

Table of responses to the public written consultation (England) on:

Draft Commission Regulation concerning the composition and labelling of foods suitable for people intolerant to gluten.

(Consultation letter issued: 23/07/2008)

(Consultation end: 30/09/2008)

Name/ Organisation	Comments	FSA Response
<p>Industry</p> <p>Infant and Dietetic Foods Association</p>	<p>IDFA broadly supports the draft proposal,</p> <p>However, the comment stated in the background information 'Eating significant amounts of foods with levels of gluten above 20mg/kg would be detrimental to coeliacs' health' contradicts the current proposed regulation allowing foods containing between 20mg/kg and 100mg/kg to be labelled as 'very low gluten'.</p> <p>'Gluten free' should be used only for dietetic foods as defined in 89/398/EEC with a gluten content <20ppm. IDFA believe that provisions in the Codex standard should be replicated in the regulations. Prefer the term 'not a source of gluten' for normal foods <20ppm. The reason being PARNUTS foods manufacturers have complex quality assurance systems in place, and incur extra expense in testing the products to ensure they are suitable for coeliacs. IDFA believe by labelling normal foods <20ppm as 'gluten free' it implies that 'normal' food manufacturers have a similar level of quality assurance and testing in place.</p> <p>Agree with the three year transition period, and feel this would absorb any costs.</p>	<p>The provision which allows foods to be labelled 'very low gluten' is only available to foods for particular nutritional uses which include ingredients from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten. This category of labelling on these foods is permitted for specially formulated foods in which the gluten content cannot be reduced below 20ppm for technological reasons. This limited category of foods containing the gluten-reduced ingredients are important to provide choice but by specifying different labelling requirements, this allows coeliacs to make informed choices about the types of products they eat.</p> <p>The purpose of the Regulation is to make it easier for consumers to make informed choices and manage their condition effectively. Therefore, using one labelling statement for all products below 20ppm is easier for consumers to use and understand. All products labelled 'gluten free' will have to comply with the strict compositional criteria set out in the Regulation; therefore manufacturers of parnuts and normal foods making that claim will need to have adequate quality assurance and testing systems in place.</p>
<p>Gluten Free Foods Ltd.</p>	<p>The comment included in the background '<i>eating significant amounts of foods with levels above 20mg/kg would be detrimental to coeliacs' health;</i>' contradicts with allowing</p>	<p>The provision which allows foods to be labelled 'very low gluten' is only</p>

	<p>foods containing between 20m/gk and 100mg/kg gluten to be labelled as 'very low gluten'.</p> <p>We feel that the point '<i>allowing ordinary foods to use the claim 'gluten free' if the level of gluten in the foods as sold to the final consumer is less than 20mg/kg</i>' will need further definition in order to prevent the term 'gluten free' being over used on naturally gluten free products.</p> <p>Our preferred option is option 3. We feel that the UK should negotiate for adoption of the proposal following further negotiation to take into account views of the stakeholders.</p> <p>We are in agreement with the estimate transition period of 3 years and feel that this would absorb any costs i.e. relabelling</p>	<p>available to foods for particular nutritional uses which include ingredients from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten. This category of labelling on these foods is permitted for specially formulated foods in which the gluten content cannot be reduced below 20ppm for technological reasons. This limited category of foods containing the gluten-reduced ingredients are important to provide choice but by specifying different labelling requirements, this allows coeliacs to make informed choices about the types of products they eat.</p> <p>The Regulation requires that, where the term 'gluten-free' is used in the labelling, advertising and promotion of foodstuffs for normal consumption, that it does not mislead the consumer by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics. Information provided on the label or in the presentation of a food must not be false or misleading, under section 15 of the Food Safety Act 1990 (as amended), Article 16 of Regulation (EC) 178/2002 and the Consumer Protection from Unfair Trading Regulations 2008.</p>
<p>Nutrition Point</p>	<p>Nutrition Point broadly supports the Draft Commission Regulation.</p> <p>However, we have concerns regarding the labelling of 'normal' foodstuffs <20ppm as 'gluten free'. Nutrition Point prefer the terms; 'Not contaminated by gluten' or 'Not a source of gluten' for 'normal' foodstuffs <20ppm. The reason for this is that PARNUTs food manufacturers, producing gluten-free foods, have complex quality assurance systems in place, dedicated gluten-free manufacturing sites, and incur extra expense in testing the products to ensure they are suitable for the specific population group they are intended for i.e. those intolerant to gluten. We believe by labelling 'normal' foods <20ppm as 'gluten free' it implies that 'normal' food manufacturers have a similar level of quality assurance and testing in place.</p>	<p>The purpose of the Regulation is to make it easier for consumers to make informed choices and manage their condition effectively. Therefore, using one labelling statement for all products below 20ppm is easier for consumers to use and understand. All products labelled 'gluten free' will have to comply with the strict compositional criteria set out in the Regulation; therefore manufacturers of parnuts and normal foods making that claim will need to have adequate quality assurance and testing systems in place.</p>
<p>Food and Drink Federation</p>	<p>FDF prefers Option 3: "Negotiate for amendment of the proposal to take account of issues raised by stakeholders". FDF particularly asks that:</p>	

