



## **DRAFT BUSINESS AND REGULATORY IMPACT ASSESSMENT**

### **The Foods for Specific Groups (Scotland) Regulations 2016**

**Date:** 31 May 2016  
**Stage:** Final  
**Source of intervention:** EU  
**Type of measure:** Regulation  
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## 1. Title of Proposal

The Foods for Specific Groups (Scotland) Regulations 2016

## 2. Purpose and intended effect

### • Objectives

Domestic legislation for Scotland is required to deal with consequential matters arising from the coming into force of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. This is known as the EU Foods for Specific Groups Regulation (FSG). Whilst the FSG Regulation has direct effect in all Member States, the offences and penalties for breaching the FSG Regulation will be contained in national legislation.

The purpose of the draft Scottish Statutory Instrument is to:

- Enable the enforcement of and
- Provide penalties for non-compliance with

the requirements of the FSG Regulation, which defines the categories of foods included in Foods for Specific Groups, revises the categories included in the current Foods for Particular Nutritional Uses (PARNUTs) legislation and provides a framework for the new approach from the Commission to regulation in this area.

There are now only four categories of foods within scope: infant formula and follow-on formula, food intended for infants and young children, food for special medical purposes and total diet replacement for weight control. All other foods will now be regulated under existing EU legislation on food labelling and nutrition and health claims.

The EU Regulation also reinstates some of the basic rules that are currently contained within the PARNUTs legislation on the safety, composition, labelling and advertising of the four categories. New detailed provisions in these areas are being contained within four specific Commission Regulations which will be applied within the next few years and will be consulted upon separately.

### • Background

Regulation (EU) No 609/2013 on foods for specific groups (hereafter referred to as FSG) was introduced to simplify existing rules covering foods for particular nutritional uses (Directive 2009/39/EC referred to as PARNUTS).

This was necessary to take account of food manufacturing and scientific developments, and the introduction of new pieces of EU legislation. Of particular importance in this context is the legislation on fortified food, nutrition and health claims, and food information for consumers.

Foods previously regulated under the PARNUTS framework, such as meal replacements for weight control and gluten claims will be treated as normal foods, and regulated under existing EU legislation on food labelling and nutrition and health claims. A Scottish Statutory Instrument will be needed to enforce the updated EU rules on gluten claims and was the subject of a separate consultation.

The FSG Regulation applies to all member states from 20 July 2016. The four specific Commission Regulations will have lengthy transitional arrangements which means they will not apply until 2019 at the earliest. The table below details the known transitional arrangements so far:

<b>Category of Food for Specific Groups</b>	<b>Application date</b>
Food for Special Medical Purposes	22 February 2019
Food for Special Medical Purposes (for infants)	22 February 2020
Infant Formula and Follow-on Formula	22 February 2020
Infant Formula and Follow-on Formula (manufactured from protein hydrolysates)	22 February 2021

The FSG Regulation is directly applicable in EU Member States. However, to fulfil our obligations to the EU, we need domestic legislation to enable the enforcement of and to provide penalties in the event of non-compliance with the new European requirements. In addition, consequential amendments and revocations to Scots law will be necessary following the introduction of the new EU requirements.

The amendments and revocations are as follows:

- Amend the definition of relevant foods in The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 to include only those products which are intended to replace the whole of the normal diet.
- To revoke Regulations 26 and 27 of the Infant Formula and Follow-on Formula (Scotland) Regulations 2007 on exports
- To revoke The Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2007 (as amended) on notification and restriction on sale of PARNUTS foods outwith certain categories.

- **Rationale for Government intervention**

Failure to introduce enforcement provisions for the FSG Regulation could result in infraction proceedings against the UK, therefore it is necessary to ensure that the EU requirements can be enforced in Scotland. The Foods for Specific Groups (Scotland) Regulations 2016 will enable the local authorities in Scotland to take action in the event of non-compliance with the specific labelling and / or composition standards for the products covered by the FSG Regulation.

Due to the diversification and specialisation of PARNUTS foods, Regulation (EU) No 609/2013 was adopted to simplify existing rules covering these well defined categories of food. Enforcement provisions for Regulation (EU) No 609/2013 on foods for specific groups will be via the Scottish regulations.

The FSG regulation also enables the European Commission to introduce four Delegated Regulations to establish detailed rules on the composition, labelling and advertising for each of the four specific food categories. Work in this area is not fully completed at EU level and we will consult separately on appropriate enforcement provisions for Scotland in due course.

