

POLICY NOTE

THE FOODS FOR SPECIFIC GROUPS (MEDICAL FOODS) (MISCELLANEOUS AMENDMENTS) (SCOTLAND) REGULATIONS 2018

SSI 2018 No. 392

1. Description

The Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 (“the Instrument”) is made by the Scottish Ministers in exercise of the powers conferred by sections 16(1), 17(1) and (2), 26(1) and (3) and 48(1) of the Food Safety Act 1990 and all other powers enabling them to do so. The Instrument is subject to the negative procedure.

2. Policy Objective

The main purpose of the Instrument is to provide enforcement powers to underpin the directly applicable Commission Delegated Regulation (EU) No. 2016/128 which lays down rules on the specific compositional and information requirements for food for special medical purposes.

3. Policy Background

Regulation (EU) No. 2016/128 is a Delegated Regulation under the Framework Regulation 609/2013 on food for specific groups and comes into force 22 February 2019, repealing and replacing Directive 1999/21/EC. 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). It is the first of four delegated regulations called for by Regulation (EU) No 609/2013 on foods for specific groups which was introduced to simplify existing rules covering foods for particular nutritional uses.

Commission Delegated Regulation (EU) No. 2016/128 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 EU law requirements. Failure to introduce enforcement provisions for Commission Delegated Regulation (EU) No. 2016/128 could result in infraction proceedings against the UK, therefore it is necessary to ensure that the EU law requirements can be enforced in Scotland.

The Instrument amends the Food for Specific Groups (Scotland) Regulations 2016 to extend the existing enforcement provisions for Regulation (EU) No 609/2013 to include Commission Delegated Regulation (EU) 2016/128.

In addition, the Instrument amends the definition of “dietary food” in the Food for Special Medical Purposes (Scotland) Regulations 2000 to restrict the application of those Regulations to food for medical purposes developed to satisfy the needs of infants. The definition also includes food that has been placed on the market prior to 22 February 2019 and which

complies with Directive 1999/21/EC in order to allow for stocks to be used until they are exhausted.

During Parliamentary scrutiny for the Foods for Specific Groups (Scotland) Regulations 2016, it was noted that references to “meal replacement for weight control” in the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 had not been removed and that this had led to a lack of clarity. The Scottish Government agreed to remove the redundant text at the earliest available opportunity. Accordingly, all references to “meal replacement for weight control” in Regulations 2 and 3 of the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 are omitted.

4. Consultation

A four week consultation was carried out in Scotland on a draft SSI and the supporting Business and Regulatory Impact Assessment (BRIA) from 26 September to 23 October 2018. Two responses were received from sixty-three stakeholders who received the consultation. These were received from a Local Authority Environmental Health Department and an industry body.

The Local Authority Environmental Health Department stated that there are no known manufacturers in their area that are likely to be affected by the composition and labelling requirements for foods for special medical purposes. Both respondents did not raise any concerns regarding the familiarisation costs and questions in the partial BRIA.

5. Other Administrations

The Instrument applies in relation to Scotland only and corresponding Regulations will be introduced in the other UK countries.

6. Guidance

Guidance notes for the Instrument will be prepared in due course.

7. Impact Assessment

A final BRIA has been prepared following the public consultation and accompanies this note.

8. Regulating small businesses

The Instrument will apply to manufacturers and retailers concerned with foods for special medical purposes.

9. Monitoring

Food Standards Scotland will work with Enforcement Authorities where problems or suspected infringements of the legislation arise. The effectiveness of the Instrument will be monitored via general feedback from industry and Enforcement Authorities.

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