

## FOOD STANDARDS AGENCY CONSULTATION

Title: The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013

### CONSULTATION SUMMARY PAGE

<b>Date consultation launched:</b>	<b>Closing date for responses:</b>
10 April 2013	5 June 2013

**Who will this consultation be of most interest to?**  
 Food manufacturers; Food additive, enzyme, flavouring and extraction solvent suppliers/manufacturers; Enforcement authorities; Consumers

**What is the subject of this consultation?**  
 Consolidation of 'food additive' type legislation into a single instrument (SI). 'Food additive' type legislation covers: food additives, food enzymes, flavourings (including smoke flavourings) and extraction solvents. Revocation of emergency measure on Red 2G and minor amendments to food additive and flavouring provisions.

**What is the purpose of this consultation?**  
 To provide interested parties with the opportunity to comment on The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013.  
  
 To seek views on the proposed revocation and remake of 'food additive' type legislation into one statutory instrument. The proposed Regulations will also make small amendments to the food additive and flavouring provisions and introduce the use of civil sanctions for non-food safety contraventions and the likely impact (if any) on businesses and enforcement authorities of the proposed changes.

**Responses to this consultation should be sent to:**

Name Wendy Dixon Division/Branch CSD/FAFCM FOOD STANDARDS AGENCY Tel: 0207 276 8587 Fax: 0207 276 8514	Postal address: 3B Aviation House 125 Kingsway London, WC2B 6NH Email: <a href="mailto:wendy.dixon@foodstandards.gsi.gov.uk">wendy.dixon@foodstandards.gsi.gov.uk</a>
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<b>Is an Impact Assessment included with this consultation?</b>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/> See Annex A for reason.
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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 Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013

## DETAIL OF CONSULTATION

1. We would welcome your comments on:
  - The proposed Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 (“the proposed Regulations”), attached as Annex C. The proposed Regulations will replace the current statutory instruments on food additives, flavourings, food enzymes, smoke flavourings and extraction solvents.
  - The proposed Regulations will revoke and re-enact, with necessary amendments all existing ‘food additive’ type national legislation, within the Food Standards Agency’s (FSA) remit in one consolidated instrument. This is part of the FSA’s intention to introduce a simplified system of food safety legislation in response to the UK Government’s Red Tape Challenge Initiative (RTC).
  - Details of changes to the national legislation are discussed in paragraphs 12, 14-16 below.
  - An Impact Assessment has not been produced for these proposals, as the expectation is that the impact will be negligible. If, however, the consultation should bring to light any impact on enforcement bodies or industry, which has not been anticipated, the need for an Impact Assessment will be reconsidered.
2. The FSA in Scotland, Wales and Northern Ireland will be carrying out consultations on parallel but separate Regulations relating to those parts of the UK.

## Introduction

3. The purpose of this consultation is to seek comments from interested parties on the proposed consolidation and statutory instrument, which includes the use of compliance notices for non-safety related contraventions. As the proposed legislation is mainly a consolidation of existing national measures, no significant impacts are expected.

## Background

4. Harmonised European legislation controls the use of food additives, flavourings, smoke flavourings, food enzymes and extraction solvents in the European Union. The relevant Regulations and Directives are listed in Annex B.
5. In general, all the above substances are controlled by way of positive lists e.g. only authorised substances can be used in food and substances must meet specific conditions of use. For food enzymes and for certain categories of flavourings, work is underway to establish the positive lists.
6. Schedule 5 of the proposed Regulations lists the 12 principal statutory instruments and their amendments that currently cover ‘food additive’ type (national)

legislation. The controls on food additives, flavourings (including smoke flavourings) and food enzymes are set out in European Regulations, which are directly applicable in all European Member States. Therefore, the national legislation in these areas only cover enforcement provisions for the relevant European Regulations e.g. list offences and specify penalties for non-compliance. The controls on extraction solvents are specified in European Directives and all requirements were transposed into national law (see Annex E).

### **National Regulations being revoked and consolidated**

7. The proposed Regulations will revoke the following national Regulations:

- The Extraction Solvents in Food Regulations 1993<sup>1</sup>
- The Extraction Solvents in Food (Amendment) Regulations 1995<sup>2</sup>
- The Extraction Solvents in Food (Amendment) Regulations 1998<sup>3</sup>
- The Food (Suspension of the Use of E128 Red 2G as a Food Colour) (England) Regulations 2007<sup>4</sup>
- The Extraction Solvents in Food (Amendment) (England) Regulations 2011<sup>5</sup>
- The Smoke Flavourings (England) Regulations 2005<sup>6</sup>
- The Food Enzymes Regulations 2009<sup>7</sup> Regulations 3, 4, 5 and 6
- The Food Additives (England) Regulations 2009<sup>8</sup> - All provisions except regulations 1, 2, 18 and 19
- The Food Additives (England) (Amendment) Regulations 2011<sup>9</sup>
- The Food Additives (England) (Amendment) (No.2) Regulations 2011<sup>10</sup>
- The Food Additives (England) (Amendment) and the Extraction Solvents in Food (Amendment) (England) Regulations 2012<sup>11</sup>
- The Flavourings in Food (England) Regulations 2010<sup>12</sup> - All provisions except regulations 1, 2 and 7.

### **Red Tape Challenge**

8. In April 2011 the Government launched the Red Tape Challenge (RTC) initiative<sup>13</sup> with the purpose of getting comments from businesses and the public on how the burden of legislation can be reduced. For devolved issues, such as food safety, the RTC applies to England only. On 6 May 2011 most of the FSA's legislation was published on the RTC website under the Hospitality Theme and remained on the site until 2 June 2011. The FSA has a number of initiatives being delivered under the

<sup>1</sup> SI 1993 No. 1658

<sup>2</sup> S.I. 1995/1440

<sup>3</sup> S.I. 1998/2257

<sup>4</sup> S.I. 2007/2266

<sup>5</sup> S.I. 2011/1738

<sup>6</sup> S.I. 2005/464

<sup>7</sup> S.I. 2009/3235

<sup>8</sup> S.I. 2009/3238

<sup>9</sup> S.I. 2011/258

<sup>10</sup> S.I. 2011/1456

<sup>11</sup> S.I. 2012/1155

<sup>12</sup> S.I. 2010/2817

<sup>13</sup> <http://www.redtapechallenge.cabinetoffice.gov.uk/home/index/>

RTC<sup>14</sup>, including developing a simplified system of food safety legislation. The proposed consolidation and revocation of 'food additive' type legislation is part of a wider simplification of food safety legislation, the intention of which is to make it easier for businesses and enforcement bodies to access the legislation that affects them.

