels of gluten for such claims will improve consumer health as people with coeliac disease will be able to identify foods with low gluten content confidently. In addition standardisation of the terms will reduce consumer confusion, promote consistent labelling and facilitate international trade.

(v) Scottish Position

The new EU Regulation is directly applicable in all EU Member States. However, the accompanying SSI is required to provide for the enforcement and execution of the new rules in Scotland.

³ (Bingley *et al.* British Medical Journal, 2004, 7435; 322-323)

Separate but parallel legislation will apply in England, Wales and Northern Ireland.

(vi) Provisions in Regulation (EC) 41/2009

The EC Regulation applies to **all** foodstuffs, both pre-packed and non pre-packed sold in retail and catering establishments, making claims indicating suitability for people with coeliac disease. The main focus of the legislation is to control the composition and labelling of the following foods:

- **Parnut foods** – Food for **Particular Nutritional Uses** – foods which have been specially manufactured to reduce or eliminate gluten. For example gluten-free pasta or bread mixes, and muffins where the wheat flour has been substituted with rice, potato or some other non-gluten containing flour.
- **Normal foods** – Foods that naturally do not contain gluten containing cereals. For example, ice-cream, cakes traditionally made with ground almonds instead of wheat flour etc.

The key provisions of the Regulation are:

- to define the terms ‘gluten’, ‘wheat’ and ‘foodstuffs for people intolerant to gluten’;
- to harmonise the labelling of foods for people intolerant to gluten by restricting the use of the terms ‘gluten-free’ (does not exceed 20 mg/kg of gluten) and ‘very low gluten’ (does not exceed 100 mg/kg of gluten and reserved for foods containing cereals which have been specially processed to remove gluten) and other terms indicating suitability for people intolerant to gluten;
- to permit normal foods to make the claims ‘gluten-free’ when in compliance with the Regulations. This will enable consumers to choose from as wide a range of foods as possible to maintain a diet low in gluten;
- to ensure oats labelled as ‘gluten-free’ or used in foods labelled as ‘gluten-free’ contain 20 mg/kg of gluten or less. Again this will enable consumers to choose from as wide a range of foods as possible to maintain a diet low in gluten

A summary of the compositional and labelling requirements are provided in Annex I.

(vii) Risk Assessment

The following options were available prior to the adoption of the provisions of the Regulation. These were:

Option 1: do nothing – do not adopt the proposal.

Option 2: adoption of the proposal as drafted and provision of execution and enforcement provisions for Commission Regulation (EC) 41/2009.

Option 3: negotiate for amendment of the proposal to take account of issues raised by stakeholders.

Option 4: adoption of the proposal as drafted and provision of execution and enforcement provisions for Commission Regulation (EC) 41/2009 and apply a UK derogation to extend the scope of the Regulation to non pre-packed foods including those sold by caterers.

Some of these options carried risks to consumers, industry and Government. These are discussed below:

Option1: This would not fulfil the Agency's commitment to provide consumers with labelling information in order to allow them to make fully informed choices. It would not protect the health of UK consumers who have coeliac disease or take into account the needs of UK industry. Failure to put in place legislation to enforce the EC Regulation would constitute a breach of the UK's obligations under Article 226 of the EC Treaty.

Option 2: Putting into place legislation to enforce the EC Regulation would fulfil the UK's obligation under the EC Treaty. This would provide informed consumer choice and improve health protection for consumers with coeliac disease. However, this option would not allow the UK to negotiate to take account of issues raised by stakeholders.

Option 3: This would allow further clarification of the positioning of the claims on packaging and address any national concerns identified during the consultation process.

Option 4: This would take advantage of the derogation in the parnuts framework Directive to extend the scope of the new Regulation to include food sold non pre-packed. Businesses will only be allowed to use the voluntary claims 'gluten-free' and 'very low gluten' if the products meet the compositional requirements.

(viii) Negotiations in Europe

Member States and stakeholders were broadly in support of the provisions as presented. However, the UK would have liked to have seen the new compositional criteria apply to not only foods as sold to the final consumer, but also, where appropriate, to reconstituted or dehydrated foods (for example powdered soup and bread mixes). Since these foods are not designed to be eaten as sold, it would not be appropriate, or helpful, if the assessment of the gluten level was applied to the dry or dehydrated form of these products. The levels of gluten in these foods are higher than the compositional criteria in the Regulations, but when made up in accordance with the manufacturing instructions, the products are below the permissible gluten level. The UK lobbied the Commission and other Member States to incorporate these changes, but was unsuccessful in gaining support.

The UK successfully negotiated a 3 year transition period, which was welcomed by the industry. This will provide sufficient time for businesses to make any necessary changes to labels/menus/advertising and minimise one-off costs of the Regulation.

3. CONSULTATION

(i) Within Government

The new EC Regulation does not impact directly on the work of other government departments but the Scottish Government and Scottish Government Health Officials were consulted since this Regulation may impact on their responsibilities. The Better Regulation & Industry Engagement Unit within the Scottish Government was consulted with regard to the preparation of this Business and Regulatory Impact Assessment (BRIA).

The Local Authorities Coordinators of Regulatory Services (LACORS), which includes Scottish Local authorities, were consulted and no specific cost impact of any of the options in relation to their work was noted.

(ii) Public Consultation

The EC Regulation was discussed by EU Member States at meetings of the Dietetic Foods Working Group and the Standing Committee on the Food Chain and Animal Health (SCoFCAH) during the period from January 2008 to October 2008. The Agency represented the interests of the UK during these discussions and consulted stakeholders throughout the process, via formal consultations and informal mechanisms such as interested party letters.

In Scotland, the Food Standards Agency formally consulted with a wide range of stakeholders, (including consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other Government Departments) on the draft European Regulation and the partial Regulatory Impact Assessment (RIA). This public consultation took place between 23 July and 30 September 2008. The Agency had also consulted with these stakeholders via informal mechanisms such as interested party letters throughout negotiations in Europe and international negotiations on the Codex standard.

The Agency in Scotland received two responses to the 2008 consultation, a 'no comment' and a response which had also been sent to our London office. The Agency across the UK received 35 responses in total to the public consultation with all respondents supporting the principle of regulated limits relating to claims regarding the absence or reduction of gluten. The majority of respondents, whilst supportive of the Regulation did not specifically support either option 2 or 3. Coeliac UK and the Allergy Alliance, enforcement authorities, the Food and Drink Federation (FDF), British Retail Consortium (BRC) and various companies supported option 3 such that the compositional criteria applied not only to foods as sold to the final consumer, but also, where appropriate, to be applicable to reconstituted versions of dry or dehydrated foods (such as bread mixes or dehydrated soups). In addition, the majority of responses from the manufacturers of normal foods requested that the 'very low gluten' claim should also be made available for normal foods to avoid restricting

consumer choice as many foods currently labelled as ‘gluten-free’ would not be able to meet the 20mg/kg limit but would be able to reach the 100mg/kg limit.

