



Guidance on the Composition and Labelling of Foodstuffs Suitable for People Intolerant to Gluten

January 2012

If you require this information in an alternative format – such as audio, large print, Braille – please contact us.

CONTACT TELEPHONE 020 7276 8532

Summary

Intended audience:	Food manufacturers, producers, retailers, caterers, and enforcement authorities and other interested parties, who are interested in claims which highlight the suitability of foods for people intolerant to gluten (coeliac disease).
Regional coverage:	UK
Purpose:	To help all food manufacturers, producers, retailers, caterers, enforcement authorities and other interested parties, understand and comply with the requirements of Commission Regulation (EC) 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten and the corresponding National Regulations, covering both foods sold pre-packed and non pre-packed.
Legal status:	The guidance gives both regulatory and best practice advice; the latter is enclosed in shaded boxes labelled 'best practice'.
Essential actions to comply with regulation(s):	<p>The Commission Regulation defines the terms 'gluten', 'wheat' and 'foodstuffs for people intolerant to gluten' (paragraph 18).</p> <p>The claim 'very low gluten' can only be made where the level of gluten is 100mg/kg or less and the food contains cereal ingredients that have been specially processed to reduce the level of gluten e.g. Codex wheat starch¹ (paragraphs 30-32).</p> <p>The claim 'gluten-free' can only be made where the level of gluten is 20mg/kg or less, either through substitution of cereals containing gluten or through reduction in the levels of gluten in the cereals containing gluten (paragraphs 33-</p>

¹ Specially manufactured wheat starch where the gluten has been reduced through washing to the level set out in the Codex Standard.

	<p>34).</p> <p>Oats contained in foodstuffs for people intolerant to gluten must be produced, prepared and/or processed in a way to avoid contamination by wheat, rye, barley or their crossbred varieties. Only oats with 20mg/kg of gluten or less can claim 'gluten-free' or be used in products with the claim 'gluten-free' or 'very low gluten' (paragraph 35).</p> <p>Any claims made on Foods for Particular Nutritional purposes (Particular Nutritional foods) have to be notified to the relevant authority (paragraphs 38-41).</p> <p>'Normal foods' can use the claim 'gluten-free' where the level of gluten is 20mg/kg of gluten or less. (paragraphs 42-45).</p>
--	--

REVISION HISTORY

This guidance follows the Government [Code of Practice on Guidance](#). If you believe this guidance breaches the Code for any reason, please contact us using the number on the front sheet. If you have any comments on the guidance, again please contact us on the number on the front sheet.

Revision No.	Revision date	Purpose of revision	Revised by
1	October 2009	Draft Guidance	Dionne Davey, FSA
2	September 2010	Post Consultation Revision	Dionne Davey, FSA
3	May 2011	Updated Guidance	Sarah Hardy, FSA
4	January 2012	Updated Guidance	Sarah Hardy, FSA

CONTENTS

REGULATIONS REFERRED TO IN THIS GUIDANCE	1
INTRODUCTION	2
INTENDED AUDIENCE.....	2
PURPOSE OF GUIDANCE	3
LEGAL STATUS OF GUIDANCE.....	3
OTHER RELEVANT LEGISLATION AND GUIDANCE.....	3
MAIN PURPOSE OF THE COMMISSION REGULATION	4
SCOPE AND DEFINITIONS.....	5
WHAT IS A FOOD FOR A PARTICULAR NUTRITIONAL USE (PARNUT FOOD)? .	6
WHAT IS A NORMAL FOOD?	7
SECTION A - QUICK REFERENCE GUIDE	8
Summary of products covered by the legislation and permitted claims	8
How to label your product.....	9
SECTION B – FURTHER DETAILS.....	10
I. PARNUTS FOODS SUITABLE FOR PEOPLE INTOLERANT TO GLUTEN.....	10
Use of claims on food specially prepared for people intolerant to gluten	10
Position on the label	10
Use of gluten logos, symbols and supplementary phrases	11
Which claims should I use?.....	11
Parnuts Notification arrangements.....	13
II. ‘NORMAL FOODS’ AND OTHER PARNUTS FOODS NOT SPECIALLY PREPARED FOR PEOPLE INTOLERANT TO GLUTEN	15
Foods not specially prepared for people intolerant to gluten	15
Which claim should I use?.....	15
How should you label weaning foods?.....	15
Misleading claims.....	16

Use of gluten logos, symbols and supplementary phrases	16
Position on label	17
III. WHAT OTHER INFORMATION CAN BE PROVIDED?	18
Factual statements	18
Business to business transactions	20
IV. PRODUCT TESTING	22
When is testing required?.....	22
What method should be used?	23
Method variability	23
VI. THE USE OF ‘MAY CONTAIN’ TYPE WARNINGS TO INDICATE POSSIBLE ALLERGEN CROSS-CONTAMINATION	23
ANNEX 1: OTHER RELEVANT LEGISLATION AND GUIDANCE	25
ANNEX 2: SUMMARY OF REGULATION BY UK COUNTRY.....	28
ANNEX 3: GLOSSARY OF TERMS AND PHRASES.....	29
ANNEX 4: CONTACT DETAILS FOR FURTHER INFORMATION	32

REGULATIONS REFERRED TO IN THIS GUIDANCE

These Guidance Notes cover separate but parallel regulations in all four countries of the UK.

Details are below of how the Regulations are referred to in the text, plus the full name and number of the respective Regulation in each country. A summary of these Regulations by country is in Annex 2.