## **Proposals**

9. For the majority of the 'food additive' type legislation no changes are required to the current measures i.e. enzymes, smoke flavourings and extraction solvents. The changes relating to food additives and flavourings are described in the following paragraphs. For extraction solvents, the provisions have been simplified and will refer directly to Annex I of the European Directive (as amended) with the effect that any changes to the list of permitted extraction solvents or their conditions of use will directly apply. Annex E of this consultation document contains a transposition table which shows the link between the regulations on extraction solvents in the draft SI and the relevant Articles in Directive 2009/32/EC.

## **Compliance Notices**

10. The proposed Regulations introduces the use of compliance notices for non-food safety related contraventions, including labelling provisions for business to business sales, the aim of which is to ensure that sanctions are appropriate and proportionate. For food safety offences existing criminal sanctions will apply. The criminal sanctions for food safety offences will include the use of unpermitted additives or exceeding specified maximum permitted levels.

11. Consideration will be given to updating the Food Law Code of Practice guidance document regarding the use of compliance notices.

## **Additives**

12. Currently the Food Additives (England) Regulations 2009 No. 3238 has a dual function - as well as enforcing the Additives Regulation (EC) No. 1333/2008 it also enables the Annexes and associated Articles of the three previous Directives on sweeteners, colours and miscellaneous additives to continue to apply by way of transitional provisions. This dual function is required until 1 June 2013 when the relevant provisions in the three Directives are transferred to Annexes II and III of Regulation (EC) No. 1333/2008 and so will cease to apply.

13. Food Standards Agency guidance on the food additives legislation, in particular Annexes II and III, is being prepared and will be consulted on shortly.

## **Flavourings**

14. An amendment is required to the Flavourings in Food (England) Regulations 2010 No. 2817 to reflect the different dates of application of the Union (positive) list of flavourings and the new transitional periods as set out in Commission Regulation (EU) No. 873/2012 (see para 16). The existing SI No. 2817 simply refers to the transitional measures as set out in Article 30 of the Flavourings Regulation (EC) No. 1334/2008 and therefore does not take into account the recently agreed different dates of application of the Union list as set out in Regulation 873/2012.

<sup>14</sup> <http://www.food.gov.uk/enforcement/regulation/betregs/red-tape-challenge/>

15. Initially, the Union list will only cover one category of flavouring - chemically defined flavouring substances - as the other categories of flavourings and non-food source materials that also require approval have not yet been evaluated. Therefore, the date of application for the Union list for the other categories of flavourings (and non-food source materials) has been deferred to allow the time for evaluation and authorisation process.

16. The date of application of the Union list for flavourings substances will be 22 April 2013 and for the other categories of flavourings and non-food source materials the date of application of the Union list is 22 October 2016. The transitional periods are 22 October 2014 and 22 April 2018 for flavouring substances and source materials/other types of flavourings respectively.

## **Red 2G**

17. As part of EFSA's re-evaluation of all permitted food additives, in 2007 the safety of the approved colour E 128 Red 2G was reassessed. Due to concerns over the safety of a metabolite of Red 2G (i.e. aniline) the Acceptable Daily Intake (ADI) for E 128 was withdrawn. Subsequently the Commission adopted emergency measures suspending the use of Red 2G as a food additive (Regulation (EC) No. 844/2007). Additionally Red 2G will not appear on the Union list of food additives i.e. Annex II of Regulation (EC) No. 1333/2008. The emergency measure was implemented into national legislation by The Food (Suspension of the Use of E 128 Red 2G as a Food Colour) (England) Regulations 2007 SI No. 2266.

18. Regulation 1129/2011 establishes the Union list of food additives (Annex II of Regulation 1333/2008) and also repeals the emergency measure on Red 2G from 1 June 2013. Therefore the associated national measure banning the use of this additive is no longer required and can be revoked from 1 June 2013.

## **Proposed SI – The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013**

19. The proposed Regulations will revoke and remake in a single consolidated instrument all 'food additive' type legislation. This will aid businesses and enforcement officers in identifying the relevant legislation in this area. No significant changes are being proposed to the current legislation; however, minor amendments are required to the food additives and flavouring legislation. Additionally there will be a change to how the provisions for extraction solvents are drafted. We do not envisage any cost impacts for this new SI, but would welcome comments on this aspect.

20. The key proposals on which this consultation seeks comments are as outlined below:

### **Key proposal(s):**

- **To consolidate the food additives, flavourings, smoke flavourings, food enzymes and extraction solvents national legislation into a single instrument**
- **To introduce the use of compliance notices for non-safety related offences for enforcement purposes**
- **To update the food additive legislation to reflect the**

**establishment of Annexes II and III to the Additive Regulation (EC) No. 1333/2008 and the removal of the transitional measure for the additive Directives.**

- **To amend the flavouring legislation to refer to the revised transitional measures.**
- **To revoke The Food (Suspension of the Use of E 128 Red 2G as Food Colour) (England) Regulations 2007 No. 2266**

### **Impact on Businesses and Enforcement Authorities**

21. The FSA considers that the impact on both enforcement authorities (EA) and industry of the proposed Regulations will be negligible. As such, we have not produced an Impact Assessment; if, however, the consultation should bring to light any impact on enforcement bodies or businesses, which has not been anticipated, the need for an impact assessment will be considered.

