

Explanatory Memorandum to the Food Additives (Wales) (Amendment) (No.2) 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 Food Additives (Wales) (Amendment) (No.2) Regulations 2011.

Lesley Griffiths AM

Minister for Health and Social Services

8 June 2011

Explanatory Memorandum for the Food Additives (Wales) (Amendment) (No.2) Regulations 2011

1. Description

This Statutory Instrument will provide for the enforcement in Wales of Commission Directive 2011/3/EC (“the 2011 Directive”), which amends existing European Union rules governing the purity criteria on colours for use in foodstuffs.

2. Matters of Special Interest to the Relevant 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 2011 Directive amends existing European Union legislation regarding specific purity criteria on colours for use in foodstuffs, which is provided in Commission Directive 2008/128/EC. The purpose of the amendment is to revise the existing purity criteria for lycopene obtained from red tomatoes, and to set purity criteria for, and permit the use of, two new sources of lycopene. The two new sources of lycopene are synthetic lycopene and lycopene obtained from the fungus *Blakeslea trispora*.

This Statutory Instrument provides for the implementation in Wales of the 2011 Directive by amending the Food Additives (Wales) Regulations 2009 (S.I 2009/3378 (W.300)). The provisions relating to the two new sources of lycopene will come into force on 1 July 2011, and the provisions relating to the revised purity criteria for lycopene from red tomatoes will come into force on 1 September 2011 (the latest date for implementation stipulated in the 2011 Directive).

In 2007, the European Food Safety Authority (EFSA) assessed available information on the safety of the use of lycopene as a food colour from all sources, specifically, solvent extraction of the natural strains of red tomatoes, synthetic lycopene and lycopene from *Blakeslea trispora*. In its opinion, published in early 2008, EFSA reaffirmed the safety of lycopene from tomatoes and for use as a food colour and gave a favourable opinion on the safety of the other sources for such use. In July 2009, the European Commission issued a proposal to make amendments to Commission Directive 2008/128/EC (purity criteria for food colours) in order to revise the purity criteria for lycopene obtained from tomatoes, and to set a purity criteria for, and permit the use of, the two sources of lycopene on which EFSA have given a favourable opinion.

The Commission's proposal was adopted by a Qualified Majority in the EU Standing Committee on the Food Chain and Animal Health (SCoFCAH) on 10 September 2010 and Commission Directive 2011/3/EU was published in the Official Journal of the EU on 18 January 2011 (OJ ref, L13, 18.1.2011, p59).

5 Consultation

The Food Standards Agency consulted industry whilst EU negotiations on the 2011 Directive were ongoing. This consultation revealed that industry is already able to comply with the revised specification for lycopene from tomatoes. Permitting the use of the two additional sources of lycopene will be beneficial to industry as it would be able to use these sources for the first time.

A four week consultation was carried out in Wales from 22 April to 25 May 2011 on the draft implementing Regulations. Parallel consultations were carried out in England, Scotland and Northern Ireland. A full 12-week consultation was not considered necessary due to the minimal impact identified through earlier consultation and the intention to implement the permissive elements of the Commission Directive. No comments were received from stakeholders on the proposed Regulations to implement the provisions of the 2011 Directive.

6. Regulatory Impact Assessment

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

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