The Foodstuffs Suitable for People Intolerant to Gluten Regulations

The Foodstuffs Suitable for People Intolerant to Gluten (England) Regulations 2010

The Foodstuffs Suitable for People Intolerant to Gluten (Wales) Regulations 2010

The Foodstuffs Suitable for People Intolerant to Gluten (Scotland) Regulations 2010

The Foodstuffs Suitable for People Intolerant to Gluten Regulations (Northern Ireland) 2010

INTRODUCTION

1. These Guidance Notes aim to help the food industry, enforcement officers and other interested parties interpret and comply with the provisions of Commission Regulation (EC) No 41/2009² (referred to in these Guidance Notes as the 'Commission Regulation') and corresponding national legislation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.
2. The Commission Regulation is directly applicable in all EU Member States, and gave food producers until 1 January 2012 to comply with it.
3. **From 1 January 2012, any foods not complying with the law must be removed from sale.**
4. To provide for the execution and enforcement of this Commission Regulation, national legislation has been introduced, as follows:
 - The Foodstuffs Suitable for People Intolerant to Gluten (England) Regulations 2010
 - The Foodstuffs Suitable for People Intolerant to Gluten (Scotland) Regulations 2010
 - The Foodstuffs Suitable for People Intolerant to Gluten (Wales) Regulations 2010
 - The Foodstuffs Suitable for People Intolerant to Gluten Regulations (Northern Ireland) 2010.
5. These national Regulations also came into force on the 1st January 2012. Throughout this document these Regulations will be referred to as "the National Regulations".

INTENDED AUDIENCE

6. These guidance notes are intended to help all food manufacturers, producers, retailers, caterers, other interested parties and enforcement

² OJ L 16, 21.1.2009, p. 3.

authorities understand the requirements of the Commission Regulation, including the terms or claims that have to be used on foods suitable for people intolerant to gluten and the compositional requirements that must be met in order to use such claims.

PURPOSE OF GUIDANCE

7. To help all food manufacturers, producers, retailers, caterers, enforcement authorities and other interested parties, understand and comply with the requirements of the Commission Regulation and the National Regulations, covering both foods sold pre-packed and non pre-packed.

LEGAL STATUS OF GUIDANCE

8. These guidance notes have been produced to provide advice on:
 - the legal requirements of the Commission Regulation and the National Regulations and
 - best practice in this area.
9. The guidance notes on legal requirements cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances. If you do follow the guidance notes they will help you to comply with the law. You are **not** required by law to follow best practice advice. **To distinguish between the two types of information, all advice on best practice is in shaded boxes, with a heading of Best Practice.**
10. Businesses with specific queries should seek the advice of their local enforcement agency, which will usually be the trading standards/ environmental health department of the Local Authority³.

OTHER RELEVANT LEGISLATION AND GUIDANCE

11. It may also be helpful to consult other relevant legislation and the associated guidance when interpreting the Commission Regulation. This includes the

³ or equivalent

Parnuts Framework Directive (Directive 2009/39/EC) on foodstuffs intended for particular nutritional uses (information on Parnuts foods can be found in paragraphs 19-20 of this document). References to the legislation applying to these foods and guidance to compliance with it are given in Annex I. This Annex also provides references for other relevant legislation and guidance such as the Guidance on the notification of Parnuts foods, the Allergen and Miscellaneous Labelling Provisions and the associated legislation e.g. Directive 2000/13/EC and the best practice guidance on the provision of allergen information for non pre-packed foods.

MAIN PURPOSE OF THE COMMISSION REGULATION

12. The main purpose of the Commission Regulation is:
- To require that the claim '**gluten-free**' is only used in relation to foodstuffs for people intolerant to gluten **where the level of gluten is 20mg/kg or less**, either through substitution of cereals containing gluten with cereals that do not contain gluten, or through reduction in the levels of gluten in the cereals containing gluten.
 - To require that the claim '**very low gluten**' is only used in relation to foodstuffs for people intolerant to gluten **where the level of gluten is 100mg/kg or less and which contain cereal ingredients that have been specially processed to reduce the level of gluten e.g. Codex wheat starch**.
 - To require that **oats** contained in foodstuffs for people intolerant to gluten must have been produced, prepared and/or processed in a way to **avoid cross-contamination** by wheat, rye, barley or their crossbred varieties. Only oats with **20mg/kg of gluten or less** can claim to be '**gluten-free**' or be used in products with the claims '**gluten-free**' or '**very low gluten**'.
 - To specify when '**normal foods**' (foods not specially prepared for people intolerant to gluten – paragraphs 21-22) can use the claim '**gluten-free**' (where the level of gluten is **20mg/kg or less**).
 - To specify when **other Parnuts foods** which are specially prepared to meet the dietary needs of people other than those who are intolerant to gluten, but are nevertheless suitable for them can use the claim '**gluten-free**' (where the level of gluten is **20mg/kg or less**).

- To specify that the requirements **apply to food as sold** to the final consumer and apply irrespective of whether the gluten is present as a deliberate ingredient or as a result of cross contamination.
- To define the term 'gluten'.
- To define the term 'wheat'.
- To define the term 'foodstuffs for people intolerant to gluten'.

See the Quick Reference Guide at section A for a summary of the main requirements of the Regulation and section B for further detailed guidance.

13. Although the main purpose of the Commission Regulation is outlined above, there may be more specific requirements not mentioned here. You are advised to consult the rest of this guidance in conjunction with the Commission Regulation and/or seek the advice of your local enforcement agency, to ensure you are in compliance.

SCOPE AND DEFINITIONS

14. The Commission Regulation applies to **all foods** (including alcohol, food supplements etc.) except infant formulae and follow-on formulae. Commission Directive 2006/141/EC on infant formulae and follow-on formulae prohibits the inclusion of gluten in any infant formulae and follow-on formulae. Therefore, 'gluten-free' and 'very low gluten' claims are not allowed on these products.
15. The compositional requirements for the use of the claims 'gluten-free' and 'very low gluten' apply to **all** foods, both those which are sold pre-packed and those foods which are non pre-packed (for example foods sold in delicatessens, bakeries, restaurants, at charity events, meals delivered to the home and meals served in schools, canteens and hospitals).
16. The Parnuts Framework Directive (Directive 2009/39/EC) (Article 10) specifically requires that all Parnuts foods are sold pre-packed. However, this Directive enables Member States to choose in their national legislation to take advantage of an exemption to allow Parnuts foods to be sold non pre-packed, which the UK has done. Without this exemption it would not be

possible for any Parnuts food which is not pre-packed (i.e. in a restaurant) to be sold as 'gluten-free' or 'very low gluten'.

