Annex C

PARTIAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

The Food Information (Scotland) Amendment Regulations 2016

Date:	22 March 2016
Stage:	Consultation
Source of intervention:	EU
Type of measure:	Commission Implementing Regulation
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1. Title of Proposal

The Food Information (Scotland) Amendment Regulations 2016

2. Purpose and intended effect

- **Objectives**

The purpose of the draft Scottish Statutory Instrument (SSI) is to provide enforcement provisions in Scotland for Commission Implementing Regulation (EU) No 828/2014 to ensure the continued protection of consumers who are intolerant to gluten.

- **Background**

In January 2009, the European Commission published Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. The Regulation introduced compositional criteria for the claims:

- "gluten-free" (not more than 20 mg/kg of gluten) and
- "very low gluten" (not more than 100 mg/kg of gluten)

The latter claim only applies to foods which have been specifically manufactured to satisfy the particular nutritional requirements of people who are intolerant to gluten as provided for by Council Directive 2009/39/EC (the PARNUTS Directive). The Regulation also allows normal foods and other foods for particular nutritional uses (that are not specially prepared for people intolerant to gluten but meet the compositional requirements of the Regulation) to be labelled as "gluten-free".

Following a revision of the legislation on foodstuffs intended for particular nutritional uses, Regulation (EU) No 609/2013 of the European Parliament and of the Council will repeal Regulation (EC) No 41/2009 and Directive 2009/39/EC from 20 July 2016.

After that date, the provision of information on the absence or reduced presence of gluten in food should continue to be based on the relevant scientific data and must not be provided on a divergent basis which could mislead or confuse consumers, in accordance with the requirements laid down in Article 36 (2) of Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC). It is therefore necessary that uniform conditions for the application of these requirements to food information provided by food business operators (FBOs) on the absence or reduced presence of gluten in food are maintained across the EU and these conditions are contained in Commission Implementing Regulation (EU) No 828/2014.

Under Commission Regulation (EC) No 41/2009, businesses manufacturing or selling food were not prohibited from using a supplementary statement or symbol in conjunction with the claims "gluten-free‟ or "very low gluten‟, to reinforce the suitability of products for consumers who needed to avoid gluten in their diet. Guidance produced at the time by the Food Standards Agency suggested that the phrase "suitable for coeliacs" could be used for those foods claiming to be "gluten-free" whilst the supplementary term "suitable for most coeliacs" was recommended for those foods using the claim "very low gluten".

It was also decided that it would be possible for "normal foods" and other PARNUTS foods, to make factual statements either on the labels or on the menu/blackboard

about products which do not contain gluten-containing cereals as ingredients.

However, it was recommended that this was only appropriate for situations where gluten cross-contamination was controlled and minimised according to an established Hazard Analysis and Critical Control Point (HACCP) food safety management system.[1] Under these circumstances it was suggested that industry adopt a common approach to factual statements and the phrase "no gluten-containing ingredients" was to be used.

The gluten levels permitted by Regulation (EU) No 828/2014 for the terms "gluten free" and "very low gluten" are identical to those set previously in Regulation (EC) No 41/2009 as quoted above. However, Article 3 states that these terms may now be supported by the statements: "suitable for people intolerant to gluten" or "suitable for coeliacs".

Additionally, the supporting information "specifically formulated for people intolerant to gluten" or "specifically formulated for coeliacs" may be used if the food has been specially produced, prepared and/or processed to:
(a) reduce the gluten content of one or more gluten-containing ingredients; or
(b) substitute the gluten-containing ingredients with other ingredients free of gluten.

The phrase "no gluten-containing ingredients" can no longer be applied to "normal" foods.

- **Rationale for Government intervention**

Following the repeal of Regulation (EC) No 41/2009, the Foodstuffs Suitable for People Intolerant to Gluten (Scotland) Regulations 2010 will have no European backing. Thus to ensure continued protection of consumers who are intolerant to gluten, a new SSI is required to provide for the enforcement of Regulation (EU) No 828/2014.