22. An 8-week consultation is being launched to provide interested parties with the opportunity to comment on these proposals. The consolidation of 'food additive' type legislation is considered by the FSA to be beneficial in terms of grouping similar legislation into a single instrument. Additionally the minor amendments are required to reflect changes to the harmonised European legislation in this area.

### **Consultation Process**

23. Interested parties have previously been notified of this proposed action, most recently in the July 2012 Chemical Safety Interested Parties letter (<http://www.food.gov.uk/multimedia/pdfs/enforcement/chem-safety-july12.pdf>). It has also been reported on the FSA website - Delivery of Red Tape Challenge initiatives (<http://www.food.gov.uk/enforcement/regulation/betregs/red-tape-challenge/>).

24. The FSA now welcomes comments from all interested parties on the proposed Regulations. We would particularly encourage responses from food manufacturers, food additive, enzyme, flavouring and extraction solvent suppliers/manufacturers and enforcement authorities.

25. Interested parties are particularly invited to respond to the following questions:

#### **Questions asked in this consultation:**

**Q1: Stakeholders are invited to comment on the proposed consolidation of all 'food additive' type legislation into a single statutory instrument and whether it will make it easier for business and other stakeholders to find legislation that affects them?**

**If you agree or disagree, please provide evidence to support your views.**

**Q2: The FSA considers that the impact on both enforcement authorities and industry of the proposed consolidation will be negligible.**

**If you agree or disagree with this assessment, please provide evidence**

**to support your views.**

**Q3: Are there existing provisions which have not been replicated in the new legislation?**

**Q4(a): The proposed Regulations introduce the use of compliance notices for non-food safety contraventions. Do you have any comments on the use of compliance notices for non-food safety contraventions?**

**Please provide evidence to support your views.**

**Q4(b): Will the introduction of compliance notices for non-food safety contraventions provide adequate protection for consumers?**

**If you agree or disagree with the introduction of compliance notices, please provide evidence to support your views.**

**Q4(c): Will the introduction of compliance notices for non-food safety contraventions result in any new costs for industry and/or enforcement authorities?**

**Please provide evidence to support your views.**

**Q5: Are the proposed criminal sanctions appropriate and proportionate?**

**Q6: Do enforcement officers and/or their representative bodies have any specific comments on regulations 7 and 8 of the draft SI regarding the compliance notices?**

26. Any comments that interested parties are able to provide in relation to the proposed Regulations would be gratefully received. We are particularly keen to hear from Small and Medium Enterprises (SMEs) on any likely impact and would encourage them to comment on all aspects of this proposal.

27. Please send your response by email or post using the contact details given on page 1.

28. Following the consultation, we will review the responses received and consider whether any changes are required to the proposed legislation. A summary of all comments received and the FSA's response to each will be published on the FSA's website within 3 months following the end of the consultation period.

29. Separate consultations will be carried out in Wales, Scotland and Northern Ireland on the consolidation of the Regulations in those parts of the UK.

### **Other relevant documents**

30. Annex B contains a list of the relevant European and national legislation.

31. The national legislation mentioned in this document is available on the 'legislation.gov.uk' website and direct links are provided in Annex B.

### **Responses**

32. **Responses are required by close 5 June 2013.** 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).

33. Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours sincerely,

**Wendy Dixon**

Food Additives, Flavourings and Contact Materials Branch  
Chemical Safety Division

**Enclosed**

**Annex A: Standard Consultation Information**

**Annex B: List of relevant legislation**

**Annex C: The draft Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013**

**Annex D: List of interested parties**

**Annex E: Transposition of EU Extraction Solvents Directive**

## Standard Consultation Information - Annex A

### 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 we shall keep a copy of the completed consultation and responses, to be made available to the public on receipt of a request to the [FSA Consultation Coordinator](#) (020 7276 8140). 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 D. 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 contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.
7. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.
8. This consultation has been prepared in accordance with HM Government consultation principles<sup>15</sup>. The consultation is not being held for 12 weeks as we anticipate that any impact will be minimal.
9. We have not produced an Impact Assessment for this proposal since this is a consolidation of existing legislation with no impact on food safety and only minor amendments to existing legislation. Therefore, no impacts are expected.

<sup>15</sup> <http://www.bis.gov.uk/policies/bre/consultation-guidance>

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.

## List of relevant legislation- Annex B

### List of relevant national legislation

The legislation is available from the “legislation.gov.uk” website – see links below.

Flavourings	The Flavourings in Food (England) Regulations 2010 No. 2817 <a href="http://www.legislation.gov.uk/uksi/2010/2817/contents/made">http://www.legislation.gov.uk/uksi/2010/2817/contents/made</a>
Smoke Flavourings	The Smoke Flavourings (England) Regulations 2005 No. 464 <a href="http://www.legislation.gov.uk/uksi/2005/464/contents/made">http://www.legislation.gov.uk/uksi/2005/464/contents/made</a>
Enzymes	The Food Enzymes Regulations 2009 No. 3235 <a href="http://www.legislation.gov.uk/uksi/2009/3235/contents/made">http://www.legislation.gov.uk/uksi/2009/3235/contents/made</a>
Additives	<p>The Food Additives (England) Regulations 2009 No. 3238 <a href="http://www.legislation.gov.uk/uksi/2009/3238/contents/made">http://www.legislation.gov.uk/uksi/2009/3238/contents/made</a></p> <p>The Food Additives (England) (Amendment) Regulations 2011 No. 258 <a href="http://www.legislation.gov.uk/uksi/2011/258/contents/made">http://www.legislation.gov.uk/uksi/2011/258/contents/made</a></p> <p>The Food Additives (England) (Amendment) (No.2) Regulations 2011 No. 1456 <a href="http://www.legislation.gov.uk/uksi/2011/1456/contents/made">http://www.legislation.gov.uk/uksi/2011/1456/contents/made</a></p> <p>The Food Additives (England) (Amendment) and the Extraction Solvents in Food (Amendment) (England) Regulations 2012 No. 1155 <a href="http://www.legislation.gov.uk/uksi/2012/1155/contents/made">http://www.legislation.gov.uk/uksi/2012/1155/contents/made</a></p> <p>The Food (Suspension of the Use of E 128 Red 2G as Food Colour) (England) Regulations 2007 No. 2266 <a href="http://www.legislation.gov.uk/uksi/2007/2266/contents/made">http://www.legislation.gov.uk/uksi/2007/2266/contents/made</a></p>
Extraction solvents	<p>The Extraction Solvents in Food Regulations 1993 No. 1658 <a href="http://www.legislation.gov.uk/uksi/1993/1658/contents/made">http://www.legislation.gov.uk/uksi/1993/1658/contents/made</a></p> <p>The Extraction Solvents in Food (Amendment) Regulations 1995 No. 1440 <a href="http://www.legislation.gov.uk/uksi/1995/1440/contents/made">http://www.legislation.gov.uk/uksi/1995/1440/contents/made</a></p> <p>The Extraction Solvents in Food (Amendment) Regulations 1998 No. 2257 <a href="http://www.legislation.gov.uk/uksi/1998/2257/contents/made">http://www.legislation.gov.uk/uksi/1998/2257/contents/made</a></p> <p>The Extraction Solvents in Food (Amendment) (England) Regulations 2011 No. 1738 <a href="http://www.legislation.gov.uk/uksi/2011/1738/contents/made">http://www.legislation.gov.uk/uksi/2011/1738/contents/made</a></p> <p>The Food Additives (England) (Amendment) and the Extraction Solvents in Food (Amendment) (England) Regulations 2012 No. 1155 <a href="http://www.legislation.gov.uk/uksi/2012/1155/contents/made">http://www.legislation.gov.uk/uksi/2012/1155/contents/made</a></p>

