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GLUTEN LABELLING BEST PRACTICE: HOW TO LABEL PRE-PACKED FOODS WHICH INCLUDE CEREALS CONTAINING GLUTEN.

In partnership with:



Food and Drink
Federation



Delivering Sustainable Growth

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The introduction of the Food Information to Consumers (FIC) Regulation which entered into force in December 2014 resulted in changes to the labelling of allergens. [Regulation (EU) No. 1169/2011, as amended]

This best practice aims to provide recommendations to manufacturers on how to label food products containing gluten through review of the relevant EU legislation, guidance notes and with reference to claims for gluten-free foods. Special consideration is also given to oats and wheat. This best practice has been produced to illustrate examples of the usual and also more challenging labelling situations of gluten containing foods.

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GLUTEN

The term “gluten” refers technically to a fraction of wheat and wheat-related cereals, which is insoluble in water. It constitutes around 80% of the protein in these cereals. Short peptides in gluten [“toxic” peptides] are responsible for causing the underlying damage in coeliac disease. Additionally other proteins found in gluten-containing cereal grains may trigger allergic responses.

For the purposes of labelling pre-packed foods within the European Union, Annex II of FIC Regulation (EU) No. 1169/2011 (as amended) defines the cereals containing gluten as: wheat (including varieties such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof. Also several specific products exempt from the requirement for labelling are also defined.



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FOOD INFORMATION

The purpose of labelling is to inform consumers of the presence of a constituent in food. Claims aim to inform consumers about the attributes of a particular food, resulting from either the presence or absence of a specific constituent. Thus claims about gluten aim to inform consumers of the suitability of the food either directly (“suitable for”) or indirectly (“gluten-free”); and therefore suitable. “Gluten-free” refers to a quantitative limit (concentration) rather than an absolute absence of gluten, deemed on the basis of scientific evidence to assure that the food in question can be consumed safely by the vast majority of people with an intolerance to gluten.

While coeliac disease is the primary health concern around wheat and other cereals containing gluten, these cereals can also provoke allergic reactions. However, no generally accepted management threshold has yet been defined for the protein content (both gluten and non-gluten) below which the risk to people with allergy to those cereals is considered tolerable. They must therefore be labelled when used as ingredients, irrespective of the amount present. The same applies to derivatives and products thereof, unless they are exempt in accordance with Annex II of FIC Regulation (EU) No. 1169/2011 (as amended).

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OATS

Oats and wheat belong to the same botanical family and oats also possess a gluten-like protein (avenin). In practice, uncontaminated oats can be consumed safely by the majority of people with coeliac disease; however, cross-contamination of oats with other cereals containing gluten in the supply chain (e.g. harvesting, transport, storage and processing) poses a more significant risk. [FSA Guidance on Composition and Labelling of Foodstuffs Suitable for People Intolerant to Gluten (January 2012)]

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LABELLING CEREALS CONTAINING GLUTEN

Information on the labelling of foods where gluten-containing cereals are intentionally added to the product is listed below in Table 1. The new labelling requirements as a result of the enforcement of the Food Information to Consumers Regulation regarding the labelling of allergens include the following:

- The use of 'Contains X Allergen' statement or similar are no longer permitted, except in the case that there is no ingredients list.
- The specific cereal name must be emphasised within the ingredient list e.g. using bold font.
- It is no longer permitted to state 'gluten' without a reference to a specific cereal in the ingredients list because gluten is not listed in the Annex II of Regulation (EU) No. 1169/2011, unless it is used as an ingredient in its own right.
- Whilst it is optional to add the word 'gluten' in parentheses (in non-emphasised font) after the name of the cereal; best practice is not to include the word gluten in parentheses but to solely emphasise the name of the cereal in the ingredients list.
The consistent application of this particular best practice is to be recommended, as this would ensure consumer understanding by encouraging the reading of the ingredients list for the presence of the specific gluten-containing cereal. This in turn reduces the risk to individuals looking for the word "gluten", which may not be listed.