	<p>1. Use of the term “very low gluten” be extended to apply to foods for normal consumption. Only permitting "very low gluten" claims to be made for foodstuffs for particular nutritional uses will restrict product choice for many coeliac consumers who could tolerate foods containing up to 100 mg/kg of gluten. This would appear to be inconsistent with the objective of Recital 7 of the draft Regulation, which states that: <i>“Different people with intolerance to gluten may tolerate different amounts of gluten within a restricted range. In order to enable individuals to find on the market a variety of food appropriate for their needs and for their level of sensitivity, a choice of gluten free products should be possible among products with different gluten content”.</i></p> <p>The clear definition of two levels of gluten would also make it possible for health professionals to give very clear dietary advice to patients, based on knowledge of their condition.</p> <p>2. Consideration be given to the appropriateness of the term “pure oats”, since it is the final gluten status of a manufactured product which determines which gluten category it falls into; and the term “pure” may be misleading since it might be taken to indicate “absence” of gluten.</p> <p>3. The levels be applied to food “as consumed” and not “as sold to the final consumer”, given that it is the level in the food as consumed which is the key factor in whether or not a reaction is experienced. Thus the level would apply to foods sold ready for consumption or to foods as prepared for consumption according to the manufacturer’s instructions.</p> <p>FDF supports the Commission’s proposed transition period of 3 years in the interest of minimising costs from loss of product and packaging by allowing raw materials and finished products to current specifications to pass through the supply chain.</p> <p>The potential cost of reformulation of existing products on the market currently claiming to be ‘gluten free’ or ‘very low gluten’ Regarding foods for normal consumption, the effect of reducing the limit for “gluten free” from the draft Codex level of 200ppm to the final Codex/EU proposed 20ppm is highly significant and will involve substantial effort in the modification of ingredient supply and process control systems and in analytical checking. The impact will be ameliorated to some extent, however, by the proposed three year implementation period.</p> <p>Of wider significance is the fact that the proposal will cause loss of the ability of manufacturers to claim “suitable for coeliacs”, or the like, on foods for normal</p>	<p>This would lead to a significant increase the number of products on the market labelled as “very low gluten” and could lead to an increase in the daily consumption of gluten by coeliacs. The evidence shows that regular 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 all coeliacs. Therefore, allowing a wide range of normal products to make the “very low gluten” claim could lead to gluten consumption at levels that would be harmful to the majority of coeliacs.</p> <p>This term has been deleted from the final text.</p> <p>The Agency has raised this issue during negotiations but there was insufficient support from other Member States for it to be included in the Regulation. The Agency would welcome further information from manufacturers and consumers (which would support any negotiations when the regulation is reviewed) about whether this wording is causing significant difficulty in terms of making products and consuming a palatable, varied and suitable diet respectively.</p> <p>Noted</p> <p>Noted</p> <p>This would lead to a significant increase the number of products on</p>
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	<p>consumption with below 200ppm gluten content. Given that “very low gluten” cannot be used on foods for normal consumption, this means that these foods will have to meet the 20ppm standard before any such advice can be given, which will result in the claim being removed from many products, so limiting choice for coeliacs. It is not reasonable to expect industry to implement costly measures to reach a “free from” standard so that such advice can be given as additional, voluntary information on products aimed at the general population. This reinforces the need for “very low gluten” to be able to be used on foods for normal consumption so that at least a part of the range currently claiming “suitable for coeliacs” can continue to do so in line with the 100ppm standard.</p> <p>Any further changes that should be made to the EU proposal There remains a problem of possible consumer confusion due to inconsistency of labelling requirements between this proposal and the Labelling Directive. We assume that wheat derivatives exempted from allergen labelling in Annex IIIa of Labelling Directive 2000/13 will be included in “gluten free” products by virtue of their composition. There is a possibility, however, that non-exempted wheat derivatives used as ingredients of “gluten free” products (since their level of gluten does not compromise the overall 20mg/kg standard for the product), such as an enzyme derived from malt, would have to be labelled with reference to wheat and could thus cause confusion among gluten intolerant consumers. This should be recognised and addressed by the Commission.</p> <p>A possible solution would be to amend the allergen labelling requirements to quantify a minimum level of gluten, below which labelling was not required (as is currently the case for SO₂). It is recognised, however, that not having to label gluten present at < 20 mg/kg might cause a problem for the smaller proportion of individuals who suffer from “true” wheat allergy (i.e. reactions mediated by IgE).</p>	<p>the market labelled as “very low gluten” and could lead to an increase in the daily consumption of gluten by coeliacs. The evidence shows 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 all coeliacs. Therefore, allowing a wide range of normal products to make the “very low gluten” claim could lead to gluten consumption at levels that would be harmful to the majority of coeliacs.</p> <p>Noted The labelling provisions in both pieces of legislation will continue to apply. The Agency, together with consumer organisations, will carry out consumer education to ensure that labelling terms and the gluten levels that they describe are understood by coeliac patients.</p>
<p>Premier Foods</p>	<p>In principle we welcome the objective of the Regulation to harmonise the rules on the use of claims for absence or very low levels of gluten in foods. Premier Foods support ‘Option 3’ set out in the FSA Evidence Base Document We wish to raise the following issues:</p> <p>1. Dehydrated or concentrated compound ‘foodstuffs for normal consumption’ that are reconstituted with water.</p> <p>All of the references in the draft are to maximum levels of gluten that may be present in the foods as sold to the final consumer. The precedent in other food legislation (examples include the Food Labelling Regulations 1996 (as amended) and the Miscellaneous Additives Regulations 1995), has been to use the form of words ‘in the food ready for consumption prepared following the manufacturers’ instructions’ when referring to maximum levels of substances in foods. An example would be the exemption from declaring presence of sulphites on labels if the content is no greater than 10mg/kg.</p> <p>Premier Foods sell many such foods for normal consumption that need to be reconstituted with water during preparation by the consumer (for example dehydrated</p>	<p>The Agency has raised this issue during negotiations but there was insufficient support from other Member States for it to be included in the Regulation. The Agency would welcome further information from manufacturers and consumers (which would support any negotiations when the regulation is reviewed) about whether this wording is causing</p>

