

Explanatory Memorandum to the Addition of Vitamins, Minerals and Other Substances (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 Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2020**. I am satisfied that the benefits justify the likely costs.

Vaughan Gething
Minister for Health and Social Services
12 March 2020

1. Description

The Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2020 (these Regulations) will amend The Addition of Vitamins, Minerals and Other Substances (Wales) Regulations 2007 (The 2007 Regulations) to correct an omission in the enforcement provision.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

None.

3. Legislative background

Welsh Ministers have the powers to make the proposed Regulations under sections 16(1)(a) and (f), 17(2), 26(1)(a) 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 procedure.

4. Purpose & intended effect of the legislation

The 2007 Regulations provide for the enforcement of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods “the EC Regulation”.

Article 8 and Annex III of the EC Regulation provide for substances that could represent a potential risk to consumers. Such substances may be:

- Prohibited under Part A of Annex III
- Restricted with certain conditions of use under Part B of Annex III
- Kept under scrutiny subject to evidence of safety under Part C of Annex III.

At the time the 2007 Regulations were made, there were no prohibited or restricted substances. Consequently Article 8 and Annex III provisions were not included in the offences and penalties section of the 2007 Regulations.

Since then, two substances, Ephedra herb and Yohimbe bark, have been prohibited under part A; and trans fats have been restricted under part B.

These Regulations will amend the 2007 Regulations to include a provision for Article 8 on the prohibition or restriction of substances listed in Part A or B of Annex III. This will make it a punishable offence if a food business operator adds a substance listed in Annex 3, Part A of the EC Regulation to foods or uses such a substance in the manufacture of foods. The amendments to the regulations will also make it a punishable offence to add a substance listed in Annex 3, Part B of the EC Regulation to foods, or to use the substance in the manufacture of foods, unless that substance is added or used in accordance with the conditions specified in that Part.

These Regulations will also include a transitional provision to provide that no offence is committed in respect of any food that does not comply with the provisions of Annex 3, Part B relating to trans fat other than trans fat naturally occurring in fat of animal origin and which is placed on the market before 1 April 2021.

Enforcement

The EC Regulation came into force on 19 January 2007 and entered into application from 1 July 2007. From 1 July 2007, the EC Regulation became directly applicable in all member states, including the UK, and the provision of the EC Regulation will continue to apply after exit day.

The 2007 Regulations put in place offences linked to the EC Regulation and enforcement provisions and penalties associated with those offences to enable enforcement of the EC Regulation in Wales, but failed to include provision for Article 8 and Annex III of the EC Regulation. These Regulations will correct this and will extend the current enforcement regime to include the Article 8 and Annex III Part A and Part B provisions. The current enforcement regime is as follows:

“any person who contravenes or fails to comply with the provisions of the EC Regulation specified in paragraph (2) is guilty of an offence and liable —
(a) on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both;
(b) on summary conviction to a term of imprisonment not exceeding three months or to a fine not exceeding the statutory maximum or both.”

5. Consultation

A limited technical consultation was held for four weeks from 25 November 2019. A limited consultation was considered appropriate in this case given it focussed purely on extending the existing enforcement regime introduced by the 2007 Regulations to include provision for Article 8 and Annex III of the EC Regulations and which had already been subject to a full 12-month consultation.

The consultation was shared with enforcement bodies, industry stakeholders, health professional and consumer groups and other relevant non-government organisations.

Two response were received to the consultation, both from members of the public and both fully supportive of the proposed Regulations. Consultations were also held in the other UK countries.

No amendments were made to these or the other equivalent UK Regulations as a consequence of the consultations.

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 – The 2007 Regulations will not be amended to include a provision for Article 8 on the prohibition or restriction of substances listed in Part A or B of Annex III. It will therefore not be a punishable offence if a food business operator uses a prohibited substance listed in Part A or is non-compliant with the conditions of use for substances listed in Part B.

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.

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 Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2020 to include a provision for Article 8 on the prohibition or restriction of substances listed in Part A or B of Annex III and, make it a punishable offence if a food business operator uses a prohibited substance listed in Part A or is non-compliant with the conditions of use for substances listed in Part B.

Option 2 is the preferred approach.

Costs and Benefits

Costs to business

This legislation affects manufacturers who add nutrients to food including, but not limited to vitamins and minerals.

We are not aware of any manufacturers in the UK who use either of the two prohibited substances, Ephedra herb and Yohimbe bark, in the manufacture of food.

Those who use trans fats have been restricted under part B and will have until 1 April 2021 to remove such products from the market. We are not aware of any such business operating in the UK.

We estimate that businesses will only need to spend a short amount of time familiarising themselves with the new requirements.

Costs to local authorities

The impact on the public sector of implementing Option 2 is small. Local authorities would need to set aside time to become familiar with these Regulations, however ongoing workloads for Trading Standards Officers are not expected to increase as a result of these Regulations.

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.

Benefits to business

These Regulations will provide clarity for business in terms of the offences and penalties they will face if they do not comply with the requirements for substances provided for under Article 8 and Annex III.

Benefits to local authorities

These Regulations will provide clarity for enforcement officers in terms of the enforcement tools available to them if a business does not comply with the requirements for substances provided for under Article 8 and Annex III.

Benefits to consumers

The extension of the enforcement provision in these Regulations will provide consumers with further protection and assurance in this area.

Summary of the preferred option

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