

**EXPLANATORY MEMORANDUM TO
THE EXTRACTION SOLVENTS IN FOOD (AMENDMENT) (ENGLAND)
REGULATIONS 2011**

2011 No. 1738

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 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. 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 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.

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 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 opinion¹ 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.

- 7.2 In January 2010, the European Commission issued a proposal to make amendments to Directive 2009/32/EC² 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.
- 7.3 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 2010³. 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>

8. Consultation outcome

- 8.1 The FSA consulted industry whilst EU negotiations on the Directive were ongoing. Industry's response was that there would be no impact and 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 industry.
- 8.2 A four week consultation was carried out on the draft implementing Regulations. A full 12 week consultation was not considered necessary

¹ <http://www.efsa.europa.eu/fr/scdocs/doc/984.pdf>

² OJ Ref, L141, 6.6.2009

³ OJ Ref, L225, 27.08.2010, p10

as no impact was identified through earlier consultation and the intention to implement fully and unchanged the provisions proposed by the Commission which formed the subject of that earlier consultation.

- 8.3 One comment was received from industry 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.

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 charities or voluntary bodies, the provisions in this instrument are likely to be beneficial to industry.
- 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 extraction solvents will apply to all businesses small and large.
- 11.2 There is likely to be a beneficial impact on small businesses as there is on other parts of 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. Any review of the legislation would be undertaken by the Food Standards Agency.

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 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 II 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 regulations 2 (2) and (3) of the Extraction Solvents in Food (Amendment) (England) 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.