	<p>soup and sauce mixes, custard and gravy powders). Our experience is that gluten intolerant consumers want to know whether such products are suitable for them to consume once prepared, and it would clearly be of benefit to them if this information was stated on the pack label. We request clarification in the Regulation that for these foods, the maximum gluten content of no greater than 20mg/kg to enable the description 'Gluten-free' would be applied to the food ready for consumption as prepared following the manufacturers' on pack instructions.</p> <p>2. 'Very Low Gluten' foods (<100mg/kg gluten)</p> <p>Recital 7 to the Regulation states 'Different people with intolerance to gluten may tolerate different amounts of gluten within a restricted range. In order to enable individuals to find on the market a variety of food appropriate for their needs and for their level of sensitivity, a choice of gluten-free products should be possible among products with different gluten content'. The draft Regulation permits use of the term 'Very low gluten' for certain PARNUTS of gluten content no greater than 100mg/kg, but not for 'Foodstuffs for normal consumption' that also meet this requirement. This does not appear to be consistent with the objective set out in Recital 7.</p> <p>Premier Foods have been advised by Coeliac UK that currently use of the description 'Suitable for a Coeliac Diet' is acceptable for foods with a gluten content no greater than 100mg/kg, and we would request that the Regulation be amended to allow use of 'Very low gluten' for 'Foodstuffs for normal consumption' that contain no more than 100mg/kg gluten. It will not otherwise be possible to communicate to our gluten intolerant customers that these foods may be suitable for them to eat, once this Regulation comes into force.</p> <p>3. Pure Oats</p> <p>This term appears inappropriate. The final gluten status of a manufactured product determines which gluten category it would fall into. Additionally the term 'pure' might be taken to indicate absence of gluten and therefore be misleading.</p> <p>Impact of the draft Regulation</p> <p>Premier Foods do not manufacture any 'Foodstuffs for particular nutritional uses' that fall within the scope of this Regulation. However in common with other food manufacturers we do produce 'Foodstuffs for normal consumption' containing <100mg/kg of gluten which are currently labelled 'Suitable for a coeliac diet'. Since under the current draft of this new Regulation the 'very low gluten' claim cannot be used on foodstuffs for normal consumption containing 20-100ppm gluten, claims may no longer be made unless the foods meet the 'gluten free' claim (no more than 20ppm gluten). In practice this will result in claims being removed from most foodstuffs for normal consumption, so limiting choice for coeliacs. It is not reasonable to expect industry to implement costly measures to reach the new 'Gluten free' standard so that such advice can be given as additional voluntary information on products aimed at the general population.</p> <p>Likely costs involved</p> <p>Since the transition period is 3 years, the costs involved in changing product labelling to meet the requirements of the new Regulation should be relatively low and largely absorbed in routine label update/change activity.</p>	<p>significant difficulty in terms of making products and consuming a palatable, varied and suitable diet respectively.</p> <p>This would lead to a significant increase the number of products on the market labelled as "very low gluten" and could lead to an increase in the daily consumption of gluten by coeliacs. The evidence shows that regular 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 all coeliacs. Therefore, allowing a wide range of normal products to make the "very low gluten" claim could lead to gluten consumption at levels that would be harmful to the majority of coeliacs.</p> <p>This term has been deleted from the final text.</p> <p>The evidence shows 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 all coeliacs. Therefore, allowing a wide range of normal products to make the "very low gluten" claim could lead to gluten consumption at levels that would be harmful to the majority of coeliacs.</p> <p>Noted</p>
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The British Retail Consortium	The Agency met with the BRC, FDF, IDFA and Coeliac UK as part of the consultation. The BRC raised similar issues as the FDF (see above)	
Small Business meeting	The Agency met with several small business manufacturing 'gluten free' products as part of the consultation. The main area of concern raised by these businesses were that the claim 'very low gluten' should be allowed to be used on a wider range of foods and that clarification is given around the use of statement such as 'suitable for coeliacs'.	<p>This would lead to a significant increase the number of products on the market labelled as "very low gluten" and could lead to an increase in the daily consumption of gluten by coeliacs. The evidence shows 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 all coeliacs. Therefore, allowing a wide range of normal products to make the "very low gluten" claim could lead to gluten consumption at levels that would be harmful to the majority of coeliacs.</p> <p>It is anticipated that the Agency will be able to provide guidance on this issue for stakeholders well ahead of this date.</p>
The British Beer & Pub Association	<p>We welcome the proposal to clarify use of the terms 'gluten-free' and 'very low gluten' and the opportunity for beer produced to meet the dietary needs of people intolerant to gluten to be described as 'gluten-free' providing that the gluten content is not greater than 20 mg/kg, or as 'very low gluten' providing that the gluten content is not greater than 100 mg/Kg. Further we welcome the fact that where a standard beer has a gluten content not greater than 20 mg/Kg, it may bear the term ' gluten-free'.</p> <p>However, this raises two points on which we wish to seek clarification.</p> <p>1. Form of Declaration Under the Allergen Labelling Regulations, the deliberate addition of cereals containing gluten must be declared by marking or labelling the drink with the word 'contains' followed by the name of the allergenic ingredient, and the presence of any ingredient originating from a specified allergenic ingredient must be indicated by marking or labelling the drink with the word 'contains' followed by the name of the ingredient</p>	<p>Noted</p> <p>Noted The labelling provisions in both pieces of legislation will continue to apply. The Agency, together with consumer organisations, will carry out consumer</p>

	<p>including a reference to the allergenic ingredient from which it originates. Because there is a derogation from ingredient listing for alcoholic beverages >1.2% abv, most brewers opt to declare 'Contains: barley', or 'Contains: malted barley'. Since beer goes through a boiling stage and a number of liquid/solid separations, it is possible that a beer could also be described as 'gluten-free' by dint of the fact that it contains no more than 20 mg gluten per litre. Whereas this would meet the letter of the law, some consumers may consider the information to be contradictory or confusing. The fact of the matter is that the specified form of wording in the Allergen Labelling Regulations can be considered misleading since, although malting barley is added to the mash-tun, as explain above, beer does not literally contain malted barley. Is our interpretation correct that beer could be labelled 'Contains: barley' 'Gluten-free' providing that it met the defined criteria?</p> <p>2. Quantification A number of analyses of beer have been carried out by the brewing industry research association, BRI; using a sandwich ELISA method certain beers have shown no detectable gluten (personal communication). When the same beers are tested using a comparative ELISA, some gliadin can be detected, but this cannot be quantified in terms of gluten equivalents. One would probably need to use some form of mass spectrometry to obtain an absolute measure of gluten levels. The point here is that we agree with the levels used to define 'gluten-free' and 'very low gluten', especially since the figures are consistent with Codex recommendations, but the draft Regulation does not specify the analytical method by which these limits are to be tested.</p>	<p>education to ensure that labelling terms and the gluten levels that they describe are understood by coeliac patients.</p> <p>The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012. It is anticipated that the Agency will be able to provide guidance on this issue for stakeholders well ahead of this date.</p>
Charles Cooper Ltd	<p>Currently this company produces gluten free beers and use the R5 elisa method to ensure the level of gluten in their product is <20ppm. However we are aware of a number of new gluten free beers coming onto the market which instead of substituting ingredients are using enzymes to degrade the prolamines in the beer.</p> <ul style="list-style-type: none"> - concerned that the R5 Elisa method will not accurately measure the level of gluten in the beer for these types of products - concerned that many coeliacs may adversely react to the products as the wheat proteins (even though in a different form) will still be present in the beer. 	<p>The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012. It is anticipated that the Agency will be able to provide guidance on this issue for stakeholders well ahead of this date.</p>
National Association of British and Irish Millers	<p>Are generally supportive of a measure which should bring greater clarity to labelling so far as consumers are concerned. However, there is one aspect of the proposal which causes us some concern and would appear to be unfair to certain manufacturers.</p> <p>We accept that there should be a cut off at 20mg/kg gluten content for "gluten free"; the 100mg/kg threshold for foods described as "very low gluten" also seems perfectly sensible. However, we do <u>not</u> agree that this description should be applied only to foods specially prepared for coeliacs. It would seem perfectly reasonable for the same description to be available also to foods which are naturally low in gluten. It may well be, for example, that some manufacturers (other than those using oats) are wary of describing imported grains as "gluten free" because of concerns about possible introduction of a gluten containing grain in transit. Therefore, for good operational reasons, they may prefer to use the term "very low gluten" as a description of their product which would better inform consumers.</p> <p>We would request the FSA to seek revision of the rules so that the description "very low gluten" is available to all foods containing less than 100mg/kg gluten, not just those specially prepared from gluten containing cereals. This should enable a greater range of foods to be accurately labelled and therefore wider choice for affected consumers.</p>	<p>Noted</p> <p>The evidence shows 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 all coeliacs. Therefore, allowing a wide range of normal products to make the "very low gluten" claim could lead to gluten consumption at levels that would be harmful to the majority of coeliacs.</p>
National Association of Master Bakers	<p>Whilst we have no comments to make on the proposed lowering of the levels of gluten</p>	<p>The Agency will raise this issue with</p>

