

EXPLANATORY MEMORANDUM TO

THE FOOD FOR SPECIFIC GROUPS (INFORMATION AND COMPOSITIONAL REQUIREMENTS) (AMENDMENT) (ENGLAND) REGULATIONS 2019

2019 No. 44

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health & Social Care and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

- 2.1 This instrument provides the enforcement regime for Commission Delegated Regulation (EU) No 2016/128 on food for special medical purposes (FSMP). It provides the offences and penalties for breaching these new EU rules on FSMP, other than those for infants.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 The Joint Committee on Statutory Instruments (JCSI) 9th report for 2016-2017 identified errors in the drafting of The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016, SI 2016/688. To correct the errors, S.I. 2016/688 was amended by The Food for Specific Groups (Information and Compositional Requirements) (England) (Amendment) Regulations 2017, S.I. 2017/62.
- 3.2 However, the JCSI's 25th report for 2016-2017 reported S.I. 2017/62 for amending the amendments made in the Schedule to S.I. 2016/688, but not directly amending the individual statutory instruments, amended by S.I. 2016/688.
- 3.3 We have noted the JCSI's comments but have decided it would not be helpful to attempt to make the changes at this stage. The EU regulatory regime is in a period of transition which is likely to lead to fundamental revision of the legislation in question. We anticipate revoking the instruments that were affected by the report.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

- 3.4 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is England and Wales.
- 4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

- 5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

- 6.1 Regulation (EU) No 609/2013 ('the FSG Regulation') sets out general rules governing the composition and labelling of food intended for infants and young children, food for special medical purposes (FSMP) and total diet replacement for weight control. These categories of food are collectively referred to as 'Food for Specific Groups'.

- 6.2 Under the FSG Regulation, the Commission is required to adopt specific compositional and labelling rules through delegated acts. The Commission has made the following delegated acts:

- a) Commission Delegated Regulation (EU) 2016/128 (food for special medical purposes)
- b) Commission Delegated Regulation (EU) 2016/127 (infant and follow-on formulae)
- c) Commission Delegated Regulation (EU) 2017/1798 (diet replacement for weight control)

- 6.3 [Commission Delegated Regulation \(EU\) 2016/128](#) ('the Delegated Regulation') applies from 22 February 2019 to FSMP, other than FSMP for infants to which it applies from 22 February 2020. (The other delegated acts have dates of application from February 2020 with some dates not yet set). The Delegated Regulation repeals Directive 1999/21/EC which previously set detailed requirements for FSMP, with the exception of FSMP for infants, for which Directive 1999/21/EC will continue to apply until 22 February 2020.

- 6.4 This instrument makes provision for enforcement of the specific requirements for FSMP, other than FSMP for infants, set out in the Delegated Regulation. It does this by amending the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (S.I. 2016/688) ('The 2016 Regulations'). The 2016 Regulations implemented the FSG Regulation in England.

- 6.5 The instrument also amends the Medical Food (England) Regulations 2000 S.I. 2000/845 to exclude FSMP, other than FSMP for infants, from the current statutory regime. The instrument also makes provision for a transitional period for using up current stocks of FSMP provided the products comply with the current requirements, in accordance with Article 21 of the FSG Regulation.

- 6.6 In respect of FSMP for infants the compositional, labelling and advertising rules will continue to be enforced by existing Statutory Instruments and their amendments as follows, until their date of revocation:

- (i) The Medical Food (England) Regulations 2000
- (ii) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009

This instrument contains an ambulatory reference. References in the instrument to provisions of the Delegated Regulation are to be read as those provisions amended from time to time. Any amendments will be minor and highly technical in nature, for example, amendments to the composition of foods for specific groups. The ambulatory reference will avoid the need to introduce new Regulations every time any

of the provisions in the Delegated Regulation are amended by EU legislation, should this happen while the UK is still a member of the EU. Such new proposals/amendments can be deposited for Parliamentary scrutiny by the appropriate committees and this is done regularly through the production of an explanatory memorandum.

7. Policy background

What is being done and why?

