

Q&A on Gluten-free Regulations

Commission Regulation 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten (coeliacs)

Please find below a number of Q&A's to help answer questions on the above regulations. These are split into the following sections:

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Know the rules

1. What is the purpose of Regulation 41/2009?

Approximately, 1% of the UK population suffers from gluten intolerance and need to avoid eating cereals containing gluten. The number of foods marketed to these people is increasing rapidly to fulfil this need. However, the levels of gluten in those products can vary greatly causing confusion for the consumer and potentially can impact on their health. This EU Regulation seeks to address these issues and puts in place standards for the claims 'gluten-free' and 'very low gluten'.

2. Why is it necessary?

This is a consumer protection measure. It will ensure that all food labelled to indicate suitability for people intolerant to gluten use defined labelling terms.

In addition, consistent labelling will help consumers better understand how much gluten there might be in the foods they buy and help them manage their risk of exposure to gluten.

This Regulation aligns EC legislation with internationally agreed Codex standards¹.

3. What was the legislative situation before Regulation 41/2009 came into force?

Prior to this legislation there were no legally defined compositional standards for gluten-free foods. Manufacturers were encouraged to work to the international standard set by Codex Alimentarius. The new Regulation defines 2 labelling terms:

¹ CODEX STAN 118 - 1979

1. 'gluten-free': for foods that contain no more than 20 parts of gluten in a million (ppm).

These can be foods that:

- are specially made for someone with gluten intolerance, by using an ingredient that has been treated to reduce its gluten content (such as bread made with gluten-reduced flour)
- and/or have a gluten-containing ingredient substituted with one that does not contain gluten (such as pasta made from rice instead of wheat)
- are everyday foods that meet the gluten limit even though they are not specifically made for this purpose (such as a soup made only from vegetables).

2. 'very low gluten': only for foods that are specifically prepared for people with a gluten intolerance. They must contain no more than 100 parts of gluten in a million and contain an ingredient that has been specially processed to reduce its gluten content. They may also contain substitute ingredients.

This Regulation aligns EU law with the Codex standards.

4. Where does this legislation apply?

The Regulation applies across the whole of the EU. These Regulations are based on agreed international standards which set the same limits. This standard was agreed at the Codex Alimentarius in July 2008. This will benefit trade within the single market and third countries.

5. What foods are covered by the Regulation?

The Regulation covers all food that make a claim about their suitability for people with coeliac disease (i.e. are labelled 'gluten-free or 'very low gluten') sold either pre-packed or non pre-packed in the retail and catering sectors. Business to business sales are outside the scope of the legislation e.g. manufacturers selling food to wholesalers; but the FSA recommends that all foods labelled or described as 'gluten-free or 'very low gluten' should comply with the levels set in the Regulation.

The regulations apply to:

Parnuts foods – foods 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.

Normal foods 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.

6. Is the Agency planning to extend the scope of the Regulations to foods sold non pre-packed?

No. This European legislation applies to **all** foods – pre-packed and non-prepacked.

However, the Parnuts Framework Directive states that Parnuts food shall only be sold pre-packed, unless Member States provide exemption from this rule. The FSA therefore took advantage of this exemption and in the national implementing Regulations to allow gluten-free Parnuts foods for coeliacs, such as cakes or bread made with wheat flour substitutes, to be sold non pre-packed in cafes, restaurants, delicatessens etc. **Without this action Parnuts foods are prohibited for sale in non pre-packed form.**

7. What are the main provisions of the Regulation?

- 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'.

8. Why are the thresholds set at 20ppm and 100ppm?

Whilst most coeliacs can tolerate small amounts of gluten in their diet, sensitivity varies between individuals. The most recent scientific evidence has shown that consumption of products with gluten levels above 20ppm can lead to changes in the cells of the gut, suggesting that eating too many products with gluten levels above 20ppm, over a long period of time, is not likely to offer sufficient protection for coeliacs. Therefore, a level of 20ppm was set to protect the health of all coeliacs.

However, due to technological constraints it is not currently possible to eliminate gluten altogether from all specially formulated foods, and in some cases it is necessary to include some wheat starch to maintain the consistency and/or texture of the food. For this reason, and to maintain a wider range of products for coeliacs to choose from and in order to achieve a balanced diet, a higher limit of 100ppm has been set (e.g. bread, pasta and other staple foods).

