

FOOD STANDARDS AGENCY CONSULTATION

Title: The Extraction Solvents in Food (Amendment) (England) Regulations 2011

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
18 th May 2011	17 th June 2011

Who will this consultation be of most interest to?

Manufacturers of extraction solvents, food and flavourings manufacturers using extraction solvents and enforcement authorities.

What is the subject of this consultation?

National regulations relating to England to implement European Commission Directive 2010/59/EU. This directive permits the use of a newly approved extraction solvent dimethyl ether in the preparation of defatted animal protein products at a maximum limit of 0.009 mg/kg and clarifies the limits for two existing extraction solvents in the preparation of flavourings

What is the purpose of this consultation?

To provide stakeholders with an opportunity to comment on the provisions of the draft Extraction Solvents in Food (England) (Amendment) Regulations 2011, which would implement Commission Directive 2010/59/EU in England.

Responses to this consultation should be sent to:

Name: Nasreen Shah
Division/Branch : Chemical Safety Division
FOOD STANDARDS AGENCY
Tel: 020 7276 8553
Fax: 020 7276 8446

Postal address:
Room 3A, Aviation House
125 Kingsway, London,
WC2B 6NH.
Email: nasreen.shah@foodstandards.gsi.gov.uk

Is an Impact Assessment included with this consultation?

Yes ☐

No ☒ See Annex A for reason.



INVESTOR IN PEOPLE

If you would prefer to receive future FSA consultations by e-mail, or if you no longer wish to receive information on this subject please notify the named person in this consultation.



The Extraction Solvents in Food (England) (Amendment) Regulations 2011

DETAIL OF CONSULTATION

Background

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 its opinion (<http://www.efsa.europa.eu/fr/scdocs/doc/984.pdf>) published in early 2009, EFSA concluded that there is no safety concern provided that the maximum residual limit of dimethyl ether in the defatted protein product does not exceed 0.009 mg/kg. An amendment to the European extraction solvents legislation was considered necessary to reflect EFSA'S 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. The original extraction solvents Directive does include 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.

The European Commission Directive

2. In January 2010, the European Commission issued a proposal to make amendments to Directive 2009/32/EC (extraction solvents used in the production of foodstuffs and food ingredients) in order to (a) permit an additional extraction solvent (dimethyl ether) on which EFSA had given a favourable opinion to remove fat from animal protein raw materials and (b) clarify the levels at which levels methanol and propan-2-ol could be used in the preparation of flavourings from natural flavouring materials. 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.
3. The Commission's proposal was adopted by Qualified Majority in the EU Standing Committee on the Food Chain and Animal Health (SCOFAH) in May 2010 and was published in the Official Journal of the EU as Commission Directive 2010/59/EU on 27 August 2010. It can be downloaded from the European Union website at the link below:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:225:0010:0012:EN:PDF>

Purpose of Consultation

4. The purpose of this consultation is to provide stakeholders with an opportunity to comment on the draft Extraction Solvents in Food (England) (Amendment) Regulations 2011, which would implement the Directive in

England. Separate consultations will be carried out in Scotland, Wales and Northern Ireland on draft Regulations relating to those parts of the UK.

Draft Regulations

5. The draft Extraction Solvents in Food (England) (Amendment) Regulations 2011 are attached at Annex B. These Regulations would implement the Commission Directive by making amendments to the Extraction Solvents in Food Regulations 1993 (as amended) (S.I. 1993/1658), in accordance with the Government's Guiding Principles for EU Legislation. We propose to implement it by the Commission's deadline of 15 September 2011.

Proposals

Key proposal:

Implementation of the Commission Directive 2010/59/EU in England by means of national regulations to amend the Extraction Solvents in Food Regulations 1993 (1993/1658) as amended which will :

Implement the provisions of the directive by 15 September 2011.

Consultation Process / Impact

6. FSA consulted industry during EU negotiations on the Directive. Industry said that there would be only a negligible 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 levels methanol and propan-2-ol can be used in the preparation of flavour from natural flavouring materials will have a negligible incremental impact on industry.
7. As there will be only negligible incremental impact on UK industry arising from the implementation of the directive, the FSA has not prepared an impact assessment (IA) on this occasion. Should this consultation bring to light any new impacts, the FSA will reconsider the need for an IA.
8. Given the minimal impact and the intention to implement the Directive by the Commission's deadline of 15 September 2011, this consultation is being conducted for a shortened period of four weeks.

