

**EXPLANATORY MEMORANDUM TO**  
**THE FOOD SUPPLEMENTS AND ADDITION OF VITAMINS, MINERALS AND**  
**OTHER SUBSTANCES (AMENDMENT) REGULATIONS (NORTHERN**  
**IRELAND) 2009**

**2009 No. 407**

1. This explanatory memorandum has been prepared by The Food Standards Agency Northern Ireland and to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.
2. **Purpose of the Rule**
  - 2.1 This S.R amends the Food Supplements Regulations (Northern Ireland) 2003 ('the Food Supplements Regulations') to provide for additions, made by European Union (EU) legislation, to the lists of vitamins, minerals and their sources permitted for use in food supplements set out in existing European Union (EU) legislation. This S.R also amends the Food Supplements Regulations to provide for direct, ambulatory, references to the lists of permitted vitamins, minerals and their sources set out in EU legislation and to update references in the Regulations to EU legislation.
  - 2.2 This S.R also amends the Addition of Vitamins, Minerals and Other Substances Regulations (Northern Ireland) 2007 to provide additions to the lists of vitamins, minerals and their sources permitted for addition to food set out in EU legislation.
3. **Legislative Background**
  - 3.1 This S.R implements, in Northern Ireland, the amendments made to Directive 2002/46/EC of the European Parliament and of the Council on the approximation of laws of the Member States and to Regulation (EC) No. 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods ('Regulation 1925/2006'), by Commission Regulation (EC) No. 1170/2009 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council of as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements (OJ No. L314, 1.12.2009, p.36) ('Regulation 1170/2009'). This S.R implements Regulation 1170/2009 by amending Food Supplements Regulations and the Addition of Vitamins, Minerals and Other Substances Regulations (Northern Ireland) 2007.

- 3.2 This S.R also amends the Food Supplements Regulations to update references to EU legislation. Specifically, the instrument updates the reference, in Regulation 3(2), to Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards the definition of ‘medicinal products’ and the reference, in Regulation 6(3)(e), to the Annex to Council Directive 90/496/EEC on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions.

#### **4. Parity or Replicatory Measure**

- 4.1 This S.R applies to Northern Ireland. Parallel legislation is being made in England, Scotland and Wales.

#### **5. European Convention on Human Rights**

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

#### **6. Policy background**

##### ***Food Supplements***

- 6.1 The Food Supplements Regulations implement, in Northern Ireland, Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of Member States relating to food supplements (‘the Food Supplements Directive’).
- 6.2 The Food Supplements Regulations prohibit the sale of food supplements containing vitamins and minerals not listed in Schedule 1 to these Regulations and those which are not in a form listed in Schedule 2 to these Regulations, these schedules reflecting the vitamins and minerals and their sources respectively set out in Annexes I and II to the Food Supplements Directive.
- 6.3 The Food Supplements Directive affords a derogation for the use of vitamin and mineral substances not listed in its Annexes which expires on 31 December 2009. This is provided for by Regulation 5(3) of the Food Supplements Regulations and is conditional upon dossiers supporting the use of substances having been submitted for assessment by the European Food Safety Authority (EFSA) by 12 July 2005 and the absence of an unfavourable opinion from EFSA as to their safety for use in food supplements.

- 6.4 In the UK, all vitamin and mineral substances for which dossiers were submitted were permitted for use in food supplements under the terms of the derogation. 67 vitamin and mineral sources which are currently used under the derogation were given favourable opinions by EFSA. Regulation 1170/2009 will amend the Annexes to Food Supplements Directive to incorporate these vitamin and mineral sources.
- 6.5 This S.R amends the Food Supplements Regulations to give domestic legal effect to the amendments to the Annexes to the Food Supplements Directive, in so doing permitting the continued use of these 67 vitamin and mineral sources in food supplements after the expiry of the derogation on 31 December 2009. This Rule will achieve this by amending the Food Supplements Regulations to provide for direct, ambulatory, references to the lists of vitamins, minerals and their sources set out in Annexes I and II to the Food Supplements Directive, in exercise of the power to make ambulatory references provided by paragraph 1A of Schedule 2 to the European Communities Act 1972. This will obviate the necessity for national regulations to be made each time an amendment is made to the annexes to the Directive.
- 6.6 The Food Supplements Regulations make references to EU legislation in Regulation 3(2) and Regulation 6(3)(e). The instrument makes amendments to the Regulations in order to update references to this legislation and inserts a new regulation 12 to provide a transitional provision with regard to the requirements of Regulation 6(3)(e), as amended.

***Foods to which Vitamins and Minerals are Added ('Fortified Foods')***

- 6.7 The Addition of Vitamins, Minerals and Other Substances Regulations (Northern Ireland) 2007 provide for the enforcement, in Northern Ireland, of Regulation 1925/2006 of the Parliament and the Council on the addition of vitamins and minerals and of certain other substances to foods.
- 6.8 This S.R will give legal effect, in Northern Ireland, to the amendments to Regulation 1925/2006 to be effected by Regulation 1170/2009 by updating the definition of "the EC Regulation" in Regulation 2 of the Addition of Vitamins, Minerals and Other Substances Regulations (Northern Ireland) 2007.

## **7. Equality Impact**

- 7.1 These Regulations will apply in equal measure to all Section 75 groups. It is not expected that any of these changes will impact differentially across any of the Section 75 groups.

## **8. Consultation outcome**

- 8.1 A public consultation on a draft of the Rule based on the draft of Regulation 1170/2009 which underwent the European ‘regulatory procedure with scrutiny’ was carried out by the Food Standards Agency Northern Ireland from 28 September to 9 November 2009. No responses were received in Northern Ireland.

## **9. Guidance**

- 9.1 The Food Standards Agency’s guidance on the Food Supplements Regulations will be revised to reflect the amendments effected by the Rule as part of a review of this guidance. The revised guidance will be subject to public consultation before being made available on the Food Standards Agency website.
- 9.2 The Food Standards Agency will also be writing to stakeholders to inform them of the legislative changes.

## **10. Impact**

- 10.1 An Impact Assessment is attached to this memorandum. This IA has been prepared by FSA colleagues in England but it is believed to be equally representative of the situation in Northern Ireland.

## **11. Regulating small business**

- 11.1 This S.R applies to small business. Small business will not be exempted because the rule does not introduce any new burdens other than one-off costs involved in being aware of, and becoming familiar with, the amendments it effects to national regulations.

## **12. Monitoring & review**

- 12.1 A review of the costs and benefits will be carried out during January 2015.

### **13. Contact**

Mervyn Briggs at the Food Standards Agency Tel: 028 90 417742 or email: [mervyn.briggs@foodstandards.gsi.gov.uk](mailto:mervyn.briggs@foodstandards.gsi.gov.uk) can answer any queries regarding the Rule.