	<p>permitted in 'gluten free products', we do have concerns about the specified testing method. It is appreciated that the consultation proposal does not stipulate a method of analysis but the Codex standard prescribes that the R5 Mendez method should be used. The effect of this would be to place a significant financial and operational burden on our members that currently produce gluten free products.</p> <p>Our members are of the small to medium size and as such do not have sophisticated in-house support services available to them. Conversely current on-site testing kits provide a very cost effective alternative at providing a credible production monitoring system. It is acknowledged that laboratory based testing of samples provide the essential validation and confirmation of the on-site testing regimes. It is also understood that the Codex standard testing method is only available on licence to a limited number of providers. This will inevitably place constraints on any of our members needing to access the testing method and could lead to them having to incur unreasonably high costs because of the restricted availability.</p> <p>It is appreciated that a consistent and sustainable testing methodology needs to be established both to protect the consumer and producer. However, the present proposals appear to only address the needs of the consumer and in doing so have placed an unreasonable burden on producers. Consequently the suggestion in the consultation document that the cost impact of the proposal will be minimal are misleading and fail to take account of the impact on the small to medium producer. I would ask that the FSA make strong representations that these proposals should not be implemented until the matters raised in the letter have been satisfactorily resolved and an on-site testing method is available at a reasonable and sustainable cost.</p>	<p>the Codex Committee on Methods of Analysis and Sampling with the aim that this issue will be discussed further at the next Committee meeting in March 2009. The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012. It is anticipated that the Agency will be able to provide guidance on this issue for stakeholders well ahead of this date.</p>
<p>Farmhouse Biscuits Ltd</p>	<p>Working to the 20ppm limit is difficult and impossible to achieve 100% of the time. Raw materials contribute 10-12ppm as a result of the supply process, cross contamination can take this above the limit. The only way to achieve the 20ppm limit is to source specialised dedicated products. The cost of this is prohibitive and not a viable option for our company.</p> <p>We would clearly support the rationale to tighten the limits for gluten free. We would ideally want a reduction to 100ppm a level which we could meet consistently. This level would also be acceptable to the vast majority of coeliacs except those with the most severe of allergy. Should the limit be to reduce the limit to 50ppm we would agree to the limit, but increased control costs would have to be reflected in price. We would not be able to produce products at 20ppm without significant cost increases and an investment for a bespoke production area to be built, which is not viable. Limits of 50-100ppm are viable. If limits set to much below 50ppm then we would look to cease production of the gluten free products we make, which would mean job losses.</p> <p>If level set at 20ppm for example, (with 100ppm ceiling), an option will be to class 20-100ppm as 'low gluten'. Other than packaging changes, there would not be any significant cost impacts, although we would have to convince our customers that they are still acceptable and not any different from before. This is a different issue and a serious sales impact would be very likely.</p>	<p>Raising the 20ppm limit would lead to a significant increase the number of products on the market labelled as "gluten-free" and could lead to an increase in the daily consumption of gluten by coeliacs. The evidence shows 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 all coeliacs.</p> <p>Noted</p>
<p>Fun Foods 4 All</p>	<p>Italian law has defined gluten free pasta to contain less than 20 parts per million gluten contamination. Each production site is audited and approved by Italian governmental agency and every production batch is tested by independent lab before it is released for sale. I believe for pasta this should be the basis of new regulations.</p>	<p>The aim of the new regulation is to harmonise the rules relating to the use of the claim 'gluten free' across the EU, in the interests of manufacturers and consumers. As such any pasta labelled 'gluten free' will have to comply with these rules across all</p>

<p>Heron Foods</p>	<p>We have no problem with the labelling terms set out in the directive. The transition period is fine; except that once the regulations are in place no one will take product that is still adhering the old regulations of >200 ppm, so everyone will have to conform immediately.</p> <p>It is going to be quite costly to implement the regulations as most of our packaging will have to have new ingredient listings, and all our wheat starch based recipes will have to be updated and staff training will have to be undertaken to ensure that everyone knows the new regulations.</p> <p>Customers (particular Coeliacs) who are used to our wheat starch based products, tend to rely on them for their basic diets, if we change our recipes to conform they may not find that the new recipes suit them. We will endeavour to change the recipes without changing the taste too much.</p>	<p>Member States.</p> <p>Noted.</p> <p>The Regulation includes a three year transition period to allow for changes to products and does not impact directly on ingredients listings</p> <p>The Agency, together with consumer organisations, will carry out consumer education to ensure that the new Regulations and labelling terms are understood.</p>
<p>Doves Farm Foods</p>	<p>We have found from 20 years experience that on occasion there can be inadvertent contamination of naturally gluten free commodities such as maize, rice, buckwheat & gram with a low level of gluten containing grains prior to delivery to the mill. This can occur from the impurity of farm crops in the field, harvesting methods, cross contamination in store and in transit of the raw material to the processing site. It is also important to label this category of naturally gluten free foods, which are often minimally processed, so that they can be identified by consumers as being low in gluten. The current proposal that these 'other foodstuffs' may not bear the low gluten term, suggests some kind of inferiority compared to highly processed wheat barley and rye that still contains a residue of 100mg/kg. A category for the labelling of these naturally gluten free foods, that may contain a low level of cross contamination, but no more the 100mg/kg gluten must be included in the regulation. We would therefore propose the following amendment;</p> <p>Article 4 2. Naturally gluten free foodstuffs as referred to in paragraph 1 shall not contain a level of gluten greater than 100g/mg and may be labelled 'very low gluten'</p>	<p>The evidence shows 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 all coeliacs. Therefore, allowing a wide range of normal products to make the "very low gluten" claim could lead to gluten consumption at levels that would be harmful to the majority of coeliacs.</p>
<p>Delicious Alchemy Ltd</p>	<p>I am a coeliac who reacts to 'gluten free' food that is as high as 200ppm. I therefore welcome with open arms any proposal which ensures that food labelled gluten free is always under 20ppm. It will increase my food choices by giving me the confidence to try new products, in the knowledge that they are safe for me to eat.</p> <p>I also run a business making gluten free food for supermarkets and foodservice. All of our food is tested before it is released into the supply chain to ensure that it is under 20ppm gluten. This control measure is not overly expensive to implement and maintain and I strongly believe that all gluten free food producers should be required to test their food before releasing it.</p> <p>The sooner this proposal goes through the better for me because even most of the 'gluten free' food available on prescription on the NHS is at 200ppm gluten therefore because the levels present in gluten free foods are not required to be on the label, I cannot safely order any prescription goods. This reduces my quality of life.</p> <p>I have no interest in whether changing the regulation upsets the status quo. What's of the utmost importance to me is that I can eat safely.</p>	<p>Noted.</p>

