

GLUTEN LABELLING GUIDANCE:

Best Practice for Prepacked Foods which Include or Exclude Cereals Containing Gluten.

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FOREWORD

“The Food Standards Agency welcomes the FDF’s work to achieve greater consistency in how the presence of cereals containing gluten and gluten-free claims are labelled on prepacked foods. Having a trusted consistent approach will make it easier for people with coeliac disease or with allergies to these cereals to find and understand the labelling information they need. And that means they can make safer food choices. I am very pleased to see further progress in this important area of public health and consumer protection.”

Heather Hancock, Chairman of the Food Standards Agency

1. INTRODUCTION

The introduction of the Food Information to Consumers (FIC) Regulation, which entered into force in December 2014, resulted in significant changes to the labelling of allergens on prepacked foods.

This UK best practice guidance aims to provide advice to food business operators, irrespective of size, on how to label food products that include cereals containing gluten through review of the relevant EU and UK legislation and guidance; alongside the claims that can be made relating to the absence or reduced presence of gluten (e.g. gluten-free).

This best practice guidance has been produced to illustrate examples of the usual and more challenging labelling situations of foods made with cereals containing gluten. Special consideration is also given to oats and wheat species.

2. GLUTEN

The term “gluten” is the general name that collectively refers to the storage protein fractions (i.e. prolamins and glutelins) found in wheat and other related cereal grains (e.g. rye, barley), which are insoluble in water. It is estimated that gluten constitutes around 80% of the total protein in most cereals. Prolamins are the main storage proteins responsible for the immune reaction in coeliac disease and these differ depending on the cereal source (Table 1). It is the short peptides within these gluten proteins that cause the underlying intestinal damage in individuals with coeliac disease. Most people with intolerance to gluten can include oats in their diet without adverse effect on their health; however due to ongoing research and the contamination risk from other cereals containing gluten, oats are deemed cereals containing gluten within law. Additionally, certain proteins (including non-gluten proteins) found in cereal grains may also trigger allergic responses.

For the purposes of labelling prepacked foods within the European Union, Annex II of 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. Additionally, several specific products exempt from the requirements of allergen labelling are also defined (e.g. “wheat based glucose syrups including dextrose”).

Table 1

Cereals Containing Gluten	Allergenic Protein Fraction (prolamins)
Wheat (<i>Triticum spp.</i>), includes: - spelt (<i>Triticum spelta</i>) - khorasan wheat (<i>Triticum turanicum</i>)	Gliadins
Rye (<i>Secale cereale</i>)	Secalins
Barley (<i>Hordeum vulgare.</i>)	Hordeins
Oats (<i>Avena sativa</i>)	Avenins

3. FOOD INFORMATION

The purpose of allergen labelling is to inform consumers of the presence of a constituent of concern within a food. Claims aim to inform consumers about the attributes of a particular food, resulting from either the presence or absence of a specific constituent. Therefore, the regulated claims about gluten from Regulation (EU) No. 828/2014, as detailed in section 10, inform the consumer of its absence (i.e. “gluten-free”) or reduced presence (i.e. “very low gluten”), along with optional accompanying suitability statements (i.e. “suitable for coeliacs” or “suitable for people intolerant to gluten”). No other claims regarding gluten, such as “Free-From Gluten”, can be used as they are not prescribed within the legislation. The regulated claim “gluten-free” refers to a quantitative limit (20mg/kg (ppm)) rather than an absolute absence of gluten. This limit was set on the basis of scientific evidence to assure that the food in question can be consumed safely by the vast majority of people with coeliac disease or a gluten sensitivity.

