EXPLANATORY MEMORANDUM TO

THE FOODSTUFFS SUITABLE FOR PEOPLE INTOLERANT TO GLUTEN REGULATIONS (NORTHERN IRELAND) 2010

2010 No. 338

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency in Northern Ireland to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under Articles 15(1)(e), 16(2), 25(1)(a) and (3) and 47(2) of the Food Safety (Northern Ireland) Order 1991 and is subject to the negative resolution procedure.

2. Purpose of the Rule

2.1 This rule provides execution and enforcement provisions, in Northern Ireland, for Commission Regulation (EC) No. 41/2009, which is a food safety measure introducing compositional and labelling requirements for foods claiming suitability for people intolerant to gluten (coeliacs).

3. Legislative Background

3.1 This rule provides execution and enforcement provisions, in Northern Ireland, for Commission Regulation (EC) No. 41/2009, which introduces compositional and labelling requirements for foods claiming suitability for people intolerant to gluten. The Rule also takes advantage of the derogation in Article 10(2) of Directive 2009/39/EC, the framework directive for foods for particular nutritional use, to allow gluten-free foods for particular nutritional use to be sold non pre-packed.

4. Parity or Replicatory Measure

4.1 This Rule applies to Northern Ireland only. Parallel legislation is being made in England, Scotland and Wales.

5. European Convention on Human Rights

5.1 As this rule is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Policy background

- What is being done and why

6.1 Commission Directive 2009/39/EC provides a regulatory framework for foodstuffs intended for particular nutritional uses (Parnuts). 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 Parnuts foods include - infant formulae, follow-on formulae and medical foods. In January 2009 the Commission adopted Regulation (EC)

No. 41/2009 introducing specific rules for the composition and labelling of foodstuffs claiming suitability for people intolerant to gluten.

6.2 Approximately 1% of the UK population has an intolerance to gluten (coeliac disease) and therefore must avoid the dietary intake of cereals containing gluten. The number of foods making 'gluten-free' and similar claims is increasing rapidly to fulfil this need. However, the levels of gluten in these products has been unregulated and can vary greatly, this can cause confusion and, on occasion serious health problems. Government action is required to make a statutory rule 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.

6.3 The objective of the EC Regulation is to improve the long term health of coeliac consumers and harmonise rules throughout the Community on the use of the claims 'gluten free' and 'very low gluten'. Standardising the levels of gluten for such claims will improve the level of control coeliacs have over the foods they eat by enabling them to identify with confidence foods that are suitable for their dietary needs. In addition, standardisation of the terms will reduce consumer confusion, promote consistent labelling, improve consumer choice and facilitate international trade.

6.4 The new Regulations will come into operation on 1 January 2012.

7. Consultation Outcome

7.1 The FSA in NI held two public consultations, in July 2008 during the EU negotiations and in November 2009 on the draft statutory rule, guidance and impact assessment. Parallel consultations were undertaken in England, Scotland and Wales. One response was received to the NI consultation from Coeliac UK which was copied to FSA England, FSA Scotland and FSA Wales.

7.2 Coeliac UK highlighted that many businesses will not be able to comply with the new regulations, due to the high risk of cross-contamination in a catering setting, and will be prevented from supplying helpful information to coeliacs. The 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 new compositional criteria can supply certain information to coeliacs, should they wish to do so, on a voluntary basis and within the regulatory framework. This will take the form of factual statements about the ingredients used and whether they normally contain gluten, and advice about efforts to minimise cross-contamination.

8. Guidance

8.1 The Food Standards Agency will be issuing guidance to compliance and best practice advice for industry and enforcement officers. The Agency will also amend existing guidance on the provision of allergy information for non pre-packed foods, to provide advice on how to minimise cross-contamination with gluten-containing ingredients.

8.2 The Agency intends to work with Coeliac UK to disseminate educational material for consumers and food businesses to raise awareness of the new rules ahead of the coming-into-operation date.

9. Equality Impact

9.1 These regulations will apply in equal measure to all Section 75 groups. It is not expected that any of these changes will impact differentially across any of the section 75 groups.

10. Impact

10.1 The impact on business, charities or voluntary bodies has been assessed and is not considered significant.

10.2 There may be additional reformulation and re-labelling costs. However, we anticipate that these will be absorbed into normal business practice. Furthermore, the Agency has negotiated a 3 year transition period, which industry has indicated will help facilitate these changes.