As outlined in section 2, following the initial consultation, the Agency took forward Option 3 as it would have given the most benefit to consumers whilst being proportionate to industry. However, other Member States did not support these changes and Member States agreed the EC Regulation at the SCoFCAH meeting on 13th October 2008. The Agency was forced to take forward option 2 or option 4.

In November 2009, the Agency conducted a further 12 week formal consultation on the implementing draft Scottish Statutory Instrument; accompanying guidance notes to help businesses and enforcers understand the Commission Regulation and provide best practice advice; and the draft final Regulatory Impact Assessment (which is now in the Business and Regulatory Impact format). This consultation generated a total of 36 responses across the UK (this includes the four responses received in Scotland) from a range of stakeholders, including 8 individuals with coeliac disease and Coeliac UK.

Concerns that the Regulations will restrict what information will be available to people with coeliac disease when eating out

Whilst all people with coeliac disease welcomed the introduction of Regulations which will provide a higher level of consumer protection and reassurance on the suitability of food labelled as ‘gluten-free’, concerns were expressed that the legislation would be overly restrictive for catering businesses. This view was supported by the majority of stakeholders who responded to the consultation, voicing concerns that it is already very difficult for people with coeliac disease to eat out and the Regulations will limit choice further. Stakeholders were also concerned that a strict interpretation of the Regulations would prevent the use of product lists, which indicate products which are suitable for people with coeliac disease and foods which do not contain gluten containing ingredients. Such lists are highly valued by these consumers, a fact highlighted in a recent Define Market Research report (August 2009)⁴, commissioned by the Agency to gauge consumer understanding of the terms ‘gluten-free’ and ‘very low gluten’.

Development of a more flexible approach – Factual Statements

Comments received highlight that it is essential to have a flexible interpretation, to ensure the Regulations do not restrict the choices of the very people they are trying to protect. Restricting choice and the level of information available to people with coeliac disease, may lead them to take higher risk when making food purchases. In order to move forward, the Agency has worked with key stakeholders, including Coeliac UK, the British Retail Consortium (BRC), Food and Drink Federation (FDF), British Specialist Nutrition Association (BSNA) and caterers to explore what information can be provided on labels, menus, product lists and in oral communications, within the strict regulatory framework.

⁴<http://www.food.gov.uk/science/research/foodcomponentsresearch/allergyresearch/surveallergy/glutenintol>

The resulting discussions have led the Agency to seek a solution to the identified problems whilst keeping within the legal framework. The Agency takes the view that the requirement under the allergen labelling rules to indicate the presence of added allergenic ingredients means that it can be inferred that indicating food which does not contain added allergenic ingredients is permitted. It would not therefore be appropriate to take the view that Commission Regulation (EC) 41/2009 requires that, in the case of that particular allergenic ingredient, its absence should only be indicated if the conditions in Commission Regulation (EC) 41/2009 are met. This means that businesses will be able to make factual statements highlighting which food or meal options do not contain gluten containing cereal ingredients, without breaching the requirements of Commission Regulation (EC) 41/2009. Such statements must not make any indication as to the level of gluten or suitability for people with coeliac disease, and it remains that only food (or meals on a menu) that contains levels of gluten not exceeding 20ppm will be able to make the claim 'gluten-free'.

The ability to make this information available would apply in a range of circumstances, such as on menus, websites, verbal communications and in product lists offered to consumers. By extension, the Coeliac UK Directory would also be able to communicate the absence of gluten containing cereal ingredients in the products it features, and such factual information could also be provided via retailer product lists and customer care lines.

Therefore, the Agency has been working with key stakeholders to amend the draft guidance notes to accompany this Regulation, to ensure that food business operators and enforcement authorities understand the rules and put in place best practise advice, including examples of terms/phrases that would be permitted on foods that do not contain gluten containing ingredients, but do not meet the compositional requirements in law.

Consumer Survey on Factual Statements

To gauge the effectiveness of factual statements and help inform which statement should be recommended in the guidance to compliance, in July 2010 the Agency commissioned a survey of people with coeliac disease and health professionals to test consumer understanding of the statement "No gluten containing ingredients". The survey indicates that consumers find this statement helpful; provides greater choice for people with coeliac disease; and is suggestive that more consideration is being given to them and their condition by food businesses. The survey results do however, highlight that the phrase does not sufficiently convey the risk of cross contamination and that there is a need for consumer education to communicate the meaning of the phrase and the conditions of its use.

A copy of the survey report will be available on publication on the Agency's website: www.food.gov.uk

Separate consultations were also carried out by the relevant offices of the Food Standards Agency and comments received were considered together. Summaries of these responses are available on the Agency's website at: www.food.gov.uk/consultations/

4. OPTIONS

Option 1: do nothing – do not adopt the proposal

The majority of Member States supported the introduction of new rules in this area. The UK acting alone would not have been able to prevent its adoption in Europe. Without co-operating and influencing the negotiations, the UK would have faced infraction proceedings or had to implement a proposal that would not take into account the needs of UK consumers and UK industry. In addition, this would not have fulfilled the Agency's commitment to protect health and provide the consumer with comprehensive labelling information in order to make informed choices. Moreover, this option would have had a negative impact on the free movement of goods within the Community.

Option 2: adopt the proposal as drafted and provide execution and enforcement provisions for Commission Regulation (EC) 41/2009

The UK was broadly in support of the proposal as drafted but would have liked to see some further changes to reflect some of the requests from UK industry (see option 3).

Option 3: negotiate for adoption of the proposal following further negotiation to take account of issues raised by stakeholders

As stated in Option 2 above, the UK was broadly in support of the provisions as presented. However, the UK would have liked to have seen the composition criteria applied not only to foods as sold to the final consumer, but also, where appropriate, to be applicable to reconstituted versions of dry or dehydrated foods, such as bread mixes or dehydrated soups. Since these foods are not designed to be eaten as sold, it would not be appropriate or helpful for the consumer if the gluten level assessment was made on the dry or dehydrated product. There could be cases when the levels of gluten in the foods as sold would not meet the required criteria but the levels in the foods as prepared would be able to comply. In addition the UK would have liked further clarification regarding the positioning of the claims on packaging relative to the name of the product.

Following consultation, the Agency took forward Option 3 as it would have given most consumer benefit whilst being proportionate to industry. However, other Member States did not support these changes and the Agency was now, therefore, forced to take forward either option 2 or option 4.

Option 4: adopt the proposal as drafted and provide execution and enforcement provisions for Commission Regulation (EC) 41/2009 and apply a UK derogation to extend the scope of the Regulation to non pre-packed foods including catering

The Scottish Statutory Instrument takes advantage of the derogation in article 10(2) of the pan-European framework directive (Directive 2009/39/EC) to extend the scope of Regulation (EC) No. 41/2009 to pan-European food sold non pre-packed – thus allowing the continuation of the sale of products already on the market specially formulated for people intolerant to gluten in non pre-packed form. This will include, for example, muffins made from rice flour, or other gluten-free flour, in catering establishments. Businesses will only be able to use the claims 'gluten-free' and 'very low gluten' if the products meet the compositional criteria in the Commission Regulation.