<p>M H Foods</p>	<p>The proposed regulations are too restrictive and do not consider occasional foods and “concentrated” foods which Coeliacs desire to eat/drink.</p> <p>For example condiments eaten in small quantities such as prepared hot mustard sauces: The mustard flour ingredient, depending on the purity at harvesting, can contribute gluten to the hot mustard sauce up to 50 ppm (50 mg/kg) It should be considered that a normal serving size of mustard is 5g to 10g and would only contribute very little gluten to 100g meal.</p> <p>Similarly, Vegetarians and Vegans who depend on soya as a dietary source of protein can also be Coeliacs since the protein from soya is the only “complete” protein of plant origin available to Vegetarians and Vegans. Products made from soya for Vegetarians such as textured soya protein and imitation cheeses can have small levels of gluten varying from 10 to 50 ppm depending on where and how the soya beans were harvested (crops of soya are rotated with wheat, therefore the contamination). I recommend that the regulations permit grading of foods in accordance with <u>their serving size</u>.</p> <ul style="list-style-type: none"> a) Seasonings used in very small quantities; b) Dry or dehydrated textured soya protein; c) Dry or dehydrated soya based grated dairy-free cheese substitutes (for Vegans, Vegetarians, Hebraic customers, people allergic to milk products). 	<p>The Agency has raised the issue with regard to dry and concentrated foods during negotiations but there was insufficient support from other Member States for it to be included in the Regulation. The Agency would welcome further information from manufacturers and consumers (which would support any negotiations when the regulation is reviewed) about whether this wording is causing significant difficulty in terms of making products and consuming a palatable, varied and suitable diet respectively.</p> <p>However, this Regulation applies to a wide range of foods and to apply it based on serving size would not provide the consumer with information in a consistent and easy-to-understand format to allow them to make informed choices.</p>
<p>Halal Food Authority</p>	<p>The Halal Food Authority (HFA) is in agreement with the proposals, interventions options stated together with the articles that were included. HFA is appreciative of the fact that the food industry is doing its utmost to serve the customer with special dietary requirements. However, defining regulatory regime is bound to enhance both the understanding of the industry and it would be beneficial for the consumer.</p>	<p>Noted.</p>
<p>Food Solutions</p>	<p>Declaration of the presence of gluten is demanded in any case by the allergen regulations since November 2005. We note that the list of permitted claims under EC 1924/2006 annex 1 does not include gluten. Therefore we presume that the new regulation will be as a supplement to 1924/2006.</p> <p>We would not anticipate any significant increase in costs to our members by the introduction of this regulation.</p>	<p>No, the allergen regulation (2000/13/EC) requires declaration of the gluten containing cereal, not gluten per se. Recital 22 of Regulation 1924/2006 states that claims such as ‘gluten free’ are not intended to be covered by that Regulation. This new Regulation sets out provisions on the use of claims about the absence or reduced gluten content of foods.</p> <p>Noted.</p>
<p>Enforcement bodies LACORS</p>	<p>LACORS supports option 3 that is to allow dry foods that when made up in accordance with instructions meet the maximum levels of gluten. This will provide more choice for gluten intolerant consumers.</p>	<p>Noted – The Agency has raised this issue during negotiations but there was insufficient support from other Member States for it to be included in the Regulation. The Agency would welcome further information from manufacturers and consumers (which would support any negotiations when the regulation is reviewed) about</p>

	<p>Suggest that the declaration 'gluten free' or 'very low gluten' should appear in the name of the food in line with the requirements in the food labelling directive that the name should distinguish foods with which it could be confused. As many organisations advise gluten intolerant consumers to look carefully at the name of the food this approach would be more effective than the vaguer alternative 'in close proximity to' approach.</p>	<p>whether this wording is causing significant difficulty in terms of making products and consuming a palatable, varied and suitable diet respectively.</p> <p>This requirement is consistent with the requirements of general Food Labelling Requirements. The Agency will be able to provide guidance on this issue for stakeholders.</p>
<p>Trading Standards South East</p>	<p>The Partnership supports option 3 of the proposal i.e. negotiations for amendment of the proposal to take account of issues raised by stakeholders. They are of the opinion that if dry foods, when reconstituted, meet the relevant maximum levels of gluten, this will provide more choice for gluten intolerant consumers.</p> <p>The Partnership recommends that the declaration 'gluten free' or 'very low gluten' should be in the name of the food. This is in line with the Food Labelling Regulations provisions which require that the name should distinguish a food from other foods with which it could be confused. When Trading Standards carry out food promotion work, they emphasize to consumers the need to look at the name of the food when making choices. If the gluten status formed part of the description, this would ensure consistency for allergic/intolerant consumers rather than the concept of 'in proximity'.</p>	<p>Noted – The Agency has raised this issue during negotiations but there was insufficient support from other Member States for it to be included in the Regulation. The Agency would welcome further information from manufacturers and consumers (which would support any negotiations when the regulation is reviewed) about whether this wording is causing significant difficulty in terms of making products and consuming a palatable, varied and suitable diet respectively.</p> <p>This requirement is consistent with the requirements of general Food Labelling Requirements. The Agency will be able to provide guidance on this issue for stakeholders.</p>
<p>Kent County Council Trading Standards</p>	<p>I would support Option 3 i.e. to allow dry foods that when made up in accordance with instructions meet the relevant maximum levels of gluten as this provides more choice for gluten intolerant consumers.</p> <p>I suggest that the declaration gluten free or very low gluten should be in the name of the food. This is consistent with The Food Labelling Regulations 1996 that the name should distinguish it from foods with which it could be confused. In food promotion activity Trading Standards Officers always emphasize with consumers the need to look for the name of the food when making choices. Having the gluten status description in the name of the food would ensure consistency for allergic/intolerant consumers rather than the</p>	<p>Noted – The Agency has raised this issue during negotiations but there was insufficient support from other Member States for it to be included in the Regulation. The Agency would welcome further information from manufacturers and consumers (which would support any negotiations when the regulation is reviewed) about whether this wording is causing significant difficulty in terms of making products and consuming a palatable, varied and suitable diet respectively..</p> <p>This requirement is consistent with the requirements of general Food Labelling Requirements. The Agency will be able to provide guidance on this issue for stakeholders.</p>