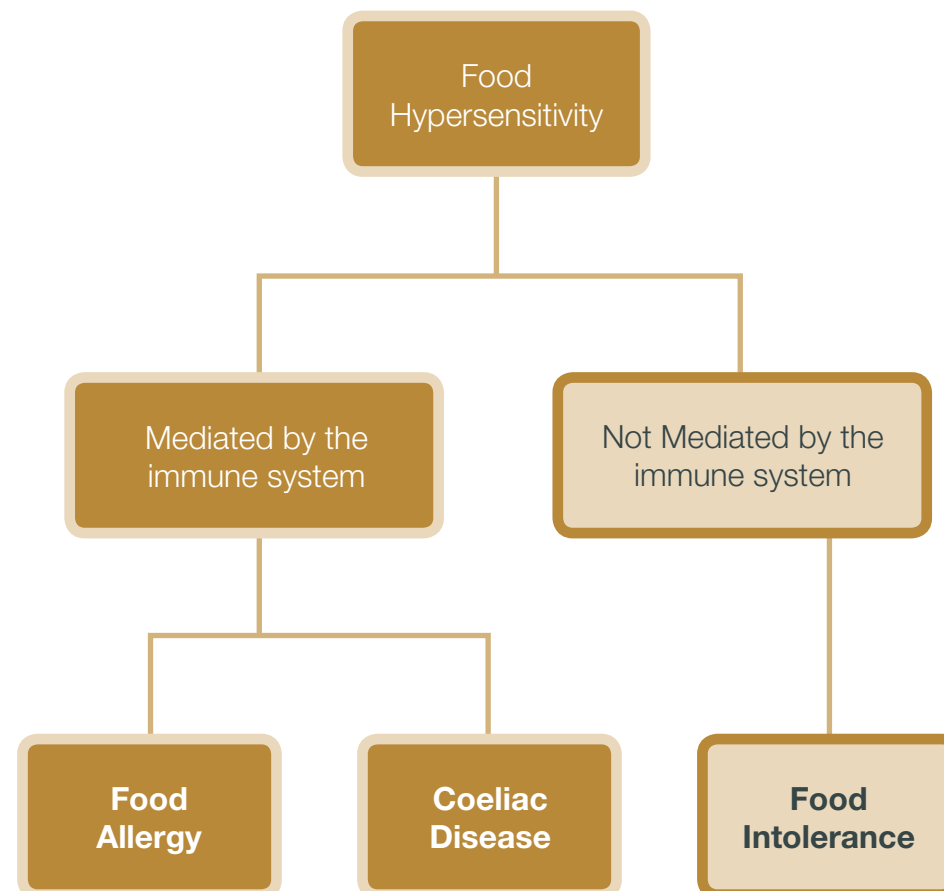
In accordance with the provisions of General Food Law (Regulation (EC) No 178/2002) food shall not be placed on the market if it is unsafe. Additionally, in relation to fair information practices, the Food Information to Consumers (FIC) Regulation states that food information shall not be misleading; particularly as to the characteristics of the food, by attributing to the food effects or properties which it does not possess or by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics. [Article 7, Regulation (EU) No. 1169/2011]. On voluntary food information, which includes information on the absence or reduced presence of gluten in food, the FIC Regulation also states that it shall not be ambiguous or confusing for the consumer and that it shall, where appropriate, be based on the relevant scientific data [Article 36, Regulation (EU) No. 1169/2011].

4. COELIAC DISEASE & CEREAL ALLERGY

Coeliac disease and allergy to cereals are two distinct conditions:

- 1. Coeliac disease:** A lifelong autoimmune disease caused by a reaction to gluten. It is the primary health concern for adults around wheat and the other cereals containing gluten, that for whom the “gluten-free” claim criterion has been established to protect. Coeliac disease is not a food allergy or a food intolerance.
- 2. Wheat and other cereal allergy:** Cereals, primarily wheat, can also provoke allergic reactions, which involve more immediate reactions to a variety of cereal proteins including non-gluten ones. No internationally accepted allergen management thresholds have yet been defined for the protein content (both gluten and non-gluten) below which the risk to people with allergy to cereals containing gluten is considered tolerable; however, within Europe and internationally, scientific research is ongoing in this field. Allergenic foodstuffs must therefore be declared and emphasised 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).

Further considerations for the declaration of such claims and other “free-from” allergen claims are set out in the [FDF/BRC Guidance on “Free-From” Allergen Claims](#).



5. OATS & WHEAT

5.1 OATS

Oats and wheat belong to the same botanical family (Poaceae) and oats also contain prolamin storage proteins called avenins, which can trigger coeliac disease in a small proportion of people. In practice, pure uncontaminated oats can be consumed safely by most but not all 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.

Oats contained in a food presented as gluten-free must have been specially produced, prepared and/or processed in a way to avoid contamination by other cereals and the gluten content of such oats cannot exceed 20mg/kg (ppm).

As oats are a regulated allergenic food under Annex II of the FIC Regulation, the reference to oats in the ingredients list must still be emphasised (e.g. in bold). This is also the case for specially produced gluten-free oats (e.g. Ingredients: gluten-free **oats**, sugar).