## List of relevant European legislation

<p>Flavourings</p>	<p>Regulation (EC) No. 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods OJ L 354, 31.12.2008 p 34 <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0034:0050:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0034:0050:EN:PDF</a></p> <p>Commission Implementing Regulation (EU) No. 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No. 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No. 1565/2000 and Commission Decision 1999/217/EC OJ L 267, 02.10.2012 p 1. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:267:0001:0161:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:267:0001:0161:EN:PDF</a></p> <p>Commission Regulation (EU) No. 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No. 1334/2008 of the European Parliament and of the Council OJ L 267 02.10.2012 p 162 <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:267:0162:0164:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:267:0162:0164:EN:PDF</a></p>
<p>Smoke Flavourings</p>	<p>Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods, OJ L 309, 26.11.2003 p 1. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:309:0001:0008:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:309:0001:0008:EN:PDF</a></p>
<p>Enzymes</p>	<p>Regulation (EC) No. 1332/2008 of the European Parliament and of the Council on food enzymes OJ L 354, 31.12.2008, p. 7. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0007:0015:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0007:0015:EN:PDF</a></p> <p>Regulation (EU) No. 1056/2012 of 12 November 2012 amending Regulation (EC) No. 1332/2008 of the European Parliament and of the Council on food enzymes with regard to transitional measures OJ L 313, 13.11.2012, p 9. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:313:0009:0010:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:313:0009:0010:EN:PDF</a></p>
<p>Additives</p>	<p>Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on Food Additives OJ L 354, 31.12.2008, p. 16 <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:EN:PDF</a></p> <p>Commission Regulation (EU) No. 1129/2011 amending Annex II to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives(as amended)<sup>16</sup></p>

<sup>16</sup> Various amendments to alter conditions of use of existing additives or to permitted new additives i.e. Regulations (EU) No 1131/2011, 232/2012, 380/2012, 470/2012, 471/2012, 472/2012, 570/2012, 583/2012, 675/2012, 1049/2012, 1057/2012, 1147/2012, 1148/2012, 1149/2012, 1166/2012 and 25/2013.

	<p>OJ L 295 12.11.2011, p 1  <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0001:0177:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0001:0177:EN:PDF</a></p> <p>Commission Regulation (EU) No. 1130/2011 amending Annex III to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients (as amended)<sup>17</sup>  OJ L 295 12.11.2011, p 178  <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0178:0204:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0178:0204:EN:PDF</a></p> <p>Commission Regulation (EU) No. 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No. 1333/2008 of the European Parliament and of the Council  OJ L 83, 22.3.2012, p 1 (as amended)<sup>18</sup>  <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:083:0001:0295:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:083:0001:0295:EN:PDF</a></p>
<p>Extraction solvents</p>	<p>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 (<b>Recast</b><sup>19</sup>)  OJ L 141, 6.6.2009 p 3  <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:141:0003:0011:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:141:0003:0011:EN:PDF</a></p> <p>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 L 255, 27.8.2010 p 10.  <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:225:0010:0012:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:225:0010:0012:EN:PDF</a></p>
<p>Common authorisation procedure</p>	<p>Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings  OJ L 354, 31.12.2008, p 1  <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0001:0006:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0001:0006:EN:PDF</a></p> <p>Commission Regulation (EU) No. 234/2011 implementing Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings  OJ L 64, 11.03.2011, p 15.  <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:064:0015:0024:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:064:0015:0024:EN:PDF</a></p> <p>Commission Implementing Regulation (EU) No. 562/2012 amending Commission Regulation (EU) No. 234/2011 with regard to specific data required for risk assessment of food enzymes  OJ L 168, 28.06.2012 p 21.  <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:168:0021:0023:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:168:0021:0023:EN:PDF</a></p>

<sup>17</sup> Amended by Regulation (EU) No 1130/2011 and Regulation (EU) No 25/2013.

<sup>18</sup> Various amendments to specification to include new additives – Regulation (EU) No. 1050/2012

<sup>19</sup> The Directive repealed Council Directive 88/344/EEC, Council Directive 92/115/EEC, Directive 94/52/EC of the European Parliament and of the Council, Directive 97/60/EC of the European Parliament and of the Council and Regulation (EC) No 1882/2003

# The draft Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 – Annex C

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## STATUTORY INSTRUMENTS

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**2013 No. 0000**

### **FOOD, ENGLAND**

## The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013

<i>Made</i>	- - - -	2013
<i>Laid before Parliament</i>		2013
<i>Coming into force</i>	- -	TBA 2013

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(a),(e) and (f),17(1) and (2), 26(1)(a) and (b), (2)(e) and (f) and (3), and 48(1) of the Food Safety Act 1990<sup>(20)</sup> and now vested in him<sup>(21)</sup>,as read with paragraph 1A of Schedule 2 to the European Communities Act 1972<sup>(22)</sup>.