Option 4 will allow the sale of non pre-packed Parnuts foods (including those in a catering setting), making a ‘gluten free’ or ‘very low gluten’ claim, after 1 Jan 2012, albeit stricter than previously. Without this derogation, no Parnuts food sold non-prepacked would be able to make any claims about the gluten content.

Difference between Option 2 (adopt proposal as drafted) and Option 4 (adopt proposal and extend scope to non pre-packed Parnuts Foods)

Scenario	Effect under Option 2	Effect under Option 4
Pre-packed Parnuts foods claiming ‘gluten-free’	Can continue to make ‘gluten-free’ claim subject to new stricter gluten-free thresholds	Can continue to make ‘gluten-free’ claim subject to new stricter gluten-free thresholds
Pre-packed ‘normal foods’ and other Parnuts foods claiming ‘gluten-free’	Can continue to make ‘gluten-free’ claim subject to new stricter gluten-free thresholds	Can continue to make ‘gluten-free’ claim subject to new stricter gluten-free thresholds
Parnuts food sold non pre-packed claiming ‘gluten-free’ (retail and catering)	Cannot make gluten-free or any similar claims.	Can make gluten-free claims subject to new stricter gluten-free thresholds
‘Normal foods’ sold non pre-packed and other Parnuts foods claiming ‘gluten-free’ (retail and catering)	Can continue to make ‘gluten-free’ claim subject to new stricter gluten-free thresholds	Can continue to make ‘gluten-free’ claim subject to new stricter gluten-free thresholds

Following consultations with stakeholders in 2009, two further sub-options for taking forward option 4 were considered:

Option 4a - Strict interpretation of the rules which would not allow the use of factual statements on foods for normal consumption that do not contain gluten containing ingredients, but do not meet the compositional requirements of the Regulation (EC) 41/2009.

Responses to a public consultation in November 2009 highlighted widespread concern that the strict regulatory requirements of the Regulations and the Agency’s interpretation of the Regulations, would mean that the majority of catering establishments would be unable to meet the compositional requirements of the new Regulations and would not be permitted to provide any information to people with coeliac disease on foods which do not contain gluten ingredients but did not meet the compositional requirements of the Regulation. This would severely limit the dietary options available to this group of consumers when eating out and deprive them of information on which to make informed choices.

Option 4b - Flexible interpretation to allow the use of factual statements on foods for normal consumption that do not contain gluten containing ingredients, but do not meet the compositional requirements of the Regulation (EC) 41/2009.

The majority of responses to the public consultation felt that 4a was too strict an interpretation, it would limit the dietary options available to people with coeliac disease and that it would be counter to the objectives of the Regulations – i.e. to give consumers the information they need to make an informed choice and to protect people with coeliac disease. The Agency has worked closely with Coeliac UK and other key stakeholders to see what information can be provided within the strict regulatory framework, on foods for normal consumption that do not contain gluten containing ingredients, but which potentially contain more than 20mg/kg of gluten. The Agency is of the opinion that the rules will allow food business operators to provide factual statements concerning the presence or absence of gluten containing ingredients, so long as such statements do not indicate suitability for people with coeliac disease or mention a level of gluten. This aims to ensure that people with coeliac disease receive sufficient information on foods and can make informed choices based on their individual level of sensitivity to gluten. This flexible interpretation is the preferred option and is described as option 4b throughout this BRIA.

The Agency acknowledges that under Options 4a and 4b, at least in the short term, it will be difficult for caterers to comply with the compositional requirements due to cross-contamination. It is expected that in such circumstances, caterers wishing to provide ‘gluten free’ meals, will need to purchase specially prepared pre-packed foods (for example a prepacked gluten-free cake served in a café) . However, the flexible interpretation outlined in Option 4b should reduce the impact of any removal of gluten-free claims, by substituting these claims with factual statements i.e. “No gluten containing ingredients”.

Option 4b is the Agency’s preferred option

(i) Sectors and Groups affected

The Regulation should improve the lives of people with coeliac disease and help health professional groups, who will have better information regarding the gluten content of foods. In particular, it will benefit around 600,000 gluten intolerant consumers in the UK (1% of population).⁵

Those manufacturers that produce and/or market foods that make claims about reduced gluten content will be affected by this Regulation as will enforcement bodies.

Number of businesses affected

The Regulation applies to all food businesses including the catering sector, wishing to make claims on foods suitable for people with coeliac disease. We assume that all businesses will need to be familiar with the Regulations, as they cover what information can and cannot be given to consumers. However, the number of businesses affected by the change in regulation will only be those who currently, or those who propose to, produce and/or sell products that are subject to the ‘gluten-free’ claims.

⁵ (Bingley *et al.* British Medical Journal, 2004, 7435; 322-323)

Coeliac UK has informed us that currently around 210 businesses in the UK produce food with gluten claims. To take account of any other businesses considering this claim, and new entrants, the calculations in the cost benefit section round this up to 300 ‘gluten-free’ producing firms.

The size of the catering market is difficult to establish, due in part to the catering sector having a high level of business start-ups, and closures and depends on which sectors of the eating out market are included in the calculation.⁶ The table below shows the number of catering firms (not outlets) according to the Inter-Departmental Business Register.⁷

Breakdown of UK catering industry by business size

Size of Business	Number of Businesses	By percentage
Micro	79,125	79.9%
Small	17,970	18.1%
Medium	1,850	1.9%
Large	95	0.1%
Total	99,040	100%

Note: Source IDBR 2009

Table 3: Breakdown of catering industry by region

SIC Codes	England	Scotland	Wales	N. Ireland	UK
5610	61,385	6,325	3,330	2,355	73,395
5621	19,935	1,865	675	380	22,855
5629	2,480	160	90	60	2,790
Total	83,800	8,350	4,095	2,795	99,040

Note: Source IDBR 2009

(ii) Benefits of the Options

Benefits of Option 1:

This does not afford any benefits. As the Regulation has direct legislative force, the UK would have been forced to accept a situation less than advantageous to the UK consumer and more onerous to the industry without positive engagement and negotiation. Furthermore, non-implementation would constitute a breach of the UK’s obligations under the EC treaty and lead to action in the European Courts of Justice.

Benefits of Options 2, 3 & 4:

The main benefit of the options 2 & 3 is the improved health of people with coeliac disease, as they will be able to choose products that are low in gluten and which are labelled so that they can make an informed choice. The additional benefit of the

⁶ Standard Industry Classification (SIC) codes used: 56.10 Restaurants and mobile food service activities, 56.21 Event catering activities, 56.29 Other food service activities. Explanation of SIC codes can be found at:

http://www.statistics.gov.uk/methods_quality/sic/downloads/SIC2007explanatorynote_s.pdf

⁷ <http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=933>

harmonisation of legislation in this area is the elimination of trade barriers such as the obstruction of free movement of such goods and unequal conditions of competition.