10.3 The EU Regulation allows catering businesses unable to meet conditions for a 'gluten-free' claim to continue to supply helpful information to coeliacs. This should give coeliacs more confidence to eat out and encourage further market growth.

10.4 Coeliac UK is the principal charity representing coeliacs in the UK and the regulation will impact on their activities. Coeliac UK has indicated significant one-off costs on legal advice, communication with its member and changes to its Food and Drink Directory, however, they do not expect any significant ongoing costs.

10.5 The impact on the public sector is minimal.

10.6 An Impact Assessment is attached to this memorandum. This IA has been prepared by FSA colleagues in England but it is believed to be equally representative of the situation in Northern Ireland.

11. Regulating small business

11.1 This regulation applies to small businesses.

11.2 It is not thought that the proposed legislation will disproportionately impact on small businesses. It is voluntary to market foods as 'gluten-free' and there are very few, if any, incremental costs involved in achieving compliance. Responses to the consultation did not contradict this view.

12. Monitoring & Review

12.1 The Agency will review the implementation of this regulation 3 years after its coming into operation date in the UK (1st January 2012).

13. Contact

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Title:	Impact Assessment (IA)
Commission Regulation 41/2009/EC concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten	**IA No:** FoodSA 0005
Lead department or agency: Food Standards Agency	**Date:** 02/09/2010
Other departments or agencies: N/A	**Stage:** Final
	Source of intervention: EU
	Type of measure: Secondary legislation
	Contact for enquiries: Claire.Boville@foodstandards.gsi.gov.uk

Summary: Intervention and Options

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

Approximately 1% of the UK population suffers from an intolerance to gluten and as such must avoid the dietary intake of cereals containing gluten. In recent years the number of foods making 'gluten-free', or similar claims, has increased dramatically to fill this gap in the market. However, these types of claims have been unregulated and the levels of gluten in these products can vary greatly which causes confusion for the consumer and could cause serious health problems for some individuals. Commission Regulation (EC) 41/2009 sets levels for the labelling terms 'gluten free' and 'very low gluten' and Government intervention is required to implement this EU Regulation.

What are the policy objectives and the intended effects?

The objective of the Regulation is to harmonise rules throughout the European Union on the use of the claims 'gluten free' and 'very low gluten'. This is an important public health measure, which will make food safer for coeliacs by lowering the amount of gluten permitted in food making these claims and provide information which will enable coeliacs to better manage their individual risk of exposure to gluten.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

1. do not adopt the proposal
2. adoption of the proposal as drafted providing execution and enforcement provisions for Commission Regulation (EC) 41/2009
3. negotiate for amendment of the proposal to take account of issues raised by stakeholders.
4. adoption of the proposal as drafted providing execution and enforcement provisions for Commission Regulation (EC) 41/2009 and make provisions so that Parnuts foods can be sold non pre-packed including catering.

Option 4 is the preferred option (see page 10).

Following consultation, the Agency took forward Option 3 as it offered the most benefit to coeliac consumers, whilst being proportionate for UK industry as explained in section 4. However, other Member States did not support these changes and the Agency is now forced to take forward either option 2 or option 4.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 01/2015
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	No

SELECT SIGNATORY Sign-off For final stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister:SELECT SIGNATORY:..... Date:.....

Summary: Analysis and Evidence Policy Option 4

Description:

Adoption of the proposal as drafted providing execution and enforcement provisions for Commission Regulation (EC) 41/2009 and extend the scope to parnuts food sold non pre-packed.

Price Base Year 2009	PV Base Year 2012	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£1.14		£0.0005	**£1.14**

Description and scale of key monetised costs by 'main affected groups'

One-off familiarisation costs to manufacturers (£4,640), caterers (£1.1m) and local authorities (£4,800). This yields a total Equivalent Annual Cost (EAC) of £0.14m.

Other key non-monetised costs by 'main affected groups'

There may be some re-labelling or reformulation costs associated with the policy but it is expected that these will be minimal. Re-labelling is likely to be absorbed into routine label/menu changes and reformulation is considered a business choice. Businesses have a 3 year transition period from the publication of the EU measure to make any necessary changes.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	-		-	**-**

Description and scale of key monetised benefits by 'main affected groups'

No benefits monetised, see non-monetised benefits below.

