

## **Explanatory Memorandum to the Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019**

This Explanatory Memorandum has been prepared by the Health and Social Services Group and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

### **Minister's Declaration**

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019. I am satisfied that the benefits justify the likely costs.

Vaughan Gething AM  
Minister for Health and Social Services  
21 January 2019

## **1. Description**

This instrument amends the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (“the 2016 FSG Regulations”) and allows for the enforcement of the Commission Delegated Regulation (EU) 2016/128 on food for special medical purposes (“the FSMP Delegated Regulation”), other than those intended for infants. It contains the offences and penalties for non-compliance with compositional and labelling rules, making the FSMP Delegated Regulation workable and enforceable in Wales. The enforcement regime will be the same as the 2016 regulation it amends, so that the first formal action would be to issue an Improvement Notice rather than a criminal sanction.

## **2. Matters of special interest to the Constitutional and Legislative Affairs**

None.

## **3. Legislative background**

Welsh Ministers have powers to make the proposed Regulations under sections 17(1) and (2), 26(1) and (3) and 48(1)(b) and (c) of the Food Safety Act 1990 (“the 1990 Act”) as read with paragraph 1A(1) of Schedule 2 to the European Communities Act 1972.

Powers under the 1990 Act, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999, as read with Section 40(3) of the Food Standards Act 1999, and were transferred to the Welsh ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (“GOWA 2006”).

These Regulations are being made under the negative resolution procedure.

## **4. Purpose & intended effect of the legislation**

This instrument provides the enforcement regime for the FSMP Delegated Regulation. It provides the offences and penalties for breaching these new EU rules on Foods for Special Medical Purposes (“FSMP”), other than those for infants.

Regulation (EU) No 609/2013 on The Food for Specific Groups (“The FSG EU 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 are collectively referred to as Foods for Specific Groups (“FSG”).

Under the FSG EU 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).

The FSMP Delegated Regulation, referred to at a) above, is the first of the Delegated Regulations to come into force. It supplements the FSG EU Regulation with detailed rules on FSMP. (FSMP are specialist foods intended for the exclusive or partial feeding of people whose nutritional requirements cannot be met by normal foods).

It 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 FSMP 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.

The FSMP 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.

The FSMP 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.

In respect of FSMP for infants, 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 Medical Food (Wales) Regulations 2000
- (ii) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009.

This instrument contains an ambulatory reference. References in the instrument to provisions of the FSMP Delegated Regulation (defined in the instrument as 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.

This SI also amends the Medical Food (Wales) Regulations 2000 SI 2000/1866 to exclude FSMP, other than FSMP for infants, from the current statutory regime. The SI 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 EU Regulation.

## **5. Consultation**

In Wales, a limited, technical consultation was held for a four week period commencing on 1 October 2018. The consultation was shared with enforcement bodies, industry stakeholders, health professional and consumer groups and other relevant non-government organisations.

There were several reasons for a shortened consultation. It ensured alignment with the rest of the UK, allowed us to stick to a timetable to ensure we meet the EU deadline of 22 February 2019 and thereby avoid potential infraction proceedings for the UK, and the proposed domestic legislation is to provide for enforcement provision and will not introduce significant costs to businesses.

No responses were received in Wales, five responses were received UK wide. No objection to the proposed approach to enforcement was expressed and no associated additional costs were identified by industry or enforcement bodies. There was confirmation of the use of Improvement Notices as a useful tool for improving compliance. No amendments to this SI (nor the equivalent UK domestic SIs) were made as a consequence of the consultation.

A limited unpublished consultation was considered appropriate in this case, focusing purely on the enforcement regime of the Regulations. The consultation generated five responses from health professional bodies and NGOs.

## **6. Regulatory Impact Assessment (RIA)**

A full regulatory impact assessment has not been carried out for this Instrument as the impact on businesses, charities or voluntary bodies is expected to be small.

### **Two options have been considered:**

**Option 1: Do nothing** – Domestic legislation will not be put in place to provide an enforcement regime for The FSMP Delegated Regulation. Other legislation, for example the Food Safety Act 1990, would provide enforcement powers in the most severe cases breaching food safety.

