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## LEGISLATIVE CHANGES IN THE EU GOVERNING GLUTEN IN FOODSTUFFS

**The current rules for foods suitable for people intolerant to gluten are harmonised in Europe, with strict conditions under which foods may be labelled as 'gluten free' or 'very-low gluten'. From this summer, the rules for all gluten-free/reduced gluten foods, including specially manufactured gluten-free foods, such as those available on prescription in the UK, will be relocated within the legislative framework.**

Consumers will be afforded the same protection as is currently provided under the existing rules, although these foods will no longer come under the same 'umbrella' legislation as food for special medical purposes, which has the potential for unintended consequences for the prescription status of these foods used in the management of coeliac disease.

### THE CURRENT SITUATION

Commission Regulation (EC) No 41/2009<sup>1</sup> lays down harmonised rules on the composition and labelling of foods suitable for people intolerant to gluten, setting out the conditions under which foods may be labelled as '**gluten free**' (<20mg/kg) or '**very low gluten**' (<100mg/kg). This legislation was largely based on the Codex standard<sup>2</sup> that preceded it.

### THE FUTURE

New rules on foods for particular nutritional uses, or PARNUTS foods as they were sometimes referred to, will come into force from 20<sup>th</sup> July 2016 onwards under Regulation (EU) No 609/2013 on Food for Specific Groups (FSG Regulation).<sup>3</sup> A three-year transition period began in July 2013 and will end in July 2016. Under the new FSG Regulation, which will replace the PARNUTS Directive,<sup>4</sup> the Commission will lay down Directives for specific groups of foods which will include, amongst other

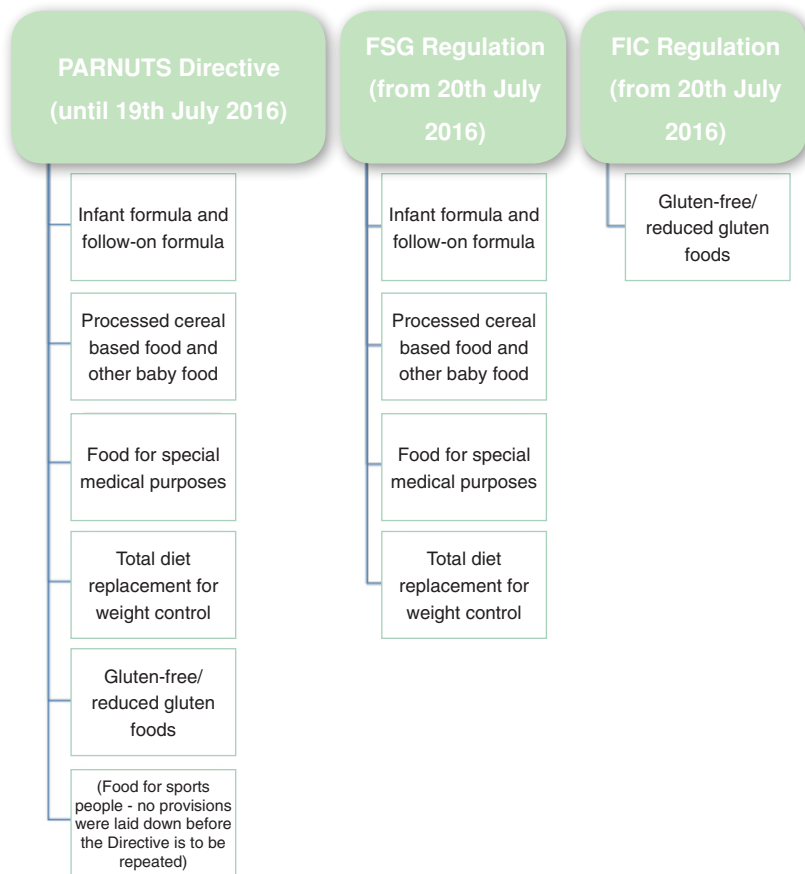
provisions, new compositional standards for some of these foods (see Figure 1).

