CONSULTATION DOCUMENT

Title: GLUTEN IN FOOD (INFORMATION FOR CONSUMERS) (ENGLAND) REGULATIONS 2017

CONSULTATION SUMMARY PAGE

Date launched:	24 NOVEMBER 2016	Closing date:	22 DECEMBER 2016

Who will this consultation be of most interest to?

Manufacturers, consumer organisations and food business operators involved in the placing on the market of gluten-free foods including importers, distributors, wholesalers and retailers, plus enforcement authorities.

What is the subject of this consultation?

The proposed Gluten in Food (Information for Consumers) (England) Regulations 2017,(the "proposed Regulations") provide for the execution and enforcement of the Commission Implementing Regulation (EU) No. 828/2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food.

What is the purpose of this consultation?

To provide interested parties with the opportunity to comment on, 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.

Responses to this consultation should be sent to:

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Division/Branch: Directorate Support Unit

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Impact Assessment included?	Yes ☒	No ☐ See Annex A for reason.

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

DETAIL OF CONSULTATION

1. We would welcome your comments on the proposed Gluten in Food (Information for Consumers) (England) Regulations 2017 ("the proposed Regulations") attached at Annex B. The proposed Regulations will provide for the execution and enforcement of the Commission Implementing Regulation (EU) No. 828/2014[1] ("the new EU Regulation") on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food. The new EU Regulation makes new provision on how labelling information should be worded for "gluten-free" and "very low gluten" foods.

2. We would particularly welcome your comments and supporting evidence in respect of any cost implications that arise from change in labelling of products from these proposals as indicated in the Impact Assessment at Annex C.

3. The new EU Regulation was published in the Official Journal (OJ) of the European Union on 31 July 2014 and came into force in force on 20 July 2016. The new EU Regulation is available to download free of charge from the EUR-Lex website at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0828

Background

4. Specific rules on gluten labelling are now governed by general food labelling requirements under the EU Food Information for Consumers Regulation (Regulation (EU) No 1169/2011)[2] specifically by a Commission Implementing Regulation made under Article 36 (3) rather than in the separate (EC) 41/2009[3] Regulation on foodstuffs intended for particular nutritional uses.

5. On 20 July 2016, the EU legislation on foods for particular nutritional uses (PARNUTS) was also revoked and replaced by Regulation (EU) No 609/2013[4] on foods for specific groups (FSG). The FSG covers a much narrower range of foods than the previous PARNUTS approach hence the change mentioned above. The Foodstuffs Suitable for People Intolerant to Gluten Regulations 2010 which implemented the previous gluten rules will be revoked by the proposed Regulations.

6. Food businesses can voluntarily label foods "gluten-free" or "very low gluten" for the benefit of consumers who wish to avoid gluten for medical reasons, such as coeliac disease. As such, the intention is to continue to ensure effective standardisation of the claims around gluten. This will help to ensure consumers are not misled or confused about gluten claims, and consumers (in particular people with coeliac disease) can have continued confidence that the foods they eat are suitable for their health needs. Another impact of the new EU Regulation is that foods suitable for those with coeliac disease or intolerance to gluten can only use the claims "gluten free" or "very low gluten" (together with prescribed supporting information); other descriptive phrases are not permitted.

7. In Wales, Scotland and Northern Ireland, there are separate domestic regulations which recently came into effect following consultation; these reflect the requirements of the EU gluten rules.

[11] OJ L 228, 31.7.2014 pg 5
[2] Ref OJ L 304, 22.11.2011, p.g. 18
[3] Commission Regulation (EC) No. 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.; OJ L 16, 21.1.2009, p.g. 3
[4] Ref OJ L 181, 29.6.2013, p.g. 35

Impact on businesses and authorities

8. The proposed Regulations enforce, in England, the EU gluten labelling rules for food businesses. Failure to properly label foods can carry serious public health implications for those with coeliac disease and intolerance to gluten. Until the proposed Regulations take effect, the FSA advises authorised food officers of interim measures they can use in respect of businesses which fail to comply with the EU gluten labelling rules. This involves using requirements under General Food Law (Regulation (EC) No. 178/ 2002) in taking action against businesses after continued breaches of the gluten rules. This also includes the option of bringing criminal proceedings under regulation 19 of the Food Safety and Hygiene (England) Regulations 2013, where a food business operator has misled a consumer. In less serious cases we would support a less formal and graduated enforcement approach being taken.

9. The EU Regulations provide clearer gluten labelling rules for businesses and greater consistency of labelling for consumers, benefitting those with coeliac disease (public health benefits).

10. The way in which businesses produce “gluten-free” or “very low gluten” options for consumers has not changed and the legal limits relating to the composition of such foods remain the same. What have changed are the rules relating to what can be used on labelling and this is covered in Regulation (EU) No 828/ 2014.

11. Another impact of the new EU Regulation is that foods suitable for those with coeliac disease or intolerance to gluten can only use the claims “gluten free” or “very low gluten” (together with prescribed supporting information); other descriptive phrases are not permitted.

