

**FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT**

**The Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments)  
(Scotland) Regulations 2018**

**Date:** December 2018  
**Stage:** Final  
**Source of intervention:** EU  
**Type of measure:** Regulation  
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## **1. Title of Proposal**

- 1.1.** The Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018.

## **2. Purpose and intended effects**

### **Objectives**

- 2.1.** The key purposes of the proposed Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 (“the proposed Regulations”) are to:
- Enable the enforcement of and Provide penalties for non-compliance with The requirements of Commission Delegated Regulation (EU) No. 2016/128 (hereafter referred to as the FSMP regulation) which lays down rules on the specific compositional and information requirements for food for special medical purposes.
  - Amend the Foods for Special Medical Purposes (Scotland) Regulations 2000 to restrict the application to food for medical purposes developed to satisfy the needs of infants and foods placed on the market prior to 22 February 2019.

### **Background**

- 2.2.** The FSMP Regulation is a Delegated Regulation under the Framework Regulation 609/2013 on food for specific groups (FSG). It was approved on 25 September 2015 to adopt specific compositional and information requirements for food for special medical purposes, taking into account the provisions of Directive 1999/21/EC (the existing harmonised legislation on dietary foods for special medical purposes, which is implemented in Scotland by the Foods for Special Medical Purposes (Scotland) Regulations 2000).
- 2.3.** The FSG Regulation applied to all Member States from 20 July 2016 and was introduced to simplify existing rules covering foods for particular nutritional uses. It repealed Directives 2009/39/EC (on foodstuffs intended for particular uses) and 1999/21/EC and is executed and enforced in Scotland by the Foods for Specific Groups (Scotland) Regulations 2016.
- 2.4.** The FSG Regulation defines the categories of foods classed as foods for specific groups and calls on the Commission to introduce four delegated regulations to lay down detailed rules on each of the categories. These categories are as follows:
- Infant formula and follow on formula
  - Foods intended for infants and young children
  - Foods for special medical purposes
  - Total diet replacement for weight control
- 2.5.** The four specific Commission Regulations have lengthy transitional arrangements, with part of FSMP regulation applying from 22 February 2019. The table below details the transitional arrangements:

| <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        |
| Total diet replacement for weight control                                     | 27 October 2022         |

- **Food for Special Medical Purposes (FSMP)**

2.6. FSMPs are developed in close cooperation with health care professionals to feed patients affected by or malnourished because of a specific diagnosed disease, disorder or medical condition that makes it impossible or very difficult for those patients to satisfy their nutritional needs through the consumption of other foods. The composition of food for special medical purposes may differ substantially depending, among others, on the specific disease, disorder or medical condition for the dietary management of which the product is intended, on the age of the patients and the place in which they receive health care support, and the products intended use. In particular, food for special medical purposes can be classified in different categories as laid out below:

- Nutritionally complete food with a standard nutrient formulation which, used in accordance with the manufacturer’s instructions may constitute the sole source of nourishment for the persons for whom it is intended
- Nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with manufacturer’s instructions, may constitute the sole source of nourishment for the persons for whom it is intended
- Nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment

### **Rationale for Government intervention**

2.7. The FSMP 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.

Failure to introduce enforcement provisions for the FSMP 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 proposed Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 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 FSMP Regulation.

### **3. Consultation**

#### **Within Government**

- 3.1.** The consultation package was discussed with Scottish Government (SG) officials from Public Health, Child & Maternal Health and Food Drink & Rural Communities. FSS (and the former Food Standards Agency Scotland) also liaised with SG officials during the development of the framework EU legislation.

#### **Public Consultation**

- 3.2.** A four week consultation was carried out in Scotland on the draft national legislation from 26 September 2018 to 23 October 2018. A total of two responses were received from sixty-three stakeholders who received the consultation.