Overall, organisations such as Coeliac UK, Allergy Alliance and the Royal College of Physicians welcome the Regulations as they should benefit the health of people with coeliac disease. Across the UK, people with coeliac disease have been generally supportive of the Regulations as this should enable them to choose foods marketed to meet their health needs more easily. However, Coeliac UK have highlighted concerns that many foods currently labelled as 'suitable for coeliacs' or 'gluten-free' will not be able to meet the new gluten levels, particularly when eating out, due to cross-contamination. The nature of the kitchen environment means that it will not be feasible to meet the lower threshold unless the kitchen is operating entirely gluten-free or buying in specialist, pre-packed meals, which are simply re-heated on site. Coeliac UK argues this will unnecessarily severely curtail both the availability of options and the quality of food for people with coeliac disease.

Further Benefits of Option 3:

Option 3 would have given the added benefit that products such as pre-mixes of foods and dehydrated foods could have been labelled as 'gluten-free' or 'very low gluten' if the final food as consumed met the compositional standard. This would have further increased consumer choice and would have therefore benefited consumer health. However, as previously highlighted, this argument was not accepted by other EU Member States.

Further Benefits of Option 4:

The extension of the Regulation to allow 'gluten-free' and 'very low gluten' Parnuts foods to be sold non pre-packed is beneficial for a number of reasons:

- Gluten-free parnuts foods are already being sold non pre-packed (e.g. muffins) and the extension would allow this to continue post 1 Jan 2012.
- Reduction in risk to people with coeliac disease when purchasing food in catering establishments i.e. all foods will have to comply with 20mg/kg limit if they want to claim 'gluten-free'.
- Standardisation of the terms 'gluten-free'/'very low gluten' across the whole food sector will give a consistent message about the associated levels and the risks involved to consumers.

Furthermore, while it is acknowledged that under Option 4 it will currently be difficult for caterers to comply with this option, due to cross contamination and costs associated with notification, the Regulation allows for future developments in the production of 'gluten-free' foods in catering establishments.

Further Benefits of Option 4a

As option 4. No additional benefits identified.

Further Benefits of Option 4b

A flexible interpretation of the Regulations would protect people with coeliac disease, whilst ensuring sufficient information is provided on foods that have no intentionally

added gluten ingredients, but which do not comply with the Regulations. Food labelled as 'gluten-free' and 'very low gluten' would be guaranteed to meet the compositional standards in the Regulations and would be suitable for most people with coeliac disease, whereas other foods that had been made with ingredients which did not contain gluten could be labelled with factual information to inform choices. This option would also ensure staff in retail and catering establishments can continue to supply information to people on foods where there are no gluten containing ingredients and ensure there is dialogue between staff and customer without fear of prosecution. The level of sensitivity varies considerably amongst people with coeliac disease. The most sensitive will be limited to foods labelled as 'gluten-free', whilst those who are more tolerant may choose to consume foods labelled as 'very low gluten'. This option has broad appeal with industry and consumers alike and would avoid restricting consumer choice.

Comments received in response to the public consultation highlight that it is essential to have a flexible interpretation, to ensure the Regulations do not restrict the choices of the very people they are trying to protect. Restricting choice and the level of information available to people with coeliac disease, may lead them to take higher risk when making food purchases.

Use of other statements

It is anticipated that use of factual statements to indicate the presence or absence of gluten containing ingredients, as outlined above, will minimise the impact of the removal of 'gluten-free' on menus and labels. These statements will be provided on foods that do not contain gluten containing ingredients and where cross contamination is controlled (but do not meet the 20mg/kg level of gluten or where testing is not viable), coupled with foods that comply with the Regulations will ensure people with coeliac disease receive sufficient information to inform their choices and ensure that these people have access to as wide a range of foods as possible to ensure a varied and healthy balanced diet.

Coeliac UK has indicated the market for foods suitable for people with coeliac disease is potentially worth over £100 million. It could be argued that this option, coupled with suitable guidance for consumers and the industry, will increase consumer confidence and willingness to eat out, and ensure there are minimal barriers for food business operators who wish to enter this market; however there is no available evidence of this.

(iii) Costs of the Options

The costs imposed by the Regulation may arise from any mandatory or voluntary changes to labelling, any voluntary reformulation, possible loss of market share and changes in enforcement requirements. There will also be some ongoing administrative costs explained in detail in the sections below.

Costs of Option 1:

Option 1 would not have changed the regulatory environment for UK industry, but could have led to trade barriers and lost business for UK firms. In addition, there would be increased consumer confusion and as such a probable increase in health

risks for people with coeliac disease. If the UK decided not to enact domestic enforcement measures to render the Regulation effective, this would have led to possible infraction proceedings against the UK and would represent a significant cost to Government in addition to the other costs associated with opposing adoption of the EU proposal.

Costs of Options 2, 3 & 4:

Labelling changes and changes to menus, tickets, notices in catering establishments

Adoption of the Regulation may require some re-labelling of products or changes to menus in catering outlets and hence represent some costs to business. The claims which this Regulation controls are claims which producers choose to make in order to clearly highlight one particular property of their product to the consumer. Many products which are specially manufactured to be gluten-free (i.e. gluten-free parnuts products) already make such claims and as such no relabelling is required. However, those products which have been specially processed to reduce their gluten content may need to be relabelled as 'very low gluten' to comply with the new Regulation.

Some 'normal foods' which manufacturers already label to indicate suitability for people with coeliac disease may also need to be relabelled to comply with the new Regulation based on the new threshold level for the claim. In addition, 'normal foods' that manufacturers wish to label to indicate suitability for people with coeliac disease may need to be relabelled as a result of the new rules on the labelling terms to be used for such products. In both situations, this would however be a business choice because additional labelling is a voluntary provision.

In light of consultation responses and discussions with industry the Agency have amended our original re-labelling costs figure of £1000 per Stock Keeping Unit (SKU). Feedback from stakeholders as part of the consultation on saturated fat reduction⁸ suggests that re-labelling costs could range from £1500 - £3000⁹ per affected product. Given the transition period available (3 years from adoption - which the UK has negotiated) it is likely that such costs will be absorbed within routine label/menu changes, and therefore no incremental costs will be incurred. We understand the Department for Environment, Food and Rural Affairs will soon be publishing a report on labelling costs, but at this stage we are unable to incorporate evidence from this report due to timings.

The Agency requested comments and evidence from the industry about the labelling costs over and above what a business would do commercially and whether the proposed transition period was appropriate. Overall, the industry commented that the 3 year transition period was appropriate and that it would minimise costs of re-labelling. Industry representatives provided limited monetised estimates of labelling costs to support their views on the impact of the Regulation. Therefore, the Agency considers the assumptions and estimates set out below are appropriate.