- 7.1 The FSG Regulation sets general compositional and information requirements for four food categories: (i) infant and follow-on formula (ii) processed cereal-based food and baby food (iii) food for special medical purposes (iv) total diet replacement for use in energy restricted diets for weight control.
- 7.2 The FSG Regulation foresaw the development of Delegated Regulations to provide the detailed compositional and information requirements for each of these four food categories. The first of these to come into force is Commission Delegated Regulation (EU) 2016/128 which supplements the FSG Regulation with the detailed rules on FSMP.
- 7.3 FSMP are specialist foods intended for the exclusive or partial feeding of people whose nutritional requirements cannot be met by normal foods.
- 7.4 The Delegated Regulation updates the composition and labelling rules for FSMP. The UK agreed with the need to update legislation in this area in order to provide adequate protection for people with particular nutritional needs.
- 7.5 In summary, the Delegated Regulation:
 - updates existing rules on FSMP, taking account of scientific developments and new legislation on food information to consumers.
 - prohibits nutrition and health claims on FSMP. This is to avoid inappropriate promotion of these specialist products which are for use under medical supervision.
 - extends to FSMP intended for infants and young children the same rules on pesticides that apply to infant formula and baby foods.
- 7.6 The Delegated Regulation was adopted in September 2015 so industry has had three years notice to allow them to prepare in advance of the rules coming into force.
Enforcement provisions of the new Regulations
- 7.7 This instrument makes the Delegated Regulation enforceable in England by setting the offences and penalties for non-compliance with the new rules.
- 7.8 This instrument extends the existing enforcement regime for the overarching FSG Regulation to cover the new FSMP rules.
- 7.9 The enforcement regime for the new FSMP rules is similar to the previous FSMP enforcement regime. The only difference being that Improvement Notices will now be the sole first formal action for breaches of the legislation. Failure to comply with an Improvement Notice can lead to a criminal offence. Under the previous regime criminal sanctions could also be used as a first formal enforcement action. Under the new regime, criminal sanctions may still be used for serious offences breaching other relevant legislation, for example, the Food Safety Act 1990.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

- 9.1 This instrument amends the Food for Specific Group (Information and Compositional Requirements) (England) Regulations 2016. Since we are likely to make further amendments to the legislation in this area as the other delegated acts made under the FSG Regulation start to apply we will consider consolidation of the legislation at that stage.

10. Consultation outcome

- 10.1 A limited technical consultation was held for a four-week period from 20th September to 18th October 2018. A limited 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 EU Delegated Regulation.
- 10.2 The consultation was sent to enforcement experts of the Food Standards and Labelling Focus Group, industry stakeholders, health professional and consumer groups and Non-Government Organisations (NGO) 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 3 responses from health professional bodies and NGOs.
- 10.3 The proposed enforcement regime was accepted by respondents with a request for data on the current use of Improvement Notices and reassurance that incorrect or misleading information would be dealt with effectively. We have not been able to ascertain figures on use of Improvement Notices but discussion with enforcement experts has confirmed that they are a welcome tool for improving compliance. 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.
- 10.4 However, it is also recognised that although Improvement Notices are a useful 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. Criminal sanctions are considered 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.

11. Guidance

- 11.1 Guidance relating to FSMP legislation will be updated to reflect the new changes by 22 February 2019. 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 local authority enforcement officers via the Knowledge Hub.

12. Impact

- 12.1 The impact on business, charities or voluntary bodies is small. The only costs faced by business are familiarisation costs with an estimated total one-off cost to industry of £7,800. This results in an estimated equivalent annual net cost to business (EANCB) of less than £0.01m.
- 12.2 The impact on the public sector is small. Local authorities would need to become familiar with the new instrument with an estimated total one-off cost to the public sector of £9,400.
- 12.3 An Impact Assessment has not been prepared for this instrument because there is low level of impact per business and not many businesses will be affected since the number of manufacturers of these specialised products is small.

13. Regulating small business

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 No specific action is proposed to minimise regulatory burdens on small businesses. This is because all businesses have had 3-years notice of the new rules since the Delegated Regulation was adopted in September 2015 and the estimated impact on businesses is small.

14. Monitoring & review

- 14.1 A statutory review clause is included in the Regulation being amended (SI 2016/688) and therefore the review of the legislation will be carried out in accordance with that existing provision.

15. Contact

- 15.1 Mary McNamara at the Department of Health & Social Care Telephone: 020 7210 4850 or email: Nutritionlegislation@dhsc.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Jenny Oldroyd/Harriet Becher at the Department of Health & Social Care can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 The Minister for Public Health and Primary Care, Steve Brine at the Department of Health & Social Care can confirm that this Explanatory Memorandum meets the required standard.