#### **Business**

- 3.3.** The consultation was sent to a number of trade organisations and local authorities who would have with a better understanding of the businesses in their area and requested details of any known businesses impacted by the proposed SSI. Three businesses in Scotland were identified as possible manufacturers of FSMP to whom the consultation was also sent to. The response from British Specialist Nutrition Association (BSNA) and the Local Authority Environmental Health Officer did not raise any concerns regarding the familiarisation costs and questions in the partial BRIA.

### **4. Options**

#### **The options considered were:**

- 4.1. Option 1 – Do nothing.** This means that the directly applicable European Regulation could not be fully enforced in Scotland.
- 4.2. Option 2 –** Introduce legislation to provide enforcement provisions in Scotland for Commission Delegated Regulation (EU) 2016/128 which would designate enforcement by local authority enforcement officers on a risk based approach. Option 2 is the preferred approach.

#### **Sectors and groups affected**

- 4.3.** While these proposed regulations apply to Scotland only, separate enforcement regulations will be introduced in England, Wales and Northern Ireland.
- 4.4. Consumers** – Non-monetised benefits to consumers from the enforcement, in due course, of clear definitions, composition and labelling of food for special medical purposes.

- 4.5. Enforcement Authorities – enforcement of the rules on food for special medical purposes is the responsibility of Local Authority Environmental Health departments.
- 4.6. Businesses – Manufacturers and retailers will be the main groups affected by the Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018.

#### **Option Appraisal: Costs and Benefits**

- 4.7. **Option 1 – Do nothing.** FSMP is binding in its entirety and directly applicable in all Member States. Doing nothing would mean the FSMP Regulation will still apply but we would not have the domestic legislation to enforce it. 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. Option 1 is therefore disregarded as an option, but it is the baseline against which other options are appraised.
- 4.8. **Option 2 – Make appropriate domestic regulations to provide for the enforcement of the FSMP Regulation.** There will be some familiarisation cost to industry and enforcement in ensuring compliance with the FSMP Regulation as identified below.
- 4.9. There will be some cost to industry and enforcement in ensuring compliance with the new EU Regulation as identified below.

#### **Option 2 – One-off Costs to Industry**

##### **One-off familiarisation cost**

- 4.10. This figure is calculated by firstly taking the 2017 Provisional ASHE (Annual Survey of Hours and Earnings)<sup>1</sup> figure for “Scotland Production managers and directors in manufacturing” £23.14 (median value) and uprating it by 30% to account for overheads, giving an hourly wage rate of £30.08. It is estimated that the reading and understanding of the FSMP Regulation will take approximately 1 hour with a further 30 minutes for dissemination to key staff within each firm (a total of 1 hour 30 minutes) at £45.12.
- 4.11. We were unable to source precise data to identify businesses and manufacturers of FSMP, however figures taken from the year 2017 indicate that there are approximately 5 manufacturers of “homogenised food preparations and dietetic food<sup>2</sup>” in Scotland<sup>3</sup>. FSMP is categorised in this group of enterprises which do not solely include FSMP therefore FSS encouraged manufacturers or retailers of FSMP to respond to the

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<sup>1</sup>

<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regionbyoccupation4digitsoc2010ashtable15>

<sup>2</sup> Included in the category of “the manufacture of homogenised food preparations and dietetic food: infant formulae, follow-up milk and other follow-up foods, baby foods, low-energy and energy-reduced foods intended for weight control, dietary foods for special medical purposes, low-sodium foods, including low-sodium or sodium-free dietary salts, gluten-free foods, foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, foods for persons suffering from carbohydrate metabolism disorders (diabetes)

<sup>3</sup> Source: [Businesses in Scotland 2017](#), Scottish Government

consultation. The responses received did not raise any concern for familiarisation costs.

4.12. Therefore, we estimate a one off familiarisation cost of £225.62 to industry.

### **Option 2 – Benefits to Consumers**

4.13. The legislation will benefit those requiring FSMP as there will be enhanced protection by way of defined compositional standards and tighter labelling restrictions as well as the need to comply with Regulation (EU) No 1169/2011 on the provision of food information to consumers (FIC). However, FSMP lays down additions and exceptions to the general rules of FIC where required to enable appropriate use to be made of the product.