In accordance with section 48(4A) of the Food Safety Act 1990, he has had regard to relevant advice given by the Food Standards Agency.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for any reference to an Article of or an Annex to any of the EU instruments specified in regulation 2(4) to be construed as a reference to that Article or that Annex as amended from time to time.

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<sup>(23)</sup>, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

<sup>(20)</sup> 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 26(3) was amended by Schedule 6 to the 1999 Act. 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.

<sup>(21)</sup> 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.

<sup>(22)</sup> 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006, c.51) and amended by Part 1 of Schedule 1 to the European Union (Amendment) Act 2008 (2008 c.7).

<sup>(23)</sup> 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

# PART 1

## Introductory

### Title, application and commencement

1. These Regulations may be cited as the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013, apply in relation to England only and come into force on [...] TBA 2013.

### Interpretation

2.—(1) In these Regulations —

“the Act” means the Food Safety Act 1990;

“Directive 2009/32” means 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<sup>(24)</sup>;

“Regulation 2065/2003” means Regulation (EC) No 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods<sup>(25)</sup>;

“Regulation 1331/2008” means Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings<sup>(26)</sup>;

“Regulation 1332/2008” means Regulation (EC) No 1332/2008 of the European Parliament and of the Council on food enzymes<sup>(27)</sup>;

“Regulation 1333/2008” means Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives<sup>(28)</sup>, as read with —

(a) Commission Regulation (EU) No 1129/2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives<sup>(29)</sup>,

(b) Commission Regulation (EU) No 1130/2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives for use in food additives, food enzymes, food flavourings and nutrients<sup>(30)</sup>, and

(c) Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council<sup>(31)</sup>;

“Regulation 1334/2008” means Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods<sup>(32)</sup>, as read with Commission Regulation (EU) No 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) 1334/2008 of the European Parliament and of the Council<sup>(33)</sup>;

“authorised officer” means any person who is authorised in writing, either generally or specifically, by a food authority or a port health authority to act in matters arising under these Regulations;

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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).

<sup>(24)</sup> OJ No. L141, 6.6.2009, p.3. This instrument was last amended by Commission Directive 2010/59/EU (OJ No. L225, 27.8.2010, p.10).

<sup>(25)</sup> OJ No. L309, 26.11.2003, p.1. This instrument was last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ No. L188, 18.7.2009, p.14).

<sup>(26)</sup> OJ No. L354, 31.12.2008, p.1. This instrument is implemented by Commission Regulation (EU) No. 234/2011 (OJ No. L64, 11.03.2011, p.15) and that Regulation has been amended by Commission Implementing Regulation (EU) No. 562/2012 (OJ No. L168, 28.06.12, p.12).

<sup>(27)</sup> OJ No. L354, 31.12.2008, p.7. This instrument was last amended by Commission Regulation (EU) No 1056/2012 (OJ No. L313, 13.11.2012, p.9).

<sup>(28)</sup> OJ No. L354, 31.12.2008, p.16. This instrument was last amended by [Commission Regulation (EU) No. 25/2013

<sup>(29)</sup> OJ No. L295, 12.11.2011, p.1.

<sup>(30)</sup> OJ No. L295, 12.11.2011, p.178.

<sup>(31)</sup> OJ No. L83, 22.3.2012, p.1.

<sup>(32)</sup> OJ No. L354, 31.12.2008, p.34. This instrument was last amended by Commission Implementing Regulation (EU) No 872/2012 (OJ No. L267, 2.10.2012, p.1).

<sup>(33)</sup> OJ No. L267, 2.10.2012, p.162.

“food authority” has the meaning given by section 5 of the Act except that it does not include the appropriate Treasurer of the Inner Temple and Middle Temple.

(2) Other expressions used in these Regulations and in the EU instruments listed in paragraph (4) have the same meaning in these Regulations as they do in those instruments [unless indicated to the contrary].

(3) Any reference in these Regulations to an Article of or Annex to any of the EU instruments listed in paragraph (4) is a reference to that Article or Annex as amended from time to time.

(4) The EU instruments are Directive 2009/32, Regulation 2065/2003, Regulation 1331/2008, Regulation 1332/2008, Regulation 1333/2008 and Regulation 1334/2008.

(5) The expression “the EU Regulations” means Regulation 2065/2003, Regulation 1332/2008, Regulation 1333/2008 and Regulation 1334/2008 .

## PART 2

### Food additives, flavourings and enzymes

#### **Offence of contravening EU requirements on food additives**

3. Any person who contravenes, or who uses or places on the market a product that fails to comply with, any of the provisions of Regulation 1333/2008 specified in the first column of Table 1 of Schedule 1, as read with transitional measures contained in or to be read with that Regulation, commits an offence.

#### **Offence of contravening EU requirements on flavourings, including smoke flavourings**

4. Any person who contravenes, or who uses or places on the market a product which fails to comply with, any of the provisions of Regulation 1334/2008 specified in the first column of Table 1 of Schedule 2, as read with Article 4 (flavouring substances under evaluation) of Commission Implementing Regulation (EU) No 872/2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council<sup>(34)</sup> and with transitional measures contained in or to be read with Regulation 1334/2008, commits an offence.

5. Any person who contravenes, or who uses or places on the market a product which fails to comply with, any of the provisions of Regulation 2065/2003 specified in the first column of Table 1 of Schedule 3 commits an offence.

#### **Offence of contravening EU requirements on food enzymes**

6. Any person who contravenes, or who uses or places on the market a product which fails to comply with, any of the provisions of Regulation 1332/2008 specified in the first column of Table 1 of Schedule 4, as read with Article 18 (transitional measures), commits an offence.