12. Other than the familiarisation costs mentioned in the Impact Assessment, the burden on enforcement authorities is likely to be minimal / medium, if not negligible, in ensuring correct “gluten-free” labelling standards are followed by businesses.

Compliance Notices

13. The proposed Regulations introduce the use of compliance notices for failing to comply with the provisions of the new EU Regulation for gluten labelling. However, if a business fails to comply with the compliance notice, a ‘backstop’ criminal offence would apply, which is a penalty on summary conviction to a fine. Subject to any applicable sentencing guidelines, the amount of the fine will be decided by the convicting court in light of all the circumstances. In addition, as in the past, the option of applying ‘frontline’ criminal penalties to businesses who fail to meet the gluten labelling standards remains.

Purpose of the Consultation

14. A 4 week consultation is being launched to provide interested parties with the opportunity to comment and express their opinion on the content of the proposed Regulations or draft Statutory Instrument at Annex B, and also to comment and express their opinion on the proposed evidence in respect of any cost implications that may arise from these proposals as indicated in the draft Impact Assessment (IA) at Annex C.

15. We would particularly welcome responses to the following questions along with any evidence that you can provide to support your views:

Stakeholder comments are invited on:

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?

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.

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 identify the number of firms affected, their location, and ideally, firm size in terms of number of employees.

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.

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.

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

6) Are you aware of any other impacts under the Specific Impact Tests as a result of the EU Regulations and the proposed Regulations? Please provide evidence to support your response.

16. Responses are required by close of business on **Thursday 22 December 2016**. Please state, in your response whether you are responding as a private individual or on behalf of an organisation / company (including details of any stakeholders your organisation represents.

Other Comments

17. Any comments that interested parties are able to provide in relation to the proposed Regulations would be gratefully received. We are particularly keen to hear from Small and Medium Enterprises on a likely impact and would encourage them to comment on all aspects of this proposal.

18. Following the consultation, we will review the responses received and consider whether any changes are required to the proposed Regulations. A summary of all comments received will be published on the FSA's website within 3 months following the end of the consultation period.

Other relevant documents

19. Commission Implementing Regulation (EU) No. 828/ 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food is available from the EUR-Lex website at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0828&from=EN

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

Nasreen Shah
Regulatory Officer
Joint Head, Corporate Support Unit

Enclosed

Annex A: Standard Consultation Information
Annex B: Draft Statuary Instrument/ The proposed Regulations
Annex C: Impact Assessment
Annex D: List of interested parties

ANNEX A

Publication of personal data and confidentiality of responses

1. In accordance with the FSA principle of openness we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the FSA Consultation Coordinator (020 7276 8308). The FSA will publish a summary of responses, which may include your full name.

2. Disclosure of any other personal data would be made only upon request for the full consultation responses. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex D. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please contact us if you require this consultation in an alternative format such as Braille or large print.

7. This consultation has been prepared in accordance with HM Government consultation principles[5].

[5] http://www.bis.gov.uk/policies/bre/consultation-guidance

ANNEX B

S T A T U T O R Y I N S T R U M E N T S

2017 No. 0000

FOOD, ENGLAND

Gluten in Food (Information for Consumers) (England) Regulations 2017

Made - - - -	*2017*
Laid before Parliament	*2017*
Coming into force - -	*2017*

The Secretary of State makes the following Regulations in exercise of the powers conferred on the Secretary of State by section 2(2) of the European Communities Act 1972([6]).

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink) including the primary production of food([7]) and measures in the veterinary and phytosanitary fields for the protection of public health([8]).

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety([9]), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Citation and commencement

1. These Regulations may be cited as the Gluten in Food (Information for Consumers) (England) Regulations 2017 and come into force on [xxxxx] 2017.

Interpretation

2.—(1) In these Regulations—

"the Act" means the Food Safety Act 1990([10]);

"authorised officer" means any person (whether or not an officer of the authority) who is authorised by a food authority in writing, either generally or specially, to act in matters arising under these Regulations and Regulation (EU) No 828/2014;

"food authority" has the same meaning as set out in section 5(1) of the Act([11]) except that it does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and Middle Temple);

([6]) 1972 c. 68.
([7]) S.I. 2003/2901.
([8]) S.I. 1999/2027.
([9]) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 652/2014 of the European Parliament and of the Council laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ No. L189, 27.6.2014, p.1).
([10]) 1990 c. 16.

"Regulation (EU) No 828/2014" means Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food;

"specified provision" means any provision of Regulation (EU) No 828/2014 that is specified in column 1 of the Schedule and whose subject matter is described in column 2 of the Schedule.

(2) Any expression used both in these Regulations and Regulation (EU) No 828/2014 has the meaning that it bears in Regulation (EU) No 828/2014.

Offences and penalties

3.—(1) [Any person who contravenes any of the specified provisions is guilty of an offence.]

(2) Any person who fails to comply with a compliance notice served on them under regulation 5 is guilty of an offence.

(3) A person guilty of an offence under this regulation is liable on summary conviction to a fine.