5.2 WHEAT SPECIES

Wheat is defined as any Triticum species, such as durum wheat, spelt, khorasan wheat and their hybridised strains (e.g. triticale). Despite the name, buckwheat (Fagopyrum esculent) is not the same genus as wheat, therefore is not an EU regulated allergen for labelling purposes.

With spelt and khorasan being types of wheat, they are not suitable substitutes for people with coeliac disease and/or wheat allergy. Therefore, where “spelt” and “khorasan wheat” varieties are present in a food product a specific reference to “wheat” in an emphasised format is required (e.g. **bold**).

In compliance with the FIC Regulation, when any wheat is used intentionally in a food product it must be declared and emphasised in the ingredients list. It is therefore possible to use wheat in a product and indicate its presence in the ingredients list and declare the claim “gluten-free” on the label, provided the gluten level in the product is lower than the legal threshold of 20mg/kg (ppm).



6. LABELLING CEREALS CONTAINING GLUTEN

The labelling of foods where cereals containing gluten are intentionally added to the product is regulated by the Food Information to Consumers (FIC) Regulation and the following key principles apply:

- The use of additional “Contains: ‘*X allergen*’” statements/boxes or similar are not permitted on prepacked foods, except in the case where there is no requirement for an ingredients list.
- It has now become industry best practice to use an Allergy Advice statement, such as: ‘For allergens see ingredients in **bold**’.
- As ‘*cereal containing gluten*’ is listed as the regulated allergen in Annex II of the FIC Regulation (and not ‘*gluten*’ itself); it is not permitted to declare and emphasise only “gluten” for allergen labelling purposes. Therefore, an emphasised reference to the specific cereal in the ingredients list is needed. This is also the case when gluten is used as an ingredient in its own right (e.g. “**wheat** gluten”).
- Whilst it is not prohibited to add the term ‘gluten’ in parentheses (not emphasised) after the name of the cereal (e.g. ‘**wheat** flour (gluten)’); best practice is not to do so, but to instead solely emphasise the name of the cereal source in the ingredients list (e.g. ‘**wheat** flour’).

The consistent application of this best practice is recommended, as this ensures consumer understanding by encouraging the reading of the ingredients list for the presence of the specific cereal containing gluten. This in turn reduces the proliferation of and reliance on the term ‘gluten’ and gives greater prominence to the actual cereal source.

Ingredients

Wheat Flour, Water, Vegetable Oils (Palm Oil, Rapeseed Oil), **Wheat** Fibre (5%), Sugar, Salt, **Wheat** Germ (1.5%), Stabiliser (Guar Gum), **Wheat** Gluten, Raising Agent (Sodium Carbonates), Preservative (Potassium Sorbate), Flavouring.

Allergy Advice

For allergens see ingredients in bold

7. LABELLING EXAMPLES

INTENTIONAL ADDITION OF CEREALS CONTAINING GLUTEN

7.1 The specific cereal name must be declared and emphasised within the ingredients list (e.g. in bold or another chosen method of emphasis)

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

7.2 For ingredients names, such as 'oatmeal' it is permissible to emphasise either just the cereal element or the entire word:

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

7.3 For ingredients where several words are used in the name of the cereal ingredient, it is only necessary to emphasise the cereal source:

Ingredients: maize flour, **barley** malt extract, sugar, honey

7.4 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

7.5 "Gluten" could be stated in the ingredients list when used as an ingredient in its own right. The cereal source must also be specified by name and emphasised (e.g. in bold):

Ingredients: sugar, palm fat, **wheat** gluten
Ingredients: sugar, palm fat, gluten (**wheat**)
Ingredients: sugar, palm fat, gluten (**wheat** protein)

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

Ingredients: Spelt (**wheat**), sugar, **milk** powder
Ingredients: Durum **Wheat** Semolina
Ingredients: Khorasan **wheat** flour

7.7 Under the FIC Regulation it is not permitted to use allergen statements such as "Contains: 'X allergen(s)'" unless there is no ingredients list declared.

Cous cous; Contains: **wheat**

7.8 Food business operators may use the following 'Allergy Advice' statement directing the consumer to the ingredients list and the emphasised allergenic ingredients.

"Allergy Advice: For allergens see ingredients in **bold.**"

7.9 Ingredients derived from cereals that have been specifically exempted from declaration under Annex II of the FIC Regulation should not refer to the allergen in the ingredients list, thus no need for emphasis.