Other key non-monetised benefits by 'main affected groups'

The main benefit from this policy is improved clarity of information and greater choice of appropriate products for the 600,000 coeliacs currently in the UK, across retail and catering settings. Non pre-packed foods are also covered by the national Regulations thus providing additional flexibility to firms and greater choice for consumers.

The more flexible approach outlined in Option 4b should reduce the impact of any removal of current gluten-free claims, by substituing these claims with factual statements i.e. "No gluten containing ingredients".

Key assumptions/sensitivities/risks **Discount rate (%)** N/A

The objective of the Regulation is to harmonise rules throughout the European Union on the use of the claims 'gluten-free' and 'very low gluten'. This is an important health measure which will make food safer for coeliacs by lowering the amount of gluten permitted in food making these claims. Failure to implement this measure or issue guidance to consumers and industry could result in a proliferation of products in the marketplace, which are potentially harmful to the health of coeliacs.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):		In scope
New AB: N/A	AB savings: N/A	Net: N/A	Policy cost savings:	N/A	No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			01/01/2012		
Which organisation(s) will enforce the policy?			Local Authorities		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** 0.04%	**Benefits:** N/A	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1]	No	
Economic impacts	***Section 3 and***	
Competition	No	
Small firms	No	
Environmental impacts		
Greenhouse gas assessment	No	
Wider environmental issues	No	
Social impacts		
Health and well-being	Yes	All
Human rights	No	
Justice system	No	
Rural proofing	No	
Sustainable development	Yes	23

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

References

No.	Legislation or publication
1	Commission Regulation (EC) No. 41/2009 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:016:0003:0005:EN:PDF
2	Consultation on draft EC proposal and initial Impact Assessment - July 2008 http://www.food.gov.uk/consultations/consulteng/2008/regulationglutenfreefoods
3	Consultation on Draft UK statutory instrument, Impact Assessment and guidance - November 2009 http://www.food.gov.uk/consultations/consulteng/2009/draftsiintolglutenregs09eng
4	Link to Interested Parties letters sent to stakeholders throughout negotiations and implementation

Evidence Base

Table 1 - Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs (EAC)[2]	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14
Annual recurring cost	0.0005	0.0005	0.0005	0.0004	0.0004	0.0004	0.0004	0.0004	0.0004	0.0004
Total annual costs	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14	0.14
Transition benefits										
Annual recurring benefits										
Total annual benefits	n/m*									

* For non-monetised benefits please see summary pages and main evidence base section



Microsoft Office Excel Worksheet

[2] Equivalent Annual Costs

Evidence Base (for summary sheets)

Section 1

Problem under consideration

1. Coeliac disease is an autoimmune disorder that is triggered by the consumption of gluten (proteins found in cereals such as wheat, rye and barley). This affects approximately 1% of the UK population. Coeliac disease can successfully be managed by controlling the diet however, until now there have been no rules governing the levels of gluten in foods targeted at coeliacs, which is recognised as a serious safety concern.

2. In July 2008, based on the latest international science, the Codex Alimentarius Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) adopted rules on the composition and labelling of foods intended for coeliacs with a view to enabling those people to find on the market a variety of food suitable to their individual level of sensitivity to gluten.

3. To align European law with the Codex Standard the European Commission, published on 20 January 2009, Commission Regulation (EC) No 41/2009[3] introducing compositional and labelling standards that set levels for foods claiming to be "gluten-free" (at 20 parts per million) and "very low gluten" (at 100 parts per million and reserved for foods containing cereals which have been specially processed to remove gluten). Not only will this Regulation make food safer for coeliacs by lowering the amount of gluten permitted in these foods, but by using these labelling standards coeliacs will be able to make safe food choices and manage their individual risk of exposure to gluten, and for the first time they will have definitive levels to guide them.

4. The Government must now decide whether to implement this measure into UK law.

Rationale for Government Intervention

5. The EU Regulation is directly applicable in all EU Member States. Government intervention is required to provide for the execution and enforcement of these provisions and to give the necessary powers to enforcement authorities. The provisions in the accompanying Statutory Instrument gives these powers to enforcement authorities in England. Separate but parallel national Regulations are being made in Scotland, Wales and Northern Ireland.