#### **Compliance notices**

7.—(1) If an authorised officer has reasonable grounds for believing that any person has not complied with, is not complying with, or is not likely to comply with —

- (a) any EU provision specified in the first column of Table 2 of Schedule 1, 2, 3 or 4; or
- (b) regulation 13(2),

the officer may serve a compliance notice on that person.

(2) A compliance notice must state —

- (a) the steps the person must take;
- (b) the date and, if appropriate, the time by which each step must be taken;
- (c) the reason for the service of the notice and for the steps required to be taken;
- (d) that a failure to comply with the notice is an offence; and
- (e) the details of the right to appeal against the notice under regulation 8.

(3) An authorised officer may serve a notice on a person withdrawing, varying or suspending a compliance notice.

<sup>(34)</sup> OJ No. L267, 2.10.2012, p.1.

(4) Any person who fails to comply with a compliance notice served on them under these Regulations commits an offence.

### **Appeal against a compliance notice**

**8.**—(1) Any person served with a compliance notice may appeal against that notice to a magistrates' court.

(2) The procedure on appeal to a magistrates' court under paragraph (1) shall be by way of complaint for an order, and the Magistrates' Courts Act 1980<sup>(35)</sup> shall apply to the proceedings.

(3) The period within which an appeal under paragraph (1) may be brought shall be one month from the date on which the compliance notice was served on the person wishing to appeal and the making of a complaint for an order shall be deemed for the purposes of this paragraph to be the bringing of the appeal.

(4) A compliance notice is not suspended pending an appeal unless —

- (a) an authorised officer suspends it under regulation 7(3); or
- (b) the court directs that it be suspended.

(5) The court may —

- (a) confirm the notice or any requirement contained in it;
- (b) vary the notice or any requirement contained in it; or
- (c) revoke the notice or any requirement contained in it.

## **PART 3**

### **Extraction solvents**

#### **Controls on extraction solvents**

**9.** In this Part any reference to a numbered Article or Annex is a reference to that Article of or Annex to Directive 2009/32.

**10.** The provisions of this Part do not apply to any extraction solvent —

- (a) used in the production of any food additives, vitamins or any other nutritional additives, unless such food additives, vitamins or other nutritional additives are listed in Annex I; or
- (b) intended for export outside the European Union.

**11.** In this Part “permitted extraction solvent” means —

- (a) an extraction solvent that —
  - (i) is listed in Annex I,
  - (ii) is used in accordance with the conditions of use and within any maximum residue limits specified in that Annex,
  - (iii) does not contain a toxicologically dangerous amount of any element or substance,
  - (iv) subject to any exceptions deriving from specific purity criteria, does not contain more than 1 mg/kg of arsenic or more than 1 mg/kg lead, and
  - (v) meets the requirements of Article 3(c) as regards purity criteria;
- (b) water to which substances regulating acidity or alkalinity may have been added; or
- (c) food substances which possess solvent properties.

**12.** No person may use as an extraction solvent in the production of food any extraction solvent that is not a permitted extraction solvent.

**13.**—(1) No person may place on the market —

- (a) an extraction solvent that is not a permitted extraction solvent; or
- (b) any food having in it or on it an added extraction solvent that is not a permitted extraction solvent.

(2) No person may place on the market an extraction solvent that does not meet the requirements of regulation 14.

<sup>(35)</sup> 1980 c.43.

**14.**—(1) Subject to paragraph (2), the following information must appear on the packaging, container or label —

- (a) the commercial name as indicated in Annex I;
- (b) a clear indication that the material is of a quality suitable for use for the extraction of food or food ingredients;
- (c) a reference by which the batch or lot may be identified;
- (d) the name or business name and address of the manufacturer or packer or of a seller established in the territory of the EU;
- (e) the net quantity given as units of volume; and
- (f) if necessary, the special storage conditions or conditions of use.

(2) The particulars specified in subparagraphs (c), (d), (e) and (f) of paragraph (1) may alternatively appear on the trade documents relating to the batch or lot which are to be supplied with, or prior to, the delivery.

(3) The information specified in paragraph (1) must be easily visible, clearly legible and indelible.

(4) The information specified in paragraph (1) may be provided in more than one language, but at least one of those languages must be easily understood by the purchaser unless other measures have been taken to ensure that the purchaser is informed of the specified information.

## PART 4

### Administration and enforcement

#### Competent authorities

**15.** The competent authority for the purpose of Article 7 of Regulation 2065/2003 is the Food Standards Agency.

#### Enforcement authorities

**16.** It is the duty of each food authority within its area or district to execute and enforce these Regulations and the EU Regulations.

#### Offences and penalties

**17.**—(1) Any person who contravenes regulation 12 or 13(1) commits an offence.

(2) Any person guilty of an offence under regulation 3, 4, 5, 6, 7(4) or 17(1) is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

#### Condemnation of food

**18.** Where any food is certified by a food analyst as being food which it is an offence to place on the market, that food shall be treated for the purposes of section 9 of the Act (under which food may be seized and destroyed under an order of a justice of the peace) as failing to comply with food safety requirements.

#### Application of various provisions of the Food Safety Act 1990

**19.**—(1) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part of it is to be construed as a reference to these Regulations —

- (a) section 20 (offences due to fault of another person);
- (b) section 21 (defence of due diligence)<sup>(36)</sup> with the modification that —
  - (i) subsections (2) to (4) shall apply in relation to an offence under regulation 3, 4, 5, 6, 7(4) or 17(1) as they apply in relation to an offence under section 14 or 15, and
  - (ii) in subsection (4) the references to “sale” are deemed to include references to “placing on the market”;
- (c) section 30(8) (which relates to documentary evidence);

<sup>(36)</sup> Section 21 was amended by S.I. 2004/3279.