⁸ Consultation on "Recommendations on saturated fat and added sugar reductions, and portion size availability, for biscuits, cakes, buns, chocolate confectionery and soft drinks" available at: <http://www.food.gov.uk/consultations/ukwideconsults/2009/saturatedfat>

⁹ This is an estimate as the cost of re-labelling will vary depending on the type of packaging and the degree of change necessary.

Reformulation

It is possible that some manufacturers will choose to reformulate their products in cases where they are not compliant with the compositional requirements of the Regulation in order to continue making the associated claims. Such a decision would be a business choice based on a desire to make a gluten-free claim therefore reformulation costs cannot be attributable to this Regulation.

Loss of sales/ removing products from sale

The Agency does not consider that any product will be removed from sale as a result of this Regulation. Some manufacturers and retailers may find it necessary to re-label certain products in order to comply with the Regulation. However, the Regulation will not stop products labelled as 'gluten free' or 'very low gluten' being placed on the market, provided they comply with the compositional requirements. Manufacturers and major retailers of 'free-from' type ranges have indicated that the vast majority of products already comply with the new low gluten levels. However, as outlined above other products currently labelled as 'gluten-free' or 'suitable for coeliacs' may need to be relabelled and/or reformulated if they do not currently meet the new gluten levels. If businesses choose not to reformulate products to comply with the new requirements they will have to be relabelled to remove any claims of suitability for people with coeliac disease. For example, a 'Chicken Tikka Masala' currently labelled as 'gluten-free' or 'suitable for coeliacs', will continue to be marketed but relabelled simply as a 'Chicken Tikka Masala'.

During consultation, manufacturers and caterers producing 'normal foods' stated that only permitting the claim 'gluten-free' (i.e. not allowing them to make the higher claim of 100 mg/kg) for 'normal foods' will restrict consumer choice as many ordinary foods currently highlighting low gluten levels would not be able to achieve the 20mg/kg limit. These concerns were also raised by Coeliac UK and individuals with coeliac disease, who are concerned that restaurants would not be able to meet the strict compositional requirements due to the increased risk of cross-contamination and many would choose to remove 'gluten-free' options from menus.

To address these concerns the Agency has worked with Coeliac UK and industry representatives to agree some additional statements that would be permitted by the Regulations and provide consumers with the information they require to make informed choices.

The statements must be factual and relate to the presence or absence of gluten containing ingredients, but must not indicate suitability for people with coeliac disease or levels of gluten. This flexible interpretation has full agreement with stakeholders, and is within the strict legal framework of the Regulations. Further advice to industry and enforcement is provided in the Agency guidance notes published on our website at www.food.gov.uk.

Industry also requested that 'normal foods' should be able to claim 'very low gluten' if they are not able to achieve the 20 mg/kg limit. However, the aim of the Regulation is to improve consumer health and facilitate informed consumer choice and to ensure

that the compositional criteria set are suitable for most people with coeliac disease. The Regulation therefore only allows for foods that contain a gluten-reduced ingredient and that meet the 100mg/kg gluten limit to make a ‘very low gluten claim’. This is because it was recognised that whilst the gluten reduced ingredients provide necessary technological properties that are needed to manufacture certain substitute staple foods, people with coeliac disease do not only eat foods with gluten-reduced ingredients and thus the overall dietary consumption of gluten would still be below levels that could cause adverse effects. The proposal by manufacturers of ‘normal’ foods would lead to a significant increase in the number of products on the market labelled as “very low gluten” and could lead to an increase in the daily consumption of gluten by people with coeliac disease. The evidence shows that regular consumption by such consumers of products with gluten levels above 20mg/kg can lead to changes in the cells of the gut, suggesting that eating too many products with gluten levels above 20mg/kg, over a long period of time, is not likely to offer sufficient protection for all people with coeliac disease. Therefore, allowing a wide range of ordinary products to make the ‘very low gluten’ claim could lead to gluten consumption at levels that would be harmful to the majority of people with coeliac disease although the Agency recognises that this may lead to a loss of choice for these consumers. This may be ameliorated by communicating to consumers the impact of the new rules and what this means for them when making food choices.

Testing products to determine levels of gluten

There are no new incremental costs associated with product testing. Companies making claims, regarding the levels of gluten, on their products should be able to demonstrate that the claim is valid and does not mislead the consumer as required by general food law. Therefore, manufacturers making claims about reduced gluten content may already have procedures in place to determine the levels of gluten in their products and as such this Regulation does not bring new costs for testing products. The Regulation does not stipulate a method of analysis; however the new Codex Standard stipulates that the R5 ELISA Mendez method be used.

It is difficult to monetise any potential costs from recommending the R5 ELISA Mendez method. There may be one-off costs for laboratories which do not currently use this method, but these are not expected to be significant.

However, a number of analysts and manufacturers have highlighted several practical problems associated with the R5 ELISA Mendez method which would make its use impractical and/or prohibitively costly. As such the Agency will raise these concerns within the Codex Alimentarius framework to try to resolve the issues ahead of 2012 when the provisions in this Regulation will become enforceable. The Agency will provide guidance and recommendations on the appropriate methods of analysis in advance of this date, taking into account the issues raised through public consultation.

Notification costs

The manufacturers of foodstuffs for people intolerant to gluten will be required to notify the Agency when gluten free Parnuts foods are placed on the EU market¹⁰. The

¹⁰ Note that ‘normal’ foods labelled as ‘gluten-free’ or ‘very low gluten’ do not have to be notified.

Agency estimates that the administrative cost to a company, over and above what it would do commercially, of completing and submitting an electronic notification form on marketing of a ‘gluten free’ or ‘very low gluten’ Parnuts food is approximately £61¹¹. The Agency receives, on average, 22 notifications per year for ‘gluten-free’ foods. The Scottish Statutory Instrument allows for the first time Parnuts foods to be sold as non pre-packed food; this is estimated to lead to a small increase in the number of notifications to no more than 30 a year. The total administrative burden has been estimated to be approximately £1350 per annum. Most of this burden is a continuation of a [notification?] requirement for Parnuts foods and only the estimated additional 8 notifications represent an increased cost. The table below provides a breakdown:

Table 4: Notification Costs of Gluten Free Foods

	Current	Additional
Total Cost per notification	£61.39	£61.39
No. of notifications	22	8
Total Annual Cost	£1,351	£491

Notes: Totals may not sum due to rounding

Cost of completing a notification is taken from the FSA's 2009 admin burdens simplification exercise

Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p and when grossed may result in rounding error

The Agency received no monetised estimates of additional administrative burdens or any quantified evidence to support the respondents’ views on the impact of the Regulations. Therefore, the Agency considers the assumptions and estimates set out above are appropriate.

Present Value¹² of Ongoing Costs

In line with impact assessment guidance¹³, it is necessary to discount the above current costs by 3.5% to obtain present values of the costs over a ten-year period. The table below illustrates:

Table 5: NPV of notification costs over a 5 year period

Year	Present Value (PV) in each Year										Net Present Value
	0	1	2	3	4	5	6	7	8	9	
Cost of Notification	£491	£475	£458	£443	£428	£414	£400	£386	£373	£360	£4,228

Notes: Costs are discounted in accordance with HMT Green Book methodology, using a 3.5% discount rate, where year 0 is the first year

This indicates that the NPV of costs of notification of Parnuts over a 10 year period is approximately £4,200.