6. Providing for the execution and enforcement of this measure will assist coeliacs to make healthier, safer, more informed choices and in doing so contribute to the Agency's overall strategic plan to improve food safety.

Policy Objective

7. The objective of Commission Regulation (EC) No 41/2009 and the UK national Regulations is to reduce the amount of gluten in the diet for coeliacs and harmonise the composition and labelling of foods targeted at this group of the population.

Background

Coeliac Disease

8. People who are intolerant to gluten suffer from a serious autoimmune disorder (coeliac disease) that is triggered by consumption of gluten (proteins found in cereals such as wheat, rye, barley). This

[3] OJ L 16, 21.1.2009, p.3.

affects approximately 1%[4] of the UK population. A diet free from cereals containing gluten is prescribed for coeliacs, and provides the only relief from the symptoms of this condition, which may include weight loss, stomach pains, diarrhoea and, in some cases, malnutrition, with attendant consequences e.g. anaemia, osteoporosis and some cancers. 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 from the diet may result in deficiencies of nutrients usually obtained from these sources.

Coeliac sensitivity to gluten

9. Whilst most coeliacs 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 the different types of products aimed at coeliacs 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 coeliacs.

Coeliac disease and oats

10. There is also some debate as to whether individuals with coeliac disease can tolerate oats, which contain a protein that is similar to gluten. Recent evidence suggests that most but not all coeliacs can tolerate oats. It may be that some individuals react to oats that are contaminated with small amounts of other cereals, such as wheat, because of the conditions under which they are grown, harvested, transported 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 minimised. The level of gluten in such products is typically very low. Special attention is therefore given to claims on oats in the Regulations.

The rise of the gluten-free/low gluten market

11. The food industry has developed a range of products in which the gluten content has either been eliminated or reduced. The increase in products marketed as gluten free is demonstrated clearly in the Mintel report on Food Intolerances and Allergies (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 £74million[5].

Elimination and reduction of gluten in food

12. 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 possible currently to eliminate gluten altogether from all specially formulated foods, and in some cases it is necessary 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 products in directories of food 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:

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

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

Provisions in Regulation (EC) 41/2009

13. The EC Regulation has been applied (as provided for in Directive 2009/39/EC – the Parnuts Framework Directive) to all foodstuffs, both pre-packed and non pre-packed sold in retail and catering establishments, making voluntary claims indicating suitability for coeliacs. The main focus of the legislation is to control the composition and labelling of the following foods:

    - **Parnut foods** – Food for **Par**ticular **Nut**ritional 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.

14. The key provisions of the EU Regulation are:

    - to harmonise the labelling of foods for people intolerant to gluten by restricting the use of the terms 'gluten-free' (20 parts per million of gluten) and 'very low gluten' (100 parts per million 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;
    - 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 parts per million 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 requirements is provided in Annex II.

Negotiations in Europe

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

16. 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 the reconstituted version of dehydrated or dry foods (for example powdered soup and bread mixes). Since these foods are not designed to be eaten as sold, the UK considered 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 often higher than the compositional criteria in the Regulation, 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.

17. The UK did however, successfully negotiate 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 and minimise one-off costs of the Regulation.

Section 2

Options

18. The following options were available prior to adoption of the EU Regulation:

    1. do not adopt the proposal (considered as baseline only)
    2. adoption of the proposal as drafted and provision of execution and enforcement provisions for Commission Regulation (EC) 41/2009
    3. negotiate for amendment of the proposal to take account of issues raised by stakeholders
    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 allow the sale of Parnuts food sold non pre-packed - including catering.

19. During consultation with UK stakeholders it was clear that there are two further sub-options to explore:

    4a. as 4 but do 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 reguirements of the Regulation (EC) 41/2009.

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

20. Each of these options carried a number of risks to consumers, industry and Government; these are discussed below:

Option 1: oppose adoption of the proposal

21. 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 in the negotiations the UK would have had to implement a proposal that would not take into account the needs of UK consumers and industry. In addition, this would not have fulfilled the Agency's commitment to protect health and to provide the consumer with comprehensive labelling information in order to make informed choices. Moreover, this option would have 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

22. 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

23. 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 compositional criteria applied not only to foods as sold to the final consumer, but also, where appropriate, to be applicable to reconsituted 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 dehyrated 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.

24. Following an initial consultation in 2008, 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 is now forced to take forward either option 2 or option 4.

