

**GLUTEN IN FOOD (INFORMATION FOR CONSUMERS) (ENGLAND)
REGULATIONS 2017**

SUMMARY REPORT OF STAKEHOLDERS RESPONSES

The **GLUTEN IN FOOD (INFORMATION FOR CONSUMERS) (ENGLAND) REGULATIONS 2017** consultation was issued on 24 NOVEMBER 2016 and closed on 22 DECEMBER 2016.

The purpose of the consultation was to provide interested parties with the opportunity to comment, and express their opinions on the proposed Regulations that will bring into force enforcement measures in England, relating to European Union rules on gluten-free foods, and the associated Impact Assessment.

1 The FSA is grateful to those stakeholders who responded and sets out in the table below responses in order of the issues considered/group responding.

2 The key proposals on which the consultation sought views were:

To make national Regulations to provide for the execution and enforcement of the Commission Implementing Regulations (EU) No. 828/2014 on the requirements for the provisions of information to consumers on the absence or reduced presence of gluten in food.

The Food Standards Agency's considered responses to stakeholders' comments are given in the last column of the table. A summary of changes to the original proposal(s) resulting from stakeholder comments is set out in the final table.

3 A list of stakeholders who responded can be found at the end of the document.

*SUMMARY OF SUBSTANTIVE COMMENTS TO THE FSA CONSULTATION – **GLUTEN IN FOOD (INFORMATION FOR CONSUMERS) (ENGLAND) REGULATIONS 2017***

1a) The adequacy of compliance notices to address non-compliance with the provisions of the new EU Regulation for gluten labelling and to protect consumers?

Respondent	Comment	Response
Coeliac UK	It is important that the the enforcement approach allows for proportionate but active enforcement to ensure continued consumer confidence in gluten-free labelling. Coeliac UK have concerns the magistrate's court appeal process outlined in this proposal may result in a court hearing occasional appeals with limited experience in making decisions in this area.	Noted. We agree effective enforcement controls to govern gluten-free labelling are important, and we aim to implement the most effective controls in this regard.

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<p>Food and Drink Federation</p>	<p>FDF supports a proportionate approach to enforcement and the introduction and use of compliance notices to address gluten-free labelling non-compliances.</p> <p>Enforcement of gluten labelling requirements should favour a collaborative approach and, similar to the application of improvement notices, compliance notices are only used as a last resort. Enforcement should also be consistent across the UK.</p>	<p>The FSA supports the hierarchy of enforcement approach, similar to allergen enforcement in general. We also plan work with stakeholders on issuing guidance. This will cover enforcement including Compliance Notices which are very similar to Improvement Notices.</p> <p>As with other different UK approaches to food enforcement resulting from a devolved system, we would engage closely with the government bodies involved for a workable solution. This would be on a case-by-case basis if a cross border issue were to arise over gluten standards.</p>
<p>Premier Foods</p>	<p>Have noted the difference in UK enforcement approaches and raised some concerns over the use of compliance notices.</p>	<p>We plan to work with stakeholders on issuing guidance. This will cover enforcement including Compliance Notices which are very similar to Improvement Notices.</p>
<p>The British Hospitality Association</p>	<p>The BHA agrees that compliance notices are an adequate measure to address non-compliance of gluten labelling requirements.</p>	<p>Noted.</p>
<p>Pret</p>	<p>Compliance notices are workable.</p>	<p>Noted.</p>

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The British Sandwich Association	The proposal appears more than adequate to protect consumers.	Noted.
London Borough of Hackney	The proposed sanctions are sufficient but questioned why compliance notices have been proposed rather than using the existing section 10 improvement notices available under the Food Safety Act.	We plan to work with stakeholders on issuing guidance. This will cover enforcement including Compliance Notices which are very similar to Improvement Notices.

1b) The use of proposed backstop criminal sanctions as indicated in regulation 3 of the draft statutory instrument? If you agree or disagree, please provide evidence to support your views

Respondent	Comment	Response
Coeliac UK	<p>Coeliac UK support the proposed backstop criminal sanctions and a proportionate enforcement approach.</p> <p>Section 10 of the Impact Assessment states ‘In addition, as in the past, the option of applying ‘frontline’ criminal penalties to businesses who fail to meet the gluten labelling standards remains’ – it is unclear in the SI whether these additional penalties include a custodial sentence. In extreme cases, where producers may benefit from charging a premium for mislabelled products, an argument can be made that a custodial sentence is a more appropriate penalty than a fine.</p>	Noted. We plan to work with stakeholders on issuing guidance once the Statutory Instrument (SI) is made. We will try to ensure that these points are addressed.