¹¹ Please note that the £61.39 figure is taken from the FSA’s Admin Burdens simplification exercise for notification of Parnuts foods see:

<http://www.food.gov.uk/multimedia/pdfs/simplification20092010.pdf> for details

¹² Present Value is defined as “The future value expressed in present terms by means of discounting” HM Treasury, Green Book.

¹³ <http://www.bis.gov.uk/assets/BISCore/better-regulation/docs/10-901-impact-assessment-toolkit.pdf> (see page 28)

Familiarisation costs

Manufacturers

The Agency originally expected that in each business one person will need to spend half an hour reading and becoming familiar with the guidance. However, in response to the public consultation, stakeholders indicated this was too low. We have therefore increased this to one hour. The cost of this time is estimated as follows. The 2009 ONS ASHE (Annual Survey of Hours and Earnings¹⁴) reports the median gross hourly pay for Managers in Distribution, Storage and Retailing as £11.90. In line with the standard cost model, this is up-rated by 30% to account for overheads to £15.47. Coeliac UK have informed us that approximately 210 businesses in the UK are producing food about which gluten claims are made. To take account of any other businesses considering this claim, and new entrants, we round this up to 300. This gives a cost to industry of approximately £4,640 in total.

Catering Sector

The median gross hourly pay for restaurant and catering managers is £8.81- Annual Survey of Hours and Earnings (ASHE). This is up-rated by 30%¹⁵ to account for overheads. For one person spending one hour reading and understanding the new legislation, the average cost per organisation is £11.45. This results in a familiarisation cost to industry of £1.13m¹⁶.

Enforcers

The median gross hourly pay for a Public Service Professional of £15.97 (ASHE 2009) is up-rated by 30%¹⁷ to account for overheads. Again, it is expected it will take one person one hour to become familiar with the guidance, therefore the cost per enforcement agency is £20.76. This cost will apply to the 231¹⁸ local authorities responsible for food standards in the UK, resulting in a total cost to enforcers of approximately £4,800, assumed to arise at the time this becomes law.

The table below summarises the familiarisation costs split by the devolved administrations. Note: The geographical allocation of the 300 manufacturers is derived using a ratio based on the distribution of all food manufacturers across England, Scotland, Wales and Northern Ireland.

¹⁴ <http://www.statistics.gov.uk/statBase/product.asp?vlnk=15313>

¹⁵ In line with Standard cost model (SCM) methodology

¹⁶ Based on 99,040 catering outlets as stated in table 2.

¹⁷ See footnote 15

¹⁸ Using Local Authority figures July 2008: 151 LAs in England, 32 in Scotland, 26 in N.Ireland and 22 in Wales with responsibility for food safety.

Table 5: Familiarisation Costs

	England	Scotland	Wales	N. Ireland	UK Total
Manufacturers	£3,620	£511	£232	£232	£4,641
Caterers	£959,761	£95,633	£46,900	£32,011	£1,134,305
Local Authorities	£3,135	£664	£457	£540	£4,796
Total	£966,516	£96,807	£47,589	£32,783	£1,143,742

Notes: Totals may not sum due to rounding

Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

Equivalent Annual Costs (EAC)

In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula¹⁹. Under Standard HMT Green book guidance²⁰ a discount rate of 3.5% is used.

Total one-off costs for Industry and Local Authorities across the UK have been estimated at approximately £1.14m (table 5 above). This yields an EAC of approximately £137,525²¹.

Additional Costs Option 4a

In addition to the costs outlined above, Option 4a could result in a reduction in sales, particularly in the catering sector. If the Regulations are interpreted as preventing the provision of information for foods not in compliance with the Regulations, this may lead to a reduction in consumer confidence and people with coeliac disease may be less willing to eat out. The 2007 Expenditure and Food Survey²² estimates that the average person spends £7.96 per week on food consumed outside of the home. If we assume that the Regulations will cause all people with coeliac disease to cease eating out, this would represent a loss in sales of approximately £250 million per annum²³. However, we consider this figure to be the upper end of any loss in sales and which does not take into account reformulation and alternative product development. We do though recognise that some caterers will face disproportionate costs based on the number of products currently sold as 'gluten free'. For instance, one caterer estimated their loss of sales in the region of £1.23 million per annum, based on current sales of 'gluten-free' food/meals²⁴.

Additional Costs of Option 4b

¹⁹ The equivalent annual cost formula is as follows: $EAC = PVC/A$, where $A = [1 - 1/(1+r)^t]/r$, PVC is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

²⁰ http://www.hm-treasury.gov.uk/data_greenbook_index.htm

²¹ Please note these figures have been rounded to the nearest £1

²² <http://www.defra.gov.uk/evidence/statistics/foodfarm/food/familyfood/documents/index.htm>

²³ Average spend per person per week = £7.96, equivalent to £1.13 per day or £415.06 per year. For 600,000 coeliacs this equates to £249,034,285 per annum.

²⁴ note this would not exclusively cover purchases by coeliacs

In addition to the costs highlighted above for options 2, 3 and 4, there is a risk that should food business operators widely apply factual statements to their products, this could undermine the claims 'gluten-free' and 'very low gluten'. However, it is thought that 'gluten-free' and 'very low gluten' will be the gold standard for people with coeliac disease and manufacturers of foods specially formulated for these consumers will continue to use these claims in compliance with the Regulations.

5. SCOTTISH FIRMS IMPACT TEST

(i) Competition Assessment

The Regulation does not impose any significant costs to industry and applies to all manufacturers equally. It should not limit the number or range of suppliers either directly or indirectly or reduce the ability of, or incentives to, suppliers to compete. Therefore, it is not expected to impose significant impact on competition. The Regulation harmonises the claims 'gluten-free' and 'very low gluten', therefore this will promote international trade within the single market.

(ii) Test Run of Business Forms

There are no new forms associated with this piece of legislation.

(iii) Small/Micro Firms Impact Test

The Agency acknowledges that the catering sector is dominated by small and medium size enterprises (see table 2). During both our formal consultation and the UK wide meeting held by the Agency to specifically discuss the new Regulation with small businesses in September 2008 (which Scottish stakeholders had the opportunity to attend via Video Conference), no issues specific to them were raised. However, at the meeting the following points were mentioned:

- that the claim 'very low gluten' should be allowed to be used on a wider range of foods.
- Small and Medium Sized Enterprises (SMEs) do not have sophisticated in-house support services available to them to control/test for gluten levels. This may effectively act as a barrier to SMEs entering the market for gluten-free/low gluten products, as laboratory testing may be too costly.