	vague concept of 'in proximity'.	
Analysts		
Campden and Chorleywood Food Research Association	<p>It would be helpful if it were clearly stated how method uncertainty should be applied - should it be taken within in the specified level e.g. if expanded uncertainty of the method is 60% then need to manufacture to 12.5mg/kg to have 97.5% confidence that product will not test greater than 20mg/kg or should it be applied 'outside' the specified level (if method uncertainty 60% then up to 32mg/kg is within 95% confidence range). This decision has an impact on extent of cleaning required to meet specified level and hence significant cost implications for manufacturers.</p> <p>Method – R5 antibody not freely available, only licensed to particular companies. Restrictive for analysts, and kit companies.</p> <p>Application of regulation to foods as consumed rather than as sold - there will be an additional cost to analyst/ client due to the need to prepare the food prior to testing (e.g. re-hydration; bake). This is also likely to be a source of variability in results unless instructions for preparation for use are very specific.</p>	<p>The Agency will raise this issue with the Codex Committee on Methods of Analysis and Sampling with the aim that this issue will be discussed further at the next Committee meeting in March 2009. The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012. It is anticipated that the Agency will be able to provide guidance for stakeholders well ahead of this date.</p> <p>The Regulation maintains the provision that the compositional and labelling criteria apply to foods 'as sold to the final consumer'.</p>
Genon labs	<p>I appreciate that this method is the Codex type 1 method, however it is unlikely to remain so for very long. To specify a preferred method could render the rules out of date very quickly. It is widely accepted throughout the world that there is no definitive method for the testing of gluten and none of the methods used by laboratories at the current time are considered perfect.</p> <p>I understand one of the main issues is the development of a pure gluten reference material to facilitate research into the development of a true gluten test and ensure consistency across methods and laboratories. By offering a number of different methods we can ensure that the most comprehensive analytical services available can be offered, and if necessary a number of tests be performed on the same sample. I believe the best option is not to promote a specific method of testing until an acceptably accurate method is established.</p> <p>Whilst my comments above relate to the appropriateness of advocating a certain method, I would also like to make comments as to the practicability for laboratories to offer the R5 method. You are no doubt aware that the R5 antibody is only licensed to two companies – R-Biopharm Rhone who supply kits to the UK and Ingenasa in Spain. The view on the R5 is therefore a very limited view of the kits available and promoting the R5 actually only promotes one kit supplied by one company. For those laboratories working on the Skerritt there are cost implications to gain accreditation for the R5 method to the tune of approximately £2k and this also renders the accreditation on the Skerritt method worthless. It is therefore my opinion that from a commercial point of view promoting the R5 method is anti-competitive and not in the interests of the analytical industry.</p>	<p>The Agency will raise this issue with the Codex Committee on Methods of Analysis and Sampling with the aim that this issue will be discussed further at the next Committee meeting in March 2009. The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012. It is anticipated that the Agency will be able to provide guidance for stakeholders well ahead of this date.</p>
Tepnel Research Products & Services	<p>With this statement (Recital 4 of the draft Commission Regulation) the draft commission regulation is clearly harmonising itself alongside the revised 'Codex standard for foods for special dietary use for persons intolerant to gluten' (July 2008). While not specifically</p>	<p>The Agency will raise this issue with the Codex Committee on Methods of Analysis and Sampling with the aim</p>

	<p>stating a required method of analysis by association with the Codex standard the Draft regulation is indirectly stipulating the use of the 'Enzyme Linked immunoassay (ELISA) R5 Mendez method' for the determination of Gluten. This gives us cause for concern on both an analytical and a commercial level for the following reasons:</p> <ol style="list-style-type: none"> 1. The Codex Committee on Nutrition and Foods for Special Dietary Uses (29th Session, Nov 2007) agreed that the method of analysis should be validated against a certified reference material (Section 5, 61, page 7). With no certified reference material being available, what are the alternative options for validating methods, whether it be the R5 ELISA Mendez method or other methods? What criteria need to be attained for such a material for it to be used for calibration of methods? Does the material used for calibrating the R5 ELISAs attain such criteria ? 2. In the absence of an internationally available certified reference material how can methods of analysis assist the application of the standard with the 20ppm and 100ppm gluten thresholds ? 3. How may the (R5 ELISA Mendez) method be made readily available to all when the R5 antibody appears to be licensed to only four companies (http://www.cnb.uam.es/~gluten/english/ukits_eng.htm) ? 4. When the Codex Standard refers to the R5 ELISA Mendez method, which commercial kit is being specified ? 5. Without the ready availability of the R5 antibody, if an antibody is used in a method with equivalent specificity to the R5 antibody will it to be deemed to be Equivalent? Which performance criteria will be needed (if any) to demonstrate equivalence? and who would grant this acceptance ? <p>By strong association with the Codex standard the Draft regulation is indirectly stipulating the use of the R5 Mendez method for analysis for Gluten. This would lead to companies with procedures already in place utilising the immediate and cost effective control of Gluten by lateral flow testing being forced to seek a lab based R5 service. This would certainly have an economic impact and possibly an effect on compliance with reduced testing. The R5 ELISA cannot satisfy the demands for screening and confirmation as well as official control.</p> <p>The stipulation for the use of R5 Mendez ELISA method for analysis for Gluten goes against this statement as the R5 antibody is specific to the 'QQPFP' amino acid sequence only found in the Gliadin like proteins and not the other toxic protein fraction of gluten namely the Glutenins.</p>	<p>that this issue will be discussed further at the next Committee meeting in March 2009. The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012. It is anticipated that the Agency will be able to provide guidance for stakeholders well ahead of this date.</p>
<p>Healthcare professionals, NGOs and Individual consumers</p>		
<p>Royal College of Physicians</p>	<p>We welcome regulation in this area and hope that the final output will lessen the confusion on gluten-free products for patients with gluten intolerance.</p> <p>Of the three options in the IA we would favour Option 3. Our major misgiving is whether a "very low gluten" labelling is appropriate. Patients with definitely diagnosed Coeliac disease should be on strict gluten-free diets. However, patients with "gluten intolerance" but with no intestinal damage may benefit from the 'very low-gluten' products.</p>	<p>Noted</p> <p>The provision which allows foods to be labelled 'very low gluten' is only available to foods for particular nutritional uses which include gluten-containing cereals which have been</p>