Example: wheat based "glucose syrups", including dextrose are exempt
Ingredients: glucose syrup, **barley** flour, **egg**

7.10 Where ingredients originate from cereals containing gluten, such as a "plant protein hydrolysate", the emphasised reference to the cereal source must also be declared.

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

7.11 Oats are legally considered to be 'cereals containing gluten'. However, oats that are not contaminated with other cereals containing gluten (e.g. wheat, barley and rye) and analysed to contain less than 20mg/kg (ppm) of gluten (as sold), may be labelled with the ingredient claim: 'gluten-free'. The term 'oats' must however should still be emphasised as the allergen.

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

7.12 In addition to containing gluten, wheat, rye, barley, and oats are the regulated allergens, therefore they must be declared and emphasised whenever used as ingredients in a product, irrespective of concentration or processing to remove the gluten constituent.

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

8. PRECAUTIONARY ALLERGEN LABELLING

8.1 GENERAL CONSIDERATIONS

The probability of cross-contamination in products and the risk arising from it must be taken into consideration by food business operators. Food business operators should conduct a full and thorough risk assessment before deciding whether a precautionary allergen labelling (PAL) statement (i.e. “may contain”) is required on certain products due to unintended allergen presence. Section 4 of the [FDF/BRC Guidance on “Free-From” Allergen Claims](#) highlights key risk assessment factors for consideration, such as supplier quality assurance, raw material approval controls, facility design, production controls and product testing.

There is currently no specific EU or UK legislation governing precautionary allergen labelling, therefore such statements are regulated in accordance with the provisions of General Food Law (Regulation (EC) No 178/2002), which establishes that food shall not be placed on the market if it is unsafe. Precautionary allergen labelling statements are voluntary and Regulation (EU) No 1169/2011 states that “voluntary information shall not mislead the consumer, shall not be ambiguous or confusing and shall be based on the relevant scientific data”. In accordance with this Regulation the European Commission can adopt additional legislation regarding information on the possible and unintentional presence in food of substances causing allergies or intolerances (i.e. cross-contamination); however, this work is yet to be started.

Essential allergen management guidance for food business operators is available from both the Food Standards Agency (FSA, 2006) and FoodDrinkEurope (FDE, 2013).

In instances where there could be the unintentional presence of cereals containing gluten via cross-contamination, a thorough risk assessment should be carried out, with consideration given to the use of precautionary allergen labelling (PAL).

The examples in section 9 suggest possible ways of labelling food products in the case of unintended presence of cereals containing gluten. Although it is not mandatory to emphasise the allergens in precautionary allergen labelling it is acceptable to do so.

8.2 GLUTEN-FREE & PAL

It is not recommended practice for a food label to declare a generic “May contain cereals containing gluten” precautionary allergen labeling (PAL) statement whilst also claiming ‘gluten-free’. As ‘gluten-free’ is perceived as an absolute claim, there is potential for consumer confusion. Like all other ‘free-from’ allergen claims, manufacturers of gluten-free products must undertake a diligent substantiation process to support the claim.

Please note that Section 4 explained the distinction between the different hypersensitivities to cereals (i.e. coeliac disease and allergy to cereals). In certain circumstances and after thorough risk management steps have been taken, there could still be a demonstrable risk to a cereal allergic consumer from the unintentional presence of a specific cereal in a gluten-free product. In such cases and providing the ‘gluten-free’ status is not compromised, a specific PAL statement (e.g. “may contain ‘cereal X’”) should be applied.

An example of this could be as follows:

- The gluten content of a product is consistently quantified as ~17mg/kg (ppm), so a ‘gluten-free’ claim can be made as this is not more than the 20mg/kg (ppm) limit.
- The source of the gluten is unintentional homogeneous cross-contact with wheat flour, so the product has a total wheat protein content of ~21mg/kg (ppm) (~75-80% of the total protein content of wheat is gluten).
- Depending upon the portion size of the product and reference dose* used for the risk assessment, the product may require precautionary allergen labelling (PAL) (i.e. ‘may contain’).
- For example, if the current Allergen Bureau VITAL® 2.0 reference dose for wheat is used, which is 1 mg total wheat protein per portion, then any portion size greater than ~50g would be indicated to require PAL (e.g. a 150g portion would contain ~3.2mg total wheat protein).

