

Explanatory Memorandum for the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016

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) (Wales) Regulations 2016. I am satisfied that the benefits justify the likely costs.

Rebecca Evans AM
Minister for Social Services and Public Health
12 July 2016

1. Description

This Instrument allows for the enforcement of certain requirements of European Regulation 609/2013 on food for specific groups (“the FSG Regulation”). The Regulations introduce a lighter touch enforcement regime so that the first formal action under the FSG Regulation will be to issue an Improvement Notice rather than a criminal sanction.

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

None.

3. Legislative background

The powers enabling this instrument to be made are 6(4), 16(1), 17(1) and (2), 26(1) and (3) and 48(1) of the Food Safety Act 1990 (“the 1990 Act”) and paragraph 1A of Schedule 2 to the European Communities Act 1972 (“the 1972 Act”).

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 1999/672. These powers were transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (“GOWA 2006”).

These Regulations will follow the negative procedure.

4. Purpose & intended effect of the legislation

The FSG Regulation was adopted to simplify existing compositional and labelling rules covering foods for particular nutritional uses (Directive 2009/39/EC referred to as PARNUTS). We have supported the need for the revision of the PARNUTS framework legislation to take account of food manufacturing and scientific developments, and the adoption of new pieces of legislation. Of particular importance in this context is the legislation on fortified food, nutrition and health claims, and food information for the consumer. Foods previously regulated under the PARNUTS framework, such as meal replacements for weight reduction will be treated as general foods, and regulated under existing EU legislation on food labelling and nutrition and health claims.

The FSG Regulation revokes and replaces the PARNUTS legislation and focuses on the general compositional and information requirements for the four new categories of food: (i) infant and follow-on formula; (ii) processed cereal-based food and baby food; (iii) medical foods and (iv) total diet replacement for use in energy restricted diets for weight control. The Delegated Regulations,

providing the detailed labelling and compositional rules for these four categories of food, will start to apply from 2019 onwards.

The offences and penalties relating to the Delegated Regulations will be put in place nearer to their dates of application (2019 at the earliest) by future amendments to this instrument. In the meantime, the majority of the compositional and labelling rules will continue to be enforced by existing Statutory Instruments (SIs) and their amendments as follows, until their date of revocation:

- (i) The Infant Formula and Follow-on Formula (Wales) Regulations 2007/3573;
- (ii) The Processed Cereal-Based Foods and Baby Foods for Infants and Young Children (Wales) Regulations 2004/314;
- (iii) The Medical Food (Wales) Regulations 2000/1866;
- (iv) The Food Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997/2182;
- (v) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009/3254.

Where rules are now unnecessary they will be revoked by this instrument, in particular the following SIs will be revoked from 2 August 2016:

- (i) The Notification of Marketing of Food for Particular Nutritional Uses (Wales) Regulations 2007/1040;
- (ii) The Food for Particular Nutritional Uses (Miscellaneous Amendments) (Wales) Regulations 2010/363.

The Foodstuffs Suitable for People Intolerant to Gluten (Wales) Regulations 2016/2651 are being revoked by a separate SI.

The majority of the compositional and labelling rules will continue to be enforced by existing SIs, but, as a matter of policy, it has been determined that we should amend the SIs to enable enforcement authorities to issue Improvement Notices in respect of breaches of the existing rules as an alternative to criminal action as a first step. The improvement notice provisions will sit alongside the criminal sanctions in the existing SIs.

This Instrument will do the following:

- operate so that an enforcement authority can issue an Improvement Notice where it is suspected that a person is failing to comply with a “specified EU requirement” of the FSG Regulation. This will be done by using powers in the Food Safety Act (1990), with appropriate modifications, to apply the provisions relating to Improvement Notices (which include powers of entry and rights of appeal) for the purposes of enforcing the specified EU requirement;

- insert the Improvement Notice regime into the existing SIs that contain criminal offences. The proposed change from frontline criminal offences to Improvement Notices backed up with a criminal offence for a failure to comply with a Notice effectively decriminalises regulatory offences in appropriate cases. This is to be achieved by amending each of the existing SIs so that they include the Food Safety Act's Improvement Notice regime alongside the existing criminal sanctions;
- provide for appeals to the Magistrates Court in Wales if a business doesn't agree with the conditions of the Improvement Notice.