Enforcement

4. It is the duty of a food authority within its area to enforce [these Regulations and] Regulation (EU) No 828/2014.

Compliance notices

5.—(1) If an authorised officer has reasonable grounds for believing that any person has not complied with, is not complying with or is not likely to comply with any of the specified provisions, the officer may serve a compliance notice on that person.

(2) A compliance notice must state —

(a) the reason for the service of the notice and the steps the person on whom the notice has been served must take;

(b) the date and, if appropriate the time, by which each step must be taken;

(c) that a failure to comply with the notice is an offence; and

(d) the details of the right to appeal against the notice.

(3) An authorised officer may serve a notice on a person withdrawing, varying or suspending a compliance notice.

Appeal against a compliance notice

6.—(1) Any person served with a compliance notice may appeal against that notice to a magistrates' court.

(2) The procedure on appeal to a magistrates' court shall be by way of complaint for an order, and the Magistrates' Courts Act 1980 shall apply to the proceedings.

(3) The period within which an appeal may be brought shall be one month from the date on which the compliance notice was served on the person wishing to appeal and the making of a complaint for an order shall be deemed for the purposes of this paragraph to be the making of the appeal.

(4) A compliance notice is not suspended pending an appeal unless —

(a) an authorised officer suspends it under regulation 5(3); or

(b) the court directs that it be suspended.

(5) The court may —

(a) confirm the notice or any requirement contained in it;

(b) vary the notice or any requirement contained in it; or

(c) revoke the notice or any requirement contained in it.

Application of various provisions of the Act

7.—(1) The following provisions of the Act apply for the purpose of these Regulations with the modification that any reference in those provisions to the Act or Part of it is to be construed as a reference to these Regulations—

(a) Section 44 (protection of officers acting in good faith); and

(b) section 49 (form and authentication of documents).

(2) Section 9 of the Act (inspection and seizure of suspected food) applies for the purposes of these Regulations as if it read as follows—

"**9.**—(1) This section applies where it appears to an authorised officer of a food authority that Regulation (EU) No 828/2014 is being, or has been, contravened in relation to any food intended for supply to consumers.

([11]) Section 5 of the Act was amended by paragraph 16(1) of Schedule 9 to the Local Government (Wales) Act 1994 (c. 19), paragraph 163(2) of Schedule 13 to the Local Government etc (Scotland) Act 1994 (c. 39), paragraphs 7, 8 and 9 of Schedule 5 to the Food Standards Act 1999 (c. 28), Part 1 of Schedule 3 to the Public Health etc (Scotland) Act (asp 5).

(2) The authorised officer may—

(a) give notice that, until the notice is withdrawn—

(i) the food, or any specified portion of it, is not to be used for human consumption; and

(ii) the food, or any specified portion of it, and any related food information, or any specified part of it, is not to be removed (or is not to be removed except to some place specified in the notice); or

(b) seize the food and remove it in order to have it dealt with by a justice of the peace.

(3) Notice under subsection (2)(a) above is to be given to—

(a) the person in charge of the food; and

(b) the owner of the food (where not the person in charge of the food).

(4) Notice need not be given in pursuance of subsection (3)(b) above if the authorised officer, after making reasonable inquiries, does not know who owns the food.

(5) An authorised officer who gives a notice under subsection (2)(a) above must, as soon as is reasonably practicable and in any event within 21 days, determine whether or not Regulation (EU) No 828/2014 has been contravened in relation to the food in respect of which the notice was given.

(6) After making a determination under subsection (5) above, the authorised officer must—

(a) if satisfied that Regulation (EU) No 828/2014 has not been contravened, forthwith withdraw the notice; or

(b) if not so satisfied, seize the food and remove it in order to have it dealt with by a justice of the peace.

(7) An authorised officer who seizes and removes food under subsection (2)(b) or (6)(b) above may also—

(a) copy, make extracts of or take away any food information relating to the food that has been seized;

(b) where any such food information is in electronic form, require the information to be produced in a legible form in which it may be copied or taken away.

(8) An authorised officer who seizes and removes food under subsection (2)(b) or (6)(b) above must inform the person in charge of the food and the owner of the food (where not the person in charge of the food) of the officer's intention to have it dealt with by a justice of the peace.

(9) The owner of the food need not be informed in pursuance of subsection (8) above if the authorised officer, after making reasonable inquiries, does not know who owns the food.

(10) Any person who might be liable to a prosecution for contravening food information law in relation to any food seized and removed under subsection (2)(b) or (6)(b) above is, if the person attends before the justice of the peace by whom the food falls to be dealt with, entitled to be heard and to call witnesses.

(11) If it appears to the justice of the peace that Regulation (EU) No 828/2014 has been contravened in relation to any food seized and removed under subsection (2)(b) or (6)(b) above, the justice of the peace may make such order as the justice considers appropriate in respect of the food and any food information relating to it.