The EU Delegated Regulation is binding in its entirety and directly applicable in all Member States. It is therefore not necessary to transpose the provisions of the Regulation into domestic law. Doing nothing would mean that the Regulation will still

come into force, but we would not have the domestic legislation to make it workable and enforceable in Wales. This could result in several unwanted impacts including:

- lack of legal clarity for enforcement officers and businesses;
- risk to vulnerable consumers if there are no sanctions for non-compliant products and such products therefore remain on the market
- impact on the supply chain of these specialist products due to uncertainty by business
- lack of consumer confidence in enforcement of the law
- the UK would be in breach of its legal obligations under the EU Treaty and may face infraction procedures.

**Option 2: Introduce Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019** to provide an enforcement regime for Wales for the FSMP Delegated Regulation.

Option 2 is the preferred approach. This option will introduce the use of Improvement Notices as the first form of action for enforcement of the FSMP Delegated Regulation. The FSG EU Regulation has enforcement provisions using Improvement Notices. This SI will extend those enforcement provisions to the requirements of the new FSMP Delegated Regulation.

Improvement notices are already in use to enforce other areas of food law including in the FSG 2016 Regulations and are well understood by trading standards officers. Enforcement bodies and industry consider Improvement Notices a less burdensome approach to resolving problems of non-compliance. We have not been able to quantify costs in relation to the use of improvement notices but evidence gathered during the development and consultation of the FSG 2016 Regulations from both industry and enforcement bodies highlighted that the use of criminal sanctions as a first formal action can cause difficulties for enforcement thus limiting the public health outcome. The introduction of Improvement Notices, as a first formal action, was supported as a way of enabling businesses to improve, leading to improved compliance and so promoting better health outcomes.

## **Costs and Benefits**

### **Costs to business**

This legislation affects manufacturers and retailers of food for special medical purposes. **There are no known manufacturers of FSMP products in Wales.**

No significant changes are being proposed under Option 2. We estimate that businesses will only have to spend a short amount of time familiarising themselves with the new procedures. Guidance documents will be updated and published accordingly. Once implemented, the proposed regime is deregulatory. That means that any business found not to be complying with the regulations will (except in the most serious cases) face a non-legislative, less burdensome approach to resolving the problem. Compliance costs are thus expected to fall.

## **Costs to local authorities**

The impact on the public sector of implementing Option 2 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. Ongoing workloads for Trading Standards Officers are not expected to increase as a result of this instrument, as enforcement work for the products affected is already required.

It is estimated that it would take one Trading Standards Officer one hour to read and become familiar with the SI and the new enforcement regime. The hourly pay rate for Qualified Trading Standards Officers is between £16 and £25 – averaging approximately £27 per hour once updated to account for non-wage labour costs and overheads, taken as 30%. The total one-off cost to the 22 local authorities in Wales is therefore estimated at £594.

Local authorities may also benefit from reduced costs from fewer prosecutions since issuing an Improvement Notice would be the first formal action rather than a prosecution.

## **Benefits to business**

### **There are no known manufacturers of FSMP products in Wales.**

There would be minimal change for businesses if Option 2 was adopted, as the FSG 2016 Regulations already provides for Improvement Notices as an option alongside criminal sanctions in the Medical Food (Wales) Regulations 2000. This SI will consolidate the use of IN as the first formal action for existing and new provisions under the FSG 2016 Regulation. The broad benefit to industry is moving from the possibility of facing criminal sanctions to the new regime where enforcement will be carried out by way of an IN as the first formal action, followed up by a criminal offence in cases where businesses continue to ignore the Notice. This may give Food Business Organisations a better chance to rectify issues before the matter comes before a criminal court.

## **Benefits to local authorities**

There are potential benefits of Option 2 in terms of moving to the Improvement Notice regime. It is anticipated these will include: reduced court costs - the number of hearings will be reduced as issues will be resolved through issuing Improvement Notices, and there will be a time saving for enforcement officers who will be able to resolve issues more quickly instead of preparing for a magistrates' court case.

Option 2 is also likely to result in better monitoring of the market regarding food for special medical purposes as Improvement Notices will be recorded whereas informal warnings from enforcement practitioners will not.

## **Benefits to consumers**

If Option 2 is adopted, this legislation will benefit those requiring food for special medical purposes as there will be better protection by way of better defined compositional standards and tighter labelling restrictions.

**Summary of the preferred option**

Option 2 is the preferred option because it ensures the proper enforcement of the FSMP Delegated Regulation in Wales and avoids the associated risk of infraction proceedings and consequent fines.