We agreed with the need to clarify and simplify legislation in this area in order to achieve improved consistency of how the legislation is interpreted and applied across the EU, whilst providing adequate protection for people with particular nutritional needs. This Instrument repeals rules that are no longer necessary and will be amended in future to repeal existing rules when the four Delegated Regulations apply from 2019 onwards. At that time we will consolidate existing domestic laws into one single Instrument, thus simplifying the legal framework making the legislation easier to enforce and removing unnecessary rules and burdens on businesses.

There is a requirement to put in place national legislation to allow for the enforcement of the FSG Regulation which will apply across all member states from 20 July 2016. The Regulations will come into force in Wales on 2 August 2016.

5. Consultation

A limited technical consultation was held for a six week period from 12th January to 25th February 2016. A limited consultation was considered appropriate in this case, focusing purely on the enforcement regime of the Regulations.

The consultation was sent to enforcement officers, food businesses and trade associations in the food areas affected by the FSG Regulation.

Four responses were received following the consultation – summarised below.

There were concerns that certain breaches of the regulations which would attract an improvement notice, as they are not considered a risk to immediate health, may have more far reaching consequences. Respondents were of the view that officers should have a level of discretion in determining whether a criminal sanction is appropriate or not, taking into account the wider impact on individuals.

There were also concerns that the SI would need to address the issue of serial offenders. Improvement notices whilst in force give the business a time limit to comply. Once this runs out the business could in theory decide not to comply again.

It was recognised that although Improvement Notices are a good thing and an additional 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. Most respondents indicated that criminal sanctions are 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.

No changes have been made to the legislation as a result of the consultation responses.

6. Regulatory Impact Assessment (RIA)

A full regulatory impact assessment has not been carried out for this Instrument as the impact on business, charities or voluntary bodies is expected to be small. Apart from the new enforcement regime, the proposed changes are purely consolidative with no impacts on business from the change in regulations which are not a result of the directly applicable FSG Regulation.

Two options have been considered:

Option 1: Do Nothing

Under this option, the FSG Regulation would come into force but there would be no legislation to enforce it in Wales. The UK is obliged to provide for the enforcement of EU legislation and any failure to do so may result in infraction proceedings against the UK and consequent fines. Under this option, Wales would be liable for at least part of any UK fine.

Option 2: Introduce regulations for the enforcement of the FSG Regulation

Costs

Local Authorities

Local Authorities will need to become familiar with the new SI. 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 (TSOs) is between £16 and £25 – averaging approximately £27 per hour once uprated to account for non-wage labour costs and overheads, taken as 30%. The total one-off cost to the 22 local authorities is therefore estimated at approximately £600. Ongoing workloads for TSOs are not expected to increase as a result of this SI, as enforcement work for the products affected is already required.

Enforcement practitioners will be familiar with the use of Improvement Notices so additional familiarisation costs are considered negligible.

Food Businesses

The main groups that are likely to be affected are manufacturers of products where the FSG legislation has changed in relation to the current legislation. There are now only four categories of foods within scope: infant formula and follow-on formula, food intended for infants and young children, food for special medical purposes and total diet replacement for weight control. All other foods will now be regulated under existing EU regulations on food labelling and nutrition and health claims. Furthermore, we are unaware of any businesses which produce foods for specific groups being based in Wales. As such, there will be no additional cost to food business in Wales.

Benefits

Consumers

Although the SI does not affect consumers directly, it is worth noting that the FSG Regulation maintains the high level of consumer protection as PARNUTS, ensuring adequate nutritional composition of the food to protect the most vulnerable consumers and appropriate consumer information (e.g. foods intended for infants and young children and medical foods). Removing the concept of dietetic food may impact some consumers e.g. those who found dietetic statements such as “suitable for diabetics” helpful. However, views expressed in the parallel consultation that took place in England by, for example, Diabetes UK suggest that regulating food under general food law is a benefit.

Government

There is a potential benefit to Government in terms of moving from the current frontline criminal sanctions regime to the new Improvement Notice regime. It is anticipated that any gains would originate from reduced court costs as the number of hearings will be reduced as issues will be resolved through issuing Improvement Notices, and the time saved to enforcement officers in resolving the issues more quickly instead of preparing for a magistrates’ court case. Government will also benefit as Option 2 is likely to result in better monitoring of the market regarding foods for specific groups as Improvement Notices will be recorded whereas informal warnings from enforcement practitioners will not.

Summary of the preferred option

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