EXPLANATORY MEMORANDUM TO

THE FOOD ADDITIVES (ENGLAND) (AMENDMENT) (No.2) REGULATIONS 2011

2011 No. 1456

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Purpose of the Instrument

2.1 This instrument 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. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 This instrument will implement the provisions of Commission Directive 2011/3/EU, by making an amendment to the Food Additives (England) Regulations 2009 (SI 2009/3238).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).

5. Territorial Extent and Application

5.1 This Instrument applies to England only. Separate but parallel legislation is being enacted for Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As the Instrument is subject to the negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- What is being done and why

7.1 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, specifically: (a) solvent extraction of the natural strains of red

tomatoes, and (b) synthetic lycopene from Blakeslea trispora[1]. 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.

7.2 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.

7.3 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[2].

7.4 Amendments are necessary to the purity criteria set down in EU legislation to reflect the changes in industry practices and changes to international standards. In accordance with the Government's Guiding Principles for EU Legislation, the FSA's intention is that national Regulations should implement the permissive element of the Directive (the two new sources of lycopene) on the earliest practicable date (1st July 2011) and the restrictive element (the revised purity criteria for lycopene from tomatoes) on the latest date for implementation stipulated in the Directive of 1st September 2011. The restrictions are very minor (with reference to changed lead limits and disuse of dichloromethane) and not considered burdensome by industry.

8. Consultation outcome

8.1 The FSA consulted industry whilst EU negotiations on the 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 will be able to use these sources for the first time.

8.2 A four week consultation has been carried out on the draft implementing Regulations. 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 as soon as practicable.

8.3 No comments were received from stakeholders on the proposed Regulations to implement the provisions of the Commission Directive.

---

[1] Lycopene from Blakeslea trispora is extracted from the fungal biomass and purified by crystallisation and filtration.

[2] OJ Ref, L13, 18.1.2011, p59

9. Guidance

9.1 It is not intended to issue guidance as the current controls, with which industry and the enforcement authorities are familiar, remain unchanged.

10. Impact

10.1 There will be no impact on business, charities or voluntary bodies.

10.2 There is no impact on the public sector as there are no identifiable costs.

10.3 An Impact Assessment has not been prepared for this instrument. The consultation did not bring to light any new impacts.

11. Regulating small business

11.1 The legislation on purity criteria will apply to all businesses small and large.

11.2 There will be no impact on small businesses as there are no identifiable costs to industry.

12. Monitoring & review

12.1 Central and local authorities in England routinely monitor foodstuffs on sale to the public to ensure compliance with the new Regulations. The European Commission reviews purity criteria for additives to ensure that they meet the latest international safety standards, any review of the legislation would be undertaken by the European Commission in liaison with EFSA.

13. Contact

13.1 Glynis Griffiths at the Food Standards Agency, Tel: 020 7276 8556, Email: glynis.griffiths@foodstandards.gsi.gov.uk can answer any queries regarding the instrument.

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 and the Annex to Directive 2011/3/EU amend Directive 2008/128/EC by substituting revised entries for lycopene in Annex I to that Directive. The changes relate to provisions regarding the purity criteria for lycopene, to take account of international safety standards and new technological developments.	Article 1 and the Annex are implemented by reference, in Regulation 2 (2) of the Food Additives (England) (Amendment) (No.2) Regulations 2011.	The Secretary of State for Health on the advice of the Food Standards Agency is responsible for the measures taken to implement the Directive in England.