EXPLANATORY MEMORANDUM TO

THE FOOD ADDITIVES (AMENDMENT) (NO.2) REGULATIONS (NORTHERN IRELAND) 2011

2011 No. 217

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency in Northern Ireland to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under Articles 15(1)(a) and (f), 16(1) and 47(2) of the Food Safety (Northern Ireland) Order 1991.

2. Purpose of the Rule

2.1 This rule 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 This rule will implement the provisions of Commission Directive 2011/3/EU, by making an amendment to the Food Additives Regulations (Northern Ireland) 2009 (S.R. 2009 No. 416). 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).

4. Parity or Replicatory Measure

4.1 This Statutory Rule applies to Northern Ireland only. Separate but Parallel legislation is being enacted for Scotland, England and Wales.

5. European Convention on Human Rights

5.1 As this rule is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Policy background

- ***What is being done and why***

6.1 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.

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

6.2 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.

6.3 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].

6.4 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.

7. Consultation

7.1 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.

7.2 The FSA in NI undertook a four week consultation in order to gather stakeholder views 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.

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

8. Guidance

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

9. Equality Impact

9.1 These regulations will apply in equal measure to all Section 75 groups. It is not expected that any of these changes will impact differentially across any of the section 75 groups.

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 rule. The consultation did not bring to light any new impacts.

[2] OJ Ref, L13, 18.1.2011, p59

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 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

Mervyn Briggs at the Food Standards Agency NI, Tel: 028 9041 7742,
Email: mervyn.briggs@foodstandards.gsi.gov.uk or

Hayley Hamilton, Tel: 028 9041 7763
Email:hayley.hamilton@foodstandards.gsi.gov.uk