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Food and Drink Federation (FDF)	FDF supports the proposed use of a backstop criminal sanction but expressed concerns over the seizure and removal of powers, as these are not in place for other food labelling safety offences, and differences in appeals processes.	Noted. We intend to work with stakeholders on issuing guidance on enforcement measures, once the SI has been made, and will try to address these points.
Premier Foods	Greater clarity is needed with regard to product seizures and whether they are appropriate.	We intend to work with stakeholders on issuing guidance on enforcement measures, once the SI has been made.
British Hospitality Association	The regulations seem reasonable and agree that gluten-free standards should be consistent and protect public health.	Noted.
Pret	Agreed with backstop sanctions.	Noted.
The British Sandwich Association	Expressed concerns over finished product testing for short life products.	We would expect the food business to demonstrate due diligence, to the best of their ability, in making sure gluten-free options meet required standards.
London Borough of Hackney	It would be useful for additional guidance to be provided for food authorities to accompany the Regulations to clarify the circumstances in which a compliance notice would be a suitable sanction. For example, are businesses expected to undertake verification testing or obtain verification information from a supplier?	We expect food businesses to demonstrate due diligence and for finished products to meet gluten-free standards if such claims are made. We intend to work with stakeholders on issuing guidance.

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2) Whether the attached Impact Assessment (IA) at Annex C adequately captures the UK market? If not, please provide us with further information to help us with further information to help us identify the number of firms affected, their location, and ideally, firm size in terms of number of employees

Respondent	Comment	Response
Coeliac UK	Yes.	Noted.
Food and Drink Federation.	As a trade association, FDF does not produce or analyse UK market data for the gluten-free sector but recognises Coeliac UK is a reliable source of relevant market data.	Noted.

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Premier Foods	<p>‘Section 4 - Evidence Base’ identifies that sufferers from coeliac disease must avoid dietary intake of cereals but there is no direct reference in the Impact Assessment to the recognition that some sufferers are able to tolerate some exposure to gluten.</p> <p>Paragraph 4.1 states “...the levels of gluten in these products may vary considerably, which can mislead consumers..”. The cause of this variation should be discussed and addressed.</p>	<p>It is generally understood that gluten-free products are safe for people with coeliac disease, and those with other gluten intolerances do not necessarily require such a strict adherence to a gluten-free diet.</p> <p>Para 4.1 refers to food businesses not following gluten-free standards, and gluten levels being higher than they should. The proposed enforcement measures aim to prevent this and ensure consistent standards.</p>
The British Hospitality Association	The regulations seem reasonable in protecting public health.	Noted.
The British Beer and Pubs Association	BBPA agree the introduction of the new EU rules on gluten labelling (828/2014) provides a clearer set of labelling rules but concerned over the interpretation over no gluten containing ingredients (NGCI).	<p>In the past NGCI could be used when gluten-free standards could not be guaranteed due to possible gluten cross-contamination.</p> <p>The recent EU rules are more prescriptive, and we have considered our NGCI advice in liaison with legal experts and evidence from industry.</p>

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Pret	Not able to comment.	Noted.
The British Sandwich Association	Assumptions appear reasonable	Noted.
London Borough of Hackney	Consideration needs to be given to the impact on businesses other than manufacturers, packers and caterers. While the principal burden of compliance will lie with the business types identified, other food businesses may need to ensure that suppliers comply with the Regulations.	Noted and to be considered in planned guidance accompanying the regulations.

3) Whether our estimates (outlined in Table 3 of the IA) of familiarisation costs to industry and our assumption that it will take businesses up to one hour to familiarise themselves with the requirements of the EU Regulations and one hour to disseminate to other members of staff (two hours in total) is reasonable.

Respondent	Comment	Response
Coeliac UK	An hour spent reading a guidance document is likely to be sufficient to provide the information needed to be able to meet the requirements, but without this an hour would not be sufficient.	Noted.