- (d) section 35(1) (punishment of offences)<sup>(37)</sup>, in so far as it relates to offences under section 33(1) as applied by paragraph (3)(b);
- (e) section 35(2) and (3)<sup>(38)</sup>, in so far as it relates to offences under section 33(2) as applied by paragraph (3)(c);
- (f) section 36 (offences by bodies corporate); and
- (g) section 36A (offences by Scottish partnerships)<sup>(39)</sup>.

(2) In the application of section 32 of the Act (powers of entry) for the purposes of these Regulations, the references in subsection (1) to the Act are to be construed as including references to the EU Regulations.

(3) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act is to be construed as including a reference to the EU Regulations and these Regulations —

- (a) section 3 (presumption that food is intended for human consumption) with the modification that the references to “sold” and “sale” are deemed to include references to “placed on the market” and “placing on the market” respectively;
- (b) section 33(1) (obstruction etc. of officers);
- (c) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” is deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub-paragraph (b); and
- (d) section 44 (protection of officers acting in good faith).

(4) Section 34 of the Act (time limit for prosecutions) applies to offences under these Regulations as it applies to offences punishable under section 35(2) of the Act.

## PART 5

### General

#### **Consequential and other amendments**

**20.**—(1) For subparagraph (d) of regulation 3(1) (exemptions) of the Mineral Hydrocarbons in Food Regulations 1966<sup>(40)</sup> substitute the following —

“(d) any food containing mineral hydrocarbon that is used in the food as a food additive as defined in Article 3.2(a) of Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives and in compliance with the requirements of that Regulation.”.

(2) In regulation 2(1) (interpretation) of the Food Labelling Regulations 1996<sup>(41)</sup>, in the definition of “the additives regulations” omit the expression “the Food Additives (England) Regulations 1999”.

(3) In regulation 2(1) (interpretation) of the Jam and Similar Products (England) Regulations 2003, in the definition of “permitted sweetener” for the expression “the Food Additives (England) Regulations 2009” substitute “Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives”.

#### **Revocations**

**21.** The instruments listed in the first column of Schedule 5 are revoked to the extent specified in the second column.

#### **Review**

**22.**—(1) The Food Standards Agency must from time to time —

- (a) carry out a review of the operation and effect of regulations 1 to 19;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

<sup>(37)</sup> Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c.44), Schedule 26, paragraph 42, from a date to be appointed.

<sup>(38)</sup> Section 35(3) was amended by S.I. 2004/3279.

<sup>(39)</sup> Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.

<sup>(40)</sup> S.I. 1966/1073. The relevant provision was amended by S.I. 2009/3238.

<sup>(41)</sup> S.I. 1996/1499. Relevant amending instruments are S.I. 2010/2817 and 2012/2619.

(2) In carrying out the review the Food Standards Agency must, so far as is reasonable, have regard to how Directive 2009/32 is implemented and the EU Regulations executed and enforced in other Member States.

(3) The report must in particular —

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if they do, the extent to which they could be achieved with a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding 5 years.

Signed by authority of the Secretary of State for Health

*Name*  
Parliamentary Under Secretary of State  
Department of Health

Date

## SCHEDULE 1 Regulations 3 and 7

### Specified provisions of Regulation 1333/2008

**Table 1**

<i>Provision of Regulation 1333/2008</i>	<i>Subject matter</i>
Article 4.1 (as read with Articles 11.3 and 11.4, 12, 13.2, 15, 16 and 18.1(a), 18.2 and 18.3)	Requirement that only food additives included in the list in Annex II to Regulation 1333/2008 be placed on the market as such and that they be used in accordance with any conditions specified in that Annex.
Article 4.2 (as read with Articles 12, 13.2 and 18.3)	Requirement that only food additives included in the list in Annex III to Regulation 1333/2008 may be used in food additives, food enzymes, food flavourings and nutrients and under the conditions of use specified in that Annex.
Article 4.5	Requirement that food additives comply with the specifications referred to in Article 14 of Regulation 1333/2008.
Article 5	Prohibition on placing on the market of food additives or food containing food additives if the use of the food additive does not comply with Regulation 1333/2008.
Article 11.2	Requirement to use food additives in accordance with the <i>quantum satis</i> principle where no maximum numerical level fixed for the additive concerned.
Article 15	Prohibition on use of food additives in unprocessed foods except where provided for in Annex II to Regulation 1333/2008.
Article 16	Prohibition on use of food additives in foods for infants and young children (including dietary foods for infants and young children for special medical purposes) except where provided for in Annex II to Regulation 1333/2008.
Article 17	Requirement to use only food colours listed in Annex II to Regulation 1333/2008 for the purpose of health marking meat or meat

	products, decorative colouring of eggshells or stamping of eggshells.
Article 18.1(b) (as read with Article 18.2)	Requirement that food additives be present in food to which a food additive, food enzyme or food flavouring has been added, only if the additive is permitted in the additive, enzyme or flavouring under Regulation 1333/2008, has been carried over to the food via the additive, enzyme or flavouring and has no technological function in the final food.
Article 18.1(c) (as read with Article 18.2)	Requirement that food additives be present in foods to be used solely in the preparation of a compound food only if the compound food complies with Regulation 1333/2008.
Article 18.4	Requirement that food additives be used as sweeteners in compound foods with no added sugars, energy reduced compound foods with no added sugars, energy reduced compound foods, compound dietary foods intended for low calorie diets, non cariogenic compound foods and compound foods with an increased shelf life only if the sweetener is permitted in any of the ingredients of the compound food.
Article 26.1	Requirement that producers and users of food additives inform the Commission immediately of any new scientific or technical information which might affect the assessment of the safety of the food additive concerned.