(12) An order made under subsection (11) above may, in particular, order—

(a) that the food be destroyed or otherwise disposed of so as to prevent it from being used for human consumption;

(b) that any food information relating to the food be modified, destroyed or otherwise disposed of;

(c) that any food which is fit for human consumption (and any related food information, modified as the justice considers appropriate) be—

(i) returned to the person who was in charge of the food; or

(ii) distributed to such other person as the justice may determine.

(13) An order made under subsection (11) above—

(a) must, where the owner of the food is known, require the owner to meet any expenses reasonably incurred in connection with any destruction, modification, disposal, return or distribution of any food or food information which is carried out in pursuance of the order; and

(b) may require the owner of the food to meet any expenses reasonably incurred by the food authority in connection with any action taken by the authorised officer, or otherwise by or on behalf of the authority, in respect of any food or food information to which the order relates.

(14) Subsection (15) below applies if—

(a) a notice under subsection (2)(a) above is withdrawn; or

(b) the justice refuses to make an order under subsection (11) above in respect of any food seized and removed under subsection (2)(b) or (6)(b) above (or any food information which relates to it).

(15) Where this subsection applies, the food authority must compensate the owner of the food for any depreciation in its value resulting from the action taken by the authorised officer.

(16) Any disputed question as to the right to or the amount of any compensation payable under subsection (15) above is to be submitted to arbitration for resolution."

Revocation

8. The Foodstuffs Suitable for People Intolerant to Gluten (England) Regulations 2010([12]) are revoked.

Review

9.—(1) The Secretary of State [Food Standards Agency] must from time to time—

(a) carry out a review of the operation and effect of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory provisions made by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(3) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(4) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Signed by authority of the Secretary of State for Health

Name
Parliamentary Under Secretary of State
Department of Health

Date

THE SCHEDULE

Column 1	*Column 2*
Article 3 (1) as read with Article 3 (2) and Article 3 (3).	Requirement that where statements are used to provide information to consumers on the absence or reduced presence of gluten in food, such information shall be given only through the statements and in accordance with the conditions set out in the Annex.
Article 4.	Prohibition of the provision of food information on the absence or reduced presence of gluten in infant formulae and follow-on formulae as defined in Directive 2006/141/EC.

EXPLANATORY NOTE

(This note is not part of the Regulations)

([12]) S.I. 2010/2281.

ANNEX C

Title: The Proposed Gluten in Food (Information for Consumers) (England) Regulations 2017 **IA No: FOOD0159** **Lead department or agency:** **Food Standards Agency** **Other departments or agencies:**	Impact Assessment (IA) **Date: November 2016** **Stage: Consultation** **Source of intervention: EU** **Type of measure: Secondary legislation** **Contact for enquiries: Nasreen Shah, Tel: 020 7276 8538,** Nasreen.shah@foodstandards.gsi.gov.uk

1.Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
£m	£m	£m	Yes/No	In/Out/zero net cost

What is the problem under consideration? Why is government intervention necessary?

Approximately 1% of the UK population suffers from coeliac disease (a condition caused by intolerance to gluten) and it is estimated nearly half a million people are undiagnosed with coeliac disease[13]. People with coeliac disease must avoid the dietary intake of cereals containing gluten. The number of food producers making "gluten-free" and similar claims is also increasing rapidly, to fulfil this need, and there is inconsistency in how these claims are being made. This can be misleading for consumers and cause serious health problems for those with intolerance to gluten, as well as consumers being overcharged for products believed to be "gluten-free". Furthermore, in extreme cases reputable suppliers of gluten-free foods may be deterred from entering the market while other producers benefit from charging a premium for mislabelled products. Government intervention is necessary in England to effectively enforce Commission Implementing Regulation (EU) No 828/2014 ("the new EU Regulation") on "gluten-free" foods to ensure consistency of information for consumers and adequate health protection for people with gluten intolerance.

What are the policy objectives and the intended effects?

The statutory objective is to protect public health regarding food and consumers' interests relating to food. To make domestic legislation (a statutory instrument) to enable the execution and enforcement of the new EU Regulation on gluten-free foods. This will promote consistency in the labelling of "gluten-free" foods and adequate health protection for consumers with gluten intolerance.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: – Do Nothing: do not enforce the new EU Regulation.

Option 2: - Introduce national legislation to enforce the new EU Regulation. This is the preferred option (More detailed information on the 2 Options is in the Evidence Base in the Impact Assessment)

Will the policy be reviewed? It **will/will not** be reviewed. **If applicable, set review date: Month/Year**

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro Yes**	**< 20** Yes	**Small Yes**	**Medium Yes**	**Large Yes**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: ..... Date: .....

[13] Stats from the Coeliac UK website: https://www.coeliac.org.uk/coeliac-disease/coeliac-disease-faqs/

2.Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing: do not enforce the new EU Regulation.

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2015	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0.0	High: 0.0	Best Estimate: 0.0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0.0			0.0

Description and scale of key monetised costs by 'main affected groups'

This is the baseline option against which other options are compared.

Other key non-monetised costs by 'main affected groups'

The government could face an infraction penalty from the EU.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

This is the baseline option against which other options are compared.

Other key non-monetised benefits by 'main affected groups'

This is the baseline option against which other options are compared.