4.14. The use of nutrition and health claims to promote food for special medical purposes have been prohibited since consumers of such products are patients under medical supervision and are therefore not part of the general healthy population. Consumers will therefore not be subjected to inappropriate promotion of products via nutrition and health claims.

### **Option 2 – Costs to Enforcement**

#### **One-off familiarisation cost**

4.15. The SSI allows for the enforcement of the new requirements which include a prohibition on nutrition and health claims as well as an amended nutrition declaration. Local Authorities would need to become familiar with the new provisions. There are 210 enforcement officers throughout the 32 local authorities in Scotland and it is our estimation 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 £15.29<sup>4</sup> – averaging approximately £19.88 per hour once uprated to account for non wage labour costs and overheads, taken as 30%. The total one-off cost is therefore estimated at approximately £4174.80.

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

5.1. The consultation was circulated to Local Authority Environmental Health departments and trade bodies with a specific request to help identify manufacturers of foods for special medical purposes within Scotland. They were also requested to consider all questions posed in the partial BRIA and the cost estimates. There were no concerns raised on any aspect of the new regulations.

### **Competition Assessment**

5.2. The proposed legislation will apply to all businesses and individuals involved in the Scottish foods for special medical purposes trade equally, allowing them to trade across EU Member States, if appropriate. It should not limit the number or range of

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<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/regio-nbyoccupation4digitsoc2010ashtable15>

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.

### **Test run of business forms**

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

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

- 6.1. During the consultation period the Justice Directorate was contacted to ascertain whether the new regulations will have any legal aid implications. The Scottish Legal Aid Board confirmed that these Regulations will have no impact on the legal aid fund.

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

### **Enforcement**

- 7.1. Enforcement of the regulations will be the responsibility of Local Authority Environmental Health departments. Enforcement should be risk based and proportionate, in line with the approach taken with the current Scottish legislation on medical foods. Enforcement officers would not be expected to initiate separate inspections in relation to the enforcement of these new provisions, but instead to include these as part of their existing regimes.

### **Sanctions**

- 7.2. 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.
- 7.3. No changes are being proposed to the criminal sanctions or civil penalties contained in existing legislation.

### **Monitoring**

- 7.4. The effectiveness and impact of the regulations will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process. Food Standard Scotland's mechanisms for monitoring and review include; open fora, stakeholder meetings, surveys and general enquiries.

## **8. Implementation and Delivery Plan**

- 8.1. The publication of the Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 will be communicated to stakeholders by means of an Interested Parties' letter. This will be done shortly after the SSI has been published on the legislation.gov.uk website.

## **9. Post Implementation Review**

- 9.1. 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

(Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 come into force.

## 10. Summary and Recommendation – Summary Costs and Benefits Table Declaration

| Option | Total benefit per annum:<br>economic, environmental, social   | Total cost per annum:<br>economic, environmental,<br>social policy and<br>administrative  |
|--------|---|---|
| 1      | Do nothing therefore no cost  | Possible infraction fines   |
| 2      | <p><b>Industry:</b> Working to a consistent legal standard throughout the EU.</p> <p><b>Consumers:</b> Enhanced protection by way of defined compositional standards and tighter labelling restrictions.</p> <p>No infraction fines due to introducing the new Scottish Statutory Instrument for the execution and enforcement of the FSMP Regulation</p> | <p><b>Industry:</b> One-off familiarisation cost: £225.62</p> <p><b>Enforcement:</b> One-off familiarisation cost: £4174.80</p> |

Option 2 is considered to be the preferred option. It ensures that Scottish Ministers will meet their obligation to implement agreed EU legislation.

## 11. 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.

Minister's signature    JOE FITZPATRICK

Minister's title        MINISTER FOR PUBLIC HEALTH, SPORT AND WELLBEING

Date                        19th December 2018

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