

Explanatory Memorandum to the Food Labelling (Nutrition Information) (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 accordance with Standing Order 24.1.

Description

These Regulations implement in Wales Commission Directive 2008/100/EC which amends Council Directive 90/496/EEC on nutrition labelling for foodstuffs by replacing the recommended daily allowances for vitamins and minerals in Part II of Schedule 6 to the FLRs with an updated list, by introducing a definition of fibre into regulation 2 and by introducing new energy conversion factors in Schedule 7 Part I.

Matters of special interest to the Subordinate Legislation Committee

None

Legislative Background

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

Purpose and Intended effect of the legislation

Legislative rules on nutrition labelling of foodstuffs need to be updated:

- to reflect recent scientific and technological developments: Directive 2008/100/EC establishes a definition of 'fibre', adds energy conversion factors for fibre and erythritol, updates the list of vitamins and minerals which may be declared and their recommended daily allowances;
- to ensure coherence between nutrition labelling legislation and other legislation; EC Regulation EC/1924/2006- The Nutrition and Health Claims made on Foods Regulation (NHCR) and EC Regulation EC/1925/2005- the Addition of Vitamins and Minerals and of Certain Other Substances to Foods Regulation (AVMR)

The purpose of the Food Labelling (Nutrition Information) (Wales) Regulations 2009 is to amend the Food Labelling Regulations 1996 (as previously amended) (the FLRs) as regards the recommended daily allowances for vitamins and minerals, introduce energy conversion factors for dietary fibre and erythritol and introduce a definition for fibre. The Regulations will:

- Create coherence between various pieces of legislation on nutrition and health claims and addition of minerals and certain other substances to foods

- Provide industry and enforcement authorities with a clear technical framework to work within
- Provide consumers with consistent and accurate information based on up-to-date scientific evidence

Background

Food labelling is an area of European Union competence. The rules which govern nutrition labelling are laid out in the Council Directive 90/496/EEC on Nutrition Labelling of Foodstuffs (NLD). The NLD defines the requirements for nutrition labelling on pre-packed foods, including technical requirements, and was implemented into law for England, Scotland and Wales by the Food Labelling Regulations 1996 (as amended), and by similar but separate legislation for Northern Ireland.

Food labelling helps consumers make informed choices about the food they buy or consider buying. The current rules lack clarity about legal requirements for industry and enforcement authorities. There is a need to update specific technical issues within the NLD as set out in more detail below.

Fibre

NLD does not define fibre. However the Regulation EC/1924/2006 on Nutrition and Health Claims made on Foods (NHCR) lays down conditions for nutrition claims to be made about fibre (source of fibre, high fibre). There is therefore a need to define fibre to ensure there is a consistent basis within the UK and across Europe for fibre labelling and claims.

The definition of 'fibre' in Annex II to Commission Directive 2008/100/EC states:

"fibre" means carbohydrate polymers with three or more monomeric units, which are neither digested nor absorbed in the human small intestine and belong to the following categories:

- edible carbohydrate polymers naturally occurring in the food as consumed;
- edible carbohydrate polymers which have been obtained from food raw material by physical, enzymatic or chemical means and which have a beneficial physiological effect demonstrated by generally accepted scientific evidence;
- edible synthetic carbohydrate polymers which have a beneficial physiological effect demonstrated by generally accepted scientific evidence.

Energy conversion factors

The NLD defines energy conversion factors; these are required to calculate the energy present in a foodstuff. Scientific and technological advances relating to food ingredients mean that new energy conversion factors are required to ensure the consumer is not misled as to the overall energy content of some foodstuffs. Directive 2008/100/EC adds energy conversion factors for fibre (2 kcal/g (8 kJ/g) and erythritol (0 kcal/g (0 kJ/g).

Vitamins and minerals and their recommended daily allowances

The Annex to the NLD lists the vitamins and minerals which may be declared as part of nutrition labelling and specifies their recommended daily allowances (RDAs). The NHCR, AVMR and the Food Supplements Directive (FSD) all refer to the NLD Annex, and the RDAs listed there, for the purposes of labelling. However these Regulations and Directives contain a fuller list of vitamins and minerals than the one currently given in the older NLD. In order to ensure coherence with these Regulations and Directives there is therefore a need to update the current list of vitamins and minerals and associated RDAs.

Reason for Intervention

The nutritional composition of a food product is an essential piece of information used to inform consumer choice. This legislation updates existing nutritional labelling in accordance with recent scientific opinion.

