

EXPLANATORY MEMORANDUM TO
THE ADDITION OF VITAMINS, MINERALS AND OTHER SUBSTANCES
(ENGLAND) (AMENDMENT) REGULATIONS 2020

2020 No. 256

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health & Social Care and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

- 2.1 This instrument amends the Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 to include provisions to allow Regulation (EC) 1925/2006 to be fully enforced in England. It provides the offences and penalties for breaching the rules on restricted or prohibited substances.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

- 3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is England and Wales.
4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

- 5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

- 6.1 [The Addition of Vitamins, Minerals and Other Substances \(England\) Regulations 2007](#) (“the England Regulations”) provide for the enforcement in England of [Regulation \(EC\) No 1925/2006](#) on the addition of vitamins and minerals and of certain other substances to foods (“the EC Regulation”).
- 6.2 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.

- 6.3 The EC Regulation is directly applicable in the UK and is not required to be transposed into UK legislation. However, the Regulation puts in place enforcement provisions and penalties so that the European legislation can be enforced in England.
- 6.4 The England Regulations include enforcement for most of the EC Regulation provisions. However, the England Regulations did not include the Article 8 and Annex III provisions in the offences and penalties section of the original instrument. This was because there were no prohibited or restricted substances at the time the instrument was made in 2007. Since then, two substances, Ephedra herb and Yohimbe bark, have been prohibited under part A; and trans fats have been restricted under part B. Although these provisions are applicable, and businesses must comply with them, they are not entirely enforceable in England.
- 6.5 This Statutory Instrument (SI) amends the England Regulations to include a provision in the offences and penalties section for substances listed in Part A or Part B of Annex III. It will make it a punishable offence if a food business operator uses a prohibited substance listed in Part A or is non-compliant with the restrictive conditions of use for substances listed in Part B. Part C relates to keeping substances under scrutiny, so requires no enforcement provision.
- 6.6 The SI includes a transitional measure which means that products that do not comply with the restrictions on trans fats under Part B, may continue to be placed on the market until 1 April 2021.
- 6.7 Similar instruments are being made in Scotland, Wales and Northern Ireland.
- 6.8 The amending SI will extend the current enforcement regime for the original instrument to include the Article 8 and Annex III Part A and Part B provisions.

7. Policy background

What is being done and why?

- 7.1 Regulation (EC) No 1925/2006 seeks to protect consumers from consuming quantities of any vitamin, mineral or other substance which could be harmful to health.
- 7.2 Where substances are found to represent a potential risk to health, the EC Regulation puts in place a mechanism to allow such substances to be prohibited, restricted or kept under scrutiny.
- 7.3 This Statutory Instrument amends the England Regulations to include a provision for substances that are prohibition or restricted under the EC Regulation. This will make it a punishable offence if a food business operator uses a prohibited substance listed in Part A of Annex III or is non-compliant with the conditions of use for substances listed in Part B of Annex III.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

- 9.1 This instrument amends the Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007. We are not considering consolidation of the legislation at this stage.

10. Consultation outcome

- 10.1 A limited technical consultation was held for a three-week period from 29 January to 19 February 2020. A limited consultation was considered appropriate in this case, because stakeholders are already familiar with the regulatory framework and the existing enforcement regime, which this legislation does not amend. The consultation focused purely on the enforcement of the provisions missing from the Regulations.
- 10.2 The consultation was sent to enforcement experts of the Food Standards and Labelling Focus Group, industry stakeholders, health professional and consumer groups and Non-Government Organisations (NGO) and the consultation documents were also placed on the Knowledge Hub, a closed forum for Local Authorities to discuss views on enforcement issues. These are groups representing the interests of people affected by the legislation. The consultation generated responses from two local authority enforcement representatives and one industry trade association.
- 10.3 The consultation proposed the current enforcement regime is extended to include the two missing provisions. Respondents supported the proposal, but the enforcement officers also requested that consideration be given to making legislation to allow enforcement officers a wider range of enforcement tools across all areas of nutrition legislation. The Department has agreed to consider this further with the enforcement community.

11. Guidance

- 11.1 Guidance relating to this legislation will be updated to reflect the amendment by 3 April 2020. Interested parties including enforcement authorities will be informed when the new Regulations come into force and information about the key changes will be highlighted. Updated guidance will be published online at www.gov.uk and information will be circulated directly to local authority enforcement officers via the Knowledge Hub.

12. Impact

- 12.1 There is no, or no significant, impact on business, charities or voluntary bodies.
- 12.2 The impact on the public sector is small. Local authorities would need to become familiar with the new instrument with an estimated total one-off cost to the public sector of £4766.
- 12.3 An Impact Assessment has not been prepared for this instrument because there is no significant impact on business.

13. Regulating small business

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 No specific action is proposed to minimise regulatory burdens on small businesses. This is because the European legislation has been in place for several years and the impact of the instrument is estimated to be small.

14. Monitoring & review

- 14.1 The regulation does not include a statutory review clause as a review would be disproportionate taking into account the economic impact of the regulatory provision.
- 14.2 The whole instrument and wider nutrition legislation will be subject to internal review within two years, taking into consideration feedback and data from enforcement officers and other stakeholders.

15. Contact

- 15.1 Mary McNamara at the Department of Health & Social Care, Telephone: 020 7210 4850 or email: Nutritionlegislation@dhsc.gov.uk, can be contacted with any queries regarding the instrument.
- 15.2 Jenny Oldroyd/Harriet Becher at the Department of Health & Social Care can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 The Minister for Prevention, Public Health and Primary Care, Jo Churchill, at the Department of Health & Social Care can confirm that this Explanatory Memorandum meets the required standard.