These concerns have been raised by various stakeholders and have been considered carefully by the Agency but we do not consider that they will disproportionately impact on small businesses and we have sought to address this concern in the Agency's guidance to compliance. In the area of testing, businesses currently claiming 'gluten-free' must have procedures in place to determine the levels of gluten in the products they make and sell, as such this measure does not bring new costs for testing products.

It is unclear how many caterers currently selling food with the voluntary claim 'gluten-free' will be able to meet the compositional criteria in the new Regulations. However, the preferred option (option 4b) should provide sufficient flexibility for

businesses to substitute 'gluten-free' claims with factual statements, should products not meet the compositional requirements of the Regulations.

6. LEGAL AID

The Scottish Statutory Instrument, The Foodstuffs for People Intolerant to Gluten (Scotland) Regulations 2010, which will implement the execution and enforcement requirements for the EU Regulation, will introduce a new criminal sanction. Legal aid will be available for offences under this new Regulation.

7. ENFORCEMENT, SANCTIONS AND MONITORING

Local Authority Environmental Health Officers will be responsible for the enforcement of the new Regulations. We sought information on costs to enforcement authorities that could arise as a result of this Regulation. None of the enforcement authorities who responded to the consultation (UK as a whole) noted specific cost impacts of any options on their work.

The provision of clear guidance to compliance and educational material for businesses, consumers and enforcers, should help enforcement of the legislation.

The FSA intends to review the implementation of this regulation 3 years after its coming into force date in the UK (1st January 2012).

8. IMPLEMENTATION AND DELIVERY PLAN

The draft Regulation was discussed by EU Member States at meetings of the Dietetic Foods Working Group and the Standing Committee on the Food Chain and Animal Health (SCoFCAH) during the period from January 2008 to October 2008.

Member States agreed the EC Regulation at the SCoFCAH meeting on 13th October 2008.

The Agency represented the interests of the UK during these discussions and consulted with consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other Government departments who had an interest in foods for particular nutritional uses.

The Agency consulted these stakeholders via informal mechanisms such as interested party letters throughout negotiations in Europe and international negotiations on the Codex standard. In addition, the Agency met with the Food and Drink Federation (FDF), the British Retail Consortium (BRC), the Infant and Dietetic Foods Association (IDFA) and Coeliac UK as part of the consultation and separately held a meeting in September 2008 specifically for small and medium sized enterprises that may be affected by the Regulation.

In Scotland, the Agency consulted from 23rd July to 30th September 2008 on the draft Regulation. The consultation invited comments and evidence from stakeholders regarding:

- their preferred option with regard to adoption of the EU proposal
- the potential costs associated with each option

- the potential benefits associated with each option
- other impacts such as the impact of the Regulation on enforcement authorities and on sustainability issues
- any other aspect of the proposal.

The Agency in Scotland received two responses to the consultation – a ‘no comment’ and a response which was also received in England.

The UK as a whole received the following responses to the consultation:

- 2 responses from non-governmental organisations and charities (Coeliac UK, Foods Matter)
- 1 response from Healthcare professionals (Royal College of Physicians)
- 18 responses from food manufacturers (the Infant and Dietetic Foods Association (IDFA), Gluten-free Foods Ltd, Nutrition Point Ltd, Food and Drink Federation (FDF), Premier Foods, the British Retail Consortium (BRC), The British Beer and Pub Association, Charles Cooper Ltd, National Association of British and Irish Millers, National Association of Master Bakers, Farmhouse Biscuits Ltd, Fun Foods 4 All, Heron Foods, Doves Farm Foods, Delicious Alchemy Ltd, M H Foods, Halal Food Authority, Food Solutions)
- 3 responses from enforcement authorities (LACORS, Trading Standards South East, Kent County Council Trading Standards).
- 3 responses from analysts (Campden and Chorleywood Food Research Association, Genon Labs, Tepnel Research Products and Services).
- 7 responses from individuals.

A summary of the responses, all of which were considered before the SCoFCAH meeting of 13th October 2008, can be found at

<http://www.food.gov.uk/multimedia/pdfs/consultationresponse/glutensumresponse.pdf>

and

<http://www.food.gov.uk/multimedia/pdfs/consultationresponse/glutenintolsumm.pdf>

Separate consultations were carried out by the relevant offices of the Food Standards Agency in Scotland, England, Wales and Northern Ireland. The comments received from the four consultations were considered together prior to the SCoFCSAH meeting.

The Agency conducted a further 12 week consultation in November 2009 on:

- the draft Scottish Statutory Instrument that provides execution and enforcement provisions in Scotland for Commission Regulation (EC) No. 41/2009;
- accompanying guidance notes to help businesses and enforcers understand the Commission Regulation and provide best practise advice; and
- the draft Regulatory Impact Assessment

The consultation generated 4 responses from Scottish Stakeholders with a further 32 responses to the parallel consultations in England, Wales and Northern Ireland.

A summary of responses can be found at:

<http://www.food.gov.uk/multimedia/pdfs/consultationresponse/respdraftsiintoglutenr egs09.pdf>

Post Implementation Review (PIR) Plan

<p>Basis of the review: To review the effectiveness of the EU Regulations and accompanying guidance. In addition, assess the uptake of the Agency best practice guidance.</p>
<p>Review objective: To ensure application of the EU Regulations has resulted in a consistent approach to labelling of foods suitable for people with coeliac disease and that they are able to make healthier, safer and more informed choices.</p>
<p>Review approach and rationale: In addition to stakeholder consultation, the Agency may, if necessary, commission a survey to gauge consumer understanding of the new labelling terms and analyse the level of gluten present on foods labelled as suitable for people with coeliac disease.</p>
<p>Success criteria:</p> <p>Increase in the number of retail and catering businesses providing foods suitable for people with coeliac disease.</p> <p>Increase in consumer understanding of the new labelling terms.</p> <p>High number of products in compliance with the new levels of gluten.</p>
<p>Monitoring information arrangements: Under European rules businesses are required to notify the Food Standards Agency when placing prepacked and non prepacked Parnuts foods on the market making the claims ‘gluten-free’ or ‘very low gluten’ (for example cakes, biscuits, soups where the gluten containing ingredient has been substituted). This will help the Agency monitor the market.</p> <p>The Agency will also keep in regular contact with representatives from affected groups as part of routine business to gauge effectiveness and impact of the provisions.</p>

9. SUSTAINABLE DEVELOPMENT

A sustainability assessment has been carried out on the proposed options in the light of the information we have concerning the costs and benefits listed above. Impacts under all three pillars of sustainable development, economic, social and environmental, have been considered in the preparation of this BRIA.

Option 1 does not create any new economic or social benefits. It may however, incur economic disadvantages to the Government which may be subject to infraction proceedings for not implementing enforcement sanctions related to the Regulation. This option may be detrimental in terms of the health of people with coeliac disease as products placed on the UK market would not always be meeting the compositional criteria expected by these consumers.

Options 2 and 3 may bring economic costs to the industry due to possible reformulation and/or re-labelling. In light of the evidence available to the Agency these economic costs cannot be quantified.