Commission Directive 2008/100/EC updates certain technical aspects of NLD to recognise scientific and technological developments since 1990. It adds:

- a definition of 'fibre'
- energy conversion factors for fibre and the food additive erythritol which is a type of polyol
- an updated list of vitamins and minerals which may be declared and their recommended daily allowances (see table below).

Vitamin/mineral	Recommended Daily Allowance
Vitamin A	800 µg
Vitamin D	5 µg
Vitamin E	12 mg
Vitamin K	75 µg
Vitamin C	80 mg
Thiamin	1.1 mg
Riboflavin	1.4 mg
Niacin	16 mg
Vitamin B6	1.4 mg
Folic acid	200 µg
Vitamin B12	2.5 µg
Biotin	50 µg
Pantothenic acid	6 mg
Potassium	2000 mg
Chloride	800 mg

Calcium	800 mg
Phosphorus	700 mg
Magnesium	375 mg
Iron	14 mg
Zinc	10 mg
Copper	1 mg
Manganese	2 mg
Fluoride	3.5 mg
Selenium	55 µg
Chromium	40 µg
Molybdenum	50 µg
Iodine	150 µg

These amendments will ensure coherence between the NLD and other European legislation, particularly the NHCR, the AVMR and the FSD). It will provide greater legal clarity to the food industry in terms of providing information to consumers and will facilitate more consistent enforcement of this aspect of food law.

These amendments may be expected to benefit industry and food law enforcement officers.

Implementation

It is intended that these Regulations will come into force on 30 October 2009. This Statutory Instrument applies only to Wales. Separate but parallel legislation will be made for England, Scotland and Northern Ireland.

Regulatory Impact Assessment

Options

Option 1 – do nothing - fail to implement Directive 2008/100/EC.

Option 2 – implement the provisions of Directive 2008/100/EC within the timescale set out in the Directive.

Option 1: Failure to implement would bring disadvantages to consumers, industry and enforcement authorities. Failure to implement would mean consumers would not have access to certain aspects of the nutritional content of some foods in the market; industry would be unable to comply with all the legislation as it is not coherent; and enforcement officers would have to enforce legislation which is contradictory.

Failure to implement would also be a risk to government in that it would result in a serious breach of the UK's obligations under the EC treaty and would be likely to attract infraction proceedings by the Commission against the UK under Article 226 of the EC treaty and potential fines. Other Member States

could also initiate action under Article 227. Ultimately, the UK would be forced to implement.

Option 2: The Food Standards Agency agrees with the rationale for amending Commission Directive 90/496/EEC and with the requirement (in Article 2 of Commission Directive 2008/100/EC) to bring implementing legislation into force by 31 October 2009. As set out in Article 2, the implementing SI will prohibit trade in non-compliant products from 31 October 2012. This will provide three years for re-labelling of products to ensure compliance and for redesign of labels outside of the normal redesign cycle if necessary.

Costs and Benefits

Food businesses affected by the implementation of Commission Directive 2008/100/EC are those that market food supplements and any that choose to provide voluntary nutrition labelling, make a nutrition or health claim on a product or voluntarily add vitamins or minerals to foodstuffs.

The energy conversion factors are likely to influence products where a low calorie or reduced calorie claim is made and the responses to the public consultation indicated that the main product groups affected by changes to vitamin and mineral RDAs is likely to be Vitamin C claims for fruit juices and to food supplements generally.

Costs

Option 1: As this is the current legislative environment, there are no immediate costs/benefits. However, if this Regulation is implemented into other EU Member States and the UK fails to implement, this could potentially lead to trade barriers and lost business for UK companies; in addition it could result in consumer confusion. If the countries of the UK did not implement the operative provisions of the Directive this would lead to infraction proceedings (as described above) and would lead to a significant cost to government.

Option 2: costs are outlined below.

Costs to food businesses for re-labelling and analysis

The main direct potential cost to food businesses would be a necessary labelling change. The average labelling cost of £1,000 per SKU (Stock Keeping Unit – A food product with its own unique barcode) has been widely accepted during previous consultations with industry. This is an average figure used for aggregation because the costs vary widely in re-labelling dependent upon: the medium a label is printed on, the colours used and whether the label requires a plate change, amongst other factors. However, given the three-year transition period, it is assumed that most products will be relabelled within this period and therefore the labelling changes will be absorbed within normal product re-labelling cycles. The majority of consultation responses

have agreed with this assumption that the transition time is sufficient to make any adjustments within normal business re-labelling cycles.