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LABELLING EXAMPLES

Intentional Addition of Gluten-Containing Cereals

- The specific cereal name must be emphasised within the ingredients list (e.g. using bold font)

Ingredients: sugar, **milk** powder, **rye** flour, rolled **oats**, palm fat, salt

[Regulation (EU) No. 1169/2011, as amended]

- For ingredients, such as 'Oatmeal' it is permissible to emphasise either just the cereal element or the entire word

Ingredients: sugar, **oatmeal**, salt OR
Ingredients: sugar, **oatmeal**, salt

[European Commission Questions and Answers on the application of the Regulation (EU) No. 1169/2011]

- For ingredients where several words are used in the name of the cereal ingredient, it is necessary just to label the cereal source

Ingredients: **barley** malt extract, **milk** powder, dried **egg**

[European Commission Questions and Answers on the application of the Regulation (EU) No. 1169/2011]

- Where ingredients derived from the same allergenic material appear more than once in the ingredients list the allergen must be emphasised on each occurrence

Ingredients: whole rolled **oats**, sugar, **oatmeal**, salt

[Regulation (EU) No. 1169/2011, as amended]

- 'Gluten' would be stated in the ingredients list when used as an ingredient in its own right. The cereal source must be specified by name and highlighted.

Ingredients: sugar, **milk** powder, **rye** flour, rolled **oats**, palm fat, gluten (**wheat**)
[OR...'**wheat** gluten or '**wheat** protein']

[BRC Guidance on Allergen Labelling and the Requirements in Regulation 1169/2011]

- Spelt and Khorasan are types of wheat, which are not suitable substitutes for people with coeliac disease and/or wheat allergy. Where 'spelt' and 'Khorasan' wheat species are present, a specific reference to wheat is required

Ingredients: spelt (**wheat**), sugar, milk powder

Ingredients: Khorasan (**wheat**)

[Addendum to BRC Guidance on Allergen Labelling and the Requirements in Regulation 1169/2011]

Labelling examples contd...

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LABELLING EXAMPLES

Intentional Addition of Gluten-Containing Cereals

- It is no longer permitted to use allergy advice statements/boxes such as 'Contains: ... (list of allergens)' unless there is no ingredients list present.

Cous cous; Contains: **Wheat**

[FSA Technical Guidance Food Allergen Labelling and Information Requirements under the EU Food Information for Consumers]

- For companies who used allergy advice statements/boxes they should be replaced by the following phrase directing the consumer to the ingredients list:

"Allergy Advice: For allergens, including cereals containing gluten, see ingredients in **bold**."

[BRC Guidance on Allergen Labelling and the Requirements in Regulation 1169/2011]

- **Ingredients derived from cereals that have been specifically exempted from declaration under Annex II of the EU FIC should not make reference to the allergen in the ingredients list, thus no need for emphasis.**

Example: wheat based 'glucose syrups' including dextrose

Ingredients: glucose syrup, **barley** flour, **egg**

[Regulation (EU) No. 1169/2011, as amended]

- In case of ingredients originating from cereals containing gluten, such as "plant protein hydrolysate", the reference to the cereal in question should also be made.

Ingredients: plant protein hydrolysate (**wheat**)

[FSA Technical Guidance Food Allergen Labelling and Information Requirements under the EU Food Information for Consumers]

- Oats are considered to be a cereal which contains gluten. However oats that are not contaminated with other gluten-containing cereals (e.g. wheat, barley and rye) and when analysed contain 20 parts per million (ppm) gluten or less, as sold, may be labelled as 'gluten-free'. The oats must however still be emphasised as an allergen.

Ingredients: gluten-free **oats**, sugar

[Regulation (EU) No. 1169/2011, as amended]

- In addition to gluten, wheat itself is an allergen, therefore must be labelled whenever it is an ingredient in a product, irrespective of concentration.

Ingredients: gluten-free **wheat** starch, sugar, salt

[Regulation (EU) No. 1169/2011, as amended]

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PRECAUTIONARY ALLERGEN LABELLING

The probability of contamination in products and the risk arising from it should be taken into consideration by food business operators. Manufacturers are required to conduct a full and thorough risk assessment before deciding whether a precautionary allergen statement is required on certain products due to unintended allergen presence. Essential allergen management guidance for food manufacturers is available from both the FSA and FDE. [FSA Guidance on Allergen Management and Consumer Information (2006) & FDE Guidance on Food Allergen Management for Food Manufacturers (2013)]

The examples on the next page suggest possible ways of labelling the food products in case of unintended presence of gluten-containing cereals. Although it is not mandatory to highlight the allergens in the precautionary allergen label it is acceptable to do so.