3. Consultation

- **Within Government**

This consultation package regarding the proposed SSI was discussed with Scottish Government officials from the Health and Wellbeing Directorate and officials from the Food, Drink and Rural Communities Division.

- **Public Consultation**

A 7 week public consultation will be carried out in Scotland on the draft national legislation from 23 March to 16 May 2016.

- **Business**

A selection of Scottish businesses of different sizes and from various geographical areas will be approached during the public consultation period to ascertain the likely impact on their business of the proposed SSI.

[1] http://www.foodstandards.gov.scot/food-safety-standards/advice-business-and-industry/catering-retail#start

4. Options

Option 1 – Do nothing.

'Do nothing' is not an option that would be legally acceptable for the Scottish Government. Regulation (EU) No 828/2014 is directly applicable and legally binding in Scotland and the rest of the UK. Without an SSI, enforcement authorities in Scotland would not have the necessary powers to enforce the provisions of the EU Regulation; offences could not be prosecuted and penalties could not be imposed on those in breach of the Regulation. There would be no legal controls on the use of the claims "gluten free" and "very low gluten".

Under EU law, the UK is obliged to provide for the enforcement of EU legislation. Failure to do so may lead to the UK being liable to infraction proceedings and consequent fines. Scotland would be required to pay a percentage of any UK fine if the infraction related to a devolved matter.

Option 2 – Introduce domestic legislation to provide for the enforcement of Regulation (EU) No 828/2014 in Scotland.

This option requires FBOs to continue to label foods with gluten claims as they had been required to do under the Foodstuffs Suitable for People Intolerant to Gluten (Scotland) Regulations 2010.

Regulation (EU) No 828/2014 removes the control of reduced gluten labelling requirements from the PARNUTS legislative framework (which will be replaced by the expression Foods for Specific Groups) into the general labelling of Regulation (EU) No 1169/2011 (FIC). This will mean that gluten claims will be treated as normal foods and the enforcement of the EU rules on allergens, intolerances and gluten claims will be via the Food Information (Scotland) Regulations 2014 (as amended).

- **Sectors and groups affected**

  While these proposed Regulations apply to Scotland only, separate but similar Regulations will be introduced in England, Wales and Northern Ireland.

  Consumers – Since the proposals only affect the legislative framework and make no change to the actual labelling claims, consumers should see no difference in the the products they purchase and will not be affected.

  Enforcement Authorities – Responsibility for enforcement of the The Food Information (Scotland) Amendment Regulations 2016 will rest with Local Authorities. There would be one-off familiarisation cost to Local Authorities due to the need for Enforcement Officers to read and be aware of the new Regulations and the change to the legislative framework.

  Industry – Affected businesses are assumed to include manufacturers and retailers of food which makes claims regarding the gluten content of the product. These costs include:

  - One-off familiarisation costs to FBOs from senior managers having to be aware of the new Regulations and the change to the legislative framework.

- One-off costs to FBOs of re-labelling products to comply with the new Regulations. FBOs who only make claims for “gluten free” or “very low gluten” for their products should be unaffected. However, FBOs who use supplementary phrases in addition to the approved claims may need to amend their labels slightly. Additionally, manufacturers who claim their “normal” foods have “no gluten containing ingredients” will no longer be able to use this statement.

Small and Micro Business Assessment

We do not propose to seek a derogation for small and micro businesses from the need to provide voluntary information on the gluten content of foods in line with the European Regultion. Small businesses are defined as those with up to 49 full-time equivalent (FTE) employees. Micro businesses are types of small businesses with up to 10 FTE employees.

Since the FIC Regulation is directly applicable in all Member States, Scotland does not have the scope to put forward any alternatives to the legislation. Furthermore, an exemption for small and micro businesses would significantly reduce the likelihood of achieving the desired benefits of FIC, as a large portion of FBOs in Scotland are small and medium enterprises. Data in Table 1 indicates that small and micro businesses accounted for 96% of all FBOs in Scotland in 2011. We have assumed that these proportions will remain constant over the period considered in this BRIA. However, it is unclear what proportion of these FBOs will be affected by this regulation since not all FBOs will handle foods with gluten content claims as described in this BRIA.