17. The Commission Regulation applies to the labelling, presentation and advertising of foods. Therefore, the provisions related to the use of the claims 'very low gluten' and 'gluten-free' do not apply solely to the labelling of foods but also to any form of advertising and presentation, which includes, for example, off pack labelling, such as websites, leaflets, products lists, customer care lines and shelf labels.
18. The following definitions are set out in the Commission Regulation:
 - **'Foodstuff for people intolerant to gluten'** means foodstuffs for particular nutritional uses which are specifically produced, prepared and/or processed to meet the special dietary needs of people intolerant to gluten.
 - **'Gluten'** means a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some persons are intolerant and which is insoluble in water and 0.5M sodium chloride solution.
 - **'Wheat'** means any Triticum species.

WHAT IS A FOOD FOR A PARTICULAR NUTRITIONAL USE (PARNUT FOOD)?

19. A food for a **particular nutritional use** (a Parnuts food), is a food that, owing to its special composition or manufacturing process, is clearly distinguishable from a foodstuff for normal consumption, which is suitable for its claimed nutritional purpose and which is marketed in such a way as to indicate such suitability.
20. With regard to the Commission Regulation, a **foodstuff suitable for people intolerant to gluten** is a category of Parnuts food, which has been specially produced, prepared and /or processed to meet the specific dietary needs of coeliacs.

Examples include:

- Pasta that has been made specially to be gluten-free e.g. wheat flour has been substituted with maize flour.
- A cake or bread that has been made specially to be gluten-free, for example where the amount of gluten in the wheat flour has been reduced so it is suitable for coeliacs.

WHAT IS A NORMAL FOOD?

21. A food for normal consumption is a food, which has **not** been processed, manufactured or prepared in order to meet the specific needs of people with a particular nutritional requirement.
22. With regard to the Commission Regulation, a normal food is one that is considered suitable for coeliacs without any changes to the way in which it has been processed, manufactured or prepared. Examples include:
 - Malt vinegars.
 - An almond biscuit, which is traditionally made with ground almonds (which do not contain gluten), rather than wheat flour.
 - A cereal bar traditionally made with puffed rice.

