# Explanatory Memorandum to the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009

This Explanatory Memorandum has been prepared by the Food Standards Agency Wales and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 24.1.

## Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009. I am satisfied that the benefits outweigh any costs.

Gwenda Thomas

# **Deputy Minister for Health and Social Services**

8 December 2009

# 1. Description

These Regulations provide execution and enforcement provisions in Wales for Commission Regulation (EC) No. 953/2009, which consolidates and amends existing EC legislation on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.

## **2. Matters of special interest to the Subordinate Legislation Committee** None

# 3. Legislative Background

The powers enabling the Regulations to be made are contained in Sections 16(1)(e) and 17(2) of the Food Safety Act 1990. These are exercisable by Welsh Ministers. The Regulations are subject to the Assembly's negative resolution procedure.

Commission Regulation (EC) No. 953/2009 consolidates and amends current EC legislation providing for the addition of certain substances to Parnuts foods. This EC Regulation repeals Directive 2001/15/EC and Directive 2004/6/EC with effect from 31 December 2009.

The Regulations repeal the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002 (SI 2002/2939 (W.280));

## 4. Purpose and Intended effect of the legislation

The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009 ('the Regulations') provide execution and enforcement provisions, in Wales, for Commission Regulation (EC) No. 953/2009 on the substances that may be added for specific nutritional purposes in foods for particular nutritional uses. The main purpose of the Regulations is to align domestic law with EC law to consolidate and amend the list of permitted substances for use in foods for particular nutritional uses ('Parnuts').

## **Background**

EC legislation requires that foods for particular nutritional uses are safe and that they meet the nutritional requirements of the persons for whom they are intended. A Parnuts food is a food which, owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and is sold in such a way as to indicate its suitability for its claimed nutritional use. Examples of Parnuts foods include - infant formulae, follow-on formulae and medical foods.

To facilitate consumer choice, the widest possible choice of substances such as vitamins, minerals and amino acids should be available for use in foods for particular nutritional uses. To ensure consumer protection, it is also important that the safety of these substances is scientifically proven before they are used in the manufacture of foods for particular nutritional use. In order to fulfil these requirements, a European Commission Directive was agreed in 2001 ('Directive 2001/15/EC') which listed the types of chemical substances that may be used in the manufacture of foods for particular nutritional uses. Any chemical substance that is listed in the Directive must have received a favourable scientific evaluation either by the European Food Safety Authority (EFSA), or its forerunner, the Scientific Committee on Food (SCF).

If a manufacturer wishes a new substance to be added to the list of authorised substances in Directive 2001/15/EC the new substance must first receive a positive assessment from EFSA. The European Commission Standing Committee on the Food Chain and Animal Health (SCoFCAH) must then agree that the new substance should be added to the relevant list in Directive 2001/15/EC.

Earlier this year the European Commission published Commission Regulation (EC) No. 953/2009 to consolidate and amend Directive 2001/15/EC. This increases the range of sources of vitamins and minerals and other substances that may be added to foods for particular nutritional uses and represents simplification of current legislation as the provisions will be consolidated into a single regulation making it easier to read.

# 5. Consultation

The Food Standards Agency Wales carried out a shortened 4 week public consultation on the draft Regulations which ran from 6 October to 3 November 2009. A list of those consulted can be found at Annex 1. Parallel consultations were conducted in England, Scotland and Northern Ireland. The Food Standards Agency consulted over 400 interested parties across the UK on the proposed Regulations. The primary business sector that will be affected by the regulatory proposals will be manufacturers of foods for particular nutritional uses. The consultation did not generate any replies. Meetings with interested parties confirmed the new Regulations will not place additional burdens on industry and are welcomed by all stakeholders.

## 6. Regulatory Impact Assessment

A Regulatory Impact Assessment has not been prepared to accompany these Regulations as there are no identified costs to consumers, businesses or enforcement authorities associated with implementation of these new Regulations.

The Regulations would not impose any significant new burden on Government or enforcement officers. Rural areas and members of the ethnic communities, or of any particular racial group are unaffected by these proposals. Charities and voluntary organisations are unaffected by these proposals.

Annex 1

Stakeholders consulted:

OrganisationName Abergavenny Fine Foods Ltd **ADAS Wales** All Wales Dietetic Advisory Committee Allison's Celebration Cakes Association of Voluntary Organisations Authentic Curry Company Ltd Avana Bakeries limited AWDAC **B A Jenkins & Sons** Bar & Restaurant Foods Ltd Baraka Foods Ltd **Barons Patisserie** Beehive Preserves Berwyn Bakery **Braces Bakery Limited** Briwsion **Cardiff Scientific Services** Carolin's Real Bread Co Castell Howell Foods Ltd Children's Information Service **Congenital Anomaly Register & Information Service Consumer Focus Wales Dairy Development Centre** DEE DAIRY SERVICES Farm Assured Welsh Livestock Federation of Small Businesses (South Wales) fedwen Bakerys (Cardigan) Ltd Food Centre Wales G C Hahn & Co Ltd **Garth Bakeries** Garth Bakeries Ltd Gelynis Fruit Farm and Vineyard Glutafin Goetre Farm Preserves Good Food Distributors Gower Coast Seafoods Gower Spring Water Co. Grace Foods **Greggs Wales** Health Protection Agency Henllan Bread Hybu Cig Cymru - Meat Promotion Wales **Iceland Foods Limited** JM & A hughes (Station Bakery) KK Finefoods Lewis' Pies Ltd Media Wales Memory Lane Cakes Ltd

Meridian Foods Ltd Montgomery Spring Water Co National Farmers Union Cymru National Federation Of Women's Institutes National Public Health Service Wales NFU Cymru Ogmore Vale Bakery Limited Peters Food Service Rachel's Organic **RCGP** Wales Rowan Foods Ltd Royal Welsh Agricultural Society **Slaters Bakery** Snowdrop Bakery South Caernarfon Creameries Tan y Castell The Bay (Public Affairs Itd) The Co-operative Group The Unusual food Co (Cymru) Ltd The Village Bakery (Coedpoeth) Limited Tillery Valley Foods Ltd Trading Standards Institute (Wales) Unilever UK Ltd UWIC Vydex Corporation Ltd Wales Council for Voluntary Action Welsh Assembly Government (Food & Market Developme Welsh Food Alliance Welsh Hills Bakery Welsh Organic Scheme Welsh Quality Meats White's Golden Crust Bakery Zorba Foods