Questions asked in this consultation

Q1: Do you agree with the key proposals detailed above?

Q2: What impact (if any) would the key proposals have on your current formulation process costs? The FSA welcomes responses, preferably with an evidence backing, to inform any estimated costings.

Q3: If applicable, how much is this likely to cost/save, broken down by activity?

Q4: Would industry be required to familiarise itself with the key proposals? If applicable, how much time would a business need to invest to read and familiarise itself with this Regulation and disseminate to key staff?

Q5: Would you be able to comment and provide evidence on any additional costs and benefits (if any) associated with the key proposals?

Q6: Do you think that the Regulations, if enacted as drafted, would achieve these aims of the Commission Directive?

Other relevant documents

9. Commission Directive 2010/59/EU of 26 August 2010 amending European Parliament and Council Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. This can be found at the following location on the European Union website at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:225:0010:0012:EN:PDF>
10. Responses are requested by close of business on **17th June 2011**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).
11. Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours faithfully,

**Nasreen Shah
Regulation and Business Support Unit
Chemical Safety Division**

Enclosed

Annex A: Standard Consultation Information

Annex B: Draft Statutory Instrument

Annex C: Commission Directive 2010/59/EU

Annex D: List of interested parties

Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. The FSA will publish a summary of responses, which may include your full name. Disclosure of any other personal data would be made only upon request for the full consultation responses. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at <http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc>. Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.
3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.
4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex B. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.
6. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.
7. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: <http://www.berr.gov.uk/files/file47158.pdf>. The Consultation Criteria from that Code should be included in each consultation and they are listed below:

The Seven Consultation Criteria

Criterion 1 - When to consult

Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 - Duration of consultation exercises

Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 - Clarity of scope and impact

Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 - Accessibility of consultation exercises

Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 - The burden of consultation

Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 - Responsiveness of consultation exercises

Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 - Capacity to consult

Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

8. Criterion 2 states that *Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.* This consultation is not being held for a full 12 weeks. It is instead being held for a shortened period of 4 weeks due to the minimal impact identified through earlier consultation and the need to implement the Commission Directive by 15 September 2011.
9. The Code of Practice states that *an Impact Assessment should normally be published alongside a formal consultation.* We have not produced an Impact Assessment for this proposal because (a) permitting the use of the an additional extraction solvent and clarifying levels of methanol and propan-2-ol for use in the preparation of flavourings from natural flavouring materials is of negligible impact to industry and (b) the FSA consulted industry during EU negotiations on the Directive. Industry said that there would be only a negligible impact and raised no objection. As such, there will be no incremental impact on UK industry arising from the implementation of the Directive. Should this consultation bring to light any new impacts, the FSA will reconsider the need for an IA.
10. For details about the consultation process (not about the content of this consultation) please contact: [Food Standards Agency Consultation Co-ordinator](#), Room 2B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

Comments on the consultation process itself

11. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at:
<http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc>.
12. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at:
<http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc>. The questionnaire can also be used to update us about your existing contact details.

STATUTORY INSTRUMENTS

2011 No. 0000

FOOD, ENGLAND

**The Extraction Solvents in Food (Amendment) (England)
Regulations 2011**

<i>Made</i>	- - - -	<i>2011</i>
<i>Laid before Parliament</i>		<i>2011</i>
<i>Coming into force</i>	- -	<i>Nth Month 2011</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a) and (c), 17(1) and 48(1) of the Food Safety Act 1990(a) and now vested in him(b).

In accordance with section 48(4A) of that Act, he has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

Title, application and commencement

1. These Regulations may be cited as the Extraction Solvents in Food (Amendment) (England) Regulations 2011, apply in relation to England only and come into force on [xxxxx] 2011.

-
- (a) 1990 c. 16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.
- (b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c. 28). Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32).. Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.
- (c) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Commission Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p14).

Amendment of the Extraction Solvents in Food Regulations 1993

2.—(1) The Extraction Solvents in Food Regulations 1993(a) are amended in accordance with paragraphs (2) and (3).