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

Maximum of 5 lines

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	Yes/No	IN/OUT/Zero net cost

3.Summary: Analysis & Evidence

Policy Option 2

Description: Option 2: Introduce national legislation to enforce the new EU Regulation.

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2015	Time Period Years: -10	Net Benefit (Present Value (PV)) (£m)		
			Low: -0.09	High: -0.09	Best Estimate: -0.09

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0.0		0.0	**0.0**
High	0.0		0.0	**0.0**
Best Estimate	0.1		0.0	**0.1**

Description and scale of key monetised costs by 'main affected groups'

Familiarisation costs to industry: £77k (net present value)
Familiarisation costs to local authorities: £13.6k (net present value)

Other key non-monetised costs by 'main affected groups'

Maximum of 5 lines

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

Maximum of 5 lines

Other key non-monetised benefits by 'main affected groups'

The government would not face infraction costs from the EU

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

It is assumed that any labelling costs will be incorporated into the usual cycle of changing labels for other commercial reasons (as opposed to changing labels.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0.0	**Benefits: 0.0**	**Net: 0.0**	No	NA

4. Evidence Base (for summary sheets)

Problem under consideration and rationale for intervention

1. Approximately 1% of the UK population suffers from intolerance to gluten and they must avoid the dietary intake of cereals containing gluten. The numbers of food producers making "gluten-free" and similar claims are increasing rapidly, to fulfil this need. However the levels of gluten in these products may vary considerably, which can mislead consumers and cause serious health problems for those with intolerance to gluten. As such, there is inconsistency in how "gluten-free" claims are made and there is some potential of consumers being misled and overcharged for products believed to be "gluten-free". Moreover, in extreme cases good suppliers may be deterred from entering the market as other producers benefit from charging a premium for mislabelled products.

2. Commission Implementing Regulation (EU) No. 828/2014[1] (the "new EU Regulation") was published in the Official Journal (OJ)[2] of the EU on 31 July 2014, and has applied from 20 July 2016. Government intervention is necessary to provide for the execution and enforcement of the new EU Regulation in England, to ensure consistency of information for consumers and to help secure adequate health protection for consumers with gluten intolerance especially coeliac disease.

Policy objective

3. The statutory objective is to protect public health in relation to food and consumers' other interests in relation to food.

4. To make domestic legislation (a statutory instrument) to enable the execution and enforcement of the new EU Regulation in England. This will allow for consistency in the labelling of "gluten-free" foods, and health protection for consumers with gluten intolerance.

5. The proposed Gluten in Food (Information for Consumers) (England) Regulations 2017 (the "proposed Regulations") provides for enforcement of the new EU Regulation. The way in which businesses produce "gluten-free" or "very low gluten" options for consumers has not changed and the legal limits relating to the composition of these foods remain the same as those which applied prior to the new EU Regulation coming into force. The main change made by the new EU Regulation is the new wording which must be used on labelling.

Background

6. Specific rules on gluten labelling are now governed by general food labelling requirements under the EU Food Information for Consumers Regulation (Regulation (EU) No 1169/2011)[3] specifically by a Commission Implementing Regulation made under Article 36 (3) rather than in the separate (EC) 41/2009[4] Regulation on foodstuffs intended for particular nutritional uses.

7. On 20 July 2016, the EU legislation on foods for particular nutritional uses (PARNUTS) was also revoked and replaced by Regulation (EU) No 609/2013[5] on foods for specific groups (FSG). The FSG covers a much narrower range of foods than the previous PARNUTS approach hence the change mentioned above. The Foodstuffs Suitable for People Intolerant to Gluten Regulations 2010 which enforced the previous gluten rules will be revoked by the proposed Regulations.

8. Food businesses can voluntarily label foods "gluten-free" or "very low gluten" for the benefit of consumers who wish to avoid gluten for medical reasons, such as coeliac disease. The intention is to continue to ensure effective standardisation of the claims around gluten. This will help to ensure consumers are not misled or confused about gluten claims, and consumers (in particular people with coeliac disease) can have continued confidence that the foods they eat are suitable for their health needs. Another impact of the changes is that foods suitable for those with coeliac disease or intolerance to gluten can only use the claims "gluten free" or "very low gluten" (together with prescribed supporting information) and no additional descriptive phrases are permitted.

Regional coverage

9. In Wales, Scotland and Northern Ireland, there are separate domestic regulations which recently came into effect following consultation; these reflect the requirements of the EU gluten rules.

[1] Commission Implementation Regulation (EU) No. 828/2014, of 31 July 2014 on the requirement for the provision of information to consumers on the absence or reduced presence of gluten in food
[2] Ref OJ L 228, 31.7.2014, p.g. 5
[3] Ref OJ L 304, 22.11.2011, p.g. 18
[4] Commission Regulation (EC) No. 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.; OJ L 16, 21.1.2009, p.g. 3
[5] Ref OJ L 181, 29.6.2013, p.g. 35

Compliance Notices

10. The proposed Regulations introduce the use of compliance notices for failing to comply with the provisions of the new EU Regulation. However, if a business fails to comply with the compliance notice, a 'backstop' criminal offence would apply, which is a penalty on summary conviction to a fine. Subject to any applicable sentencing guidelines, the amount of the fine will be determined by the convicting court based on all the circumstances. In addition, as in the past, the option of applying 'frontline' criminal penalties to businesses who fail to meet the gluten labelling standards remains.