There may be some costs associated with erythritol analysis and fibre analysis for companies to correctly label these food components. We will not be able to determine whether there will be costs associated with the recommended methods of analysis for fibre until we know what these are. In the case of fibre, the FSA will maintain its current guidance until European Commission guidance is adopted (see paragraph under benefits below). In this regard the European Commission in July 2009 circulated a working paper on the subject for discussion with Member States later in 2009.

We assume that, given the three-year transition period, any direct incremental costs associated with implementation of Commission Directive 2008/100/EC will be low, apart from a small potential cost for erythritol and fibre analysis and that associated with reading and understanding the new legislation.

Costs associated with loss of nutritional claims

A secondary effect to food businesses, following a labelling change caused by the proposed regulations, could be the loss of nutritional claims as identified in some of the consultation responses. A lost nutritional claim may result in a potential loss in sales or in costs to mitigate this loss in sales such as product re-positioning or reformulation. Although the Agency recognises these costs to businesses, there is currently insufficient evidence to make a reasonable cost estimate. We understand from the responses that the majority of these costs arising from the nutritional claim will be marketing costs associated with product positioning and product communication.

Costs of new fibre analysis method

There may be costs associated with putting in place new methods of analysis for fibre, however we will not be able to determine whether this is so until we know what the recommended methods of analysis for fibre are.

Familiarisation

There is a total familiarisation cost of approximately £207,000 for the whole of the UK. This breaks down, using VAT registered business data¹ to approximately: £166,000 in England, £22,000 in Scotland, **£11,000 in Wales** and £8,000 in Northern Ireland (all rounded to nearest £1000). The table below summarises the familiarisation costs to both industry and local authorities, split by England, Scotland, Wales and Northern Ireland.²

¹ Ibid

² All figures are rounded to the nearest £1000 and one decimal place, therefore £161.9 represents £161,900 (rounded).

£,000s	England	Scotland	Wales	N.Ireland	UK
Industry	£161.9	£21.9	£10.7	£7.8	£202.3
LAs	£3.9	£0.3	£0.2	£0.3	£4.7
Total	£165.8	£22.2	£10.9	£8.1	£207.0

Familiarisation methodology: Costs to enforcement officers

In terms of reading and understanding the new legislation, the FSA estimates a time of 30 minutes per local authority (LA) to be realistic. This equates to a cost per LA of £10.00 (all figures are rounded). This figure is taken from the 2008 ONS ASHE (Annual Survey of Hours and Earnings) figures for Public Service Professionals of £15.40 per hour (median value), which, in-line with the Standard Cost Model, is then up-rated by 30% to account for overheads, to give a figure of £20.00 per hour.³ Divided by two for half an hour, gives £10.00. There are 469⁴ LAs in the UK who will need to read the new legislation: £10.00 x 469 yields a one-off familiarisation cost of approximately £4,700 (**£220 for Wales**).

Familiarisation methodology: Costs to food businesses

In terms of reading and understanding the new legislation, the FSA estimates a time of 30 minutes per business to be realistic. This equates to a cost per business of £7.50 (all figures are rounded) This figure is taken from the 2008 ONS ASHE (Annual Survey of Hours and Earnings) figures for Managers in Distribution, Storage and Retailing of £11.59 per hour (median value), which, in-line with the Standard Cost Model, is then up-rated by 30% to account for overheads, to give a figure of £15.06 per hour. Divided by two for half an hour, gives £7.53.

There are 9,865 food related manufacturing premises and 43,830 non-specialised food retailer premises registered in the UK.⁵ Both figures include businesses, which will not need to read the legislation (approximately 28,000 of the businesses above have less than 5 employees), in the absence of accurate estimates on how many businesses the legislation will affect a mid-point of 26,848 is assumed. If they all need to read the legislation this will equate to 26,848 x £7.53 which yields a one-off familiarisation cost estimated at approximately £202,000 for the whole of the UK (**£10.700 for Wales**). This is likely to be an overestimate, as the nutritional labelling updates are specific to food product groups.

³ Annual Survey of Hours and Earnings is available from ONS at: <http://www.statistics.gov.uk/statBase/product.asp?vlnk=13101>

⁴ As local authorities have many different enforcement systems in place many enforcement officers have multiple duties; we have maintained our initial estimate of 469 LAs needing to read and understand the new legislation.