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Food and Drink Federation	The familiarisation costs to industry seem fairly reasonable, however would suggest that it could be closer to three hours of familiarisation time for smaller FBOs.	We intend to work with stakeholders on issuing guidance.
Premier Foods	If the Regulation was accompanied by official guidance then the estimates would be appropriate.	Noted.
The British Hospitality Association	We agree that the attached Impact Assessment adequately captures the UK market.	Noted.
Pret	The level of training will be high across the supply chain, and therefore costs and time would be greater.	We intend to work with stakeholders on issuing guidance, which will aim to assist in this regard.
The British Sandwich Association	This appears reasonable.	Noted.
London Borough of Hackney	No comments.	Noted.

4) Whether our estimates of familiarisation costs (outlined in Table 3 of the IA) to enforcement bodies and our assumption that it will take enforcement bodies one hour to familiarise themselves with the requirements of the EU Regulations, and one hour to disseminate to other members of staff (two hours in total) is reasonable.

Respondent	Comment	Response
Coeliac UK	No comments.	Noted.

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Food and Drink Federation	FDF is not best placed to comment on the familiarisation costs to enforcement. A priority for enforcement however, relating to dissemination, should be for collaborative working so that a consistent UK enforcement approach is taken. This includes clear guidance to promote compliance and reduce food waste.	Noted.
Premier Foods	Premier Foods not best positioned to comment.	Noted.
The British Hospitality Association	The cost estimates are reasonable but an understanding of the new regulations should be had by all UK companies in order to ensure compliance.	Noted.
Pret	Not able to comment.	Noted.
The British Sandwich Association	Seems appropriate.	Noted.
London Borough of Hackney	The estimated time for familiarisation and dissemination is within reason. But the estimated cost of £13,600 would appear to be wrong based on the figures provided. The costs should be £39.76 per local authority multiplied by 354 = £14,075.04.	The £13,600 figure is equivalent to the £14,075 figure, once it has been discounted to transform it into a 2015 base year figure.

5) Whether our assumption that there will not be a significant impact on small businesses as a result of the legislation is correct?

Respondent	Comment	Response
Coeliac UK	No comments.	Noted.

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Food and Drink Federation	FDF members would agree that the legislation would not amount to a significant impact. The changes to the use of ‘no gluten containing ingredients’, and similar factual statements, have been managed in England following recent FSA advice.	Noted.
Premier Foods	Premier Foods not best positioned to comment but believe SME, who have limited access to technical advice, many struggle.	We intend to work with stakeholders on issuing guidance.
British Hospitality Association	Agree there would be no significant impact on small businesses.	Noted.
Pret	Small businesses are likely to be significantly impacted, particularly where there is low interaction with enforcement ordinarily.	We intend to work with stakeholders on issuing guidance.
The British Sandwich Association	There may be a significant increase in swabbing by smaller manufacturers that could make the cost of producing these products prohibitive, thus reduce the number of choices available to those with some intolerance.	We would hope the gluten measures lead to safer food options for people with coeliac disease. The gluten-free sector is also a growing market and we are aware of many businesses – big and small – who are innovating and adapting to recent changes in allergens laws.
London Borough of Hackney	There would be limited impact on SMEs, and the transitional arrangements for products labelled with ‘no gluten containing ingredients’ also help businesses adapt to the change.	Noted.

6) Are you aware of any other impacts under the Specific Impact Tests as a result of the EU Regulations and the proposed

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Regulations? Please provide evidence to support your response.

Respondent	Comment	Response
Coeliac UK	No.	Noted.
Food and Drink Federation	No.	Noted.
Premier Foods	No.	Noted.
Pret	No.	Noted.
The British Sandwich Association	No.	Noted.
London Borough of Hackney	No.	Noted.

OTHER COMMENTS:

Respondent	Comment	Response
Coeliac UK	Clear and accessible guidance should be available for the industry on the options for signposting in line with Regulation (EU) No. 828/2014. Businesses should be made aware of when it is appropriate to label gluten-free.	Noted.