	<p>We are aware that the WHO CODEX Alimentarius has proposed the two levels of gluten labelling against the advice of the CODEX Alimentarius prolamins subcommittee. The levels put forward are 20 PPM for naturally gluten-free and 100 PPM for rendered gluten-free. This could be very confusing for patients and health care workers. Many naturally gluten-free products do not comply with the 20 level so could not be sold as naturally gluten-free. This is usually because of cross contamination with wheat flour. Rendered gluten-free products variably fail to meet the 100 PPM level so will have to be withdrawn from the market. The introduction of the two levels of 20 and 100 PPM is flawed and will create problems in the market place both for health care professionals but also the patients. At worst case scenario this could result in unnecessary litigation.</p> <p>Gluten levels are obtained by measuring the gliadin content with the R5 kit and multiplying this value by 2 to obtain the gluten value. It has been shown that if one measures the individual components the true value is up to ten fold different from the R5 kit value, in some cases with more and others less gluten. The majority of North European gluten-free foods are based on wheat starch for which the two fold multiplication factor is invariably grossly wrong.</p> <p>Administrative costs: These are really extremely low as given, even though they are worked out on the basis of some evidence. However, we do not believe that half an hour is sufficient time for managers to fully understand the implications of the objective. The costs should therefore be raised.</p> <p>Other costs: For e.g. relabelling/reformulation/loss of products is probably underestimated. This cost would be borne by the industry and transferred onto the consumer.</p> <p>Another problem is that of sustainability of the Directive and who will audit it. Clearly this is a major problem for the long-term. Individual companies are regularly visited by various Agencies and we would hope that this would be followed in this particular directive.</p> <p>Consumer education will need to focus on conveying clear information on the categories and the associated terminology to ensure that the regulation does not result in misinterpretation and therefore incorrect advice on food selection. In addition, education will need to take into account anomalies which are already in existence regarding the requirements of the Allergen Labelling Directive e.g. gluten-free products that contain gluten-containing cereals and specifically the inclusion of pure oats as a gluten-free cereal. This inclusion will require a significant change in consumer knowledge as oats</p>	<p>processed to remove the gluten. This category of labelling on these foods is permitted as some of the specially formulated foods form part of the staple diet and the gluten content cannot be reduced below 20ppm for technological reasons. In these cases it is important to provide unambiguous labelling to allow coeliacs to make informed choices.</p> <p>The Agency, together with consumer organisations, will carry out consumer education to ensure that the new Regulations and labelling terms are understood.</p> <p>The Agency will raise this issue with the Codex Committee on Methods of Analysis and Sampling with the aim that this issue will be discussed further at the next Committee meeting in March 2009. The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012. It is anticipated that the Agency will be able to provide guidance for stakeholders well ahead of this date.</p> <p>Noted, comment will be taken into account in finalising the impact assessment.</p> <p>Noted, comment will be taken into account in finalising the impact assessment.</p> <p>Enforcement of the provisions in the Regulation will be carried out by Local Authorities as for all food legislation.</p> <p>The Agency, together with consumer organisations, will carry out consumer education to ensure that the new Regulations and labelling terms are understood.</p>
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	<p>have historically been considered unsafe for Coeliac consumers. Healthcare professionals, in particular Registered dietitians, will also require education and training to deliver patient education that is in line with the regulation.</p> <p>With the more stringent Codex standard and associated EC Regulation it will also be imperative to provide the food industry with adequate support and guidance to ensure that availability of gluten-free products and main stream products that are suitable for coeliacs will not be unduly affected or restricted.</p> <p>Finally we would stress that the most simple concept of all foods being labelled as either gluten free or not would be immensely helpful for patients.</p>	<p>The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012. It is anticipated that the Agency will be able to provide guidance for stakeholders well ahead of this date.</p>
Coeliac UK	<p>The Agency met with the BRC, FDF, IDFA and Coeliac UK as part of the consultation. Coeliac UK's main concern was that the industry response to the new Regulation would severely restrict consumer choice.</p>	<p>The evidence shows that for coeliacs 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 all coeliacs. Therefore, allowing a wide range of normal products to make the "very low gluten" claim could lead to gluten consumption at levels that would be harmful to the majority of coeliacs. In addition the three year transition period should ameliorate the effect for both industry and consumers.</p>
Editor for Food Matters	<p>We fully support Option 3. Any extra information which allows consumers to make a more informed choice is to be welcomed so the two tier gluten warning is excellent. We would also fully support your suggested amendment to cover dry and dehydrated foods.</p> <p>Our only concern would be with reference to the foods which are naturally gluten free. Although we can see the logic of this provision in terms of informing less-aware consumers, we fear that it might be open to abuse by some members of the food industry wishing to 'cash in' on the g-f craze who might use it indiscriminately. However, rather too much information than too little.</p>	<p>The Agency has raised this issue during negotiations but there was insufficient support from other Member States for it to be included in the Regulation. The Agency would welcome further information from manufacturers and consumers (which would support any negotiations when the regulation is reviewed) about whether this wording is causing significant difficulty in terms of making products and consuming a palatable, varied and suitable diet respectively.</p>
Asperger's Diet Campaigner UK	<p>My concerns are about derivatives and factory cross contamination which I feel is not getting enough attention and causes a great deal of stress to people with allergies.</p> <p>I will only discuss gluten (including wheat here, however, what I am saying also is relevant if you ever have a lactose/casein regulations case.) I realise that diet alone is not the only cause for my conditions improvement, however, it is the biggest change in my life since my diagnosis and the improvements are such a massive change in my life they cannot be avoided.</p> <p>In my opinion gluten-free and wheat-free should mean exactly that: Free from gluten and wheat – no matter how much per part per million. 0% is free and anything above that</p>	<p>The evidence shows that for coeliacs 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 all coeliacs which is why the level of 20ppm was set. In addition, the allergen regulation (2000/13/EC)</p>