Option 4: adoption of the proposal as drafted and provide execution and enforcement provisions for Commission Regulation (EC) 41/2009 and apply a UK derogation to allow the sale of Parnuts food sold non pre-packed including catering

25. The UK Statutory Instrument intends to take advantage of a provision in article 10(2) of the Parnuts framework directive (Directive 2009/39/EC) to allow Parnuts foods to be sold non pre-packed in UK national legislation – thus allowing the continuation of the sale of products in non pre-packed form specially formulated for people intolerant to gluten that are already on the market. This will include, for example, muffins made from rice flour, or other gluten free flour, in catering establishments. However, businesses will only be able to use the voluntary claims 'gluten-free' and 'very low gluten' if the products meet the compositional criteria in the Commission Regulation.

26. 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 with stricter controls than previously Without this derrogation, no Parnuts food sold non-prepacked would be able to make any claims about the gluten content.

The difference between Option 2 (adopt proposal as drafted) and Option 4 (adopt proposal and allow sale of Parnuts foods sold non pre-packed) is shown below:

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 claims 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

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

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

28. Responses to a public consultation in November 2009 highlighted widespread concern that the Agency's approach would mean that the majority of catering establishments would be unable to meet the compositional requirements of the EU Regulation and would not be permitted to provide any information to coeliacs on foods which do not contain gluten ingredients but did not meet the compositional requirements of the EU Regulation. This would severely limit the dietary options available to coeliacs when eating out and deprive them of information on which to make informed choice.

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

29. The majority of responses to the public consultation felt that 4a was too restrictive an approach, it would limit the dietary options available to coeliacs and that it would be counter to the objectives of the EU Regulation – i.e. to provide information to give consumers the information they need to make an informed choice and to protect coeliacs. The Agency has worked closely with Coeliac UK and other key stakeholders to see what information can be provided within the regulatory framework, on foods for normal consumption that do not contain gluten containing ingredients, but which potentially contain more than 20ppm of gluten. The Agency is of the opinion that the EU 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 coeliacs or mention a level of gluten. This aims to ensure that coeliacs receive sufficient information on foods and can make informed choices based on their individual level of sensitivity to gluten. This more flexible approach is the prefered option and is described as option 4b throughout this IA.

30. The Agency acknowledges that under Option 4a and b, 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 existing gluten-free claims, by substituing these claims with factual statements i.e. "No gluten containing ingredients".

Option 4b is the Agency's preferred option

Section 3

Sectors affected by the Regulation

31. The legislation should improve the lives of coeliacs and help healthcare professionals, as they 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[6]).

32. The Regulation applies to all food businesses, including the catering sector, wishing to make voluntary claims on foods suitable for coeliacs. 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 directly affected by the change in this 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.

33. Coeliac UK has informed the Agency that currently around 210 manufacturers in the UK (making pre-packed foods) 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.

34. The size of the catering market is more 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[7]. The tables below show the number of catering establishments according to the Inter-Departmental Business Register[8].

[6] (Bingley *et al.* British Medical Journal, 2004, 7435; 322-323)
[7] 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/SIC2007explanatorynotes.pdf
[8] http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=933[8] IDBR published annually by the ONS. http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=933

Table 2: Breakdown of 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

Costs of the Options

35. 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 section dealing with adminstrative burdens.

Cost of Option 1

36. 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 coeliacs. Alternatively, if the UK decided not to enact domestic enforcement measures to render the Regulation effective, this would lead 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.

Cost of Options 2, 3 & 4

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

37. 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 voluntary claims in order to allow manufacturers 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 re-labelling 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.

38. Some 'normal foods' which manufacturers already label to indicate suitability for coeliacs may also need to be relabelled to comply with the new Regulation based on the new threshold level for the claim. In addition, ordinary foods that manufacturers wish to label to indicate suitability for coeliacs 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.

39. In light of consultation responses and discussions with industry we have amended our original re-labelling costs figure of £1000 per SKU. Feedback from stakeholders as part of the consultation on

saturated fat reduction[9] suggests that re-labelling costs could range from £1500 - £3000[10] 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.

40. The Agency requested comments and evidence from 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 Regulations. Therefore, the Agency considers the assumptions and estimates set out above are appropriate.

