EXECUTIVE NOTE

THE FOOD ADDITIVES (SCOTLAND) AMENDMENT (NO. 2) REGULATIONS 2011 SSI 2011/305

1. Description

1.1 The above instrument was made under the powers in sections 16(1)(a) and (f), 17(1) and 48(1) of the Food Safety Act 1990([1]). The instrument is subject to negative resolution procedure and does not amend primary legislation.

2. Policy Objective

2.1 This instrument, which extends to Scotland only, provides for the implementation of Commission Directive 2011/3/EU amending the existing European Union rules governing the purity criteria for the permitted food colour lycopene.

3. Legislative Background

3.1 The main purpose of the new Regulations are to implement the provisions of Commission Directive 2011/3/EU, by making an amendment to the Food Additives (Scotland) Regulations 2009 (SSI 2009/436), Directive 2011/3/EU revises the purity criteria for the sole source of lycopene currently permitted for use (obtained from tomatoes) and permits the use of, and sets purity criteria for two additional sources of lycopene (synthetic lycopene and lycopene from the fungus Blakeslea trispora([2])).

4. Policy Background

4.1 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. The sources that were considered were: (a) E160d lycopene obtained by solvent extraction of the natural strains of red tomatoes with subsequent removal of solvent, (b) synthetic lycopene and (c) lycopene from Blakeslea trispora[2]. In its opinion, published in early 2008, EFSA reaffirmed the safety of lycopene from tomatoes for use as a food colour and gave a favourable opinion on the safety of the other two sources for such use.

4.2 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: (a) adjust the purity criteria for lycopene obtained from tomatoes, and (b) set purity criteria for, and permit the use of, the two sources of lycopene on which the EFSA had given a favourable opinion.

4.3 The Commission's proposal was adopted by a Qualified Majority in the EU Standing Committee on the Food Chain and Animal Health on 10 September 2010 and

([1]) 1990 c.16.
([2]) Lycopene from Blakeslea trispora is extracted from the fungal biomass and purified by crystallisation and filtration.

Commission Directive 2011/3/EU was published in the Official Journal of the EU on 18 January 2011[3].

4.4 Amendments are necessary to the purity criteria set down in EU legislation to reflect the changes in industry practices and changes to international standards**.**

5. Consultation

5.1 Industry across the UK was consulted during the EU negotiations on the Directive. This consultation revealed that industry is already able to comply with the revised specification for lycopene from tomatoes and permitting the use of the two additional sources of lycopene will be beneficial to industry as it will be able to use these sources for the first time.

5.2 On the 5th April 2011, a shortened four week consultation was launched on the draft implementing Regulations in Scotland involving approximately 235 Scottish stakeholders including trade associations, local authorities, consumer organisations and sector specific organisations of the draft implementing Regulations. A full 12 week consultation was not considered necessary due to the minimal impact identified through earlier consultation. On both occasions, Scottish stakeholders made no comments on the proposed Regulations. As far as we are aware there are currently no food colour manufacturers based in Scotland.

6. Other Administrations

6.1 Equivalent Regulations will apply in England, Wales and Northern Ireland.

7. Impact

7.1 A Business and Regulatory Impact Assessment has not been produced for this instrument for the reasons outlined in paragraph 5.2. No impact on the private, public or voluntary sectors is foreseen.

8. Contact

Claire Moni at the Food Standards Agency Scotland (Telephone 01224 285158)
(email: claire.moni@foodstandards.gsi.gov.uk

Food Standards Agency Scotland
15 August 2011

([3])OJ Ref, L13, 18.1.2011, p59

TRANSPOSITION NOTE
THE FOOD ADDITIVES (SCOTLAND) AMENDMENT (NO.2) REGULATIONS 2011

EUROPEAN COMMISSION DIRECTIVE 2011/3/EU AMENDING DIRECTIVE 2008/128/EC LAYING DOWN SPECIFIC PURITY CRITERIA ON COLOURS FOR USE IN FOODSTUFFS

Articles	**Objectives**	***Implementation***	**Responsibility**
Article 1	Article 1 of Directive 2011/3/EU amends Directive 2008/128/EC by way of a reference to the Annex to the Directive, which contain provisions regarding the purity criteria for colours and amends the existing specifications to take account of international safety standards and new technological developments.	Article 1 is implemented by Regulation 2 of the Food Additives (Scotland) Amendment (No.2) Regulations 2011.	The Scottish Ministers.