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British Beer and Pubs Association	BBPA is broadly supportive of the approach proposed by the FSA. However, they would like clarity on enforcement measures, and have some concerns around consistency in UK enforcement and differences in the labelling of gluten-free foods and those suitable for people with other gluten intolerances.	Noted. We intend to work with stakeholders on issuing guidance.
Sam Jennings, Berry Ottaway & Associates	Supportive of the proposed enforcement measures.	Noted.
Roger and Shirley	The FSA should advise on which method should be used for sampling foods when testing for gluten.	Noted. We intend to work with stakeholders on issuing guidance.
Amy Palmer, SureFoot Solutions Ltd	Some concerns around what labelling terms can be used, especially for specialist products. The consultancy have helped the businesses review their systems, provided training and conducted sampling, yet the concern remains that using “gluten-free” could be misleading.	We aim to address these points in further guidance, in collaboration with key stakeholders. .
Alex Lisle, Regulatory Delivery Division, Food Standard Agency	Questions the impact on the Food Hygiene Rating Scheme, especially if environmental health officers will be involved in enforcing the legislation.	We will try to clarify enforcement measures and hold further discussions within the FSA on these points.

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<p>Keith Bond, Gluten Free Food Products Limited</p>	<p>Raised some questions in relation to when gluten-free or very low gluten can be used</p>	<p>“Gluten-free” and “very low gluten” should take into account any possible gluten cross-contamination. The amount of gluten present must be within the specific levels if these claims are being used. This relates to prepacked and non-prepacked foods, and all types of labelling information. This information can be written or, where prepacked products are involved, verbal.</p> <p>Relevant advice can be found on the FSA’s website at: https://www.food.gov.uk/business-industry/allergy-guide/labelling-of-gluten-free-foods</p> <p>The FSA’s Safer Food Better Business Pack provides advice on controlling cross-contamination: https://www.food.gov.uk/business-industry/caterers/sfbb/sfbbcaterers</p>
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<p>Kate Jackson katejackson.accountant@hotmail.co.uk</p>	<p>Believes food outlets should be allowed to describe their food in writing as "prepared without gluten" and verbally as "gluten free" (we all use this shorthand, therefore it should not be prohibited) based on certain conditions.</p> <p>Very low gluten is intended to be used for gluten reduced grains, where the overall final level of gluten is 20-100ppm. In practice, it seems to be more widely used by chain restaurants to disclaim responsibility if their kitchen practices cause a customer to become ill. This should not be encouraged.</p>	<p>The EU regulations are very specific on when “gluten-free” statements can be used. We intend to work with stakeholders on issuing guidance.</p> <p>We agree with the point about “very low gluten” and fully take on board.</p>
<p>London Borough of Hackney</p>	<p>An earlier implementation would have provided the public health and consumer choice benefits for coeliacs and persons intolerant to gluten. Earlier implementation could also have coincided with the implementation of the nutritional labelling requirements of Regulation 1169/2011 so that manufacturers and packers could have made one change to labelling.</p> <p>It would be useful to have guidance on the circumstances in which the description “gluten-free” could be used.</p>	<p>Noted.</p>

SUMMARY OF CHANGES MADE:

Comment	Response

*SUMMARY OF SUBSTANTIVE COMMENTS TO THE FSA CONSULTATION – **GLUTEN IN FOOD (INFORMATION FOR CONSUMERS) (ENGLAND) REGULATIONS 2017***

ACTIONS TO BE IMPLEMENTED:

- The FSA to work with key stakeholders on guidance for businesses and food enforcement bodies on the proposed regulations.
- The FSA to have further discussions within the FSA on relevant enforcement arrangements.
- Amy Palmer (Surefoot Solutions Ltd) to be included in the interested parties list in the future
- Coeliac UK to be included in any further consultation on this topic.

List of Respondents:

1.	Coeliac UK	32.	66.
2.	Food and Drinks Federation	33.	67.
3.	Premier Foods	34.	68.
4.	British Hospitality Association	35.	69.
5.	Pret	36.	70.
6.	The British Sandwich Association	37.	71.
7.	London Borough of Hackney	38.	72.
8.	Sam Jennings - Berry Ottaway & Associates	39.	73.
9.	Roger and Shirley	40.	74.
10.	Amy Palmer - Surefoot Solutions	41.	75.
11.	Alex Lisle – Food Standards Agency	42.	76.
12.	Keith Bond - Gluten Free Food Production Limited	43.	77.
13.	Sandy Cox - RMS Health Safety Consultancy	44.	78.
14.	Kate Jackson	45.	79.
15.		46.	80.
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17.		48.	82.
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24.		55.	89.
25.		56.	90.
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27.		58.	92.
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29.		60.	94.
30.		61.	95.
31.		62.	96.
		63.	97.
		64.	98.
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List of Respondents:

100.