(2) At the end of the table in Schedule 2 (foods in which certain permitted extraction solvents may be used only for certain purposes), insert the following entries —

<i>“Column 1</i>	<i>Column 2</i>	<i>Column 3</i>	<i>Column 4</i>
10 Defatted protein products	Dimethyl ether	Preparation of defatted animal protein products	0.009 mg/kg in the defatted protein products”

(3) At the end of the table in Schedule 3 (maximum residues of extraction solvent permitted in foods due to the use in those foods of food consisting of flavourings prepared from natural flavouring materials by using those extraction solvents), insert the following entries —

<i>“Column 1</i>	<i>Column 2</i>
Methanol	1.5 mg/kg
Propan-2-ol	1 mg/kg”

Signed by authority of the Secretary of State for Health

Date

Name
Parliamentary Under Secretary of State
Department of Health

(a) S.I. 1993/1658. These Regulations have been amended by S.I. 1998/2257, and in relation to England only by S.I. 2005/2626.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations amend the Extraction Solvents in Food Regulations 1993 (S.I. 1993/1658) in order to implement in England Commission Directive 2010/59/EU amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ No. L225, 27.8.2010, p.10).

2. The amendments to the 1993 Regulations consist of —

- (a) the listing in Schedule 2 of dimethyl ether as an extraction solvent that may be used in the preparation of defatted animal protein products (*regulation 2(2)*); and
- (b) the inclusion in Schedule 3 (which concerns the use of extraction solvents in the preparation of natural flavourings) of methanol and propanol-2-ol, with associated prescribed residue limits (*regulation 2(3)*).

3. An impact assessment has not been prepared for this instrument as it has no impact on business or the public or third sectors.

COMMISSION DIRECTIVE 2010/59/EU**of 26 August 2010****amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients ⁽¹⁾ and in particular Article 4 thereof,

Whereas:

(1) Directive 2009/32/EC applies to extraction solvents used or intended for use in the production of foodstuffs or food ingredients. That Directive does not apply to extraction solvents used in the production of food additives, vitamins and other nutritional additives, unless such food additives, vitamins or nutritional additives are listed in its Annex I. The European Food Safety Authority (the Authority) evaluated the safety of dimethyl ether as an extraction solvent to remove fat from animal protein raw materials and expressed its opinion of 29 January 2009 ⁽²⁾. The Authority concluded that there is no safety concern provided that the maximum residual limit of dimethyl ether is 9 µg/kg of extracted animal proteins. Therefore the use of dimethyl ether as an extraction solvent to remove fat from animal protein raw materials should be authorised under the condition of a maximum residual limit of dimethyl ether of 9 µg/kg in the defatted protein product.

(2) Part III of Annex I to Directive 2009/32/EC does not establish specific residue limits in foodstuffs for methanol and propan-2-ol resulting from the preparation of flavourings. Member States and the Commission pointed out that the general residue limit of 10 mg/kg for methanol and propane-2-ol, as set out in Part II of Annex I to Directive 2009/32/EC, is too strict if applied directly to flavourings.

(3) Therefore specific limits should be set in foodstuffs for methanol and propan-2-ol resulting from their use for the preparation of flavourings from natural flavouring materials. Those limits should be lower than the limit of 10 mg/kg assessed as safe by the Scientific Committee for Food ⁽³⁾, in order to be considered as safe.

(4) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 2009/32/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 September 2011 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 3*This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 141, 6.6.2009, p. 3.

⁽²⁾ Scientific opinion of the panel on Food Contact Materials, Enzymes, Flavourings and Processing aids (CEF) on request from European Commission on the safety in use of dimethyl ether as an extraction solvent. *The EFSA Journal* (2009) 983, 1-13.

⁽³⁾ Scientific Committee for Food. Second opinion on extraction solvents expressed on 21 June 1991. Food Science and Techniques Reports of the Scientific Committee for Food (29th series), p. 1-11.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 26 August 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

Annex I to Directive 2009/32/EC is amended as follows:

1. in Part II the following row is added:

'Dimethyl ether	Preparation of defatted animal protein products	0,009 mg/kg in the defatted protein product'
-----------------	---	--

2. in Part III the following rows are added:

'Methanol	1,5 mg/kg
Propan-2-ol	1 mg/kg'

**European Commission Directive 2010/59/EU amending Directive
2009/32/EC on extraction solvents: Public Consultation on Draft National
Implementing Regulations**

List of Stakeholders

**Food Additives and Industry Association
British Essence Manufacturers Association
Food and Drink Federation
British Retail Consortium
APHA
LGR**