# EXECUTIVE NOTE

# THE EXTRACTION SOLVENTS IN FOOD AMENDMENT (SCOTLAND) REGULATIONS 2011
# SSI 2011/306

## 1. Description

1.1 The above instrument was made under the powers in sections 16(1)(a) and (c), 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 2010/59/EU which permits the use of a newly approved extraction solvent and clarifies the limits for two existing extraction solvents in the preparation of flavourings.

## 3. Legislative Background

3.1 The main purpose of the new Regulations are to implement the provisions of Commission Directive 2010/59/EU, by making an amendment to the Extraction Solvents in Food Regulations 1993 (as amended) (SI 1993/1658). Directive 2010/59/EU amends Directive 2009/32/EC on extraction solvents used in the production of foodstuffs and food ingredients so as to permit the use of a new approved extraction solvent, dimethyl ether, in the preparation of defatted animal protein products at a maximum limit of 0.009 mg/kg and to clarify the limits for two existing extraction solvents in the preparation of flavourings.

## 4. Policy Background

4.1 The European Food Safety Authority (EFSA) evaluated the safety of dimethyl ether as an extraction solvent to remove fat from animal protein raw materials. In 2009 the EFSA published its opinion[2] and concluded that there is no safety concern provided that the maximum residual limit of dimethyl ether in defatted protein products does not exceed 0.009 mg/kg. An amendment to the European extraction solvents 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 solvents methanol and propan-2-ol for use in the preparation of flavourings from natural flavouring materials. Directive 2009/32/EC 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.

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([1]) 1990 c.16.

[2] http://www.efsa.europa.eu/fr/scdocs/doc/984.pdf

4.2 In January 2010, the European Commission issued a proposal to make amendments to Directive 2009/32/EC[3] in order to (a) permit an additional extraction solvent (dimethyl ether) on which the EFSA had given a favourable opinion to remove fat from animal protein raw materials and (b) clarify the levels at which levels of methanol and propan-2-ol could be used in the preparation of flavourings from natural flavourings. The general residue limit of 10 mg/kg for methanol and propan-2-ol in Directive 2009/32/EC is too strict in terms of industry's ability to comply if applied directly to flavourings.

4.3 The Commission's proposal was adopted by Qualified Majority in the EU Standing Committee on the Food Chain and Animal Health (SCoFCAH) and was published in the Official Journal (OJ) of the EU as Commission Directive 2010/59/EU on 27 August 2010[4]. It can be downloaded from the European Commission website at the link below: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:225:0010:0012:EN:PDF

## 5. Consultation

5.1 Industry across the UK was consulted during the EU negotiations on the Directive and their views taken into account. Industry raised no objections to the proposed changes to the extraction solvents legislation. Permitting the use of the new extraction solvent and clarifying the levels at which methanol and propan-2-ol can be used in the preparation of flavourings from natural flavouring materials is likely to be beneficial to UK industry.

5.2 A shortened 4 week consultation was carried out in Scotland from the 23rd May to 20th June 2011 on the proposed national implementing regulations involving approximately 235 Scottish stakeholders, including trade associations, local authorities, consumer organisations and sector specific organisations. A full 12 week consultation was not considered necessary as there was no indication from industry from earlier consultation that any incremental costs would arise from the implementation of the Directive. However the consultation letter asked stakeholders to advise us of any related impact. No responses were received. These Regulations are mostly relevant to extraction solvent and food flavouring manufacturers and to the best of our knowledge none of these are currently based in Scotland.

5.3 FSA in England received one comment from industry during this consultation, 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. Other Administrations

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

[3] OJ Ref, L141, 6.6.2009
[4] OJ Ref, L225, 27.08.2010, p10

## 7. Impact

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

## 8. Contact

8.1 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**

**TRANSPOSITION NOTE**
**EXTRACTION SOLVENTS IN FOOD AMENDMENT (SCOTLAND) REGULATIONS 2011**

**EUROPEAN COMMISSION DIRECTIVE 2010/59/EU AMENDING DIRECTIVE 2009/32/EC EXTRACTON SOLVENTS USED IN THE PRODUCTION OF FOODSTUFFS AND FOOD INGREDIENTS**

| **Articles** | **Objectives** | ***Implementation*** | **Responsibility** |
|---|---|---|---|
| | | | |
| Article 1 | Article 1 of Directive 2010/59/EU amends Annex 1 of Directive 2009/32/EC by inserting new entries in Parts ll and III of that Directive. The changes take account of a recent opinion by the European Food Safety Authority and of the need to clarify the permitted limits of two approved extraction solvents when used in the preparation of flavourings. | Article 1 and the Annex are implemented in regulation 2 of the Extraction Solvents in Food Amendment (Scotland) Regulations 2011 | The Scottish Ministers |