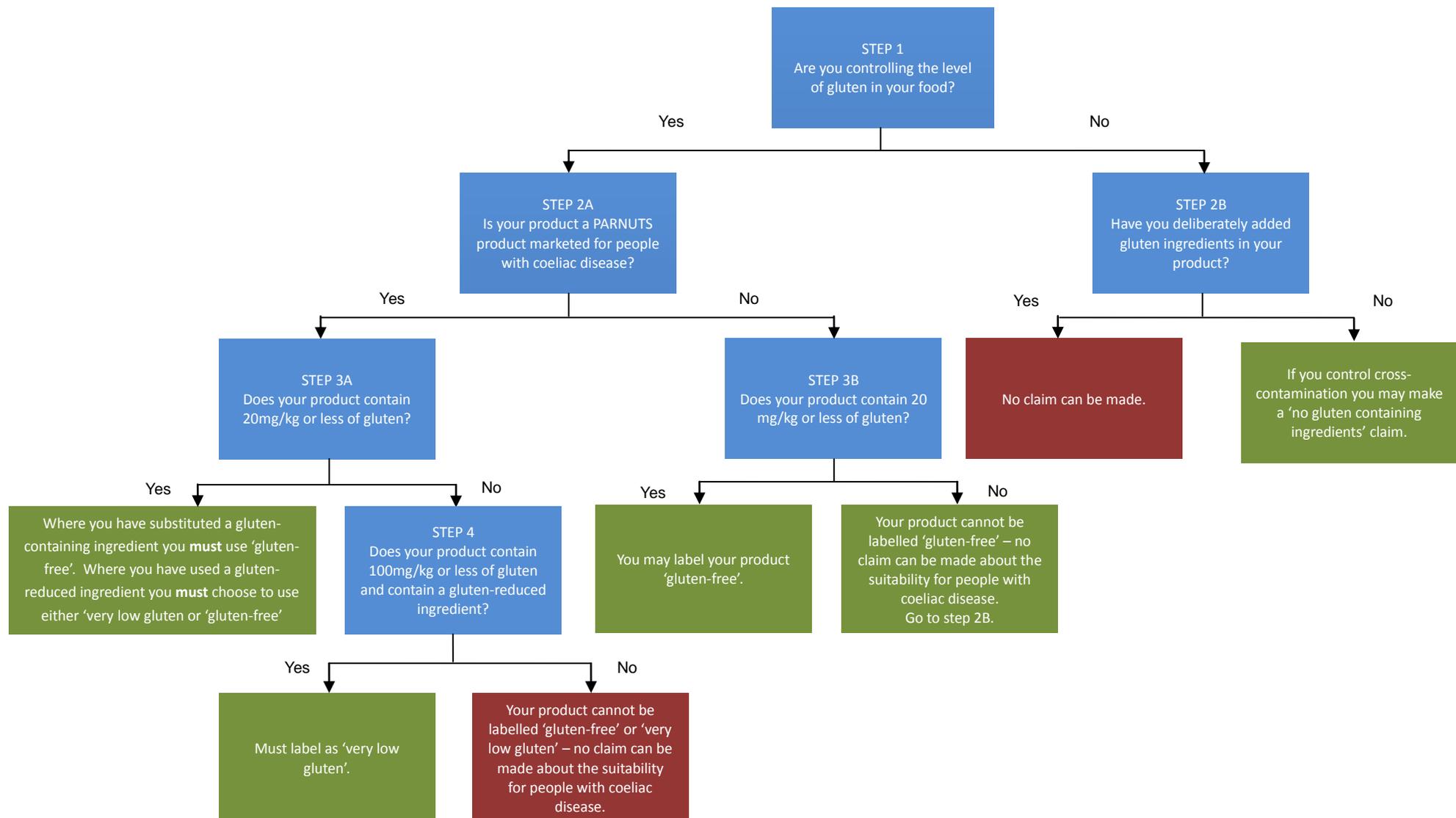
Section A - Quick reference guide

Summary of products covered by the legislation and permitted claims

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 a gluten claim
Food specially prepared for people intolerant to gluten (see paragraphs 30-34)	Includes one or more ingredients made from wheat, rye, barley, or oats ⁴ 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</u> 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 (see paragraph 33-34).	Includes substitutes for one or more ingredients made from wheat, rye, barley, or oats or their crossbred varieties.	20mg/kg	<u>Have to</u> use 'gluten-free'.	3(4)	Y
Food specially prepared for people intolerant to gluten (see paragraphs 30-34)	Includes substitutes for one or more ingredients made from wheat, rye, barley, or oats or their crossbred varieties <u>and</u> 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</u> 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 ³ or oat ingredients which are used in food specially prepared for people intolerant to gluten (see paragraph 35).	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 <u>choose to</u> use 'gluten-free' or be used in products with a 'gluten-free' or 'very low gluten' claim.	3(3)	Y
Other foods suitable for people intolerant to gluten ('normal foods' and other Parnuts foods) (see paragraphs 42-45)	N/A	20mg/kg	If the level is 20mg/kg of gluten or less can <u>choose to</u> use 'gluten-free'.	4(1)	N

⁴ Oats should not exceed 20mg/kg of gluten. Oats should be produced, prepared or processed to avoid contamination by wheat, barley or rye.

How to label your product - If you would like to make a claim about the suitability of your product for people intolerant to gluten, the following flow diagram will help you to determine the most appropriate claim for the product: -



SECTION B – Further details

I. PARNUTS FOODS SUITABLE FOR PEOPLE INTOLERANT TO GLUTEN

Use of claims on food specifically prepared for people intolerant to gluten

23. The Commission Regulation introduced two terms or claims, to be used when describing the gluten content of foods specifically marketed for people intolerant to gluten (i.e. Parnuts foods – paragraphs 19–20), these are:
- ‘very low gluten’, and
 - ‘gluten-free’
24. No other **claims** are allowed.
25. Foods specially produced for people intolerant to gluten have to be described with one or other of these claims and satisfy the criteria below to be able to use them.
26. The levels of gluten in foods described as either ‘very low gluten’ or ‘gluten-free’ must refer to the final product as sold to the ultimate consumer.
27. The Commission Regulation does not specify that a particular method has to be used to reduce the level of gluten in the cereal e.g. repeated washing of the cereal grain.

Position on the label

28. The claims ‘very low gluten’ and ‘gluten-free’ should appear in the same field of vision as the name under which the food is sold.

Best Practice

The Government has produced guidance to help manufacturers and retailers provide clear information on food labels. This can be found at:

www.food.gov.uk/multimedia/pdfs/clearfoodlabelling.pdf

Use of gluten logos, symbols and supplementary phrases

29. Under the Commission Regulation, businesses manufacturing or selling food are not prohibited from using a supplementary statement or symbol **in conjunction with** the claims 'gluten-free' or 'very low gluten', to reinforce the suitability of products for this particular group of consumers. If using a symbol or supplementary phrase, it must be clear that this has the same meaning as the claim 'gluten-free' or 'very low gluten'. All products carrying such a symbol or supplementary phrase, must meet the relevant compositional requirements. **Such supplementary information cannot be used on its own and must not be used in conjunction with the phrase 'no gluten containing ingredients' (see section III).**

Best Practice

These statements should be kept as short as possible and it is advisable for industry to adopt a common approach. For consistency and ease of consumer understanding, the supplementary term **"suitable for coeliacs"** is recommended for those foods using the claim **"gluten-free"** whilst the supplementary term **"suitable for most coeliacs"** is recommended for those foods using the claim **"very low gluten"**.

Consumers may find it helpful if these statements were printed in close proximity to the claim 'gluten-free' or 'very low gluten'

Which claims should I use?

'Very low gluten'

30. Foods described as 'very low gluten'⁵ must not contain more than 100mg/kg gluten in the food as sold to the final consumer **and** must contain a cereal ingredient which has been specially processed to reduce the level of gluten e.g. Codex wheat starch.
31. Normal foods cannot be described as 'very low gluten' as they do not contain a gluten-reduced ingredient.

⁵ To which may be added the equivalent wording in any other language.

32. Foods specially produced for people intolerant to gluten have to be described as 'very low gluten' where:
- **They include one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties that have been processed to reduce gluten, (such as the use of Codex wheat starch as an ingredient).** An example would include wheat flour treated to reduce the gluten content or a muffin made using gluten-reduced wheat flour. The gluten content of these products has to be 100mg/kg or less. If the gluten content is 20mg/kg or less, the claim 'gluten-free' can be used instead (step 2A on page 9).
 - **They contain a combination of substitute and gluten-reduced ingredients** (see above). Bread made from rice flour as a substitute but with added Codex wheat starch for texture. The gluten content of these products has to be 100mg/kg or less. If the gluten content is 20mg/kg or less, the claim 'gluten-free' can be used instead.

'Gluten-free'

33. Foods described as 'gluten-free'⁶ must not contain more than 20mg/kg gluten in the food as sold to the final consumer.
34. Where foods have been specially prepared for people intolerant to gluten **and** include substitutes for one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties and the level of gluten is 20mg/kg or less the claim 'gluten-free' has to be used, for example a muffin made with rice flour instead of wheat flour or pasta made from corn (See step 2A on page 9). A 'gluten-free' claim can also be used on products containing a gluten reduced ingredient or a combination of substitute and gluten-reduced ingredients (see paragraph 32).

Oats

35. Oats contained in foodstuffs for people intolerant to gluten must be produced and prepared and/or processed in a way to avoid contamination by wheat, rye, barley or their crossbred varieties⁷. **Only oats that have a level of 20mg/kg of gluten or**

⁶ To which may be added the equivalent wording in any other language.

⁷ The allergen labelling legislation defines cereals containing gluten as wheat, rye, barley, oats, spelt, kamut or their hybridised strains. The labelling legislation requires that the cereal rather than gluten is declared in the ingredient listing of pre-packed foods and therefore oats should be declared on the label if they are present as a deliberate ingredient.

less can be labelled as 'gluten-free' or used in products labelled as 'gluten-free' or 'very low gluten'.