⁵ Taken from the category 'manufacturer of food products and beverages' and 'Retail sale in non-specialised stores with food, beverages or tobacco predominating' ONS: TABLE A3.1 UNITED KINGDOM - NUMBER OF LOCAL UNITS in VAT and/or PAYE BASED ENTERPRISES in 2008. Using premise data rather than businesses is likely to over-estimate familiarisation costs (as legislation is likely to be read per business rather than per premise) but premises are used to be consistent with the previous consultation.

Administrative Burden Costs

Labelling is an administrative burden on business. However, with the proposed 3-year transition period any changes should generally be within businesses normal commercial re-labelling cycle and so no additional burdens should result from implementing option 2.

Corporate communication costs

Larger businesses that carry nutritional information on their websites or as part of their promotional material may also incur a labour cost in updating them in light of the new regulations. There may also be an increase in consumer enquiries. However, these costs are unlikely to affect a large proportion of the potentially 26,800 businesses affected and there is insufficient evidence to make accurate cost estimates.

Benefits

Option 1: failure to implement would not bring any benefits to consumers, industry, enforcement authorities or government.

Option 2: benefits are outlined below

Benefits to consumers

At present, there are no legislative controls on the definition of 'fibre' for food labelling purposes nor on the methods of analysis to be used in determining the fibre content of food products. The FSA has issued guidance on methods of analysis. However, food business operators are not compelled to follow that guidance to satisfy themselves of the fibre content of food products and, as a result, claims on different products may relate to different forms of fibre with varying (or no) proven human health benefits.

Once there are clear recommendations about the methods of analysis for fibre to be used in relation to food labelling (see below) there should be a clear benefit of applying a consistent definition since consumers will be better informed about the fibre content of foods they buy or consider buying.

Benefit to food businesses and to enforcement officers

By providing a definition of 'fibre' the new legislation aims to provide clarity in terms of how claims about fibre relate to the fibre content of a food; ultimately this will be a benefit for the food industry and for enforcement officers. However, the legislation does not link the 'functional' definition of fibre to methods of analysis, thereby leaving some uncertainty for food business operators and enforcement officers at present. The European Commission agreed to produce guidance on suitable methods of analysis for fibre and in July 2009 circulated a working paper on the subject for consideration by EU

member states. However, until this is agreed with EU member states the uncertainty remains.

Consultation

The Food Standards Agency Wales carried out a 12 week public consultation on the draft Regulations and impact assessment which ran from 6 March to 29 May 2009. A list of those consulted can be found at Annex 1. Parallel consultations were conducted in England, Scotland and Northern Ireland.

Stakeholders including consumer and health professional groups, manufacturers and food industry bodies, enforcement bodies, individuals and government departments were consulted. The consultation package was also posted on the Agency's website.

Responses to this consultation were generally in agreement with the cost assumptions included in the draft impact assessment. The impact on business, charities or voluntary bodies will be minimal as the transition period will provide three years for re-labelling of products to ensure compliance and for redesign of labels outside of the normal redesign cycle if this is necessary.

One concern raised by a number of stakeholders related to the continued lack of agreed analytical methodology for fibre. The European Commission (EC) has indicated that it plans to introduce guidance on suitable methods of analysis and has recently circulated a discussion paper to Member States. The FSA will engage in these discussions with the EC and other Member States to ensure that appropriate European guidance is developed as soon as possible.

Additionally some stakeholders indicated that the transition period of 3 years may not be long enough to mitigate the impact of these new rules for all products, and in particular some longer shelf life foods, such as food supplements. However the majority of manufacturers of such products agreed they will be able to deal with these changes via usual relabelling cycles.

One response to the consultation in Wales was received from Hybu Cig Cymru – Meat Promotion Wales (HCC) who had no comment to make.

Post Implementation Review

Trade in products that do not comply with the new rules will be prohibited from 31 October 2012. The effects of the legislation will be reviewed in October 2015 at the latest.

Summary

In summary, these Regulations will ensure coherence between the NLD and other European legislation, particularly EC Regulation 1924/2006 on Nutrition and Health Claims made on Foods, EC Regulation 1925/2005 on the Addition of Vitamins and Minerals and of Certain Other Substances to Foods (the AVMR) and Commission Directive 2002/46/EC on Food Supplements Directive. It will provide greater legal clarity to the food industry in terms of

providing information to consumers and will facilitate more consistent enforcement of this aspect of food law.