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LABELLING EXAMPLES

Unintentional Presence of Gluten-Containing Cereals

- **Where there is a risk of cross-contamination it is advisable to use precautionary allergen labelling (PAL). The use of such statements is voluntary, but must not mislead.**

May also contain wheat, barley and milk

May also contain other gluten sources (oats and rye)

[BRC Guidance on Allergen Labelling and the Requirements in Regulation 1169/2011]

- **It may not always be possible to specify the cross-contaminant cereal(s) due to complexity in the cereal production and supply chain. In this situation it is advisable to use the following precautionary allergen labelling.**

May also contain a gluten containing cereal

[BRC Guidance on Allergen Labelling and the Requirements in Regulation 1169/2011]

- **If the level of non-intentional gluten is <20ppm in the product as sold then it is not necessary to use precautionary allergen labelling (PAL)**

[BRC Guidance on Allergen Labelling and the Requirements in Regulation 1169/2011]

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CLAIMS

Under EU Commission regulations, companies are allowed to use claims such as 'gluten-free' and 'very low gluten' if they meet the relevant compositional requirements. 'Gluten-free' and 'very low gluten' are allowed to be made where the food as sold to the final consumer contains no more than 20 mg/kg and 100mg/kg of gluten respectively. [Commission Regulation (EC) No 41/2009 and Commission Implementing Regulation (EU) No 828/2014]

The 'gluten-free' claim in the European Union is harmonised with that at international level in the Codex standard. [CODEX STAN 118 - 1979]

In 2012, the Food Standards Agency produced a decision tree (Figure 1) aiming to help companies to decide the appropriate claim regarding the suitability of the product for people intolerant to gluten. This guidance refers to 'PARNUTS' legislation which is to be repealed in July 2016. [FSA Guidance on composition and labelling of foodstuffs suitable for people intolerant to gluten (2012)]

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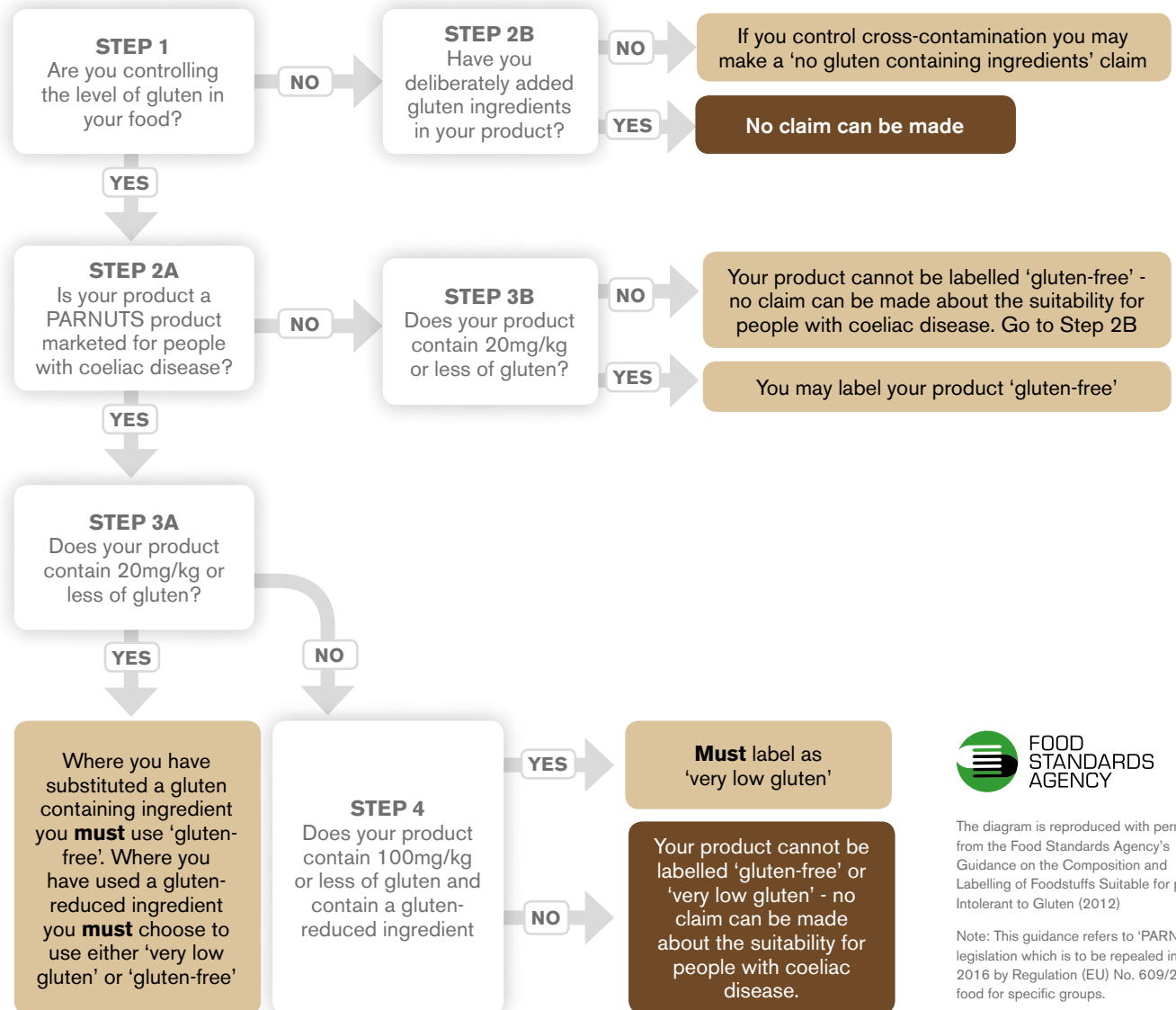
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HOW TO CLAIM:

