**EXPLANATORY MEMORANDUM TO**

**THE FOOD FOR SPECIFIC GROUPS (INFORMATION AND COMPOSITIONAL REQUIREMENTS) (ENGLAND) REGULATIONS 2016**

**2016 No. 688**

## 1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

## 2. Purpose of the Instrument

2.1 This Instrument implements the minimal requirements of European Regulation 609/2013 on food for specific groups ("the FSG Regulation"). It contains the offences and penalties for non-compliance of compositional, labelling and advertising rules, making the FSG Regulation workable and enforceable in England. The Regulations also introduce a new lighter touch enforcement regime so that the first formal action under the FSG Regulation would be to issue an Improvement Notice rather than a criminal sanction.

## 3. Matters of special interest to Parliament

***Matters of special interest to the Joint Committee on Statutory Instruments***

3.1 None.

***Other matters of interest to the House of Commons***

3.2 As this Instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

## 4. Legislative Context

4.1 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. This Instrument implements the minimal requirements of the FSG Regulation, making it workable and enforceable in England, which we are obliged to do under EU Law. Failure to implement EU legislation would result in infraction proceedings.

4.2 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.

4.3 The House of Commons European Scrutiny Committee and the House of Lords EU Select Committee previously cleared the FSG framework Regulation 609/2013 from scrutiny. During negotiations the Committees agreed with the Government that the FSG framework Regulation accords well with Government policy on Better Regulation, simplifying existing legislation relating to foods for specific groups. In particular the Committees welcomed that the transitional period for the FSG Regulation was increased from two to three years, mitigating the burdens on business in relation to any change of labelling of products to fit in with the typical three-year re-labelling cycle.

4.4 Two of the four Delegated Regulations under the FSG framework have cleared scrutiny (Document 12430/15 relating to infant formula and follow-on formula, and Document 12431/15 relating to medical foods).

4.5 The House of Lords EU Select Committee has been updated on an objection relating to Delegated Regulation Document 12428/15 relating to processed cereal-based food and baby food. The objection, on the grounds that it does not take the necessary steps to protect against obesity by continuing to allow levels of sugar in baby foods that are above World Health Organisation recommendations, has been upheld and adopted by the European Parliament. The resolution calls on the European Commission to delay the adoption of Delegated Regulation Document 12428/15 until the European Food Safety Authority (EFSA) has published its review regarding the evidence on sugar and the early introduction of processed foods in relation to optimal infant feeding recommendations, and this is likely to take about 12 months.

4.6 The fourth Delegated Regulation on specific compositional and information requirements for total diet replacement for weight control is further behind in its adoption and will be deposited for Parliamentary scrutiny in due course.

4.7 The transition period for the Delegated Regulations is expected to be 3-5 years, as set out in paragraph 4.2. Once we have confirmed dates of application for the four

Delegated Regulations we will make arrangements to amend these Regulations and ensure industry is made aware of the new requirements so that they can begin to prepare in advance of amendments to the Regulations. The transitional measures in Article 21 of Regulation 609/2013 apply.

4.8 The Regulations contain some ambulatory references. By virtue of regulation 2(5), references in the Regulations to the provisions listed in Schedule 1 are references to those provisions amended from time to time. These amendments will be minor and highly technical in nature, for example, amendments to the composition of foods for specific groups. The ambulatory references will avoid the need to introduce new Regulations every time any of the provisions in 609/2013 are amended by EU legislation. Such new proposals/amendments of EU regulation can be deposited for Parliamentary scrutiny by the appropriate committees and this is done regularly through the production of an explanatory memorandum.

## 5. Extent and Territorial Application

5.1 This Instrument extends only to England.

5.2 This Instrument applies only to England.

5.3 Scotland, Wales and Northern Ireland are introducing their own separate but parallel Instruments to similar timescales.

## 6. European Convention on Human Rights

6.1 As the Instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

## 7. Policy background

***What is being done and why***

7.1 European Regulation 609/2013 was adopted to simplify existing compositional and labelling rules covering foods for particular nutritional uses (Directive 2009/39/EC referred to as PARNUTS). We have supported the need for the revision of the PARNUTS framework legislation to take account of food manufacturing and scientific developments, and the adoption of new pieces of legislation. Of particular importance in this context is the legislation on fortified food, nutrition and health claims, and food information for the consumer. Foods previously regulated under the PARNUTS framework, such as meal replacements for weight reduction will be treated as general foods, and regulated under existing EU legislation on food labelling and nutrition and health claims.

7.2 The FSG Regulation revokes and replaces the PARNUTS legislation and focuses on the general compositional and information requirements for the four new categories of food: (i) infant and follow-on formula (ii) processed cereal-based food and baby food (iii) medical foods (iv) total diet replacement for use in energy restricted diets for weight control. The Delegated Regulations providing the detailed labelling and compositional rules for these four categories of food will start to apply from 2019 onwards.