Consultation Question

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?

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.

Economic intervention

11. In terms of the economic rationale for intervention in the "gluten-free" foods market is that there is inconsistency in the standards that are being applied. Food businesses have more information about implicated products than consumers, which can lead to adverse selection. This could mean that the seller effectively over charges consumers because the consumer is not aware of the true level of gluten in the product. This intervention will ensure that there is effective standardisation of gluten related claims, and consumers (in particular people with coeliac disease) have continued confidence about the foods they eat being suitable for their health needs. This will also help to ensure that affected consumers are not confused and / or misled.

Sectors and groups affected

12. The legislation will continue to affect consumers and health professionals, who will have a better understanding and will be well informed regarding the gluten content of foods. In particular, it will benefit around 600,000 gluten intolerance consumers in the UK (1% of population). Those manufacturers that produce and / or market foods that make voluntary claims about reduced gluten content (including caterers) will be affected by this legislation as will enforcement bodies.

13. The consumer charity Coeliac UK have informed the FSA that they are aware of 638 food businesses making a gluten-free claim on pre-packed foods. Moreover, in terms of caterers selling food loose, gluten-free information is used on a large proportion of menus. Coeliac UK is aware of 6,177 businesses that offer "gluten-free" food on their menus.

14. The regulatory change relates to England only. As such, IDBR ONS data on three sectors (manufacturers, restaurant/ catering and packaging) have been used to estimate the conversion rate of UK FBO numbers to England numbers (see table 1). A rate of overall rate of 84% has been used (see table 2)

Table 1

	UK	England
Manufacturers	7,985	6,380
Restaurant/ catering	118,470	98,975
Packaging	1,165	1,035
Total	**127,620**	**106,390**

Table 2

	UK	England (Estimate)
Number of food businesses making GF claim on pre-packed food	638	532
Number of caterers selling food loose, gluten-free (with menus)	6,177	5,149
Total affected FBOs in England (estimate)	6,815	5,681
	UK	England (Estimate)

Source: Coeliac UK, 2016

Consultation Question

2) Whether the Impact Assessment adequately captures the UK market? If not, please provide 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.

Stakeholder engagements

No Gluten Containing Ingredients

15. Another impact of the new EU Regulation is that individual items of foods suitable for those with coeliac disease or intolerance to gluten can only use the claims "gluten free" or "very low gluten" (together with supporting information). Other descriptive phrases such as "No gluten containing ingredients (NGCI)" can no longer be used. However, the FSA has engaged with affected businesses, consumers and food enforcement bodies in dealing with this change. The key points are:

    - For prepacked foods the use of NGCI is not be permitted on the labelling of a single product. It is however acceptable to describe a selection of products in a sales/product catalogue of foods provided by a wholesaler for example.
    - For non-prepacked foods, NGCI cannot be attributed to a single dish – for example "Cottage pie – No gluten containing ingredients". Nevertheless, we consider a section on NGCI choices on a menu to be permissible. We also consider it acceptable to use NGCI in menus titles provided that none of the items use gluten containing ingredients, such as *"No gluten containing ingredients menu*" or statements such as *"None of the dishes on this menu use gluten containing ingredients".*

16. The FSA ran an informal consultation with key stakeholders including some enforcement officers regarding the use of the phrase NGCI in July 2016. This resulted in the FSA issuing guidance and allowing food businesses in England until 20 February 2018 to change labels and menus which use the phrase NGCI. This is to help industry to work to a set deadline and enable the enforcement community to do checks more effectively. This also provides a level playing field for industry and enforcement officers to work, and help manage potential food waste, enable packaging and labelling changes and substantially reduce costs to food businesses.

Options considered

Option 1: Do Nothing: do not enforce the new EU Regulation.

17. This is the baseline against which the other option is considered. However, there are potential EU infraction penalty costs should this option be pursued.

18. Under this option the new EU Regulation will still be applicable in England, as it is already legally binding and applicable throughout the EU since its publication. However, enforcement authorities will not have the necessary powers to enable them to enforce the provisions of the new EU Regulation.

Option 2: Introduce national legislation to enforce the new EU Regulation.

19. This is the preferred option. This option would provide enforcement authorities with the necessary powers to provide for the execution and enforcement of the new EU Regulation.

20. Please note, the option of enforcing the new EU Regulation through Government guidance has been considered, but this was not seen as a realistic option as legal compulsion is necessary to ensure food safety standards are followed.

Option Appraisal

Costs and Benefits

Option 1: Do Nothing – Do not enforce the new EU Regulation.

21. There are no costs or benefits associated with this option as it is a baseline against which all other policy options are appraised. This means that there would be no specific rules relating to gluten labelling in England.