	Micro	Small	Medium	Large	Total
Scotland	3,605	600	150	40	4,395
England	38,245	4,610	870	245	43,970
Wales	1,920	240	45	10	2,215
Northern Ireland	1,490	305	75	15	1,885
UK	**45,260**	**5,755**	**1,140**	**310**	**52,465**

Table 1: Food Business Operator manufacturer, retailer and wholesaler numbers operating in 2011, by country and firm size. Source: Bespoke analysis from 2011 ONS Business Demography publication data.

- **BENEFITS**

Option 1

Do nothing. There are no incremental benefits. This is the baseline against which other options are appraised.

If no action is taken, the existing Foodstuffs Suitable for People Intolerant to Gluten (Scotland) Regulations 2010 would have no EU legal basis after Regulation (EC) No 41/2009 is repealed by Regulation (EU) No 609/2013 from 20 July 2016.

Consumers

There are no consumer benefits with this option.

Industry

There would be no familiarisation costs to industry since there would be no new legislation to read. Presumably they would continue to label food products as they do now so incurring no relabelling costs.

Enforcement

There would be no familiarisation costs for Enforcement authorities since there would be no new legislation.

Option 2

The Food Information (Scotland) Amendment Regulations 2016 will permit the enforcement of 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.

Consumers

The needs of consumers with coeliac disease for accurate information on gluten content of foods would continue to be protected.

Industry

The move of gluten claims legislation from the PARNUTS legislative framework to that of general labelling means that manufacturers will no longer need to notify Food Standards Scotland (FSS) of their intention to market foods which make claims regarding their gluten content.

Enforcement

There are no benefits to Enforcers by introduction of the new Regulations.

- **COSTS**

Option 1

Do nothing. The main cost for this option would be to Government arising from possible infraction proceedings and consequent fines due to non-enforcement of the EU Regulation. The minimum infraction fine that can be imposed on the UK is 9.446 million Euros.

There would be no enforcement provisions for 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.

Consumers

Consumers with coeliac disease would be at risk of buying foods with inaccuarate labelling regarding the gluten content.

Industry

There could be possible loss of trade with the other Member States who have introduced enforcement arrangements for the EU Regulation.

Enforcement

There would be no familiarisation costs to Enforcement authorities since there would be no new legislation to read.

Option 2

Consumers

There should be no costs for consumers since most foods will continue to be labelled as now. Any labelling changes which are required should be relatively minor and have little or no effect on product prices.

Industry

These would split into (a) familiarisation costs and (b) relabelling costs.

(a) Let us assume that a manager in each business required approximately 1 hour to read and become familiar with the new Regulations. Salary has been estimated using ASHE provisional 2015 median wage data for production managers and directors.[2] The average hourly rate is up rated by 30% to take account of overheads in line with standard cost model methodology to £27.34.

Coeliac UK has informed us that currently around 477 businesses in the UK produce food with gluten claims but they have no information on how many of these are based in Scotland. The information from Table 1 suggests that approximately 1 in 12 of UK businesses are based in Scotland which would approximate to 50 businesses in Scotland which make gluten claims for their products.

Thus the familiarisation cost for Scottish industry would be in the order of 50 x £27.34 = £1,370.

(b) There are a number of drivers that can result in the need for labelling changes; legislative requirements are one of four main sources:

• change in legislation;

• marketing driven;

• product reformulation; and

• voluntary inclusion of information.

Research by Campden BRI shows that as a percentage of all the drivers contributing to re-labelling, on average 14% will arise solely from implementing new legislation. This indicates that changing labels in response to new Regulations will often be incorporated at the same time as other changes are made such as product refreshes and redesigns. Therefore in the majority of cases, labelling changes as a result of legislation do not create any substantial costs on their own, as they are implemented as part of labelling changes initiated through commercial decisions. Estimated costs for labelling changes per stock keeping unit (SKU) or product line are set out in table 2.