The FSG regulation is directly applicable in EU Member States. However, to fulfil our obligations to the EU, we need domestic legislation to enable the enforcement of and to provide penalties in the event of non-compliance with the new European requirements. In addition, consequential amendments and revocations to Scots law

will be necessary following the introduction of the new EU requirements and to update the current Scottish Regulations as described above.

### 3. Consultation

- **Within Government**

The consultation package was discussed with Scottish Government (SG) officials from Public Health, Child & Maternal Health and Food Drink & Rural Communities.

- **Public Consultation**

A shortened 8 week consultation was carried out in Scotland on the draft national legislation from 16 March 2016 to 15 May 2016. A total of 2 responses were received from 64 stakeholders on the consultee list.

- **Business**

The main new EU policy requirements will be contained within the specified regulations and this statutory instrument in effect just reinstates the previous enforcement provisions within the new framework, therefore we anticipate the impact to be minimal. Our initial engagement with industry did not raise any concerns.

Our consultation requested details of any known businesses impacted by the proposed SSI. It was circulated to a wide group of industry bodies, retailers and enforcement officers but we were unable to identify any manufacturers of foods for specific groups within Scotland. The response from British Specialist Nutrition Association advised that whilst products made by BSNA member companies are sold and distributed in Scotland, BSNA member companies do not manufacture any products in Scotland which fall under FSG regulation.

### 4. Options

**Option 1** – Do nothing. The FSG Regulation will not be enforced.

**Option 2** – Provide for the enforcement of the FSG Regulation

- **Sectors and groups affected**

While these proposed regulations apply to Scotland only, separate enforcement regulations will be introduced in England, Wales and Northern Ireland; as such the impact on the UK as a whole has been assessed.

Consumers – Non-monetised benefits to consumers from the establishment, in due course, of clear definitions, composition and labelling of infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes, and total diet replacement for weight control

Enforcement Authorities – enforcement of the rules on foods for specific groups is the responsibility of Local Authority Environmental Health Services.

Businesses – Manufacturers and retailers will be the main groups affected by the Food for Specific Groups (Scotland) Regulations 2016

- **Option Appraisal: Costs and Benefits**

The main groups that are likely to be affected are manufacturers of products where the FSG legislation has changed in relation to the PARNUTS legislation. The categories of foodstuffs covered by the FSG legislation is restricted to infant formula, follow-on formula, baby foods, foods for special medical purposes and total diet

replacement for weight control (TDR). The FSG Regulation removes other foodstuffs regulated under the current framework, such as gluten claims, which will in future be regulated under other existing food law measures. The Regulation also asks the commission to produce a report on the necessity of specific rules on sports foods and milks for older children (young child formulae also known as growing up milks). This follows concerns by some member states and the European Parliament that there is currently no evidence to support the need for such products as FSGs and they can more appropriately be regulated under existing EU food law.

The main food sectors affected include slimming foods, very low calorie diet foods (VLCDs), gluten claims, growing up milks and sports foods and drinks. Other sectors where little regulatory changes are proposed (infant formula, follow-on formula, baby foods and medical foods), will nevertheless need to understand the changes to the legislation, and impact should be limited to familiarisation costs.

In early 2015, prior to FSS taking over its responsibilities, the Food Standards Agency in Scotland issued two Interested Parties letters giving updates on the FSG matters including any progress on the draft Delegated Regulations. Stakeholders in Scotland did not make any comments at that time.

At a UK level, in March 2015 the Department of Health received comments from the British Specialist Nutrition Association (BSNA) the European Specialist Sports Nutrition Alliance (ESSNA) and the European Very Low Calorie Diet Industry Group.

**Option 1** – Do nothing. As an EU Regulation, the FSG Regulation is binding in its entirety and directly applicable in all Member states. It is therefore not necessary to transpose the provisions of the FSG Regulation into domestic law. Doing nothing would mean that the FSG Regulation will still come into force, but we would not have the domestic legislation to enforce it in Scotland. 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 1 is therefore disregarded as an option, but it is the baseline against which other options are appraised.

## **Option 2**

### **Industry**

Option 2 would maintain the status quo regarding the enforcement of European regulation in this area.

We anticipated that there would be transition costs due to the need for firms to familiarise themselves with the new SSI so we indicated the costs associated with familiarisation to businesses within our consultation. However, the response from British Specialist Nutrition Association has indicated that although their members retail in Scotland, they do not have any members who manufacture or produce foods for specific groups in Scotland. FSS consultation and industry engagement work has not identified any other Scottish food manufacturers or businesses with the responsibility for labelling FSG products who are likely to be affected.

There is therefore no costs to businesses in Scotland associated with this SSI.