Option 2: Introduce national legislation to enforce the new EU Regulation.

22. This option will provide enforcement authorities with the necessary powers and administrative arrangements to execute and enforce the provisions of the new EU Regulation in England. This ensures that enforcement authorities fulfil the requirements placed upon them and that the courts can impose penalties that are in line with others elsewhere in food law.

Costs to Industry

Labelling change costs to industry (monetised)

23. The new EU Regulation may require some re-labelling of products or changes to menus in catering outlets and hence represent some direct costs to business.

24. Evidence from a Defra commissioned study (Campden BRI Study, 2010) suggests cost of £1,800 per stock keeping unit (SKU) for an assumed minor label change and £3,300 per SKU for a major label change[6,7].It is estimated that such re-labelling costs could be up to £1,800 per SKU. However, the transition period is two years (from adoption). This should allow such costs to be absorbed within routine label changes. [8]

25. The FSA has sought information from FBOs that would potentially face such labelling changes costs. Based on the feedback obtained, those relevant FBOs would change their labels within a two year period in any case for commercial reasons: they would incorporate the change in the business cycle for labelling changes. As such, no costs are expected.

26. As such, other than the one-off familiarisation costs mentioned below, the burden on industry is likely to be minimal / medium, if not negligible, in ensuring correct “gluten-free” labelling standards are followed by businesses**.**

Familiarisation costs to industry (monetised)

27. It is assumed that in each business one person will need to spend half an hour reading the guidance also half an hour disseminating the information. The 2014 ONS ASHE (Annual Survey of Hours and Earnings) gives the median gross hourly pay for ‘Managers and directors in retail and wholesale’ as £11.65. In line with the standard cost model, this is up-rated by 20%, to account for overheads, to give a figure of £13.98. For one person spending an hour for familiarisation and dissemination, the average cost per organisation is therefore estimated to be £13.98. The numbers of FBOs affected are estimated to be 5,681. This gives a cost to industry of approximately £77k (2014 prices, 2015 Net Present Value[9][NPV]).

28. In order for one-off costs and ongoing costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to ‘equivalently annualise’ costs (EACs) using a

[6] A stock keeping Unit is a products identification code that allows a product to be tracked for inventory purposes.
[7] Where ‘minor’ change relates only to text on a single face of the label and no packaging size modification is required to accommodate this; and ’major’ change relates to text as well as layout and/or colours and/or format and/or multiple faces are affected, or packaging size modification is required. Campden BRI Study (2010): http://archive.defra.gov.uk/evidence/economics/foodfarm/reports/documents/labelling-changes.pdf
[8] This estimation has been made in previous IAs and has not been challenged.{insert link}

[9] Net Present Value is the difference between the Present Value of a stream of costs and a stream of benefits.

standard formula[10]. Under Standard HMT Green book[11] guidance a discount rate of 3.5% is used. The total one-off familiarisation cost to FBOs in England under this proposal is approximately is £77k which yields an equivalent annual cost of £9k over a 10 year period.

Familiarisation costs to Local Authorities (monetised)

29. The cost to enforcers (local authorities) is estimated in the same way. It has been estimated that that there would be two EHOs and two TSO per local authority that would need to become familiarised with the changes. The median gross hourly wage rate for an 'Inspector of Standards' of £14.90 (AHSE 2014) is up-rated by 20% for overheads % to account for overheads in line with Standard Cost Model (SCM) methodology[12] to give a figure of £17.88 per hour. The median gross hourly wage rate for 'Environmental Health Professionals' is £18.23 (ASHE 2014). This is similarly uprated to a figure of £21.88. The expected time taken for familiarisation and dissemination is 30 minutes for one person, so the cost per enforcement body is £39.76. Given that there are 354 local authorities in England, this implies an estimated 708 EHOs and 708 TSOs will need to be familiarised. Hence, the total enforcement cost will be £13.6k. (2014 prices, 2015 Net Present Value[13][NPV]).

Table 3: Summary table of costs and benefits

COSTS	Yr 0	Yr1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Total	PV	Annual Average
Enforcement													
Local Authorities													
One-off Costs													
Learning and dissemination	£13,598	£0	£0	£0	£0	£0	£0	£0	£0	£0	£13,598	£13,598	£1,580
Total Cost: Local Authorities	**£13,598**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£13,598**	**£13,598**	**£1,580**
Industry													
One-off Costs													
Learning and dissemination	£76,739	£0	£0	£0	£0	£0	£0	£0	£0	£0	£76,739	£76,739	£8,915
Total Cost: Industry (central)	**£76,739**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£76,739**	**£76,739**	**£8,915**
Consumer													
Total Cost: Consumer	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**
Total Cost (central estimate)	**£90,336**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£0**	**£90,336**	**£90,336**	**£10,495**
SUMMARY OF TOTAL BENEFITS													
BENEFITS	Yr 0	Yr1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Total	PV	Annual Average
Total Benefit	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0
NET IMPACT	Yr 0	Yr1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Total	PV	EAC
Net Enforcement	-£13,598	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£13,598	-£13,598	-£1,580
Net Industry (central estimate)	-£76,739	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£76,739	-£76,739	-£8,915
Net Consumer	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0	£0
Net Society (central estimate)	-£90,336	£0	£0	£0	£0	£0	£0	£0	£0	£0	-£90,336	-£90,336	-£10,495

Consultation Question

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.

