

**EXPLANATORY MEMORANDUM TO**  
**The Food Safety (Information and Compositional Requirements)**  
**(Amendment) Regulations (Northern Ireland) 2019**

**SR 2019 No. 9**

**1. Introduction**

- 1.1. This explanatory memorandum has been prepared by the Food Standards Agency in Northern Ireland to accompany the Statutory Rule (SR) (details above) which is laid before the Northern Ireland Assembly.
- 1.2. The SR is made under Articles 16(1) and (2), 25(1) and (3) and 47(2)(b) of the Food Safety (Northern Ireland) Order 1991 and paragraph 1A of Schedule 2 to the European Communities Act 1972.
- 1.3 The SR is due to come into operation on 22<sup>nd</sup> February 2019.

**2. Purpose of the Rule**

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

**3. Policy Background**

- 3.1. Regulation (EU) No 609/2013 (“the Food for Specific Groups (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 (FSMP); and (iv) total diet replacement for use in energy restricted diets for weight control. These categories of food are collectively referred to as ‘Food for Specific Groups (FSG)’.
- 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. 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.
- 3.3. FSMP are specialist foods intended for the exclusive or partial feeding of people whose nutritional requirements cannot be met by normal foods.
- 3.4. 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)

- 3.5. 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 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.
- 3.6. This SR 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 Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 (S.R. 2016 No. 251), ('The 2016 Regulations'). The 2016 Regulations implemented Regulation (EU) No 609/2013, the FSG Regulation, in Northern Ireland.
- 3.7. The SR also amends the Medical Food Regulations (Northern Ireland) 2000 (S.R. 2000/187) to exclude FSMP, other than FSMP for infants, from the current statutory regime as well as making 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.
- 3.8. In respect of FSMP for infants 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:
  - i) The Medical Food Regulations (Northern Ireland) 2000
  - ii) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) Regulations (Northern Ireland) 2009

*What is being done and why?*

- 3.9. 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.
- 3.10. 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.
- 3.11. 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.

#### **4. Consultation**

4.1. FSA in NI held a shortened four-week consultation between 2<sup>nd</sup> and 30<sup>th</sup> October 2018 with stakeholders and interested parties. No responses were received.

#### **5. Equality Impact**

5.1. This SR will apply in equal measure to all Section 75 groups. It is not expected that any of these changes will impact differentially across any of the section 75 groups.

#### **6. Regulatory Impact**

6.1. A Partial Impact Assessment was carried out to focus on the costs and benefits of different enforcement options only. The costs to business and district councils as a result of the new SR are estimated at £106 and £300 respectively (total of £406). This total is substantially below £1 million for any reasonable estimate.

#### **7. Financial Implications**

7.1. N/A

#### **8. Section 24 of the Northern Ireland Act 1998**

8.1. This SR will apply in equal measure to all groups. It is not expected that any of these changes will impact differentially across any as determined by Section 24.

#### **9. EU Implications**

9.1. This SR does not relate to withdrawal from the European Union. However, the EU implications of the FSMP for infants to which 'the Delegated Regulation' applies from 22 February 2020 are at present unknown.

#### **10. Parity or Replicatory Measure**

10.1. Equivalent legislation will be introduced in GB by the Department of Health and Social Care in England, Food Standards Scotland and the Welsh Assembly Government.

#### **11. Additional Information**

11.1. N/A