7.3 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 this Instrument. In the meantime the majority of the compositional, labelling and

advertising rules will continue to be enforced by existing Statutory Instruments (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

(vi) The Foodstuffs Suitable for People Intolerant to Gluten (England) Regulations 2010 (to be revoked by a separate SI).

7.4 Where rules are now unnecessary they will be revoked by this Instrument, 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.

***Key changes in the enforcement provisions of the new Regulations***

7.5 While the FSG Regulation has direct application in all Member States (and therefore does not require us to transpose it in domestic law), the offences and penalties for non-compliance will be contained in national legislation. As detailed in paragraph 7.3, the majority of the compositional and labelling rules will continue to be enforced by existing SIs, but, as a matter of policy, it has been determined that we should amend the enforcement provisions to enable enforcement authorities to issue Improvement Notices in respect of breaches of the existing rules as an alternative to criminal action as a first step.

7.6 This Instrument will do the following:

- Use powers in the Food Safety Act (1990), with appropriate modifications, to apply the provisions relating to Improvement Notices (which include powers of entry and rights of appeal) for the purposes of enforcing the requirements of the FSG Regulation. This is to be achieved by amending each of the existing SIs so that they include the Food Safety Act's Improvement Notice regime.
- Operate so that an enforcement authority can issue an Improvement Notice where it is suspected that a person is failing to comply with a "specified EU requirement".
- Provide for appeals to the First-tier Tribunal in England if a business doesn't agree with the conditions of the Improvement Notice.
- Enable application of the Primary Authority principle through an amendment of the Co-ordination of Regulatory Enforcement (Enforcement Action) Order 2009 (CORE). This will extend to these Regulations the Primary Authority scheme which will mean consistency for businesses as any enforcement action has to go through their lead Local Authority.

7.7 The outcome will be the insertion of the Improvement Notice regime into the existing SIs that contain criminal offences, thus the first formal action under the FSG

Regulation would be to issue an Improvement Notice rather than a criminal sanction. The proposed change from frontline criminal offences to Improvement Notices backed up with a criminal offence for a failure to comply with a Notice effectively decriminalises regulatory offences in appropriate cases.

***Consolidation***

7.8 We agreed with the need to clarify and simplify legislation in this area in order to achieve improved consistency of how the legislation is interpreted and applied across the EU, whilst providing adequate protection for people with particular nutritional needs. This Instrument repeals rules that are no longer necessary and will be amended in future to repeal existing rules when the four Delegated Regulations apply from 2019 onwards. At that time we will consolidate existing domestic laws into one single Instrument, thus simplifying the legal framework making the legislation easier to enforce and removing unnecessary rules and burdens on businesses.

7.9 The simplification of the FSG Regulation is in line with the Government's "Red Tape Challenge" which aims to rationalise the number of regulations by reviewing their purpose and balancing the benefits against the burden they impose on industry.

## 8. Consultation outcome

8.1 A limited technical consultation was held for a four week period from 27th January to 24th February 2016. A limited unpublished consultation was considered appropriate in this case, focusing purely on the enforcement regime of the Regulations. It was not appropriate to consult on the directly applicable FSG Regulation.

8.2 The consultation was considered by enforcement experts of the Food Standards and Labelling Focus Group and the consultation documents were also placed on the Knowledge Hub, a closed forum for Local Authorities to discuss views on enforcement issues. The consultation generated 9 written responses from trade associations representing views of affected sectors of the industry (infant formulae and infant food, specialist medical food, low calorie diet food, and specialist sports food sectors), Non-Government Organisations (NGOs, mostly in relation to infant formulae) and Local Authorities.

8.3 The use of Improvement Notices was welcomed by two thirds of respondents as a way of enabling enforcement to improve, but NGOs indicated a preference for the status quo so that all provisions would continue to attract a criminal sanction if breached. For those in favour of Improvement Notices, it was recognised that their use in other areas of food labelling has been shown to be proportionate and sensible, and they give enforcement officials flexibility to take whatever action they think necessary to protect the health of consumers and have led to improved compliance.

8.4 However, it was also recognised that although Improvement Notices are a good thing and an additional tool for enforcement, they should not be a complete substitution for criminal sanction e.g. for actions which pertain to consumer safety or which are potentially harmful to human health. Most respondents indicated that criminal sanctions are an appropriate enforcement mechanism for a failure to comply with an Improvement Notice. In this context, it was considered that most businesses will take an Improvement Notice seriously and will take steps to remedy the situation.