*Reference Dose (RD): an amount of total protein from an allergic food per portion of food. RDs aim to protect a defined proportion of the allergic population from reactions. Immediate allergic reactions occur after ingestion of an amount of protein during an eating occasion, therefore RDs are used as the basis to assess the risk to allergic consumers. RDs can be converted to action levels (a concentration of total protein from allergenic food per kg product) based on a given portion size.

9. LABELLING EXAMPLES

UNINTENTIONAL PRESENCE OF CEREALS CONTAINING GLUTEN

9.1 Where, based on a risk assessment, there is a demonstrable risk of cross-contamination with cereals containing gluten, which could pose a food safety risk, it is advisable to use precautionary allergen labelling (PAL) (e.g. 'may contain'). The use of such statements is voluntary, but must not mislead.

May contain wheat and rye

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

May contain other cereals containing gluten

10. GLUTEN ABSENCE CLAIMS

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10.1 CRITERIA TO CLAIM GLUTEN-FREE

Under EU legislation, food business operators are only allowed to use the following claims regarding the absence or reduced presence of gluten in food: 'gluten-free' and 'very low gluten'; this is providing they meet the relevant compositional requirements (Table 2). Under certain conditions these claims may be voluntarily accompanied by specified statements (Table 3).



GLUTEN FREE

Table 2

Claim	Condition	Additional Criteria
'Gluten-free'	no more than 20mg/kg of gluten as sold to the final consumer	
'Very low gluten'	no more than 100mg/kg of gluten as sold to the final consumer	Must consist or contain one or more ingredient made from wheat, rye, barley, oats or their crossbred varieties which have been specially processed to reduce the gluten content

Table 3

Optional Statements	Condition	Additional Criteria
'Suitable for people intolerant to gluten'	Only used when accompanying a "Gluten-free" or 'Very low gluten' claim	
'Suitable for coeliacs'		
'Specifically formulated for people intolerant to gluten'	Only used when accompanying a "Gluten-free" or 'Very low gluten' claim	The food is specially produced, prepared and/or processed to: (a) reduce the gluten content of one or more gluten-containing ingredients; or (b) substitute the gluten-containing ingredients with other ingredients naturally free of gluten.
'Specifically formulated for coeliacs'		

The condition to make a 'gluten-free' claim in the European Union is harmonised with Codex Alimentarius. Regulation (EU) No. 828/2014 specifically states that Codex Standard 118 - 1979 should be taken appropriately into consideration, therefore regarding analytical testing the Enzyme-linked Immunoassay (ELISA) R5 Mendez Method is recommended.

