

Explanatory Memorandum to the Infant Formula and Follow-on Formula (Wales) 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 Infant Formula and Follow-on Formula (Wales) 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 set out in Commission Delegated Regulation (EU) 2016/127 on infant formula and follow-on formula (“the IFFOF Delegated Regulation”), which was adopted in all EU Member States in September 2015.

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

None.

3. Legislative background

Welsh Ministers have the powers 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) 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 by way of 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 IFFOF 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 IFFOF.

The IFFOF Delegated Regulation applies from 22 February 2020 except in respect of infant formula and follow-on formula (“IFFOF”) made from protein hydrolysates, for which the rules will apply from 22 February 2021. It updates the compositional, labelling and marketing rules for IFFOF, taking account of scientific developments and new legislation on food information to consumers, prohibits nutrition and health claims on infant formula and requires businesses to notify infant formula and some follow-on formula products to the Welsh Ministers.

The IFFOF Delegated Regulation repeals Directive 2006/141/EC (“the 2006 Directive”) with effect from 22 February 2020, and from 22 February 2021 in the case of infant formula and follow-on formula manufactured from protein hydrolysates. The

2006 Directive was implemented in Wales by the Infant Formula and Follow-on Formula (Wales) Regulations 2007 (“the 2007 IFFOF Regulations”). The 2007 IFFOF Regulations are revoked by these Regulations, along with the provisions which amend the 2007 IFFOF Regulations, but will continue to have effect in respect of IFFOF manufactured from protein hydrolysates, until 21 February 2021. In respect of IFFOF made from protein hydrolysates, the compositional, labelling and advertising rules will continue to be enforced by the 2007 IFFOF Regulations, until 21 February 2021.

These Regulations come into force on 22 February 2020, except for infant formula and follow-on formula made from protein hydrolysates, for which they come into force on 22 February 2021.

There are transitional provisions within these Regulations which provide that where infant formula or follow-on formula has been placed on the market or labelled prior to 22 February 2020 or, in the case of infant formula or follow-on formula manufactured from protein hydrolysates, 22 February 2021, it can (subject to certain requirements) continue to be marketed until stocks are exhausted.

These Regulations provide food authorities in Wales with powers under the 1990 Act, as modified, to enforce compliance with the provisions of the IFFOF Delegated Regulation in Wales. Those powers include a power to enter premises for the purpose of ascertaining whether there has been a failure to comply with the provisions of the IFFOF Delegated Regulation and/or whether there is any evidence on the premises of any such failure to comply. Improvement Notices will be the first formal action for any failure or suspected failure to comply with the IFFOF Delegated Regulation. Failure to comply with an Improvement Notice can lead to a criminal offence.

Criminal sanctions relating to food safety under the 1990 Act, or food crime under the Fraud Act 2006, may also apply in appropriate cases.

These Regulations contain an ambulatory reference. References within the Regulations to provisions of the IFFOF 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.

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) 2016/128 on food for special medical purposes. 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. It was proposed by an enforcement officer that the existing enforcement regime for the 2007 IFFOF Regulations should remain in place. 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 is 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 Food Safety Act 1990, and the ability to respond to deliberate food crime under the Fraud Act 2006. Failure to comply with an improvement notice is in itself a crime. This is in accordance 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 IFFOF Delegated Regulation in so far as it relates to IFFOF. Existing legislation such as, for example, the Food Safety Act 1990 or the Fraud Act 2006, 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 Infant Formula and Follow-on Formula (Wales) Regulations 2020 to provide an enforcement regime for Wales for the IFFOF 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 IFFOF Delegated Regulation.

Improvement Notices can already be applied under the 2007 IFFOF Regulations after being introduced by the overarching Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (“the 2016 FSG Regulations”). The difference now is that an under these Regulations an Improvement Notice will no longer, of itself constitute a criminal offence. The use of Improvement Notices in this way is 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 IFFOF 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 these Regulations. 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 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 IFFOF products in Wales.

There would be minimal change for businesses if Option 2 was adopted. Improvement Notices can already be applied under the 2007 IFFOF regulations after being introduced by the 2016 FSG regulations. These Regulations introduce Improvement Notice as the first formal action, followed up by a criminal offence in cases where businesses fail to comply with 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

As mentioned above enforcement officers are already able to use Improvement Notices for IFFOF breaches. Under these Regulations however their use will no longer give rise, of itself to a criminal offence thereby reducing the necessity in some instances of court action reducing associated costs to local authorities.

Option 2 is also likely to result in better monitoring of the market regarding IFFOF 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 infant formula or follow on formula 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 IFFOF Delegated Regulation in Wales and avoids the associated risk of infraction proceedings and consequent fines.