Reformulation

41. 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

42. 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 provisions therein. 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 coeliacs. For example, we see no reason why a 'Chicken Tikka Masala' currently labelled as 'gluten-free' or 'suitable for coeliacs', will not continue to be marketed simply as a 'Chicken Tikka Masala'.

43. 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 individual coeliacs, 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.

44. 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 EU Regulation and provide consumers with the information they require to make informed choices.

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

46. 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

[9] 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

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

health and facilitate informed consumer choice and to ensure that the compositional criteria set are suitable for most coeliacs. 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, coeliacs 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 ordinary 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 coeliacs. The evidence shows that regular consumption, by coeliacs 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 coeliacs. 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 coeliacs although the Agency recognises that this may lead to a loss of choice for people with coeliac disease. 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

47. 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 proposal does not bring new costs for testing products. This Regulation does not stipulate a method of analysis; however the recommended procedure for analysis according to the Codex Standard is the R5 ELISA Mendez method.

48. 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. The Agency has not received any information to suggest analytical costs to businesses will be any higher than methods already on the market.

49. 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 has raised these concerns within the Codex Alimentarius framework in order to try and 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

50. 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 market[11]. The 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 £61[12]. The Agency receives, on average, 22 notifications per year for 'gluten-free' foods. The 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 requirement for Parnuts foods and only the estimated additional 8 notifications represent an increased cost. The table below provides a breakdown:

[11] Note that 'normal' foods labelled as 'gluten-free' or 'very low gluten' do not have to be notified.
[12] 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

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

51. 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 Value[13] of Ongoing Costs

52. In line with impact assessment guidance[14], 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

	Present Value (PV) in each Year										
Year	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**Net Present Value**
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

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

Familiarisation costs

Manufacturers

54. 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 Earnings[15]) 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

55. The median gross hourly pay for restaurant and catering managers is £8.81 (ASHE). This is up-rated by 30%[16] 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 £1.13m[17].

[13] Present Value is defined as "The future value expressed in present terms by means of discounting" HM Treasury, Green Book.
[14] http://www.bis.gov.uk/assets/BISCore/better-regulation/docs/10-901-impact-assessment-toolkit.pdf (see page 28)
[15] http://www.statistics.gov.uk/statBase/product.asp?vlnk=15313
[16] In line with Standard cost model (SCM) methodology
[17] Based on 99,040 catering outlets as stated in table 2.

Enforcers

56. The median gross hourly pay for a Public Service Professional of £15.97 (ASHE 2009) is up-rated by 30% [18]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 231[19] 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.

57. 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.

Table 6: Familiarisation Costs

	England	*Scotland*	*Wales*	*N. Ireland*	*UK Total*
Manufacturers	£3,632	£513	£251	£246	£4,641
Caterers	£959,761	£95,633	£46,900	£32,011	£1,134,305
Local Authorities	£3,135	£664	£457	£540	£4,796
Total	£966,528	£96,810	£47,608	£32,796	£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 formula[20]. Under Standard HMT Green book guidance[21] 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 £137,525[22].

Additional Costs Option 4a

58. 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 coeliacs may be less willing to eat out. The 2007 Expenditure and Food Survey[23] 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 coeliacs to cease eating out, this would represent a loss in sales of approximately £250 million per annum[24]. 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/meals[25].

Additional Costs of Option 4b

[18] See footnote 15
[19] 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.
[20] 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.
[21] http://www.hm-treasury.gov.uk/data_greenbook_index.htm
[22] Please note these figures have been rounded to the nearest £1
[23] http://www.defra.gov.uk/evidence/statistics/foodfarm/food/familyfood/documents/index.htm
[24] 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.
[25] note this would not exclusively cover purchases by coeliacs

59. 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 coeliacs and manufacturers of foods specially formulated for coeliacs will continue to use these claims in compliance with the Regulations.

Benefits

Benefits of Option 1

60. Option 1 does not have any incremental benefits as it would continue the current regulatory framework as the EU Regulation would not be enforced.

Benefits of Options 2, 3 & 4

61. The main benefit of options 2 and 3 is improved health of coeliacs as they will be able to choose products that are low in gluten and which are labelled such that consumers can make an informed choice. The additional benefit of the 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.