Best Practice

It is recommended that manufacturers producing foods for people intolerant to gluten ensure that their facilities are either adequately cleaned down or dedicated to the production of such foods to eliminate any risk of cross-contamination that could occur from multi-purpose food manufacturing.

If challenged, the food producer will need to demonstrate that they had put in place appropriate procedures and controls, in order to ensure that the final product does not contain more than the specified level of gluten. Showing due diligence through Critical Control Points, a system of record keeping and regular testing to demonstrate consistent results is advisable.

Non pre-packed foods which are specially produced for people intolerant to gluten

36. The Parnuts Framework Directive (Directive 2009/39/EC) (Article 10) specifically requires that all Parnuts foods are sold pre-packed. However, the Directive provides that Member States can in their national legislation allow Parnuts foods to be sold non pre-packed. Unless advantage is taken of this provision, Parnuts foods for people intolerant to gluten **could not be sold non pre-packed**, for example in restaurants or delicatessens.
37. Therefore, the UK has taken advantage of this provision in the National Regulations to allow Parnuts foods, which are sold non pre-packed, to be able to make either of the claims 'gluten-free' or 'very low gluten', provided they comply with all of the conditions outlined above. These claims can be made, for example, on menus, blackboards, or in discussions between the customer and the serving staff.

Parnuts Notification arrangements

38. **Foods specially prepared for people intolerant to gluten** making either 'gluten-free' or 'very low gluten' claims must be notified to the relevant authority⁸ when placed on the market for the first time. This is because of an EC obligation to monitor the market. It is therefore the responsibility of the manufacturer, or in the

⁸ Contact details for further information on the notification process can be found in Annex 4.

case of imported foods, the importer, to notify the relevant authority whenever products are marketed in one or more Member States. Notification is required in each country in which the product is marketed. **In the UK it is therefore the responsibility of the food producer** (including restaurants, takeaways, delicatessens etc), to notify the relevant authority. This entails:

- **for pre-packed Parnuts foods** specially prepared for people intolerant to gluten labelled as 'gluten-free' or 'very low gluten' – a copy of the label must be provided; and
- **for Parnuts food sold unpackaged** specially prepared for people intolerant to gluten that are described as 'gluten-free' or 'very low gluten' – as these products do not have labels and to minimise burdens on the business, details of the Food Business Operator, category of foodstuff and claims used (i.e. 'gluten-free' or 'very low gluten') must be provided by the notifier.

In both cases, notification is of the food as sold to the consumer.

39. Foods specially prepared for people intolerant to gluten, that were already on the market when the Commission Regulation came into force, must be notified to the relevant authority as Parnuts foods.
40. 'Normal foods' do not need to be notified when they are put on the market, as the obligation to notify only applies to Parnuts foods.
41. Links to guidance and forms for making notification are listed in Annex I and contact details for further information on the notification process can be found in Annex 4.

II. 'NORMAL FOODS' AND OTHER PARNUTS FOODS NOT SPECIALLY PREPARED FOR PEOPLE INTOLERANT TO GLUTEN

Foods not specially prepared for people intolerant to gluten

Which claim should I use?

42. The Commission Regulation contains a provision allowing manufacturers of foods not specially prepared for people intolerant to gluten ('normal foods') to choose to describe them as 'gluten-free'⁹ if the level of gluten is 20mg/kg or less in the food as sold to the final consumer. This legislation applies to normal foods sold both pre-packed and non pre-packed; for example, a soup made from vegetables and stock, which does not contain any gluten, sold either pre-packed or in a restaurant (See step 2A on page 9).
43. In addition, Parnuts foods that are specially prepared to meet the special dietary needs of people other than those who are intolerant to gluten, but which are nevertheless suitable for people intolerant to gluten (hereafter referred to as 'other Parnuts foods'), can be described as 'gluten-free', providing the level of gluten is 20mg/kg or less in the food as sold to the final consumer.
44. No other term or claim can be used to indicate suitability for people intolerant to gluten, for instance, 'free from gluten' or 'naturally gluten-free' is not allowed.
45. As the claim 'very low gluten' is only permitted for foods with gluten-reduced ingredients, it cannot be used on 'normal foods' or other Parnuts foods.

How should you label weaning foods?

46. Under Directive 2006/125/EC, cereal-based baby foods and other baby foods (hereafter referred to as weaning foods) must provide information as to the presence or absence of gluten if the indicated age from which the product may be used is below six months. Recital 10 of the Commission Regulation states that the **absence** of gluten in these weaning foods should be indicated on the label in

⁹ To which may be added the equivalent wording in any other language.

accordance with the Commission Regulation i.e. as 'gluten-free' meaning 20mg/kg or less.

47. Our concern is that this could potentially lead to an increase in the level of gluten present in weaning foods. This is because manufacturers are currently using the lowest limit of detection (LOD) (according to the Elisa R5 Mendez method (see paragraphs 59), which is around 3-4mg/kg of gluten, to label their foods with the absence of gluten ('gluten-free').
48. The level of 20mg/kg was set based on scientific evidence to prevent symptoms in people who were already diagnosed with coeliac disease, not as a threshold for determining the presence/absence of gluten in weaning foods. We do not have the scientific evidence to establish whether the potential increase in exposure to gluten (from 3-4mg/kg to potentially 20mg/kg) in baby foods for infants less than 6 months of age will increase the chance of infants developing coeliac disease, and/or an allergy to cereals containing gluten, later on in life. In light of these concerns, we recommend the following best practice.

Best Practice

Manufacturers of weaning foods should continue to use the lowest limit of detection (LOD) to establish the presence or absence of gluten and label such products as either 'Contains gluten' or 'gluten-free'

Misleading claims

49. When the claim 'gluten-free' is used on 'normal foods' or other Parnuts foods, this must not mislead the consumer by suggesting that the particular food is special in having that property, when all other foods of that type are also 'gluten-free'. For example, whilst it may be helpful for coeliacs to have information that an individual product, such as a processed potato chip product, is 'gluten-free', it would be misleading to use such a claim on unprocessed fruits or vegetables or bottled milk or water.