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.

[10] The annuity factor is essentially the sum of the discount factors across the time period over which the policy is appraised. The equivalent annual cost formula is as follows:

$$a_{t,r} = \sum_{j=0}^{t-1} \prod_{i=0}^{j} \left(\frac{1}{1+r_i} \right)$$

[11] https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent
[12] SCM methodology http://www.berr.gov.uk/files/file44503.pdf
[13] Net Present Value is the difference between the Present Value of a stream of costs and a stream of benefits.

Health benefits to consumers (non-monetised)

30. The main benefit of option 2 is continued health protection for people with coeliac disease and intolerance to gluten. This is because they will be able to continue to make informed choices of products that are low in gluten and which are labelled appropriately.

Avoidance of infraction penalty UK government (non-monetised)

31. The government would avoid potential EU infraction costs.

Burdens on Industry FBOs

32. The cost to Industry is believed to be negligible, as familiarisation of the new EU Regulation and changing of labels are seen as routine and are anticipated.

Burdens on Enforcement

33. Other than the familiarisation costs mentioned above, the burden on enforcement authorities is likely to be minimal / if not negligible, in ensuring correct "gluten-free" standards are followed by businesses. To have greater success sooner would be necessary to have an extensive promotion campaign of awareness for SMEs food service and at home cooks. This could be burdensome on the FSA and LAs

Risks

34. There are no associated risks; gluten rules will become clearer and more consistent for businesses which will benefit consumers with coeliac disease who eat "gluten-free" products.

Consultation

Within Government

35. During the course of negotiations with the Commission, officials of the FSA have kept other government departments informed of its progress. These included; the Department of Health, the Department for Business Innovation and Skills, the Foreign and Commonwealth Office, the Cabinet Office and the Office of Fair Trading. To date no adverse comments have been received from any department.

Public Consultation

Formal Public Consultation

36. The FSA will conduct a formal public consultation from 24 November 2016. Manufacturers, consumer organisations and food business operators involved in the placing on the market of gluten-free foods including importers, distributors, wholesalers and retailers, plus enforcement authorities.

One In, Two Out Status

37. The proposed Regulations are out of scope of One-In-Two-Out, as the requirements are of EU origin and the do not introduce any gold plating. Identification of savings equivalent to twice the burden of the estimated costs to business is not therefore required.

Wider Impacts

Small & micro business assessment

38. The UK food industry sector is comprised of mainly small and micro businesses and therefore the greatest impact from changes in from the new EU Regulation introduced in the UK will, in the vast majority of cases, be on small and micro businesses. For this reason the FSA assesses the impact on small and micro businesses as standard when undertaking impact assessments.

39. EU legislation generally applies to food businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken. Due to the high ratio of small and micro food businesses in the UK it is often not feasible to exempt smaller businesses from new food measures as this would fail to achieve the intended effect of reducing risks to consumer health. That said, FSA makes every effort to minimise burdens on small and micro businesses and pays particular attention to impacts on them.

Consultation Question

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

Race/Gender/Disability Equality Issues

40. There will be no impacts on existing health, wellbeing or other social inequalities, on human rights, on levels of crime or crime prevention, or on skills and education. There will be no differential impact on rural or urban areas, nor any specific local or regional effects.

Consultation Question

6) Are you aware of any other impacts under the Specific Impact Tests as a result of the EU Regulations and the proposed Regulations? Please provide evidence to support your response.

ANNEX D

Acardia Group

Allergy Action

Allergy UK

Anaphylaxis UK

Better Regulation Delivery Office

Brakes

British Beer and Pubs Association

British Dietetic Association

British Hospitality Association

British Retail Consortium

Campden BRI

Care Quality Commission

Chartered Institute of Environmental Health

Children's Food Trust

Coeliac UK

Compass Group

Council for Responsible Nutrition UK

Debenhams

Department of Health

Department of Food, Environment and Rural Affairs

Droppa & Droppa Limited

Easy Jet

Food and Drink Federation

Food Aware

Food Solutions

Food Maestro

Gate Gourmet Group (airline caterers)

Greene King Pubs

Greggs

JD Wetherspoons

John Lewis

Just Eat

Kafoodle

Kent County Council

Marks and Spencer

Marston’s Inns & Taverns

Menuanalyser

National Care Association

Norfolk Council

Norfolk Council

Pepsico

Portsmouth University

Premier Foods

Pret

Proprietary Association of Great Britain

Provtrade

Reading Scientific Services Ltd

Sandwich Association

Sodexo

The European Snacks Association

The Institute of Food Safety, Integrity and Protection

The University Caterers Organisation

Trading Standards Institute

Wagamama

24 Vend

3663 Bidvest