## 9. Guidance

9.1 For the most part the current guidance relating to PARNUTS legislation remains relevant but these will be updated to reflect the new changes. All interested parties including enforcement authorities will be informed when the new Regulations come into force and information about the key changes will be highlighted. Updated guidance will be published online at www.gov.uk and information will be circulated directly to enforcement authorities via the Knowledge Hub.

9.2 Guidance on the use of Improvement Notices has been published by the Food Standards Agency. Enforcement bodies are familiar with the use of Improvement Notices from the enforcement of other food labelling legislation that has been introduced in recent years.

## 10. Impact

10.1 The impact on business, charities or voluntary bodies is small. The impact is assessed as low cost and has been cleared by the Regulatory Policy Committee (ref: RPC-3046(1)-DH). Apart from the new enforcement regime, the proposed changes are purely consolidative with no impacts on business from the change in regulations which are not a result of the directly applicable FSG Regulation. The only costs faced by business are familiarisation costs of £15,700. This results in a slight IN with an estimated equivalent annual net cost to business (EANCB) of less than £0.01m.

10.2 The impact on the public sector is small. Although these Regulations would maintain the status quo regarding the enforcement of European regulation in this area, Local Authorities would need to become familiar with the new Instrument with an estimated cost of £9,400. The use of Improvement Notices in this Instrument is a change from the current enforcement regime, but enforcement practitioners will be familiar with their use for other food labelling legislation (e.g. the Food Information Regulations 2014) and therefore additional familiarisations costs are considered negligible. However, there will be a requirement to provide funding for the Tribunals who will be determining appeals against an Improvement Notice, estimated at a cost of £7,200 to set up and a cost of £3,500 per appeal. Ongoing workloads for Trading Standards Officers are not expected to increase as a result of these Regulations, as enforcement work for the products affected is already required.

10.3 As these Regulations implement the rules covering the composition, labelling and advertising of foods purchased and consumed by potentially nutritionally vulnerable people, our policy has taken account of public health, safety and consumer protection aspects. In this respect we have taken due regard of Secretary of State's duties to reduce inequalities in access to care and the outcomes of care, and in particular with respect to section 1C of the NHS Act 2006 (duty to reduce health inequalities) and the Equality Act 2010 (S.149 Public sector equality duty).

10.4 We have paid due regard to advancing equality of opportunity and, in particular, regarding the views of NGOs who could be considered as representing groups (e.g. women, maternity and pregnancy, and families with infants) with a protected characteristic. NGOs have concerns regarding the advertising and marketing of infant formulae in relation to the impact on parents' perceptions and decisions regarding infant feeding, and have advocated the maintenance of criminal sanctions in the SI. Whist this is their view, the current criminal regime has caused difficulties for enforcement which has limited the public health outcome. Evidence gathered during the development of these Regulations and from the consultation indicates that

Improvement Notices will make businesses more compliant, thus advancing equality of opportunity and fostering good relations with the aim of promoting better health outcomes.

10.5 Regarding the power of entry for Authorised Officers such as Trading Standards Officers and Environmental Health Officers who have the right to enter any premises unannounced within their Authority's area, we have considered the case of private dwellings if used by food businesses and implications for The Human Rights Act 1998. In such cases we are satisfied that the power of entry is made subject to a magistrates warrant so that, in the case of an initial request, Authorised Officers have to get a warrant before they can request entry.

10.6 The implementation of updated food composition and labelling standards as required by the FSG Regulation to protect public health is evidence of complying with Secretary of State duties and the consultation responses support the introduction of Improvement Notices as a way of enabling enforcement to improve, with the aim of leading to improved compliance. This Instrument will be updated when the four Delegated Regulations start to apply (from 2019) and public sector equality duties and duties to reduce health inequalities will be considered again at that time.

10.7 An Impact Assessment has not been prepared for this Instrument.

## 11. Regulating small business

11.1 The legislation applies to activities that are undertaken by small businesses, although there are very few in this sector.

11.2 To minimise the impact of the requirements on small businesses (employing up to 50 people), the approach taken is implementation of the minimal requirements of the FSG Regulation. More detailed rules will apply from 2019 onwards and this Instrument will be amended at that time and subject to scrutiny, including the impact on small businesses.

## 12. Monitoring & review

12.1 The requirements set out in this Instrument should ensure that the labelling and composition of foods for specific groups are in compliance with EU measures in the FSG Regulation. The rules will be monitored though discussions with industry and enforcement authorities. These discussions with inform future amendments to the Instrument which will be necessary to enforce the detailed labelling and composition provisions contained within the four Delegated Regulations that will apply from 2019 onwards.

## 13. Contact

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13.2 Kathryn.callaghan@dh.gsi.gov.uk or Nutritionlegislation@dh.gsi.gov.uk can answer any queries regarding the Instrument.