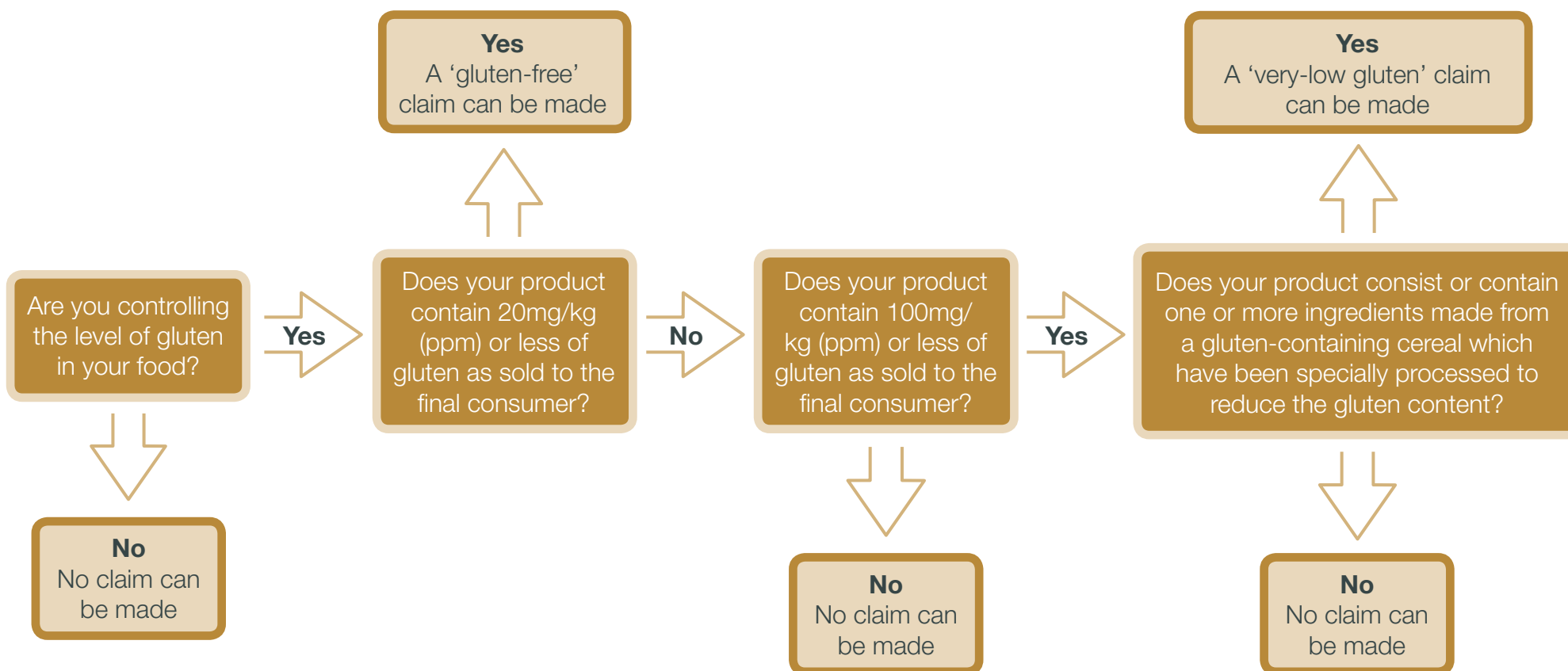
Following discussions with the EU Commission and other Member States, it has been confirmed by the Food Standards Agency (FSA) and Food Standards Scotland (FSS) that the information provided to consumers about gluten must be confined to only that as prescribed by Regulation (EU) No 828/2014 (as described in Tables 2 & 3). Therefore, since 20 July 2016, the phrase 'no gluten-containing ingredients' or other similar statements are not permitted on the label of prepacked foods. The FSA has produced a factsheet on the labelling statement "No Gluten-Containing Ingredients", which applies in England only, to give advice to both manufacturers and caterers.

10. GLUTEN ABSENCE CLAIMS contd

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10.2 FLOW DIAGRAM FOR MAKING CLAIMS

If a food business operator would like to make a claim about the suitability of its product for people intolerant to gluten, the following flow diagram will help to determine the appropriate claim for the product:



11. REFERENCES

11.1 LEGISLATION

- › 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 (*Applied 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*)
- › 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) (*Applied from 20 July 2016; repealing Directives 92/52/EEC, 96/8/EC, 1999/21/EC, 2006/125/EC, 2006/141/EC, and 2009/39/EC & Regulations (EC) No 41/2009 and (EC) No 953/2009*)
- › 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*)
- › Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (*Applied from 1 January 2005*)

11.2 GUIDANCE

- › Specialised Nutrition Europe (SNE) Guidance on Gluten-Free Labelling [January 2018, Link: [Guidance](#)]
- › Commission Notice of 13.7.2017 relating to the provision of information on substances or products causing allergies or intolerances as listed in Annex II of Regulation (EU) No 1169/2011 on the provision of food information to consumers (July 2017, Link: [Notice](#))
- › FSA Changes to 'No Gluten-Containing Ingredients' Information Factsheet (2016, Link: [Factsheet](#))
- › FSA Technical Guidance Food Allergen Labelling and Information Requirements under the EU Food Information for Consumers Regulation No. 1169/2011 (April 2015, Link: [Guidance](#))
- › FDF & BRC Guidance on "Free-From" Allergen Claims (November 2015, Link: [Guidance](#))
- › FDE Guidance on Food Allergen Management for Food Manufacturers (January 2013, Link: [Guidance](#))
- › FDE Guidance on the Provision of Food Information to Consumers (September 2013, 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](#))
- › FSA Guidance on Allergen Management and Consumer Information (2006, Link: [Guidance](#))
- › University of Manchester, InformAll Allergenic Food Database, Biochemical Data (Link: [Database](#))
- › Allergen Bureau - Voluntary Incidental Trace Allergen Labelling - VITAL® 2.0 Reference Doses (Link: [Website](#))

About FDF

The Food and Drink Federation (FDF) is the voice of the UK food and drink industry, the largest manufacturing sector in the country. We communicate our industry's values and concerns to Government, regulators, consumers and the media. We also work in partnership with key players in the food chain to ensure our food is safe and that consumers can have trust in it.

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