62. Overall, organisations such as Coeliac UK, Allergy Alliance and the Royal College of Physicians welcome the Regulations as it should benefit the health of coeliacs. Likewise, individual coeliacs were generally supportive of the Regulations as this should enable them to more easily choose foods marketed to meet their health needs. 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 their quality of food for coeliacs.

Further Benefits of Option 3

63. 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, this argument was not accepted by other EU Member States.

Further Benefits of Option 4

64. Allowing 'gluten free' and 'very low gluten' Parnuts foods sold 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 derogation would allow this to continue post 1 January 2012.
    - Reduction in risk to coeliacs when purchasing food in catering establishments i.e. all foods will have to comply with 20mg/kg if they want to claim 'gluten free'
    - Standardised 'gluten free'/'very low gluten' across the whole food sector which may reduce costs for operators present in both retail and catering settings.
    - Standardisation of the phrases 'gluten free'/'very low gluten' across the whole food sector will give a consistent message about associated levels and the risks involved to consumers.
65. 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

66. As option 4. No additional benefits identified.

Further Benefits of Option 4b

67. This approach to the Regulations would protect coeliacs, whilst ensuring sufficient information is provided on foods that have no intentionally added gluten containing ingredients, but which do not comply with the Regulation. 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 coeliacs, 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. This option has broad appeal with industry and consumers alike and would avoid restricting consumer choice.

68. Comments received in response to the public consultation highlight that it is essential to have this more flexible approach, to ensure the Regulation does not restrict the choices of the very people it is trying to protect. Restricting choice and the level of information available to coeliacs, may lead them to take higher risk when making food purchases.

Use of other statements

69. 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. The provision of these statements 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 Regulation will ensure coeliacs receive sufficient information to inform their choices and ensure coeliacs have access to as wide a range of foods as possible to ensure dietary variety and a healthy balance diet.

70. Coeliac UK has indicated the market for foods suitable for coeliacs is potentially worth over £100 million (upward to £250 million as outlined in paragraph 57). 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.

Consultation

71. 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, informal mechanisms such as interested party letters, stakeholder meetings and bi-laterals with key stakeholders including the Food and Drink Federation (FDF), the British Retail Consortium (BRC), the Infant and Dietetic Foods Association (IDFA), Coeliac UK and caterers.

72. The Agency conducted an initial consultation in July 2008, asking stakeholders for views on the EC Regulations, to inform policy decisions during the negotiations. The Agency received 35 responses, 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 1, following the initial 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 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.

73. In November 2009, the Agency conducted a further 12 week formal consultation on the implementing draft Statutory Instrument; accompanying guidance notes to help businesses and enforcers understand the Commission Regulation and provide best practise advice; and the draft final Impact Assessment. This consultation generated 31 responses from a range of stakeholders, including 7 individuals with coeliac disease and Coeliac UK.

Concerns that the regulations will restrict what information will be available to coeliacs when eating out

74. Whilst all coeliacs 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, there are concerns 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 coeliacs 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 coeliacs and foods which do not contain gluten containing ingredients. Such lists are highly valued by coeliacs, a fact highlighted in a recent Define Market Research report (August 2009[26]), 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

75. 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 it is trying to protect. Restricting choice and the level of information available to coeliacs, 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.

76. The resulting discussions have lead the Agency to seek a solution to the identified problems whilst keeping within the legal framework. We take the view that the requirement under the allergen labelling rules to indicate the use 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 coeliacs, 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'.

[26] http://www.food.gov.uk/science/research/foodcomponentsresearch/allergyresearch/surveyallergy/glutenintol

77. 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.

78. That said, 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 practice 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. The Agency therefore recommends option 4b, which best addresses stakeholder views.

Consumer Survey on Factual Statements

79. To gauge the effectiveness of factual statements and help inform which statement should be recommended in the guidance to compliance, the Agency commissioned in July 2010 a survey of coeliacs 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 coeliacs; 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.

80. Separate consultations were also carried out by the relevant offices of the Food Standards Agency in the devolved administrations. These comments were also considered together with the responses to the England consultation. Summaries of these responses are available on the Agency's website at: www.food.gov.uk/consultations/

Enforcement

81. Local Authority enforcement officers will be responsible for enforcement of the new provisions. None of the enforcement authorities who responded to the Agency consultation noted specific cost impacts of any of the options on their work.

