

To:

Heads of Environmental Health Service (England)
Directors of Trading Standards Services (England)

cc: CIEH, TSI

Date: 1 August 2016

ENF Ref: ENF/E/16/041

Dear Colleagues

Subject: New Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016	
FOR INFORMATION/POSSIBLE ACTION	Category: <ul style="list-style-type: none">○ Standards
Action requested: Officers are asked to familiarise themselves with the new requirements	

Please bring this letter to the attention of all relevant officers in your Authority.

Issue

This letter is to alert you to the fact that the English Statutory Instrument, [‘The Food for Specific Groups \(Information and Compositional Requirements\) \(England\) Regulations 2016’ \(SI 2016/688¹\)](#), was laid before Parliament on 29th June 2016 and came into force on 20th July 2016.

The Regulations put enforcement provisions in place to enable the European Regulation on foods for specific groups (referred to as FSG Regulation) on [Regulation \(EU\) 609/2013](#) to be enforced in England. Scotland, Wales and Northern Ireland have made their own foods for specific groups Regulations. The Regulations implement the minimal requirements of the FSG Regulation and give enforcement officers the power to serve Improvement Notices for failure to comply with existing provisions for labelling, composition, and advertising of foods for specific groups (see ‘What the SI does’ below).

¹ You can find a published version of the SI at:
<http://www.legislation.gov.uk/id/uksi/2016/688>.

Officer Action - Officers are asked to:

• Read the content of this letter and familiarise themselves with the new requirements;

• Support businesses in their areas to comply with the requirements of this legislation;

Background

From 20 July 2016, the FSG Regulation repeals the framework Directive 2009/39/EC on foodstuffs intended for particular nutritional uses (referred to as PARNUTS) and replaces it with a new regime for regulating the compositional, labelling and advertising requirements for food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. The new SI implements the minimal requirements of the FSG Regulation, making it workable and enforceable in England, which we are obliged to do under EU Law.

The FSG Regulation has adopted two Delegated Regulations, and will adopt a further two in due course, which update the detailed composition and labelling rules under the FSG framework Regulation:

- (i) Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. It shall apply from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which it shall apply from 22 February 2021.
- (ii) Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes. It shall apply from 22 February 2019, except in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants, to which it shall apply from 22 February 2020.
- (iii) Commission draft Delegated Regulation (EU) .../...of XXX supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for processed cereal-based food and baby food. It shall apply from 3 years after entry into force.

- (iv) Commission draft Delegated Regulation (EU) .../... of XXX supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control. It shall apply from 5 years after entry into force.

The transition period for the Delegated Regulations on the four categories of food is expected to be 3-5 years, as set out above. The transitional measures in Article 21 of Regulation 609/2013 apply and will allow affected foods (such as sports foods and young child formulae) which are placed on the market or labelled before 20 July 2016 to continue to be marketed after that date until stocks of such food are exhausted.

What the SI does

The offences and penalties relating to the Delegated Regulations will be put in place nearer to their dates of application (2019 at the earliest) by future amendments to the SI. In the meantime the majority of the compositional, labelling and advertising rules will continue to be enforced by existing SIs and their amendments as follows, until their date of revocation:

- (i) The Infant Formula and Follow-on Formula (England) Regulations 2007
- (ii) The Processed Cereal-Based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003
- (iii) The Medical Food (England) Regulations 2000
- (iv) The Food Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997
- (v) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009

The Regulations give enforcement officers the power to serve Improvement Notices under Section 10 of the Food Safety Act 1990 for failure to comply with identified provisions in the Regulations, by making amendments to the existing SIs.

Where rules are now unnecessary they will be revoked by the new SI, in particular the following SIs will be revoked from 20 July 2016:

- (i) The Notification of Marketing of Food for Particular Nutritional Uses (England) Regulations 2007
- (ii) The Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2010.

