

Explanatory Memorandum to the Food for Specific Groups (Information and Compositional Requirements (Wales) (Amendment) Regulations 2020

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) (Amendment) Regulations 2020. I am satisfied that the benefits justify the likely costs.

Vaughan Gething AM
Minister for Health and Social Services
31 January 2020

1. Description

These Regulations make provision for the enforcement in Wales of the specific requirements for food for special medical purposes ('FSMP') for infants set out in Commission Delegated Regulation (EU) 2016/128 on food for special medical purposes ("the FSMP Delegated Regulation"). It does so by amending the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 ("the 2016 FSG Regulations") to extend the existing enforcement regime under those regulations to apply to FSMP developed to satisfy the nutritional requirements of infants, setting the penalty for non-compliance with the new rules.

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

None.

3. Legislative background

Welsh Ministers have the power to make the proposed Regulations under sections 6(4), 16(1)(a) and (e) and (2)(b), 17(1) and (2), 26(1) and (3) and 48(1)(b) of the Food Safety Act 1990 ("the 1990 Act") and section 2(2) of, and paragraph 1A 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"). Welsh Ministers have been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink) including the primary production of food (The European Communities (Designation) (No. 2) Order 2005 (S.I. 2005/1971).

These Regulations are being made under the negative resolution procedure.

4. Purpose & intended effect of the legislation

The FSMP Delegated Regulation supplements the overarching EU Regulation (EU) No 609/2013 on Food for Specific Groups ("the FSG EU Regulation"), which 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, with detailed rules on Infant Formula and Follow on Formula ("IFFOF").

These Regulations provide the enforcement regime for the FSMP Delegated Regulation in so far as it relates to infants. It provides the offences and penalties for breaching these new EU rules on FSMP relating to infants by amending the 2016 FSG Regulations to extend the existing enforcement regime to this category of food.

The FSMP Delegated Regulation 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). The date of application of the first part of this 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) (Wales) Regulations 2019 ('the 2019 FSG Regulations').

The provisions of the FSMP Delegated Regulation relating to food developed to satisfy the nutritional requirements of infants apply from 22 February 2020 and are being enforced in these Regulations.

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

These Regulations revoke the Medical Food (Wales) Regulations 2000. It also makes provision for a transitional period for selling through stocks of FSMP for infants placed on the market or labelled before 22 February 2020, which reflects the position in the 2019 FSG Regulations which makes provision for a transitional period for selling through stocks of FSMP other than FSMP for infants placed on the market or labelled before 22 February 2019.

The FSMP Delegated Regulation updates the composition and labelling rules for FSMP. In respect of FSMP for infants it:

- 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.

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.

These Regulations contain an ambulatory reference. References within the Regulations to provisions of the FSMP 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 bound by EU rules.

These Regulations make miscellaneous amendments to the 2016 FSG Regulations to provide clarity regarding the application of section 35 of the 1990 Act so as to make clear that the reference to section 33 of the 1990 Act in section 35 of the 1990 Act is to section 33 as applied by regulation 4 of the 2016 FSG Regulations. They also correct a drafting error in regulation 4(5) of the 2016 FSG Regulations to

provide that section 39 of the 1990 Act applies to an appeal against an improvement notice.

5. Consultation

A limited technical consultation was held for four weeks from 8 November 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.

This consultation covered these Regulations and the Regulations which provide enforcement provision for EU Delegated Regulation (EU) 2016/127 on infant formula and follow on formula. Parallel consultations were conducted in England, Scotland and Northern Ireland. The consultation was shared with enforcement bodies, industry stakeholders, health professional and consumer groups and other relevant non-government organisations.

15 responses were received UK wide, six from Welsh stakeholders. Of those we received in Wales one was from a local authority, one from an NHS maternity lead and one from Baby Feeding Law Group UK (BFLG UK), the rest were from members of the public.

Concerns were raised from four respondents (including the NHS and BFLG) regarding the use of improvement notices particularly in relation to infant formula and follow on formula.

BFLG UK responded to all of the UK consultations querying the breadth of the enforcement provisions and the appropriateness of an informal first step for enforcement bodies. Officials have discussed this issue with UK counterparts and have concluded that due to the niche market, small supplier base and well-defined governing compositional/labelling legislation, the improvement notice regime remains appropriate. Furthermore we are content that under this new enforcement regime enforcement officers continue to have the enforcement tools in respect of safety where something could be injurious to health under the 1990 Act, and the ability to respond to deliberate food crime under the Fraud Act 2006. Failure to comply with an improvement notice can lead to a criminal offence. All this is in line with the Food Law (Wales) Code of Practice.

No amendments were made to these Regulations (or the equivalent UK domestic SIs) as a consequence of the consultation.

6. Regulatory Impact Assessment (RIA)

A full regulatory impact assessment has not been carried out for these Regulations 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 in so far as it relates to infants. Other legislation, for example the 1990 Act, 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 of business,
- lack of consumer confidence in enforcement of the law,
- the UK would be in breach of its legal obligations under the EU Treaty, as applied by the Withdrawal Agreement, and may face infraction proceedings.

Option 2: Introduce the Food for Specific Groups (Information and Compositional Requirements) (Wales) (Amendment) Regulations 2020 to provide an enforcement regime for Wales for the FSMP Delegated Regulation in so far as it relates to infant foods.

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 2016 FSG Regulations have enforcement provisions using Improvement Notices. These Regulations will extend those enforcement provisions to the requirements of the FSMP Delegated Regulation relating to food developed to satisfy the nutritional requirements of infants.

Improvement Notices are already in use to enforce other areas of food law including in the 2016 FSG 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 were not able to quantify costs in relation to the use of improvement notices but evidence gathered during the development and consultation of the 2016 FSG 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 application 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 to this legislation 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 these Regulations, 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 these Regulations 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 uprated 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 2016 FSG Regulations already provide for Improvement Notices as an option alongside criminal sanctions in the Medical Food (Wales) Regulations 2000. These Regulations will consolidate the use of IN as the first formal action for existing and new provisions under the 2016 FSG Regulations. 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 will therefore give food businesses the opportunity 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 as a first formal action. Failure to comply with an IN will not of itself amount to a criminal offence (criminal sanctions can continue to be used under other

legislation for serious breaches) potentially resulting in reduced associated court costs

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 were 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.