EXPLANATORY MEMORANDUM TO

THE FOOD FOR SPECIFIC GROUPS (FOOD FOR SPECIAL MEDICAL PURPOSES FOR INFANTS, INFANT FORMULA AND FOLLOW-ON FORMULA) (INFORMATION AND COMPOSITIONAL REQUIREMENTS) (AMENDMENT ETC.) (ENGLAND) REGULATIONS 2020

2020 No. 43

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 the second part of Commission Delegated Regulation (EU) 2016/128 on food for special medical purposes (FSMP) developed to satisfy the nutritional requirements of infants, and for Delegated Regulation (EU) 2016/127 on infant formula and follow-on formula (IFFOF). It provides the penalties for breaching these updated EU rules on FSMP for infants and IFFOF.

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 now amended those instruments in the correct manner in these Regulations.

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 The Food for Specific Groups 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. The FSG Regulation is enforced by The Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (S.I. 2016/688) ('the 2016 Regulations').

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).

Food for Special Medical Purposes

6.3 Commission Delegated Regulation (EU) 2016/128 ('the FSMP Delegated Regulation') was adopted in September 2015. The date of application of the first part of the FSMP Delegated Regulation relating to FSMP, other than FSMP for infants was 22 February 2019. This is enforced by The Food for Specific Groups (Information and Compositional Requirements) (Amendment) (England) Regulations 2019 (S.I. 2019/44) ("the 2019 Regulations"). The second part of the FSMP Delegated Regulation relating to FSMP for infants applies from 22nd February 2020.

6.4 The FSMP Delegated Regulation repeals Directive 1999/21/EC which previously set detailed requirements for FSMP.

Infant Formula and Follow-on Formula

6.5 Commission Delegated Regulation (EU) 2016/127 ('the IFFOF Delegated Regulation') applies from 22nd February 2020 except in respect of IFFOF made from protein hydrolysates, for which the rules will apply from 22nd February 2021.

6.6 The IFFOF Delegated Regulation amends Directive 2006/141/EC so that from 22nd February 2020, Directive 2006/141/EC will only apply to IFFOF made from protein hydrolysates.

Diet Replacement

6.7 The date of application for the Delegated Regulation on diet replacement for weight control is set to apply from 27th October 2022.

Objective of this Statutory Instrument

6.8 This instrument makes provision for enforcement in England of the specific requirements for FSMP for infants and IFFOF, set out in the respective Delegated Regulations. It does this by amending the 2016 Regulations. Similar instruments are being made in Scotland, Wales and Northern Ireland.

6.9 The instrument also revokes the Medical Food (England) Regulations 2000 S.I. 2000/845 and amends the Infant Formula and Follow-on Formula (England) Regulations 2007 so that from 22nd February 2020 it no longer applies to IFFOF but will continue to apply to IFFOF made from protein hydrolysates until 22nd February 2021.

6.10 The instrument also makes provision for a transitional period for selling through stocks of FSMP for infants and IFFOF placed on the market or labelled before 22nd February 2020 provided the products comply with the current requirements, in accordance with Article 21 of the FSG Regulation.

6.11 In respect of IFFOF made from protein hydrolysates 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 Infant Formula and Follow-on Formula (England) Regulations 2007

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

6.12 This instrument contains an ambulatory reference. References in the instrument to provisions of the Delegated Regulations 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 during the Implementation Period when EU Regulations will be directly applicable. 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.

Food for Special Medical Purposes

7.3 Commission Delegated Regulation (EU) 2016/128 which supplements the FSG Regulation with the detailed rules on FSMP came into force in February 2019 in

respect of FSMP other than those for infants. The second part of this FSMP Delegated Regulation, relating to FSMP for infants applies from 22nd February 2020.

7.4 FSMP are specialist foods intended for the exclusive or partial feeding of people whose nutritional requirements cannot be met by normal foods.

7.5 The FSMP Delegated Regulation updates the composition and labelling rules for FSMP and these rules were adopted in all EU Member States in September 2015, allowing industry several years to prepare in advance of the rules coming into force. The UK agreed with the need to update legislation in this area to provide adequate protection for people with particular nutritional needs.

7.6 In summary, in respect of FSMP for infants, the FSMP Delegated Regulation:

- updates existing rules on FSMP for infants, taking account of scientific developments and new legislation on food information to consumers.
- prohibits nutrition and health claims on FSMP for infants. 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

Infant Formula and Follow-on Formula

7.7 Commission Delegated Regulation (EU) 2016/127 ('the IFFOF Delegated Regulation') was adopted in all EU Member States in September 2015 and applies from 22nd February 2020 except in respect of IFFOF made from protein hydrolysates, for which the rules will apply from 22nd February 2021.

7.8 The IFFOF Delegated Regulation updates the compositional, labelling and marketing rules for infant and follow-on formula.

7.9 In summary, the IFFOF Delegated Regulation:

- updates existing rules on IFFOF, taking account of scientific developments and new legislation on food information to consumers
- Prohibits nutrition and health claims on infant formula
- Requires businesses to notify infant formula and some follow-on formula products to the Secretary of State.

Enforcement provisions of the new Regulations

7.10 This instrument makes the Delegated Regulations enforceable in England by setting the penalties for non-compliance with the new rules.

7.11 This instrument extends the existing enforcement regime for the overarching FSG Regulation to cover the new rules.

7.12 Improvement Notices will be the first formal action for breaches of these new provisions in the legislation. Failure to comply with an Improvement Notice can lead to a criminal offence. Criminal sanctions under other legislation may also be used as a first formal enforcement action in appropriate cases, for example, food safety under the Food Safety Act 1990 or food crime under the Fraud Act 2006.

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 14th November to 12th December 2019. 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 EU Delegated Regulations which were adopted in 2015.

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 responses from one NGO, one industry representative and four local authority enforcement representatives, including a regional local authority enforcement association.

10.3 The consultation proposed an enforcement regime which would mean Improvement Notices would be the first formal action in the case of non-compliance with the rules on IFFOF and FSMP for infants. Respondents supported the proposal, on the understanding that criminal sanctions could be used via other legislation in case of risk to health or food fraud.

10.4 The enforcement regime remains consistent with the 2016 Regulations and the 2019 Regulations so that enforcement officers will use Improvement Notices as the first line action to deal with non-compliance of these provisions.

11. Guidance

11.1 Guidance relating to this new legislation on IFFOF and FSMP for infants will be updated to reflect the new changes by 22nd February 2020. 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 £1,822. 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 £18,814.

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 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 four-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 Prevention, Public Health and Primary Care, Jo Churchill, at the Department of Health & Social Care can confirm that this Explanatory Memorandum meets the required standard.