[2] Wage rate obtained from Annual Survey of Hours and Earnings 2015 Provisional
http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-400803
Median hourly wage rate of "production managers and directors" was used, £21.03, plus 30% overheads, totalling £27.34.

Table 2: Label change cost

Extent of change	Average cost (£/Stock Keeping Unit)	Trimmed mean (£/Stock Keeping Unit)
Minor change	£1,810	£1,800
Major change	£3,800	£3,300
"minor" change: only text on a single face of the label and no packaging size modification is required to accommodate this. "major" change: text as well as layout and/or colours and/or format and/or multiple faces are affected, or packaging size modification is required. Trimmed mean: A trimmed mean is calculated by discarding a 5% of the lowest and the highest scores and then computing the mean of the remaining scores.		

Source: Developing a framework for assessing the costs of labelling changes in the UK, Defra and Campden BRI

During the course of the public consultation we will endeavour to gather information on the numbers of products likely to require relabelling. These figures are likely to be very low since only those with supplementary information supporting their claims may need to relabel their products.

Enforcement

There will be a one-off cost to local authorities (LA) from reading and familiarising themselves with the new Regulations. We have assumed that in each LA all the Food Enforcement Officers would need an hour to familiarise themselves with the new legislation. Our calculations are based on approximately 210 Food Enforcement Officers (estimated figure provided by FSS Audit Branch) spread throughout the 32 LAs in Scotland.

The average hourly rate for an Enforcement Officer is estimated to be £24.77[3] (which includes a 30% overhead uplift in accordance with the standard cost model). Total estimated cost across Scotland would be approximately 210 x £24.77 = £5,200.

Continued verification would be carried out during routine retail label checks which are already in process.

5. Scottish Firms Impact Test

Various Scottish businesses of different sizes and from various geographical areas will be approached directly during the public consultation period to seek their views on the likely impact on their business of the changes proposed in the draft SSI. They will be requested to consider all points raised in this partial BRIA and assess the cost estimates.

- **Competition Assessment**

The proposed legislation will apply to all businesses and individuals involved in the manufacture and retail of foods for which claims are made regarding the gluten content and manufacturers of "normal foods" who claim their products have "no

[3] Wage rate obtained from Annual Survey of Hours and Earnings 2015 Provisional
http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-400803
Median hourly wage rate of an "environmental health professional" was used, £19.15, plus 30% overheads, totalling £24.77.

gluten containing ingredients". It should not limit the number or range of suppliers in Scotland either directly or indirectly or reduce the ability of, or incentives to, suppliers to compete. Therefore, it is not expected to have a significant impact on competition. Using the Competition and Markets Authority competition assessment framework[4], it has been established that the preferred policy option (Option 2) is unlikely to have any material negative impact on competition. We assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

- **Test run of business forms**

  No new or additional forms will be introduced by this proposal therefore no test run need be completed.

6. Legal Aid Impact Test

The Scottish Government Access to Justice Team has confirmed that the Scottish Legal Aid Board are content that the proposed Regulations should not pose any problems for legal aid expenditure.

7. Enforcement, sanctions and monitoring

- **Enforcement**

  Enforcement of the Regulations in Scotland will be the responsibility of Local Authority Environmental Health Departments.

- **Sanctions**

  Regulation 10 (a) of the Food Information (Scotland) Regulations 2014 (as amended) lays down that the penalty on summary conviction for an offence under any specified provision of FIC (Regulation (EU) No 1169/2011) is a fine not exceeding level 5 on the standard scale. This retains the current sanction available under the Foodstuffs Suitable for People Intolerant to Gluten (Scotland) Regulations 2010.

- **Monitoring**

  The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. FSS mechanisms for monitoring and review include: open fora, stakeholder meetings, surveys and general enquiries.

[4] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/284451/OFT1113.pdf The Competition and Markets Authority is now responsible for this area of work.

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