

POLICY NOTE

THE FOODS FOR SPECIFIC GROUPS (MEDICAL FOODS FOR INFANTS) AND ADDITION OF VITAMINS, MINERALS AND OTHER SUBSTANCES (SCOTLAND) AMENDMENT REGULATIONS 2020

SSI 2020/7

The above instrument was made in exercise of the powers conferred by sections 6(4), 16(1)(a) and (e), 17(1) and (2), 26(1) and (3) and 48(1) of the Food Safety Act 1990 and section 2(2) and paragraph 1A of schedule 2 of the European Communities Act 1972. The instrument is subject to negative procedure.

The purpose of this instrument is to enable the enforcement of and to provide penalties for non-compliance with EU Regulations, as detailed below.

Policy Objectives

These regulations are necessary to meet the following objectives:

- To amend the Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 (“the 2007 Regulations”) to enable the enforcement of and to provide penalties for non-compliance with Article 8 and Annex III of Regulation (EC) No. 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods, which lists substances in respect of which use in foods is prohibited or restricted.
- To amend the Foods for Specific Groups (Scotland) Regulations 2016 (“the 2016 Regulations”) to enforce the rules in Delegated Regulation (EU) No. 2016/128 on Foods for Special Medical Purposes (“the Delegated Regulation”) for infants and to revoke the Foods for Special Medical Purposes (Scotland) Regulations 2000 from 22nd February 2020, subject to savings provisions.
- To amend the 2016 Regulations to provide for the enforcement of Article 15 of Regulation (EC) No. 609/2013 with regard to the Union list of substances that can be added to foods for special medical purposes, infant formula and follow-on formula.

Delegated Regulation (EU) 2016/128 lays down rules on the specific compositional and information requirements for food for special medical purposes. The Regulation was adopted on 25 September 2015 and enforcement provisions were introduced through the Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 in respect of foods other than the foods for special medical purposes for infants.

The Delegated Regulation also lays down specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants, such as composition requirements and requirements in relation to nutrition and health claims and pesticide residues.

This instrument will execute and provide the enforcement of the rules on foods for special medical purposes for infants. It also amends the 2016 Regulations to insert transitional arrangements that ensure that stocks of food for special medical purposes which were

labelled or placed on the market prior to the date of application of provisions of the Delegated Regulation can continue to be marketed until those stocks are exhausted. This instrument also makes an offence not to comply with specified provisions of the Delegated Regulation that relate to the compositional requirements, pesticide use and residue, name of the food, nutrition declaration, and nutrition and health claims.

Regulation (EC) No. 1925/2006 regulates the addition of vitamins and minerals to foods and the use of certain other substances or ingredients containing substances other than vitamins or minerals. These may be added to foods or used in the manufacture of foods under conditions that result in the ingestion of amounts greatly exceeding those reasonably expected to be ingested under normal conditions of consumption of a balanced and varied diet and/or would otherwise represent a potential risk to consumers.

This instrument amends The Addition of Vitamins, Minerals and Other Substances (Scotland) 2007 Regulations with the effect that it becomes an offence to add a substance listed in Part A of Annex III of the EC regulation to foods, or to use such a substance in the manufacture of foods. It also becomes an offence to add a substance listed in Part B of Annex III of the EC regulation to foods, or to use such a substance in the manufacture of foods, unless that substance is added or used in accordance with the conditions specified in that Part.

Finally, the instrument makes an amendment to the 2016 Regulations to ensure that a penalty is provided for failure to adhere to article 15 of Regulation (EC) No. 609/2013. This, as read with the Annex of the Regulation, sets out categories of substances which may be added to food for special medical purposes, infant formula and follow-on formula, subject to certain requirements.

Consultation

A four week consultation was carried out in Scotland on the policy underpinning these Regulations and the supporting Business and Regulatory Impact Assessment (BRIA) from 4th November to 25th November 2019. Around 40 interested parties and 32 local authorities were consulted and two responses were received from Baby Feeding Law Group and British Specialist Nutrition Association. Neither of the responses raised any concerns and were happy with our proposals. However, one respondent pointed out some areas for later consideration, such as a closer alignment with the World Health Organisation Code of Marketing of Breastmilk Substitutes and subsequent World Health Assembly resolutions.

A full list of those consulted and who agreed to the release of this information is attached to the consultation report published on the Food Standards Scotland Citizen Space website, this includes the responses to the consultation from Baby Feeding Law Group and British Specialist Nutrition Association.

Impact Assessments and Financial Effects

A final BRIA has been prepared following the public consultation and accompanies this note. The impact of this policy on business is minimal.

Given that business is already working to the standards of both pieces of legislation, the impact of this policy is considered to be negligible.