Option 4 may also incur the economic cost to the industry, but will allow the continued sale of 'gluten-free' Parnuts foods sold non pre-packed and allow for future develops in the market. However, based on information obtained during consultation on this Regulation, the 3 year transition, negotiated by the UK, should enable any changes that need to be made to labelling within normal labelling cycles, allowing companies to use up existing packaging. Therefore, it is expected that there will not be any significant amounts of wasted product, packaging or labels. These options also bring social benefits in terms of improving the health of people with coeliac disease by ensuring that products are manufactured with the lowest amount of gluten possible and improve consumer information as the claims made on these products will be standardised. Option 4b also has the added benefit of ensuring people with coeliac disease have the widest possible choice when purchasing food, allowing a more flexible approach for retailers and caterers.

The Agency considers that the social benefits (health and consumer information) of adopting this legislation outweigh the possible economic costs to businesses. Environmental impacts will not be significant and the possible negative effects of the legislation on waste will be minimised by the lengthy transitional period. Options 2, 3, 4, 4a are relatively more sustainable than option 1. Option 4b is the most sustainable option, maximising the choices of people with coeliac disease and minimising economic burden.

No comments and/or quantitative estimates of the economic, environmental or social costs and benefits associated with the three options were received. As a result the sustainability assessment with respect to the Regulation cannot be further quantified.

10. RACIAL, GENDER AND DISABILITY EQUALITY

The Food Standards Agency does not consider that the Regulation has any impact on race, gender or disability equality as there is no evidence to suggest that any group is likely to be affected more than any other group.

11. ADMINISTRATIVE BURDENS

There are one-off costs for reading and understanding the new legislation and ongoing costs to parnuts manufacturers of 'gluten-free' and 'very low gluten' products but no other added ongoing administrative burdens on industry or enforcement authorities.

The manufacturers of foodstuffs for people intolerant to gluten will be required to continue notifying the Agency when ‘gluten-free’ products are placed on the EU market. The Agency estimates that the administrative cost to a company, over and above what it would do commercially, of completing and submitting a notification form on marketing of a ‘gluten-free’ or ‘very low gluten’ product is approximately in the region of £70. The Agency receives, on average, 22 notifications per year. The resulting administrative burden is therefore likely to be in the region of £1500 per annum. However, as this is a continuation of an existing requirement for products the net change in administrative burdens is zero.

The Agency received no monetised estimates of additional administrative burdens or any quantified evidence to support the respondents’ views on the impact of the Regulations. Therefore, the Agency considers the assumptions and estimates set out above are appropriate.

12. SUMMARY AND RECOMMENDATION

The new Regulation will improve information to people with coeliac disease and remove uncertainty about the levels of gluten contained in foods labelled ‘gluten-free’ or ‘very low gluten’. **The Food Standards Agency recommends option 4b** as this will give people with coeliac disease in the UK the same level of protection as other European citizens, whilst ensuring access to a healthy balanced diet. The new EC Regulation will improve consumer protection and the level of information available to people with coeliac disease, remove uncertainty about the levels of gluten contained in foods labelled ‘gluten-free’ or ‘very low gluten’. This measure will also encourage intra-community trade by harmonising rules across the EU.

The cost of regulation in this area is not likely to be great and is considered to be proportionate when balanced against the potential benefit to consumer health. Furthermore, the UK has negotiated a 3 year transition period for industry thereby further reducing any impact of this Regulation.

Summary Costs and Benefits Table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1. Do Nothing	No benefits have been identified.	Risks infraction proceedings imposed by the European Commission against the UK and loss of intra-Community trade.
2. Implement European Regulation as drafted	Improved health and provision of information on very low gluten/gluten free	One – off familiarisation costs of new legislation: Manufacturers - £4,640

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
	<p>foods for people with coeliac disease.</p> <p>Potential increase of products available on the market for people with coeliac disease.</p>	<p>Caterers - £1.1m</p> <p>Enforcement - £4,800</p> <p>Loss of sales for caterers: £250 m</p>
3. Implementation of the European Regulation with Member State amendments	As option 2 but with potential further benefits to people with coeliac disease on information regarding low gluten/gluten free pre-mix and dehydrated food.	As option 2.
4. Implement European Regulation as drafted and extend the scope to food sold non pre-packed	As option 2, but allow the continued sale of Parnuts food sold non pre-packed and minimise any reduction in the choices available to people with coeliac disease.	As option 2.
4a. Strict interpretation - Implement European Regulation as drafted and extend the scope to food sold non pre-packed	As option 4	As option 2 but, prevents the use of any statements other than 'gluten-free' and 'very low gluten', severely restricting the information and options available to people with coeliac disease when eating out.
4b. Flexible interpretation - Implement European Regulation as drafted and extend the scope to food sold non pre-packed	As option 4, but allow the use of factual information enabling people with coeliac disease to make informed choices, particularly when eating out.	As option 4a, but without the loss of sales to caterers and manufacturers.

13. DECLARATION AND PUBLICATION

I have read the Business and Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed:

Date:

Minister's Name, Title & Department:

Nicola Sturgeon, Cabinet Secretary for Health and Wellbeing, Scottish Government
Health and Wellbeing Directorate.

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ANNEX 1 Summary of composition and labelling requirements in Regulation (EC) No. 41/2009

Food Type	Method of gluten reduction	Maximum level of gluten in the food as sold to the final consumer	Permitted claim	Relevant Article of Reg. (EC) No. 41/2009	Notification required when making gluten claim
Food specially prepared for people intolerant to gluten	Includes one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been processed to reduce gluten (e.g. uses Codex wheat starch as an ingredient).	100mg/kg	<u>Have to use 'very low gluten'.</u> If the level is 20mg/kg of gluten or less can choose to use ' <u>gluten-free</u> '	3(1) and 3(2)	Y
Food specially prepared for people intolerant to gluten	Includes substitutes for one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties.	20mg/kg	<u>Have to use 'gluten-free'</u>	3(4)	Y
Food specially prepared for people intolerant to gluten	Includes substitutes for one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties and includes one or more ingredients made from wheat, rye, barley, or oats or their crossbred varieties, which have been processed to reduce gluten.	100mg/kg	<u>Have to use 'very low gluten'.</u> If the level is 20mg/kg of gluten or less can choose to use ' <u>gluten-free</u> '	3(5) (as read with 3(1) and 3(2))	Y
Oats or oat ingredients which are used in food specially prepared for people intolerant to gluten	The oats must be produced, prepared or processed to avoid cross contamination by wheat, barley, rye or their crossbred varieties.	20mg/kg	<u>Only oats containing 20mg/kg of gluten or less can choose to use 'gluten-free' or can be used in products with a 'gluten-free' or 'very low gluten' claim.</u>	3(3)	N

Other foods suitable for people intolerant to gluten ('normal foods' and other Parnuts foods)	N/A	20mg/kg	If the level is 20mg/kg of gluten or less can choose to use 'gluten-free'.	4(1)	N
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