Guidance on foods affected by the new legislation

From 20 July 2016 foods for particular nutritional uses will no longer exist. Only the four categories of foods specified in EU Regulation 609/2013 (infant formulae and follow-on formulae, weaning foods, medical foods and weight reduction foods) will be regulated as foods for specific groups. Other groups of foods formally considered as foods for

particular nutritional uses and for which specific provisions have not been laid down, in particular **sports foods** and **young child formulae** will, from 20 July 2016, be normal foods regulated by general food law.

From 20 July 2016, Regulation 609/2013 on foods for specific groups repeals Commission Regulation (EC) No 41/2009 concerning the composition and labelling of **foodstuffs suitable for people intolerant to gluten**. From that date, 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, applies. The Foodstuffs Suitable for People Intolerant to Gluten (England) Regulations 2010 which implement (EC) No 41/2009 will therefore be repealed and replaced by similar UK legislation which will not require notification as these foods will no longer be notifiable PARNUTS foods. A new Statutory Instrument is currently being drafted to this effect, and will be published in due course.

Regulation 609/2013 on foods for specific groups confirms that there will be no specific category of foods that may make claims stating they are **suitable for diabetics**. Department of Health (DH) has previously advised that the use of these statements should be evaluated in line with Article 7(1) of Regulation (EU) No 1169/2011 on the provision of food information to consumers. DH advice is that that use of statements such as "Diabetic" or "Suitable for diabetics" is misleading if all similar foods (e.g. foods bearing authorised nutrition claims for reduced sugar) are suitable for diabetics i.e. Article 7(1) (c) of Regulation (EU) No 1169/2011². As such, manufacturers have been advised to change their labels where they bear these statements and it will be for the Home/Primary Authority to liaise with the business to assist with compliance in the first instance.

From 20 July 2016, Regulation 609/2013 on foods for specific groups repeals aspects of Commission Directive 96/8/EC on **foods intended for use in energy-restricted diets for weight reduction**. The Commission will adopt a Delegated Regulation on the specific compositional and labelling rules for total diet replacement products for weight

²Article 7

Fair information practices

1. Food information shall not be misleading, particularly:

(a) as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production;

(b) by attributing to the food effects or properties which it does not possess;

(c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients;

(d) by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient.

control including very low calorie diets, which will replace those parts of Directive 96/8/EC. Rules on the use of statements on meal replacement products (between 840 kJ /200 kcal and 1 680 kJ/400 kcal) have been transferred under Regulation 1924/2006 on nutrition and health claims in order to ensure legal certainty. As such, the authorised health claims relating to food presented as replacing one (two) daily meal(s) will be amended to take account of these necessary changes in their conditions of use, and this is pending.

The guidelines '**DH Guidance Notes on the Infant Formula and Follow-on Formula Regulations 2007**' will be updated when the Delegated Regulation supplementing EU Regulation 609/2013 as regards the specific compositional and information requirements for infant formula and follow-on formula applies. The application date for these new rules is from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, which applies from 22 February 2021.

The need to develop wider guidance will be considered closer to the application date of the Delegated Regulations providing for the compositional and information requirements for weaning foods, medical foods and weight reduction foods.

Issues arising

Minimum levels of vitamins and minerals added to young child formulae and sports foods previously classified as foods for particular nutritional uses (by some Member States) may be below the "significant amount" in Regulation 1925/2006 on the addition of vitamins and minerals to foods. The European Commission is aware of these issues and indicated that derogations were possible; this will be considered further. In the meantime, food business operators (FBO) will be required to demonstrate that the levels of vitamins and minerals added to these foods is scientifically substantiated to enable enforcement authorities to come to an informed judgement (for example, where vitamins and minerals are added to young child formulae the FBO may demonstrate that the levels are equivalent to those in follow-on formulae).

In relation to young child formulae it is also noted that Regulation 1169/2011 on the provision of food information to consumers and Regulation 1924/2006 on nutrition and health claims refer to adult nutrient reference values (NRVs) for reference intake values, which are inappropriate for children. The Commission indicated that specific reference intakes (RIs) for children could be agreed; this will be considered further.

Contact details

Please contact nutrition.legislation@dh.gsi.gov.uk for further information.