Use of gluten logos, symbols and supplementary phrases

50. Businesses manufacturing or selling food may choose to use a supplementary statement or symbol in addition to the claim 'gluten-free' to reinforce the products suitability for this particular group of consumers. If using a symbol or supplementary phrase, it must be clear that this has the same meaning as the claim 'gluten-free'.

All products carrying such a symbol or supplementary phrase, must meet the relevant compositional requirements. **Such supplementary information cannot be used on its own and must not be used in conjunction with the phrase ‘no gluten containing ingredients’ (see section III).**

Best Practice

These statements should be kept as short as possible and it is advisable for industry to adopt a common approach. For consistency and ease of consumer understanding, the supplementary term “**suitable for coeliacs**”, is recommended for those foods using the claim “**gluten-free**”.

Consumers may find it helpful if this statement is printed in close proximity to the claim ‘gluten-free’.

Position on label

51. The claim that a ‘normal food’ is ‘gluten-free’ does not need to be in the same field of vision as the name under which the food is sold.

Best Practice

If you choose not to place this statement on the front of pack, it would be best practice for this information to be placed with the ingredients list and/or any allergen information.

III. WHAT OTHER INFORMATION CAN BE PROVIDED?

52. As already stated, for pre-packed or non pre-packed 'normal foods' or other Parnuts foods that comply with criteria set out in the Commission Regulation, no other terms (other than 'gluten-free') can be used to indicate suitability, on either the pack or the labelling, advertising and presentation of the food.
53. Foods that do not comply with the criteria set out in the Commission Regulation cannot be described as 'gluten-free'. It would also not be possible to suggest that these foods are suitable for people intolerant to gluten in any communication, including product lists, menus, customer care lines and in conversation with serving staff.

Factual statements

54. It is considered that it would be possible for '**normal foods**' and **other Parnuts foods**, to make factual statements either on the labels or on the menu/blackboard about products **which do not contain gluten-containing cereals as ingredients**. However, it is recommended that this is only appropriate for situations where **gluten cross-contamination is controlled and minimised** according to established HACCP¹⁰ type processes.
55. Food producers (both caterers and manufacturers) may wish to explore how they might provide consumers with this type of information either on product labels or, particularly within the **food service sector** setting, on, for instance, menus, blackboards, or in discussions **between the customer and the serving staff**. Factual statements would be permitted providing:
- **The statements only relate to the absence of gluten containing ingredients.**
 - **No indication is made about the suitability of the product for coeliacs.**
 - **No indication is made about the levels of gluten present in the food.**

¹⁰ Hazard Analysis and Critical Control Points

Best Practice

When using factual statements, food producers should take all reasonable steps to ensure that cross-contamination with a gluten-containing ingredient has not occurred.

This can be done by following simple HACCP type procedures, these would include:

- Ensuring ingredients that do not contain gluten are stored separately from the gluten-containing ones.
- Using separate equipment to weigh 'gluten free' ingredients.
- Preparing the food in a separate kitchen or using time separation.
- Cooked food is kept covered and stored away from gluten-containing food.

Best Practice

It is advised that for consistency and ease of consumer understanding, industry adopt a common approach to factual statements and the phrase 'no gluten-containing ingredients' is used.

To ensure consumers are clear about the understanding of the phrase 'no gluten-containing ingredients', business may choose to provide further information on the risks of cross-contamination and the processes used to control it, alongside the phrase 'no gluten-containing ingredients'.

When producing non pre-packed foods the following phrase would be appropriate:

'Please ask us about the steps we have taken to minimise cross-contamination with gluten-containing foods'.

When producing pre-packed foods the following phrase would be appropriate on pack:

'In manufacturing this product steps have been taken to minimise

cross-contamination with gluten-containing foods'

Such further information could also be provided on websites, leaflet, product lists etc.

If food businesses want to use statements other than 'no gluten-containing ingredients' to describe these foods, it is advised that they contact their Local Authorities to check the suitability of these alternative phrases. It is also advised that the Local Authorities are consulted before the use of any logo or acronyms etc.

56. Factual statements and further information about the risk of cross-contamination with gluten in either the manufacturing or catering environment can be communicated in a variety of different ways, including on websites, on product labels and in verbal communication between the customers and staff. By extension, product lists such as the Coeliac UK Directory would be allowed to communicate the absence of gluten-containing cereal ingredients in products. This information could also be provided via retailer product lists and customer care lines.
57. Factual statements are not permitted on foods specially prepared for people intolerant to gluten (Parnuts foods), where only 'gluten-free' or 'very low gluten' statements must be used.

Best Practice

For further information and guidance on the handling of gluten-containing ingredients and controlling cross-contamination in these situations, see the Agency's best practice Guidance on Allergen Management and Consumer Information. This can be found at:

www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/maycontainguide

Business to business transactions

58. As the levels of gluten apply to foods as sold to the final consumer, business-to-business transactions are outside the scope of the National Regulations. However, if a business chooses to use either claim, contractual arrangements would normally provide that the composition of the product must comply with the limits set for that claim by the legislation.

Best Practice

The Agency recommends that businesses label bulk ingredients in accordance with the Regulations, as this will supply final food manufacturer/caterers with the relevant information required to make the appropriate claims.

Some foods meeting the compositional criterion needed to make a 'gluten-free' claim may contain particular ingredients that themselves contain more than 20mg/kg of gluten. It would therefore be good practice for the producers of ingredients sold to other food businesses to inform their customers of the level of gluten in the ingredient. For example, the baking power in a 'gluten-free' cake could contain 250mg/kg of gluten but, when added to the other ingredients, the end product i.e. the cake, could contain less than 20mg/kg gluten. Therefore, it would be helpful for business-to-business sales to label the level of gluten in the ingredient e.g. "baking powder max 150mg/kg of gluten".

IV. PRODUCT TESTING

59. There is no requirement in the Commission Regulation for testing (including the frequency of testing required or the method to be used).

