

Gluten regulations – frequently asked questions

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

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Know the rules

1. What is the purpose of the new Regulation?

Approximately 1% of the UK population suffers from gluten intolerance and needs 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 impacting on their health. This EU Regulation seeks to address these issues by putting 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 standards.¹

¹ CODEX STAN 118 - 1979

3. What is the current legislative situation?

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. This standard was recently revised to take account of the latest scientific advice. The new standard sets a maximum level of 20 parts per million (ppm) of gluten in order for foods to be labelled as 'gluten free', and 100ppm of gluten for foods labelled as 'very low gluten' – restricted to foods processed to remove gluten. The new Regulations 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 that 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 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 – for example, 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 processed or manufactured to either reduce the level of gluten and/or substituent gluten containing ingredients. For example, a muffin made with rice/potato flour instead of wheat flour.
- Normal foods – foods that do not have any gluten-containing ingredients.

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

is therefore taking advantage of this exemption and in the national implementing Regulations will 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?

- It defines the terms 'gluten', 'wheat' and 'foodstuffs for people intolerant to gluten' as applicable in the Regulation.
- It allows foodstuffs for people intolerant to gluten that have been specially manufactured to eliminate or substitute a gluten-containing cereal (Parnuts) to make the claim 'gluten-free' if the residual level of gluten in the foods as sold to the final consumer is 20ppm or less.
- It allows foodstuffs for people intolerant to gluten that have been specially manufactured using gluten-containing cereals that have been specially processed to remove the gluten (Parnuts) to make the claim 'very low gluten' if the level of gluten in the foods as sold to the final consumer is greater than 20ppm but 100ppm or less.
- It allows oats that have been specially prepared and/or processed to avoid contamination by gluten-containing cereals to be used in foodstuffs for people intolerant to gluten and to make the claim 'gluten-free' as long as the gluten content of such oats does not exceed 20ppm.
- It allows normal foods to use the claim 'gluten-free' if the level of gluten in the foods as sold to the final consumer is 20ppm or less.

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

While 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 dietician 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 that 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 will the legislation come into effect and is there any transition period?

The new rules apply once the Regulation was published in the Official Journal of the European Union and some manufacturers have already adopted them on a voluntary basis, but **do not have to comply** with the rules until **1 January 2012**.

15. Won't having two labelling systems running in parallel be confusing for coeliacs?

Yes, there is potential for confusion in the short term. However, the Agency will produce educational material to inform coeliacs and healthcare professionals about the changing situation and will work closely with Coeliac UK and industry to disseminate information about the changes.

16. Will the Regulation require some products to be relabelled?

Yes. The levels of gluten in products currently marketed to indicate suitability for coeliacs vary greatly. Those products that are currently labelled 'gluten-free' but which cannot meet the new compositional criteria will have to be reformulated or relabelled by 2012.

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

17. Will the statement 'suitable for coeliacs' / the Coeliac UK logo disappear?

It is not anticipated that these will be removed from labelling. Consumer research indicates that consumers look for the Coeliac UK logo and check the label for additional information on suitability. These statements/logos will 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'.

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

The allergen labelling rules will 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 will therefore know which products have low gluten levels and make an informed choice.

19. Will the Regulation limit the number of products that a coeliac can eat?

It is likely that some products will 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. Consumers will be able to tell whether they contain a gluten-containing cereal by checking the ingredients 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.

20. 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

21. What can be stated 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'. However, if they do not contain any gluten-containing ingredients, and producers have made every reasonable effort to minimise cross-contamination, factual statements can be made about the presence/absence of gluten-containing cereal ingredients – for example 'no gluten containing ingredients' – provided they do not indicate suitability for those with a gluten intolerance or mention levels of gluten. These statements will help coeliacs make informed choices and prevent further restriction of their diet.

22. Has the Agency provided advice on when to use factual statements?

The Agency is working with stakeholders to draft best practice guidance on this issue, with the intention to publish advice in autumn 2010.

Parnuts notification

23. Parnuts foods need to be notified to the Agency – why is this?

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

24. Do 'gluten-free' and 'very low gluten' foods need to be notified?

Only Parnuts foods need notifying – 'normal' foods, which do not contain any gluten containing ingredients, do not need to be notified.

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

From January 2012 these foods will need to be notified to the Agency. However, the Agency is assessing what information should be notified, as these foods do not have a label.

Catering

26. Do these rules apply to caterers?

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

27. Won't caterers find it difficult to meet the levels?

Yes. The high risk of cross-contamination in the catering setting means that many caterers are unlikely to be able to meet the levels set in law.

28. How can caterers comply with the new legislation?

It may be possible for 'gluten-free' foods prepared by catering suppliers, e.g. bought in pre-prepared, to be served as 'gluten-free' if cross-contamination is controlled.

Otherwise, caterers wishing to use the claims 'gluten-free' or 'very low gluten' will need to conduct appropriate tests on batches of meals ahead of service and reduce cross-contamination using HACCP type processes to ensure compliance and will need to ensure gluten cross-contamination is controlled and minimised.

29. 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

30. What is the effect on Coeliac UK's Directory?

The CUK Directory can continue to 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.

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

eatwell.gov.uk/healthissues/foodintolerance/

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

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