# **Explanatory Memorandum to the Extraction Solvents in Food (Wales)** (Amendment) Regulations 2011

This Explanatory Memorandum has been prepared by the Food Standards Agency 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 Extraction Solvents in Food (Wales) (Amendment) Regulations 2011**. I am satisfied that the benefits outweigh any costs.

**Lesley Griffiths AM**Minister for Health and Social Services

25 July 2011

# Explanatory Memorandum for the Extraction Solvents in Food (Wales) (Amendment) Regulations 2011

### 1. Description

This Statutory Instrument will provide for the provide for the implementation and enforcement of European Commission Directive 2010/59/EU concerning extraction solvents used in the production of foodstuffs and food ingredients.

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

None.

#### 3. Legislative Background

Welsh Ministers have the powers to make these Regulations under sections 16(1)(a) and (f), 17(1) and 48(1) of the Food Safety Act 1990.

This instrument is subject to the negative procedure.

## 4. Purpose and Intended Effect of the Legislation

The Extraction Solvents in Food (Wales) (Amendment) Regulations 2011 are intended to implement the provisions of a new European Commission Directive, which amends Directive 2009/32/EU, which controls the use of extraction solvents used in the production of food and food ingredients by way of a positive list of EU approved extraction solvents, together with conditions of use, including maximum permitted levels, where appropriate.

Annex I Part III of the Directive sets out a list of extraction solvents that are permitted to be used in preparation of flavourings. The aim of the new Directive is to add the new extraction solvent, dimethyl ether, following its evaluation by the European Food Safety Authority (EFSA), to the list of approved extraction solvents in Directive 2009/32/EU. In addition, an amendment to Annex I Part III of the Directive has been included which aims to clarify the limits on the use of two currently permitted extraction solvents, methanol and propan-2-ol, in the preparation of flavourings from natural flavouring materials.

#### Background

EFSA evaluated the safety of dimethyl ether as an extraction solvent to remove fat from animal protein raw materials. In 2009 EFSA published its opinion and concluded that there is no safety concern, provided that the maximum residual limit of dimethyl ether in deflated protein products does not exceed 0.009 mg/kg. An amendment to the European extraction solvent legislation was considered necessary to reflect the EFSA opinion. In addition, the opportunity has been taken to amend the legislation to clarify limits for the approved extraction solvent methanol and popan-2-ol for use in the preparation of

flavourings from natural flavouring materials. Directive 2009/32/EU includes maximum residue limits for those two solvents in food ingredients themselves and industry was concerned that, if those limits were held to apply to extracted flavourings themselves, it would not be able to comply. Hence, the limits are being clarified by inclusion of more generous maximum residue limits in food where either of the solvents has been used in the preparation of flavourings.

#### 5. Consultation

The FSA consulted industry whilst EU negotiations on the Directive were ongoing. Industry's response was that there would be no impact and raised no objections on the proposed changes to the extraction solvents legislation, permitting the use of new extraction solvent and clarifying the levels at which methanol and propan-2-ol can be used in preparation of flavourings from natural flavouring materials is likely to be beneficial to industry.

A four-week consultation was carried out on the draft Extraction Solvents in Food (Wales) (Amendment) Regulations 2011 from 7 June to 4 July 2011. A full twelve-week consultation was not considered necessary as no impact was identifiable through earlier consultation and the intention to implement fully and unchanged the provisions proposed by the Commission which formed the subject of that earlier consultation. There were no responses to the consultation in Wales, however, one response was received UK-wide, which welcomed the clarification of the levels at which methanol and propan-2-ol can be used in the preparation of flavourings from natural flavouring materials.

#### 6. Regulatory Impact Assessment

A Regulatory Impact assessment has not been prepared for the Instrument, as there are no identifiable costs to consumers, businesses or enforcement authorities associated with the implementation of the new Regulations.

The Regulations will not impose any new burden on Government or enforcement officers. Rural areas, members of ethnic communities, or of any particular racial group, are unaffected by these proposals.

### 7. Statutory Review

The Minister for Health and Social Services has agreed to the Food Standards carrying out a review of these regulations within five years. The review period begins when the proposed Regulations that are the subject of this impact assessment come info force. In carrying out the review, the FSA is required to produce a report that will assess whether the Regulations achieved their intended objectives. The report will also assess if these objectives could be achieved by means that impose less regulation.