9. Can foods that will be diluted by the consumer contain higher levels when sold in concentrated form?

The levels apply to foods **as sold** to the consumer, therefore bread or soup mixes must contain 20ppm or less of gluten to be able to make the claim 'gluten-free' regardless of the level when the food is reconstituted according to the manufacturer's instructions.

10. Why doesn't 'gluten-free' mean zero gluten?

It is technically very difficult to achieve zero gluten in foods. Setting the limit to zero would significantly reduce the range of products available for coeliacs to choose from, further increase the costs of already expensive foods, and could lead to coeliacs making inappropriate choices.

11. Why are 'normal' foods not allowed to make the claim 'very low gluten'?

The aim of this legislation is to ensure that the levels of gluten in foods marketed for coeliacs are as low in gluten as possible. Many processed foods contain gluten by virtue of cross-contamination or through the addition of gluten containing ingredients. Allowing 'normal' foods to make the claim 'very low gluten' would not provide sufficient protection for all coeliacs and would not encourage manufacturers to produce foods with lower levels of gluten. The limit of 20ppm achieves a balance between maintaining consumer choice and appropriate consumer protection.

12. If coeliacs are eating a lot of so-called staple foods such as bread that are labelled 'very low gluten' and contain up to 100 ppm, won't this harm them over a long period?

All coeliacs should get advice from a qualified dietitian about their diet. General advice to coeliacs would be to limit their intake of products with levels of gluten above 20ppm. Coeliacs are responsible for their diet and managing their exposure to gluten.

13. Why are oats allowed to be labelled 'gluten-free'?

Recent evidence shows that most coeliacs can tolerate oats and it may be that the reaction to oats in some individuals is due to contamination from gluten containing cereals, such as wheat, because of the conditions under which they are grown, harvested or transported.

Only oats which have been specially grown or processed to remove gluten and have been tested to contain a level of 20ppm or less can be used in foods labelled 'gluten-free'.

14. When did the legislation come into effect and was there any transition period?

The new rules applied once the Regulation was published in the Official Journal of the European Union and some manufacturers adopted them on a

voluntary basis, but businesses did not have to comply with the rules until **1 January 2012**.

15. Did some products have to be relabelled when the Regulation came into force?

Yes. The levels of gluten in products marketed to indicate suitability for coeliacs varied greatly. Those products which were labelled 'gluten-free', but could not meet the new compositional criteria had will have to be reformulated or relabelled by 1st January 2012.

Only the terms 'gluten-free' or 'very low gluten' were allowed from 1st January 2012, although the term 'suitable for coeliacs' may be used to supplement these claims.

16. Has the statement 'suitable for coeliacs'/ the Coeliac UK logo disappeared?

No Consumer research indicates that consumers look for the Coeliac UK logo and check the label for additional information on suitability. These statements/logos are not be allowed to be used on their own to indicate suitability for coeliacs, but may supplement the claims "gluten-free" or "very low gluten".

17. What is the interaction between the allergen labelling rules and these rules?

The allergen labelling rules continue to apply alongside rules for gluten claims. The allergen rules require products containing gluten-containing cereals to make this clear on the label. This may be in the ingredients listing, but some manufacturers may also choose to provide allergy advice statements.

- A product may declare on the label that it is 'gluten-free' if the level of gluten is 20ppm or less, but still list a gluten-containing cereal in the ingredients list. In such situations we advise that any allergy statement should not mention gluten.
- A product containing a gluten-containing ingredient where the level of gluten in the final product is above 20ppm, will not be able to make the claim 'gluten-free' and will have to list the ingredient in the ingredients list and may choose to give an allergy warning about gluten.
- A product that does not contain a gluten containing ingredient cannot make the claim 'gluten-free' unless the product meets the requirements set out in the legislation.

Consumers therefore know which products have low gluten levels and make an informed choice.

18. Has the Regulation limit the number of products that a coeliac can eat?

Some products can no longer be able to be labelled as 'gluten-free' as the level of gluten in them is above 20ppm.