Gluten-free/reduced gluten foods will not be included among the specific Directives under this new FSG 'umbrella' legislation. The FSG Regulation will repeal the current legislation on foods suitable for people intolerant to gluten and will transfer the rules for these foods to the Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC Regulation).<sup>5</sup> The FIC Regulation already includes rules requiring the mandatory labelling of all gluten-containing ingredients, which came into force on 13<sup>th</sup> December 2014.

The Commission wanted all the rules applying to gluten to be set by the same piece of legislation and established that the FIC Regulation should be the framework for the rules related to the 'absence' of gluten in food (i.e. gluten-free and very low gluten foods) as well as its 'presence' (i.e. foods that contain gluten, either intentionally or unintentionally, requiring that the cereal source of gluten is identified on the label as it represents an allergen).

In terms of what these changes to the legislation should achieve, consumer protection and clarity for businesses seeking to comply with the rules should be improved. Any unintended consequences of the legislative changes for the prescription status of specially manufactured gluten-free foods are less certain.

Figure 1: Legislative provisions under the PARNUTS Directive and the FSG Regulation



### CONSEQUENCES OF THE NEW LEGISLATION FOR FOODS THAT ARE FREE FROM OR VERY LOW IN GLUTEN

The new rules coming into force on 20<sup>th</sup> July 2016, will not change the existing rules for using the ‘gluten free’ and ‘very low gluten’ statements, which have simply been relocated within the legislative framework. The new rules draw a distinction between foods that are naturally gluten free and foods that have been specially manufactured to be gluten free, such as gluten-free foods available on prescription. This will allow statements such as ‘suitable for people intolerant to gluten’ or ‘suitable for coeliacs’ for naturally gluten-free foods and for specially manufactured foods such as gluten-free bread, the terms ‘specifically formulated for people intolerant to gluten’ or ‘specifically formulated for coeliacs’ can be used.

### CONSEQUENCES OF THE NEW LEGISLATION FOR FOODS THAT CONTAIN GLUTEN

As one of the 14 identified major food allergens, rules governing the presence of gluten in foods came into force on 13<sup>th</sup> December 2014 as part of the FIC Regulation. If gluten is present in a food, the specific cereal name must be emphasised within the ingredients list (see Figure 2). It is no longer permitted to state ‘gluten’ without 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, as in the example below. In addition to gluten, wheat itself is an allergen and therefore must be labelled whenever it is an ingredient in a product, irrespective of the concentration.

The consistent application of the new rules should improve consumer confidence as all

Figure 2: Format for ingredient listings and allergen labelling under previous and current EU labelling rules

<b>Ingredients</b>	➔	<b>Ingredients</b>
Sugar, milk powder, rye flour, rolled oats, palm fat, gluten		Sugar, <b>milk</b> powder, <b>rye</b> flour, rolled <b>oats</b> , palm fat, gluten ( <b>wheat</b> )
<b>Allergy advice</b>		<b>Allergy advice</b>
Contains milk and gluten		For allergens, see ingredients in bold

allergens will be emphasised in the ingredients list. Under the previous rules, consumers had to look carefully at the ingredients list to find allergens that may not have been emphasised and may have looked for allergy advice statements, which were (and continue to be) optional. Allergy advice statements, where these are included on a label, must now include a phrase directing the consumer to the ingredients list (see Figure 2).

The allergen labelling rules have been broadly welcomed, although one aspect that consumer groups have been less happy about is precautionary allergen labelling (PAL), such as 'may contain...' statements, as some consumers are under the impression that manufacturers use these to ensure that they are not held liable in the event of an allergic reaction to an undeclared allergen in their product. Food manufacturers avoid using such statements where there is no need for them, appreciating that consumers on already restrictive diets would have to further restrict their intakes of foods that 'may contain' specific allergens. Typically, food manufacturers risk-assess their processes before deciding whether such statements are required. Where there is a risk of cross-contamination, it continues to be advisable to use PAL in ensuring that consumers are well informed. The use of such statements is voluntary, but must not mislead. Alternatively, the manufacturer may include a claim 'no gluten-containing ingredients' rather than PAL. If the level of non-intentional gluten is less than 20mg/kg, it is not necessary to include PAL.

