

**EXPLANATORY MEMORANDUM TO**

**The Food with Added Phytosterols or Phytostanols (Labelling)  
(Wales) (Amendment) Regulations 2014**

This Explanatory Memorandum has been prepared by the Food Standards Agency (FSA) and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

**Member's Declaration**

In my view the Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Food with Added Phytosterols or Phytostanols (Labelling) (Wales) (Amendment) Regulations 2014. I am satisfied that the benefits outweigh any costs.

Mark Drakeford AM

Minister for Health and Social Services, one of the Welsh Ministers

24 February 2014

**EXPLANATORY MEMORANDUM TO**  
**The Food with Added Phytosterols or Phytostanols (Labelling) (Wales)**  
**(Amendment) Regulations 2014**

**1. Description**

The Food with Added Phytosterols or Phytostanols (Labelling) (Wales) (Amendment) Regulations 2014 (“the Regulations”) will implement EU regulations on labelling of foods and food ingredients with added phytosterols, phytostanols and/or phytostanol esters.

**2. Matters of Special Interest to the Constitutional and Legislative Affairs Committee**

None

**3. Legislative Background**

The Regulations are made in exercise of the powers conferred on the Welsh Ministers by section 16(1)(e) and (f), 17, 26(1) and (3) and 48(1) of the Food Safety Act 1990. These functions 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 and subsequently transferred to the Welsh Ministers by virtue of section 162 and paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32)

This instrument is subject to the negative procedure.

**4. Purpose and Intended Effect of the Legislation**

The objective of the Regulations is to continue to ensure that foods with added phytosterols or stanols are consistently labelled, so that consumers who wish to either lower or maintain their blood cholesterol levels are fully informed about the appropriate use of these products.

**5. Consultation**

A public consultation was held between 19 December 2013 and 16 January 2014. The FSA in Wales received no responses to this consultation.

There had already been discussions with industry representatives across the UK, and we did not anticipate significant further comment at this stage. For this reason it was agreed to limit the public consultation to 4 weeks.

Similar public consultations were carried out in England, Scotland and Northern Ireland.

In England, one response was received from a manufacturer. The company felt that for products carrying the claim, the current statement is neither confusing nor misleading.

In response, the FSA stated that the changes to the wording will enable both disease risk reduction and/or maintenance claims to be made in future without contradiction.

Following the approval of the maintenance claims last year, there was a requirement to amend Commission Regulation (EC) No. 608/2004, as a short-term measure, in advance of the entry into force of the FIC in December 2014. The relevant text of the FIC also needed to be amended and a proposal to do this was adopted in January<sup>1</sup>.

Other comments were specific to the position in England (largely questions around industry costs). As no affected businesses in Wales have been identified, either before or as a result of the public consultation, these issues are not relevant to the position in Wales, but have been addressed in a separate Impact Assessment produced by the Food Standards Agency in England.

## 6. Regulatory Impact Assessment

### Sectors and groups effected

#### *Industry*

The proposed Regulations will impact on, in particular, companies labelling and placing foods on the market with added phytosterols or stanols; importers, distributors, as well as wholesalers and retailers; enforcement bodies and consumer organisations. By engagement with industry we have identified two large businesses in the UK who would be directly affected by the policy. These businesses produce and sell margarines, milk and yoghurt products with added phytosterols or stanols. **Neither of these businesses is based in Wales.**

We have not identified any other businesses directly affected in Wales. The public consultation specifically requested that stakeholders inform us of any businesses affected.

#### *Enforcement*

Local Authorities (LAs) are responsible for the enforcement of food law in the UK and they will be affected by the re-labelling requirement as they will need to familiarise themselves with the changes. There are 22 LAs in Wales.

#### *Consumers*

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<sup>1</sup> [http://www.parlament.gv.at/PAKT/EU/XXV/EU/00/38/EU\\_03868/imfname\\_10424678.pdf](http://www.parlament.gv.at/PAKT/EU/XXV/EU/00/38/EU_03868/imfname_10424678.pdf)

The Regulations will improve the labelling of products containing phytosterols or stanols and could therefore, have health benefits by providing more accurate and targeted information about these products.

### **Options Considered**

#### **Option 1 – Do nothing – Do not implement the new labelling provisions for phytosterols or stanols as set out in the new Commission Regulation.**

Under this option the new Commission Regulation will still be applicable in England and the rest of the UK, as it has applied since August 2013 and is already legally binding within the EU. However, enforcement authorities will not have the necessary powers to enable them to enforce the labelling provisions of the new Commission Regulation.

This option would also mean that the UK fails to meet its Treaty obligations to put in place legislation to provide for the enforcement of EU law and may lead to the UK being liable to infraction proceedings.

#### **Option 2 - Make appropriate domestic Regulations for the execution and enforcement of the new Commission Regulation**

Providing for the enforcement of the new Commission Regulation would remove the risk of the UK incurring infraction proceedings and ensure that foods and food ingredients containing added phytosterols or stanols are labelled consistently throughout the EU.

This option also meets the Government's commitment to fulfil its EU obligations and contributes significantly to provide for the means of protecting consumers. European Regulations are binding in their entirety and directly applicable in Member States from the date they take effect. The UK has a legal obligation to ensure that the provisions are in place to provide for the enforcement in full of the new Commission Regulation.

### **Option Appraisal**

#### **Option 1 – Do nothing – Do not implement the new labelling provisions for phytosterols or stanols as set out in the new EU Regulation**

##### **Costs and Benefits**

There are no costs or benefits associated with this option. This is the baseline against which the policy option (Option 2) is appraised.

#### **Option 2 – Make appropriate domestic Regulations for the execution and enforcement of the new EU Regulation**

##### **Costs**

##### **Costs to Industry**

No affected food businesses have been identified in Wales. Therefore no costs to industry in Wales are identifiable.

## **Costs to Enforcement Bodies**

### ***Familiarisation Costs (One-Off Costs)***

There will be one-off costs to enforcement bodies from the need to familiarise themselves with the new requirements. Familiarisation costs can be monetised as a time cost by multiplying the time required for familiarisation by the wage rate of the official carrying out the familiarisation. We envisage that it will be an Environmental Health Officer (EHO) (wage rate of £21.10<sup>2</sup>) who will need to familiarise themselves with the new requirements and that it will take one official per local authority approximately one hour. Multiplying the wage rate by the number of LAs (22) generates a total cost to enforcement of £464.20

## **Benefits**

### **Benefits to Consumers**

#### *Improved Information (Non-Monetised Benefit)*

The new EU Regulation will improve the labelling of products containing phytosterols or stanols and could therefore, have health benefits, in terms of improved information, to the consumers of these products. One of the businesses contacted by the FSA commented that the labelling change would protect consumers from interpreting the statement as a cholesterol lowering claim. The company also highlighted that the negative financial impact on their brands from misleading communication claims in the market would be significantly higher than the additional financial impact of re-labelling their products.

## **Risks and Assumptions**

LAs will need to invest time to familiarise themselves with the new legislation as they would be responsible for the enforcement and compliance.

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<sup>2</sup> Wage rate obtained from Annual Survey of Hours and Earnings 2012 (ASHE), (<http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcM3A77-280149>). Median hourly wage rate of a 'health and safety officer' was used, (16.25, plus 30% overheads, totalling £21.1).