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

Risks and Assumptions

83. The objective of the Regulation is to harmonise rules throughout the European Community on the use of the claims 'gluten-free' and 'very low gluten'. This is an important health measure which will make food safer for coeliacs by lowering the amount of gluten permitted in food making these claims. Failure to implement this measure or issue guidance to consumers and industry could result in a proliferation of products in the marketplace, which are potentially harmful to the health of coeliacs.

Wider Impacts

84. It is not foreseen that there are any wider impacts, other than those outlined in this Impact Assessment.

Implementation and Review

85. A Post Implementation Review (PIR) plan has been drafted and can be found at Annex I.

Summary and Recommendation

86. The Government Recommends option 4b as this will give UK coeliacs the same level of protection as other Europeans citizens, whilst ensuring access to a healthy balanced diet. The new EC Regulation will improve consumer protection and the level of information available to coeliacs, 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.

87. 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.

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 foods for coeliacs. Potential increase of products available on the market for coeliacs	One – off familiarisation costs of new legislation: Manufacturers - £4,640 Caterers - £1.1m Enforcement - £4,800 Loss of sales for caterers: £250 m
3. Implementation of the European Regulation with Member State amendments	As option 2 but with potential further benefits to coeliacs 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 coeliacs.	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 coeliacs 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 coeliacs to make informed choices, particularly when eating out.	As option 4a, but without the loss of sales to caterers and manufacturers.

Annex 1- Post Implementation Review (PIR) Plan

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.
Review objective: To ensure application of the EU Regulations has resulted in a consistent approach to labelling of foods suitable for coeliacs and coeliacs are able to make healthier, safer and more informed choices.
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 coeliacs.
Baseline: There are currently no laws regulating the composition or labelling of foods suitable for coeliacs.
Success criteria: Increase in the number of retail and catering businesses providing foods suitable for coeliacs. Increase in consumer understanding of the new labelling terms. High number of products in compliance with the new levels of gluten.
Monitoring information arrangements: Under European rules businesses are required to notify the Food Standards Agency when placing pre-packed and non pre-packed 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. The Agency will also keep in regular contact with representatives from effected groups as part of routine business to gauge effectiveness and impact of the provisions.

Annex 2 - Summary of composition and labelling requirements in Regulation 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 Regulation 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	Have to use 'very low gluten' If the level is 20mg/kg of gluten or less can choose to use 'gluten-free'	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	Have to use 'gluten-free'	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	Have to use 'very low gluten' If the level is 20mg/kg of gluten or less can choose to use 'gluten-free'	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	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.	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

Annex 3 – Statutory Equalities Duties

Race equality issues

88. No impacts on specific ethnic groups have been identified from the policy options.

Gender equality issues

89. No gender specific issues related to the policy options or accompanying guidance have been identified.

Disability equality issues

90. No disability specific issues related to the policy options or accompanying guidance have been identified.

Annex 4 – Environmental Impacts

Wider environmental issues

91. There is no identified impact on UK waste management targets. The transition period will allow sufficient time for any label changes to be included in routine label changes.

Annex 5 – Economic Impacts

Competition assessment

92. The proposed legislation applies to all UK food manufacturers and caterers equally, allowing them to trade across EU Member States, if appropriate. 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 will promote international trade within the single market.

Small Firms Impact Test

93. The Agency acknowledges that the catering sector is dominated by small and medium size enterprises (see table 2). As a result, in addition to the informal consultation carried out, the Agency held a meeting specifically to discuss the Regulations with small businesses. No issues specific to small businesses were raised. However they did raise the following points:

    - that the claim 'very low gluten' should be allowed to be used on a wider range of foods
    - 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.

94. 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 these concerns 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.

95. It is unclear how many caterers currently sell 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 existing 'gluten-free' claims with factual statements, should products not meet the compositional requirements of the regulations.

Annex 6 Sustainable development

96. 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 in section 3 above. Impacts under all three pillars of sustainable development, economic, social and environmental, have been considered in the preparation of this IA.

97. 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 bring social disbenefit in terms of coeliac health as products placed on the UK market would not always be meeting the compositional criteria expected by coeliacs.

98. Options 2 and 3 may bring economic costs to the industry due to possible reformulation and/or relabelling. 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 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 coeliacs have the widest possible choice when purchasing food, allowing a more flexible approach for retailers and caterers.

99. 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 coeliacs and minimising economic burden.

100. 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.