The rules also extend to 'loose' foods (foods sold that are not pre-packaged and food that is packaged on site for immediate consumption, such as in eating-out establishments), and require that information on allergens must be provided to consumers in a clearly obvious place. The rules extend to eating-out establishments for the first time, as under the previous rules only

pre-packaged foods were covered. In eating-out establishments, if allergen information is not provided upfront (such as on a menu, chalkboard or in an information pack), outlets must signpost to where it could be obtained, either in written or oral formats.

These new rules have brought about a seismic shift in the food industry and eating-out establishments. The Food Standards Agency regularly issues Allergy Alerts publicising recalls of products that contain allergens that manufacturers have failed to declare on the label. The company must recall all affected batches and contact its retail customers to tell them about the recall. The company must also issue point-of-sale notices to be displayed in stores that have sold the affected product. These cases usually arise because the presence of the allergen has been overlooked (for example, if it's contained within one of the constituent ingredients used in the manufacture of the product) rather than because the product has been accidentally contaminated with the allergen during manufacture. For eating-out establishments, at the very least staff now need to be made aware of the procedures and policies of the business when it comes to handling all requests for allergen information and they need to decide how best to communicate information about the presence of allergens in their products.

#### POSSIBLE IMPLICATIONS FOR THE PRESCRIPTION STATUS OF SPECIALLY MANUFACTURED GLUTEN-FREE FOODS

It should be considered how the repositioning of gluten-free foods within the EU legislative framework might affect the prescription status of these foods, given that specially manufactured gluten-free foods will not fall under the FSG Regulation. The changes to the legislation described here should have no direct affect. It has always been the case that specially manufactured

gluten-free foods cannot make the claim that their products are 'suitable for the dietary management of coeliac disease' as the descriptor 'for the dietary management of...' is only permitted for foods for special medical purposes (FSMP).

Gluten-free foods are not classed as FSMP under existing legislation, but rather as foods for particular nutritional uses (see Figure 1). In terms of reimbursability, EU member states have varying rules for these products. In the UK, the Advisory Committee on Borderline Substances considers the suitability of specially manufactured gluten-free foods for prescription at NHS expense, in line with UK guidelines that recommend only staple foods should be prescribed.<sup>6</sup> However, over recent years, specially manufactured gluten-free products have become a common sight in supermarkets, in some cases with a relatively large dedicated shelf space reflecting the popularity of self-prescribed gluten-free diets for gastrointestinal symptoms, e.g. for non-coeliac gluten sensitivity.<sup>7</sup>

Both staple and 'luxury' products are now more affordable and accessible for those with coeliac disease as well as for those who choose

such a diet for other reasons. Some Clinical Commissioning Groups have suggested that consideration should be given to gluten-free diets being self-funded by patients as a way of reducing costs to the NHS. Such a move would undoubtedly affect dietary compliance, in particular among those patients on low incomes.

It is widely recognised that the costs of treating the long-term health complications that arise from poor dietary compliance are likely to be far greater than the prescribing costs. In its most recent policy statement,<sup>8</sup> the BDA stated that the provision of staple foods on prescription plays an essential role in supporting people with this condition to adhere to a life-long strict gluten-free diet. Although the legislative changes described in this article will not directly affect the prescription status of gluten-free foods, given the pressure on healthcare providers to reduce costs and the increased availability and affordability of gluten-free foods, the repositioning of gluten-free foods may undermine the importance of their continued availability on prescription for the effective management of coeliac disease.

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