### **Consumers**

It is worth noting that the FSG Regulation maintains the high level of consumer protection under the current approach for PARNUTS foods, ensuring adequate nutritional composition of the food to protect the most vulnerable consumers and appropriate consumer information (e.g. foods intended for infants and young children,

and medical foods). Removing the concept of dietetic food may impact some consumers e.g. those who found dietetic statements such as “suitable for diabetics” helpful, but informal consultation e.g. views expressed by Diabetes UK to Department of Health in March 2015, suggests that regulating such food under general food law is a benefit.

## **Government**

Although this would maintain the status quo regarding the enforcement of European regulation in this area, Local Authorities would need to become familiar with the new SSI. It is estimated that it would take one Environmental Health Officer one hour to read and become familiar with the SSI. The hourly pay rate for Qualified Environmental Health Officers is £19.15<sup>1</sup> – averaging approximately £24.77 per hour once updated to account for non wage labour costs and overheads, taken as 30%. The total one-off cost to the 32 local authorities is therefore estimated at approximately £792.64.

Ongoing workloads for Environmental Health Services are not expected to increase as a result of this SSI, as enforcement work for the products affected is already required.

The response from Glasgow City Council Environment Health Department advises that they feel the above costs to be reasonable.

## **5. Scottish Firms Impact Test**

Various Scottish businesses of different sizes and from various geographical areas were 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 were requested to consider all questions posed in the partial BRIA and assess the cost estimates. No responses were received from industry. The response from British Specialist Nutrition Association indicates that there are no companies manufacturing foods for specific groups in Scotland

### **• Competition Assessment**

The proposed legislation will apply to all businesses and individuals involved in the UK Food for Specific Groups trade equally, allowing them to trade across EU Member States, if appropriate. 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<sup>2</sup> developed by the former Office of Fair Trading, it has been established that the preferred policy option (Option 2) is unlikely to have any material negative impact on competition. Whilst there are certain restrictions on composition and advertising of Infant Formula, these would apply equally to any business, large or small, involved in manufacturing and supply of these products. 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**

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<sup>1</sup> Wage rate obtained from Annual Survey of Hours and Earnings 2015 Provisional

<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-400803>

Median hourly wage rate of an “environmental health professional” was used, £19.15, plus 30% overheads, totalling £24.77.

<sup>2</sup> [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/284451/OFT1113.pdf](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.

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

## **6. Legal Aid Impact Test**

The Justice Directorate have advised that the new regulations will not have any legal aid implications.

## **7. Enforcement, sanctions and monitoring**

### **• Enforcement**

Enforcement of the regulations will be the responsibility of Local Authorities. In Scotland, Enforcement Officers from Local Authority Environmental Health Services will need to familiarise themselves with the new requirements and ensure they are adhered to. Enforcement action is only pursued where informal action has been unsuccessful.

### **• Sanctions**

Regulation 4 of the Foods for Specific Groups (Scotland) Regulations 2016 lays down that the penalty on summary conviction for an offence under the regulations is a fine not exceeding level 5 on the standard scale.

- No changes are being proposed to the criminal sanctions or civil penalties contained in existing legislation.

### **• 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. Agency mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

## **8. Implementation and delivery plan**

The requirements of EU Regulation 609/2013 regarding foods for specific groups come into force on 20 July 2016. These requirements will be enforced by The Foods for Specific Groups (Scotland) Regulations 2016 which will come into force on 20 July 2016

The publication of the Scottish Regulations will be communicated to stakeholders by means of an Interested Parties letter. This will be issued shortly after the Scottish Statutory Instrument has been published on the [legislation.gov.uk](http://legislation.gov.uk) website.

## **9. Post-implementation review**

A review to establish the actual costs and benefits and the achievement of the desired effects will take place 10 years from the date the Foods for Specific groups (Scotland) Regulations 2016 come into force.

## **10. Summary and recommendation**

Option 2 – This is the preferred option. It ensures that Scottish Ministers meet their obligation to implement agreed EU legislation. It also ensures that Scottish industry can compete on the same legal basis with its EU counterparts.

## **11. Summary costs and benefits table**

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: economic, environmental, social policy and administrative
1	No cost to Government as a result of the introduction of The Foods for Specific Groups (Scotland) Regulations 2016	Possible infraction fines. Possible loss of international trade if products do not comply with EU standard.
2	No infraction fines. High level of consumer protection. Industry working to a consistent legal standard throughout EU	Familiarisation costs for local authorities.

Option 2 is considered to be the preferred option

## 12. Declaration and publication

I have read the impact assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Ministers signature .....

Ministers title .....

Date .....

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