When is testing required?

Best Practice

Food businesses producing pre-packed and non pre-packed foods need to ensure that any 'gluten-free' or 'very low gluten' claims that they make are justified, and this requires some analytical testing. If testing is carried out it will not be necessary to test every batch. It may be sufficient to demonstrate that, with good practice and due diligence, it is possible to maintain the levels of control necessary to achieve the required levels. However, it is important that businesses discuss the level of control and frequency of testing required with their Local Authority¹¹.

If you are buying products which are already labelled as 'gluten-free' or 'very low gluten' and selling these as such, testing would not be required provided cross contamination with gluten containing foods has been controlled e.g. 'gluten-free' bread rolls that are served in a restaurant or complete meals/dishes that are only heated and served.

There are no threshold levels of gluten associated with factual statements such as 'no gluten containing ingredients'. Therefore, it would not be necessary to conduct analytical tests on these foods. However, due diligence should be demonstrated when making such claims, which would include taking steps to ensure that cross-contamination with a gluten-containing ingredient has not occurred.

¹¹ or equivalent

What method should be used?

Best Practice

The Commission Regulation does not specify a particular test method to determine the level of gluten in the final food. This is to allow for the possibility of technical advances in analytical methodology. The Commission Regulation refers to the Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten¹², which was agreed in July 2008. Within this Standard it states that the level of gluten should be determined using the Enzyme-linked Immunoassay (ELISA) R5 Mendez Method.

Method variability

Best Practice

As with all analytical methods, there is a degree of inter- and intra- variability in the results obtained. The analyst will express this as the measurement uncertainty associated with each result that is reported¹³. In the UK, as in all Member States, official control laboratories have to comply with defined quality standards. For control work, enforcement authorities will take the measurement of uncertainty into account when assessing the compliance of any particular sample with the legislation, thus ensuring that any sample deemed non-compliant is non-compliant beyond reasonable doubt.

VI. THE USE OF 'MAY CONTAIN' TYPE WARNINGS TO INDICATE POSSIBLE ALLERGEN CROSS-CONTAMINATION

60. Under the allergen labelling rules there is no legal requirement to use 'may contain' or 'traces of' type warnings to indicate possible allergen cross-contamination. However, many manufacturers and retailers provide this information voluntarily in

¹² http://www.codexalimentarius.net/web/more_info.jsp?id_sta=291

¹³ Please refer to the measurement of uncertainty protocol: Pure Applied Chem. 2006, Vol 78. No 1. pp 145-196.

order to indicate the possible presence of unintentional allergenic ingredients in pre-packed food.

61. Voluntary statements referring to the allergenic ingredients in a food (such as 'Contains X') are not covered by the rules. Further information can be found at: www.food.gov.uk/multimedia/pdfs/maycontainguide.pdf

Best Practice

For any foods with a small amount of a gluten-containing ingredient that are still able to meet the compositional criteria and are described as 'gluten-free' or 'very low gluten', **it is best practice not to use a 'Contains gluten' statement** on such products because it could mislead the consumer.

For foods which contain cereals containing gluten as ingredients but still meet the requirements to make the claim 'gluten-free' or 'very low gluten' it is necessary to list the cereal as an ingredient as per Commission Directive 2000/13/EC (as amended). This is to allow those with an allergy to these cereals containing gluten (such as wheat) to safely avoid such foods e.g. barley malt extract.

Best Practice

For products that meet the criteria to be labelled 'gluten-free' it is best practice **not to use a 'may contain gluten' statement.**

The 20mg/kg limit should not be considered as a threshold above which foods should be labelled as 'may contain gluten'. Such statements should only be made after careful consideration and only after all efforts have been made to eliminate cross-contamination.

Further information on precautionary labelling can be found at:

www.food.gov.uk/multimedia/pdfs/maycontainguide.pdf

ANNEX 1: OTHER RELEVANT LEGISLATION AND GUIDANCE

These guidance notes are intended to be read in conjunction with the legislation and guidance listed below:

PARNUTS FOODS

- Parnuts Framework Directive: Directive 2009/39/EC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses can be found at:

www.eur-

lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:124:0021:0029:EN:PDF

- Foods for particular nutritional uses notifications and guidance notes.

The guidance notes can be found at:

www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/parnutsguidancenotes

ALLERGEN LABELLING

- Directive 2000/13/EC of the European Parliament and the Council of 20 March 2000, on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (as amended by Directive 2007/68/EC) can be found at:
www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:310:0011:0014:EN:PDF
- The Food Labelling (Declaration of Allergens) (England) Regulations 2008 www.opsi.gov.uk/si/si2008/uksi_20081188_en_1 (and equivalents for Scotland, Wales and Northern Ireland)
- Guidance on Allergen and Miscellaneous Labelling Provisions can be found at www.food.gov.uk/multimedia/pdfs/publication/allergenlabelguidance09.pdf

GENERAL LABELLING

- Directive 2000/13/EC (as amended) can be found at:
www.eur-lex.europa.eu/pri/en/oj/dat/2000/l_109/l_10920000506en00290042.pdf
- The Food Labelling Regulations 1996 can be found at:
www.opsi.gov.uk/si/si1996/uksi_19961499_en_1.htm
- The Food Safety Act 1990¹⁴ can be found at:
www.opsi.gov.uk/acts/acts1990/ukpga_19900016_en_1.htm
- The Governments Clear Food Labelling Guidance, published in 2008 can be found at:
www.food.gov.uk/multimedia/pdfs/clearfoodlabelling.pdf

¹⁴ In Northern Ireland, the Food Safety (Northern Ireland) Order 1991 applies.

**OTHER RELEVANT GUIDANCE DOCUMENTS THAT ARE AVAILABLE ON THE
FOOD STANDARDS AGENCY'S WEBSITE (WWW.FOOD.GOV.UK)**

- The best practice 'Guidance on Allergen Management and Consumer Information' can be found at:
www.food.gov.uk/multimedia/pdfs/maycontaininguide.pdf
- The best practice guidance on the 'Provision of Allergen Information for Non Pre-packed Foods' can be found at:
www.food.gov.uk/multimedia/pdfs/loosefoodguidance.pdf

ANNEX 2: SUMMARY OF REGULATION BY UK COUNTRY

These Guidance Notes cover separate but parallel regulations in all four countries of the UK.