However, these products will still be available and over the three year transition period we have found that many products have been reformulated to meet the requirements of the new Regulation. Consumers can tell whether a food contains a gluten-containing cereal by checking the ingredient list. Some food businesses may choose to highlight on their labels or menus that the food does not contain gluten ingredients. If a coeliac has been eating a product without adverse reaction before the labelling change there is a good chance that they will be able to continue to eat it. However, they should consult a healthcare professional for specific dietary advice and check with food businesses to ensure ingredients and processes have not changed.

19. What testing methods should the industry be using?

The legislation does not specify a particular test method, although the Codex Standard recommends the Enzyme-linked Immunoassay (ELISA) R5 Mendez Method. The Agency is aware that there are some problems with the availability of this method, and will issue guidance in this area when alternative methods have been endorsed by Codex.

Factual Statements

20. What can you say on foods that do not meet the requirements?

Foods that do not meet the requirements cannot make the claims 'gluten-free' or 'Very low gluten' or imply that the food is suitable for coelics. If a food does not contain any gluten containing ingredients, and food businesses made every reasonable effort to minimise cross-contamination, factual statements can be made about the presence/absence of gluten containing cereal ingredients we recommend "No gluten containing ingredients". These statements will help coeliacs make informed choices and prevent further restriction of their diet.

21. Where can I find further information on factual statements?

The Agency has published best practice guidance which includes advice on what other information can be provided.

The Agency has also published a factsheet to help caterers understand when a food can be labelled 'gluten-free'.

A copy of both of these documents can be found here: -

<http://www.food.gov.uk/news/newsarchive/2011/may/glutenfree>

Parnuts Notification

22. Parnuts foods need to be notified to the Relevant Authority – why is this?

Under European legislation Parnuts foods generally need to be notified. This requires businesses to submit copies of products labels to the relevant authority² when a Parnut food is placed on the market, or reformulated. The primary reason is to monitor products on the market.

23. Do ‘Gluten-free’ and ‘very low gluten’ foods need to be notified?

Only Parnuts foods need notifying, therefore ‘normal’ foods, which do not contain any gluten containing ingredients, do not need to be notified.

24. Do non pre-packed Parnuts foods need to be notified?

Yes, but 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’) only needs to be provided by the notifier.

Catering

25. Do these rules apply to caterers?

Yes. Any meals or cakes claiming ‘gluten-free’ must contain no more than 20 ppm of gluten.

26. Won’t caterers find it difficult to meet the levels?

Yes. The high risk of cross-contamination in the catering setting means that it will be difficult for many caterers to meet the levels set in law.

It is advised that food businesses discuss the level of control required to make such a claim with their local Authority.

27. How can caterers comply with the new legislation?

It is advised that caterers speak to their local authority when deciding whether a ‘gluten-free’ claim can be made.

Caterers will need to ensure that any ‘gluten-free’ or ‘very low gluten’ claims that they make are justified, and this may require some analytical testing. If

² Contact details can be found in annex 4 of the guidance to compliance document.

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 Authority.

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.

28. How will coeliacs be able to make informed choices when eating out?

If a coeliac is unsure whether a meal is suitable for them or contains gluten-containing ingredients, they should ask a member of staff. Foods that do not contain gluten containing ingredients, and where cross-contamination has been controlled, will be able to be labelled with factual statements – such as “No gluten-containing ingredients”.

Coeliac UK Directory

29. What is the affect on Coeliac UK's Directory?

The CUK Directory can list Parnuts and 'normal' foods that meet the requirements of the EC regulations for foods labelled 'gluten-free' and 'very low gluten'. The Directory will also be able to list 'normal' foods, which do not meet the 20ppm limit, but do not contain a gluten-containing cereal and where cross-contamination has been controlled. This also applies to retailer products lists, call centre helplines and staff-customer communications.

Links for further information:

You can find further information on coeliac disease on the eatwell website, or from Coeliac UK.

http://www.coeliac.org.uk/about_us/default.asp

<http://www.nhs.uk/conditions/coeliac-disease/Pages/Introduction.aspx>

You can also find further information on the role of a dietician at:

<http://www.bda.uk.com/index.html>