	<p>should be labelled clearly contains gluten/wheat no matter how much is in it or even factory cross contamination.</p> <p>I realise that you are looking for opinions on gluten and not about conditions like asperger's or autism, however, you have to realise with the prevalence of autism and asperger syndrome in the UK (and elsewhere) clearer labelling would be a MASSIVE help to us to make informed choices of what we eat especially if a child or adult is helped by being gluten and casein free.</p>	<p>requires declaration of the gluten containing cereal which allows consumers to choose products which contain no gluten containing cereals.</p>
Anne Pettigrew	<p>I would like to voice the opposite view to these people (who are opposed to the proposal that the term 'gluten-free' should only apply to products with less than 20mg/kg and 'very low gluten' for products with between 20 and 100 mg/kg.) and commend you for clarifying the situation. Although I understand the concern that some people may avoid products which they can tolerate, I would much rather that labelling erred on the side of caution. As a 'super-sensitive' Coeliac myself I have often been assured that products are suitable for me because of the labelling, only to discover that upon closer inspection they are not. It is not difficult for Coeliacs to assess for themselves what is safe to eat and what isn't - it is much harder to rely on others to cater safely, whether the 'others' are professional caterers or just friends who extended an invitation for a meal.</p>	<p>Noted.</p>
John Kinnear	<p>I have coeliac disease and therefore have an interest in this. When I was diagnosed, I was given the standard advice of following a gluten free diet.</p> <p>There are two main reasons why I sometimes fail to avoid gluten: one is quite simply the current misleading labelling rules.</p> <p>A few days ago I bought a product labelled boldly on the front as gluten free. It says so twice on the front, in large and colourful letters, with a nice positive tick.</p> <p>I have not been feeling too well today and checked the package, as it is the only unusual item I have eaten recently. Yet again, in small print and on the back of the package, I now read that the product does in fact contain wheat starch as the second largest ingredient (after water). Furthermore, there is the misleading statement that "this ingredient complies with the Codex alimentarius standards for gluten-free foods" – which does not warn that it is unsuitable for someone who needs the lowest levels of gluten that are feasible.</p> <p>I find the material on your web site rather daunting, and I realise it probably is not meant for me, but I understand via Coeliac UK that the proposed rules will mean that such a product will in future only be allowed to call itself "very low in gluten", and that "gluten free" will be much closer to meaning what the words say.</p> <p>The sooner the change happens, the better, in my view. When can we expect to see the new labels?</p>	<p>Noted.</p> <p>The Agency, together with consumer organisations, will carry out consumer education to ensure that the new Regulations and labelling terms are understood.</p> <p>The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012.</p>
Tony Frost	<p>I am one of the Coeliac people that have difficulty with wheat starches and anything made or derived from wheat. I believe that foods that are classed as Gluten Free should be free from Gluten, foods that are wheat free should be wheat free. I have found that I also suffer from using "Maltodextrin" like many others.</p> <p>We as Coeliacs should be able to shop safely irrespective of response to additives that is added to most foods these days there must be a stop to wheat/gluten products being called by other names.</p>	<p>The purpose of the Regulation is to make it easier for consumers to make informed choices and manage their condition effectively. The Agency, together with consumer organisations, will carry out consumer education to ensure that the new Regulations and</p>

		labelling terms are understood and therefore used appropriately to make informed choices. In addition, the allergen regulation (2000/13/EC) requires declaration of the gluten containing cereal which allows consumers to choose products which contain no gluten containing cereals.
Anna Pearson	I have to purchase Gluten Free products for a member of the family. I find that there used to be a symbol on products which made them easier to buy. It takes extremely long to read the Allergy Advice and one can never be certain of the contents. I hope the new guidelines include a symbol again as I understand it is not required and the present system is not at all clear.	The Agency, together with consumer organisations, will carry out consumer education to ensure that the new Regulations and labelling terms are understood.
Jennie Ancell	My suggestion for clear labelling is to use the "cross grain" symbol created by the Coeliac Society. This is easily understood by all with a gluten intolerance and can be recognised by those of all languages and those with low literacy skills. The important thing about the final decision is that all labelling should conform to a common format with consistent terminology. There is currently too much ambiguity.	The Agency, together with consumer organisations, will carry out consumer education to ensure that the new Regulations and labelling terms are understood.
Paul Hemsley	<p>Concerned that the testing for gluten will be restricted to the Mendez method.</p> <p>- Would like to see the following limits and labelling being used:</p> <ol style="list-style-type: none"> 1. 'Gluten-free' restricted to naturally gluten free and contamination free 2. <5ppm gluten 3. <20ppm gluten 4. All other foods to be labelled "contains gluten" 	<p>The Agency will raise this issue with the Codex Committee on Methods of Analysis and Sampling with the aim that this issue will be discussed further at the next Committee meeting in March 2009. The newly agreed European Union Regulation concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten will not apply until 1st January 2012. It is anticipated that the Agency will be able to provide guidance for stakeholders well ahead of this date.</p> <p>The purpose of the Regulation is to make it easier for consumers to make informed choices and manage their condition effectively. Therefore, using one labelling statement for all products below 20ppm is easier for consumers to use and understand. The evidence shows that for coeliacs 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 all coeliacs which is why the level of 20ppm was set as the</p>

	<ul style="list-style-type: none"> - Would like to see a stop to companies being able to claim that foods are gluten free through modification of the protein. - Unless gluten free is restricted to naturally gluten free foods, this will be used as a loop-hole in many areas. 	<p>maximum level for the claim 'gluten-free'.</p> <p>Only those products made using specially processed cereals to reduce the gluten content to below 20ppm will be able to make the claim 'gluten free'.</p> <p>The Regulation requires that, where the term 'gluten-free' is used in the labelling, advertising and promotion of foodstuffs for normal consumption, that it does not mislead the consumer by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics. Information provided on the label or in the presentation of a food must not be false or misleading, under section 15 of the Food Safety Act 1990 (as amended), Article 16 of Regulation (EC) 178/2002 and the Consumer Protection from Unfair Trading Regulations 2008.</p>
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