A summary of the Regulations referred to for each country is below. A list of the regulations showing how they are referred to in this guidance is at the front of the document.

England
The Foodstuffs Suitable for People Intolerant to Gluten (England) Regulations 2010
The Food Labelling (Declaration of Allergens) (England) Regulations 2008
The Food Labelling (Declaration of Allergens) (England) Regulations 2009 (which amend the 2008 Regulations)
Wales
The Foodstuffs Suitable for People Intolerant to Gluten (Wales) Regulations 2010
The Food Labelling (Declaration of Allergens) (Wales) Regulations 2008
The Food Labelling (Declaration of Allergens) (Wales) Regulations 2009 (which amend the 2008 Regulations)
Scotland
The Foodstuffs Suitable for People Intolerant to Gluten (Scotland) Regulations 2010
The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2008
The Food Labelling (Declaration of Allergens) (Scotland) Regulations 2009 (which amend the 2008 Regulations)
Northern Ireland
The Foodstuffs Suitable for People Intolerant to Gluten Regulations (Northern Ireland) 2010
The Food Labelling (Declaration of Allergens) Regulations (Northern Ireland) 2008
The Food Labelling (Declaration of Allergens) Regulations (Northern Ireland) 2009 (which amend the 2008 Regulations)

ANNEX 3: GLOSSARY OF TERMS AND PHRASES

Codex - The **Codex Alimentarius Commission** was created in 1963 to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organisations.

Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten – The Codex Standard defining the composition standard and labelling for foods for people intolerant to gluten can be found at www.codexalimentarius.net/web/more_info.jsp?id_sta=291

Codex wheat starch – This is a specially manufactured wheat starch where the gluten in the cereal has been reduced to a trace level (to meet the levels set in the codex standard) through repeated washing.

End User – The person who will consume the product.

FAO - The **Food and Agriculture Organisation of the United Nations** leads international efforts to defeat hunger. Serving both developed and developing countries, FAO acts as a neutral forum where all nations meet as equals to negotiate agreements and debate policy.

Food – means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. ‘Food’ includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.

Food Business – Any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.

Food Business Operator - The natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

Food Service Sector – This is all catering businesses, including hotel catering, school catering, hospital catering, meals on wheels, sandwich bars, take aways and restaurants.

Foodstuffs for people intolerant to gluten - is a category of food for a particular nutritional use (a Parnuts food), which has been specially produced, prepared and /or processed to meet the special dietary needs of coeliacs.

Gluten-Free – is where the level of gluten in a product is 20mg/kg or less, either through substitution of cereals containing gluten or through reduction in the levels of gluten in the cereals containing gluten.

Non pre-packed – Foods sold unwrapped, for example from restaurants, bakeries and deli counters. This includes loose foods and foods sold 'pre-packed for direct sale.

Naturally free of gluten – These are foods which have not been specially designed to be 'gluten-free' but just happen to be suitable for those with a gluten intolerance, for example a chicken salad, a baked potato.

Normal Foods – A food for normal consumption is a food, which has not been processed, manufactured or prepared in a way to meet the specific needs of people with a particular nutritional requirement.

Notification – New Parnuts foods (both pre-packed and non pre-packed) must be notified to the relevant authority when they are placed on the market.

Notification of marketing of certain foods for particular nutritional uses is a statutory requirement. The duty to notify falls on:

- The manufacturer if the product is manufactured in the European Union, OR
- The importer if the product is manufactured outside the European Union and imported into the UK, OR
- The proprietor of any food business when a new dish is developed for sale in a catering establishment.

Parnuts Foods - A food for a particular nutritional use is one 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 particular nutritional purpose.

Specially Processed to Reduce Gluten – Where the gluten in the cereal (wheat, rye, barley, oats etc) has been reduced to a trace level, usually to make it suitable for coeliacs.

Threshold – a dose or exposure concentration below which there is considered not to be an adverse effect.

Very Low Gluten - A claim of 'very low gluten' can only be made where the level of gluten is 100mg/kg or less and contains cereal ingredients, which have been specially processed to remove the gluten e.g. Codex wheat starch.



WHO – The **World Health Organisation** is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

ANNEX 4: CONTACT DETAILS FOR FURTHER INFORMATION

The address for all correspondence relating to the issues set out in this advice is:

In England: Chemical Safety Division
Food Standards Agency
Aviation House
125 Kingsway
London
WC2B 6NH
Tel: 0207 276 8532
Fax: 0207 276 8193
E-mail: sarah.hardy@foodstandards.gsi.gov.uk

For information on the notification of parnuts foods: -

Derek Hampson
Nutrition Science and Delivery
Health and Wellbeing
Department of Health
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7972 4895
E-mail: derek.hampson@dh.gsi.gov.uk

In Wales: Food Standards Agency in Wales
11th Floor, Southgate House
Wood Street
Cardiff
CF10 1EW
Tel: 029 2067 8999
Fax: 029 2067 8918/8919
E-mail: wales@foodstandards.gsi.gov.uk

For information on the notification of parnuts foods: -

Alison Black
Food & Physical Activity Branch
Health Improvement Division



Department for Public Health and Health
Professions
Welsh Government
Cathays Park
Cardiff, CF10 3NQ
Tel: 02920 821617
E-mail: sarah.meredith@wales.gsi.gov.uk

In Scotland: Food Standards Agency in Scotland
St Magnus House
6th Floor
25 Guild Street
Aberdeen
AB11 6NJ
Tel: 01224 285140
Fax: 01224 285129
E-mail: christine.green@foodstandards.gsi.gov.uk

In Northern Ireland: Food Standards Agency in Northern Ireland
10 A-C Clarendon Road
Belfast
BT1 3BG
Tel: 028 9041 7742
Fax: 028 9041 7726
E-mail: mervyn.briggs@foodstandards.gsi.gov.uk