SR 2020 No. 16

EXPLANATORY MEMORANDUM TO

THE FOOD SAFETY (INFORMATION AND COMPOSITIONAL REQUIREMENTS) (AMENDMENT) REGULATIONS (NORTHERN IRELAND) 2020

1. Introduction

1.1. This Explanatory Memorandum has been prepared by the Food Standards Agency to accompany the statutory rule (details above) which is laid before the Northern Ireland Assembly.

1.2. The Statutory Rule is made under Articles 15(1)(a) and (e) and (2)(b), 16(1) and (2), 25(1) and (3), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991 and section 2(2) of, and paragraph 1A(1) of Schedule 2 to, the European Communities Act 1972 and is subject to the negative resolution procedure.

2. Purpose

2.1. This Statutory Rule 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) by way of amendments to the Food Safety (Information and Compositional Requirements) Regulations 2016 (The 2016 Regulations).

3. Background

3.1. The Food for Specific Groups Regulation (EU) No 609/2013 ('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.

3.2. The FSG Regulation foresaw the development of Delegated Regulations to provide the detailed compositional and information requirements for each of these four food categories.

3.3. Under the FSG Regulation, the Commission is required to adopt specific compositional and labelling rules for each category through delegated acts. The Statutory Rule will amend the Food Safety (Information and Compositional Requirements) Regulations 2016 (The 2016 Regulations) to extend the existing enforcement regime applicable to provisions within the parent FSG Regulation to provisions within Commission Delegated Regulation (EU) 2016/128 (food for special medical purposes) and Commission Delegated Regulation (EU) 2016/127 (infant and follow-on formulae)

Foods for Specific Medical Purposes (FSMP)

3.4. 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.

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

3.6. 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.

3.7. 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 (IFFOF)

3.8. 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 accept in respect of IFFOF made from protein hydrolysates, for which the rules will apply from 22nd February 2021.

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

3.10. 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 Food Standards Agency.

Objective of this Statutory Rule

3.11. The Statutory Rule makes provision for enforcement in Northern Ireland of the specific requirements for FSMP for infants and IFFOF, set out in the respective Delegated Regulations. It does this by amending the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 . Similar instruments are being made in England, Scotland and Wales.

3.12. This rule revokes the Medical Food Regulations (Northern Ireland) 2000 (S.R. 2000 No. 187) and the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007 (S.R. 2007 No. 506) 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.

3.13. This rule 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.

3.14. In respect of IFFOF made from protein hydrolysates the compositional, labelling and advertising rules will continue to be enforced by existing statutory rules and their amendments as follows, until their date of revocation:

a. The Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007

b. The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) Regulations (Northern Ireland) 2009 (S.R. 2009 No. 398)

3.15. This rule contains an ambulatory reference. References in the rule 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.

4. Consultation

4.1. 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 directly applicable EU Delegated Regulations which were adopted in 2015.

4.2. The consultation was sent to enforcement officers, industry stakeholders, health professionals, consumer groups and Non-Government Organisations (NGOs).

4.3. The consultation proposed an enforcement regime which would in line with existing FSG regulations, provide improvement notices as the first formal action in the case of non-compliance with the rules on IFFOF and FSMP for infants. The provision of Improvement Notices is backed up with a criminal offence for failure to comply with an Improvement Notice.

4.4. There were two responses to the consultation; one was content with the proposed formal action in relation to breaches of the provisions of Delegated Regulations (EU) 2016/128 and (EU) 2016/127, and the other expressed some concern in relation to the proposed informal first step for tackling breaches which do not pose an immediate risk to public health.

4.5. The enforcement regime remains consistent with existing FSG related regulations in providing enforcement officers with the power to use Improvement Notices as the first line action to deal with non-compliance of these provisions. This approach considers that criminal sanctions can still be used for serious offences relating to immediate risk to public health under other relevant legislation (e.g. if the food was rendered injurious to health, contrary to Article 6 of the Food Safety (Northern Ireland) Order 1991).

5. Equality Impact

5.1. This rule applies equally across society and therefore has no implications under section 75 of the Northern Ireland Act 1998.

6. Regulatory Impact

6.1. 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 £107 for industry (per manufacturer)**.** Familiarisation costs are limited as businesses have had a long transition period to comply since the rules were adopted in 2015 and are therefore already familiar with the Regulations. We are currently not aware of any manufacturers in Northern Ireland.

6.2. The impact on the public sector is small. District councils need to become familiar with the new rule with an estimated one-off cost £54 for each enforcement officer

6.3. A full Impact Assessment has not been prepared for this rule 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.

7. Financial Implications

7.1. None

8. Section 24 of the Northern Ireland Act 1998

8.1. This rule provides for the enforcement of EU law. There is nothing within it which could be construed as being discriminatory.

9. EU Implications

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

10. Parity or Replicatory Measure

10.1. Similar regulations are being made in England, Scotland and Wales.

11. Additional Information

Not Applicable