If you would like to make a claim about the suitability of your product for reduced presence of gluten, the following diagram will help you to determine the most appropriate claim for the product



The diagram is reproduced with permission, from the Food Standards Agency's Guidance on the Composition and Labelling of Foodstuffs Suitable for people Intolerant to Gluten (2012)

Note: This guidance refers to 'PARNUTS' legislation which is to be repealed in July 2016 by Regulation (EU) No. 609/2013 on food for specific groups.

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Legislation

- Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (as amended) (Applied from 13 December 2014)
- Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten (Repealed from 20 July 2016)
- Commission Implementing Regulation (EU) No 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (Applies from 20 July 2016)
- Commission Delegated Regulation (EU) No 78/2014 amending Annexes II and III to Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, as regards certain cereals causing allergies or intolerances (Applied from 19 February 2014)

Guidance

- BRC Guidance on Allergen Labelling and the Requirements in Regulation 1169/2011 (in partnership with FDF) (March 2013, Link: [Guidance](#) & [Addendum](#))
- FSA Technical Guidance Food Allergen Labelling and Information Requirements under the EU Food Information for Consumers Regulation No. 1169/2011 (August 2014, Link: [Guidance](#))
- FDE Guidance on Food Allergen Management for Food Manufacturers (January 2013, Link: [Guidance](#))
- FSA Guidance on Allergen Management and Consumer Information (2006, Link: [Guidance](#))
- FSA Guidance on Composition and Labelling of Foodstuffs Suitable for People Intolerant to Gluten (January 2012, Link: [Guidance](#))
- Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (CODEX STAN 118 - 1979) (Adopted in 1979, amended 1983, revised 2008; Link: [Standard](#))
- European Commission Questions and Answers on the application of the Regulation (EU) No. 1169/2011 on the provision of food information to consumers (January 2013, Link: [EC Q&A](#))
- Defra Food Information Regulations 2014 Guidance (October 2014, Link: [Guidance](#))
- FDE Guidance on the Provision of Food Information to Consumers (September 2013, Link: [Guidance](#))

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Legislation

- Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (Food for Specific Groups) (Applies from 20 July 2016 and aims to provide a better application of rules, and better protect consumers on the content and marketing of foods for vulnerable population groups)
- Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC (Prohibits use of gluten containing ingredients in infant formulae and follow-on formulae. Use of terms 'very low gluten' and 'gluten-free' should be prohibited) (Repealed by Regulation (EU) No. 609/2013 (food for specific groups), which requires the Commission to adopt a delegated act)
- Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children (Requires indication of presence or absence of gluten in cereal-based foods and baby foods for children below 6 months of age) (Repealed by Regulation (EU) No. 609/2013 (food for specific groups), which requires the Commission to adopt a delegated act)
- Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (Repealed from 20 July 2016 by Regulation (EU) No. 609/2013 (food for specific groups), which abolishes the concept of PARNUTS / dietetic foods)



About FDF

The Food and Drink Federation is the voice of the UK food and drink industry, the largest manufacturing sector in the country. Our sector directly employs around 400,000 people and accounts for almost 16% of the UK's total manufacturing sector by value. We are an essential partner to UK farmers, buying the bulk of what they produce.

Our membership comprises manufacturers of all sizes as well as trade associations dealing with specific sectors of the industry. In representing the interests of our members, we focus on the following core priorities:

- **Food Safety and Science**
- **Health and Wellbeing**
- **Sustainability**
- **Competitiveness**

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