Failure to make these Regulations would result in a serious breach of the UK's obligations under the EC treaty which would attract infraction proceedings by the Commission against the UK and the possibility of heavy fines.

Annex 1

Stakeholders consulted:

3M Health Care Ltd
Abergavenny Fine Foods Ltd
ADAS Wales
All Wales Dietetic Advisory Committee
Allison's Celebration Cakes
Association of Voluntary Organisations
Avana Bakeries limited
AWDAC
B A Jenkins & Sons
B Sidoli & Sons Ltd
Bar & Restaurant Foods Ltd
Barons Patisserie
Berwyn Bakery
Braces Bakery Limited
British Heart Foundation
Briwsion
Business Eye
Capita Symonds
Cardiff Scientific Services
Cardiff University
Carolyn's Real Bread Co
Children's Commissioner for Wales
Children's Information Service
Congenital Anomaly Register & Information Service
Consumer Focus Wales
Conway and Denbighshire Local Public Health Team
Country Land & Business Association
Dairy Development Centre
DEE DAIRY SERVICES
Dental Public Health Unit
Department of Dental Health and Biological Science
Education Development Inclusion Service

Farm Assured Welsh Livestock
Federation of Small Businesses (South Wales)
fedwen Bakerys (Cardigan) Ltd
Flying Start
Food Centre Wales
Food Consultancy
Friends of the Earth Cymru
FSA Advisory Committee for Wales
G C Hahn & Co Ltd
Garth Bakeries Ltd
Glutafin
Good Food Distributors
Grassland Development Centre, IGER
Greggs Wales
HAT Events
Health Protection Agency
Henllan Bread
Hybu Cig Cymru - Meat Promotion Wales
Iceland Foods Limited
Institute of Biological & Environmental Services
JM & A hughes (Station Bakery)
Lewis' Pies Ltd
Local Helth Watch Group
Lynn Stockley and Associates
Media Wales
Memory Lane Cakes Ltd
Meridian Foods Ltd
Minton Treharne Davies Ltd
Montgomery Spring Water Co
National Assembly for Wales
National Farmers Union Cymru
National Federation Of Women's Institutes
National Public Health Service Wales
NFU Cymru
North Wales NHS Trust
NPHS
Ogmore Vale Bakery Limited
Organic Centre Wales
Organic Working Group
Pantycelyn Comprehensive School
Peters Food Service
Rachel's Organic
RCGP Wales
Riverside Community Market Association Social Enterprise
Ltd

Royal Welsh Agricultural Society
Slaters Bakery
Snowdrop Bakery
South Caernarfon Creameries
Tan y Castell
The Bay (Public Affairs Ltd)
The Co-operative Group
The Monmouthshire Rural Business Centre
The Village Bakery (Coedpoeth) Limited
Tillery Valley Foods Ltd
Trading Standards Institute (Wales)
Unilever UK Ltd
University of Bangor
University of Wales in Cardiff
UWIC
Vydex Corporation Ltd
Wales Council for Voluntary Action
Welsh Assembly government
Welsh Food Alliance
Welsh Hills Bakery
Welsh Organic Scheme
Welsh Quality Meats
White's Golden Crust Bakery
Zorba Foods

TRANSPOSITION NOTE: The Food Labelling (Nutrition Information) (Wales) Regulations 2009

This transposition note indicates how Commission Directive 2008/100/EC which amends Directive 90/496/EEC on nutrition labelling will be transposed into legislation in Wales by The Food Labelling (Nutrition Information) (Wales) Regulations 2009, which amend the Food Labelling Regulations 1996.

Responsibility for implementation in Wales lies with the Minister for Health and Social Services on the advice of the Food Standards Agency, save where indicated in the table below.

Commission Legislation and Article	Objective	Implementation	Responsibility
Commission Directive 2008/100/EC Article 1 (1), 1 (4) and Annex II	Introduction of definition of fibre	Regulation 2 (2)(b)	
Commission Directive 2008/100/EC Article 1 (2)	Introduction of energy conversion factors for fibre and erythritol	Regulation 2 (5)	
Commission Directive 2008/100/EC Article 1 (3) and Annex I	Replaces and completes list of recommended daily allowances for vitamins and minerals	Regulation 2(3) & (4)	
Commission Directive 2008/100/EC Article 2	To prohibit trade in products which do not comply with Directive from 31 October 2012	Regulation 3	