**Table 2**

<i>Provision of Regulation 1333/2008</i>	<i>Subject matter</i>
Article 21.1	Requirement that food additives not intended for sale to the final consumer be labelled, in accordance with Article 22 of Regulation 1333/2008, visibly, clearly legibly and indelibly and in a language easily understandable to purchasers.
Article 22.1 (as read with Article 22.4 and 22.5)	Requirement that food additives not intended for sale to the final consumer be sold only if their packaging or containers bear specified information.
Article 22.2 (as read with Article 22.4 and 22.5)	Requirement that food additives mixed with each other and/or with other food ingredients be sold only if their packaging or containers bear a list of ingredients in descending order of their percentage by weight of the total.
Article 22.3 (as read with Article 22.4 and 22.5)	Requirement that, where substances (including food additives or other food ingredients) are added to food additives to facilitate their storage, sale, standardisation or dissolution, their packaging or containers bear a list of all such substances in descending order of their percentage by weight of the total.
Article 23.1 (as read with Article 23.2 and 23.5)	Prohibition on marketing of food additives sold singly or mixed with each other and/or other food ingredients and intended for sale to the final consumer unless their packaging contains specified information.
Article 23.3 (as read with Article 23.5)	Requirement that the labelling of table-top sweeteners containing polyols and/or aspartame

	and/or aspartame – acesulfame salt bear specified warnings.
Article 23.4	Requirement that manufacturers of table top sweeteners make available by appropriate means the information necessary to allow safe use by consumers.
Article 24.1 (as read with Article 24.2)	Requirement that labelling of the food containing the colours listed in Annex V should contain the additional information specified in that Annex.
Article 26.2	Requirement that producers and users of food additives, at the request of the Commission, inform it of the actual use of the food additive concerned.

## SCHEDULE 2

Regulations 4 and 7

### Specified provisions of Regulation 1334/2008

**Table 1**

<i>Provision of Regulation 1334/2008</i>	<i>Subject matter</i>
Article 4	Requirement that the use of flavourings or food ingredients with flavouring properties does not pose a safety risk or mislead the consumer.
Article 5	Prohibition on the placing on the market of non-compliant flavourings or non-compliant food.
Article 6.1 (as read with Part A of Annex III)	Prohibition on adding certain specified substances in foods.
Article 6.2 (as read with Part B of Annex III)	Requirement that certain substances naturally present in flavourings or food ingredients with flavouring properties should not exceed specified levels in compound foods as a result of the use of flavourings or food ingredients with flavouring properties.
Article 7.1 (as read with Part A of Annex IV)	Prohibition on the use of certain source materials to produce flavourings or food ingredients with flavouring properties.
Article 7.2 (as read with Part B of Annex IV)	Restrictions on the use of flavourings or food ingredients with flavouring properties produced from certain source materials.
Article 10	Restriction on the placing on the market or use of flavourings and source materials that are not included on the Union list.
Article 19.2	Requirement that a producer or user of an approved flavouring that is prepared by production methods or using starting materials significantly different from those included in the risk assessment must submit the necessary data to the Commission to allow an evaluation with regard to the modified production method or characteristics before marketing the flavouring
Article 19.3	Requirement on food business operators to inform the Commission immediately if they become aware of any new scientific or technical information that might affect the assessment of the safety of a flavouring

	substance.
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**Table 2**

<i>Provision of Regulation 1334/2008</i>	<i>Subject matter</i>
Article 14.1 (as read with Articles 15 and 16)	Requirements for the labelling of flavourings not intended for sale to the final consumer.
Article 17 (as read with Articles 15.1(a) and 16)	Requirements for the labelling of flavourings intended for sale to the final consumer.

## SCHEDULE 3

Regulations 5 and 7

### Specified provisions of Regulation 2065/2003

**Table 1**

<i>Provision of Regulation 2065/2003</i>	<i>Subject matter</i>
Article 4.2	Prohibition on marketing a smoke flavouring not on the list of authorised smoke flavourings, or any food in or on which such a smoke flavouring is present
Article 4.2	Prohibition on marketing an authorised smoke flavouring, or any food in or on which such a smoke flavouring is present, otherwise than in accordance with any conditions of use laid down in the authorisation
Article 5.1, first subparagraph	Prohibition on using treated wood, unless it can be demonstrated by appropriate certification or documentation that the substance used in treatment does not give rise to potentially toxic substances during combustion
Article 5.1, second subparagraph	Requirement to be able to demonstrate by documentation or certification that the prohibition in the first paragraph of Article 5.1 has been observed
Article 5.2, first sentence	Requirement to observe conditions in Annex I during production of primary products (primary smoke condensates or primary tar fractions)
Article 5.2, second sentence	Prohibition on the use of water-insoluble oily phase during the production of smoke flavourings
Article 9.4	Requirement that an authorisation holder or any other food business operator using an authorised product, or a derived smoke flavouring produced from an authorised product, must comply with any conditions or restrictions attached to the authorisation
Article 9.5	Requirement that an authorisation holder inform the Commission immediately of any new scientific or technical information relating to an authorised product which might influence the assessment of its safety

**Table 2**

<i>Provision of Regulation 2065/2003</i>	<i>Subject matter</i>
Article 13.1	Requirement that food business operators ensure the specified information is transmitted to the receiving food business operator when

	the product is first placed on the market
Article 13.2	Requirement that following the first placing on the market, on each subsequent occasion that the product is placed on the market, food business operators placing products on the market transmit the information specified in Article 13.1 to the receiving food business operators

## SCHEDULE 4

Regulations 6 and 7

### Specified provisions of Regulation 1332/2008

**Table 1**

<i>Provision of Regulation 1332/2008</i>	<i>Subject matter</i>
Article 4	Requirement that food enzymes may not be placed on the market as such or used in foods unless they appear in the list of authorised enzymes provided for in Article 17 and in accordance with the prescribed specifications and conditions of use.
Article 5	Prohibition on placing on the market of non-compliant food enzymes or foods containing such enzymes which do not comply with Regulation 1332/2008 and its implementing measures.
Article 14.1	Requirement that a producer or user of a food enzyme shall inform the Commission immediately of any new scientific or technical information that might affect its safety assessment.
Article 14.2	Requirement that a producer or user of an approved food enzyme that is prepared by production methods or using starting materials significantly different from those included in the risk assessment must submit the necessary data to the Commission to allow an evaluation with regard to the modified production method or characteristics before marketing the enzyme.

**Table 2**

<i>Provision of Regulation 1332/2008</i>	<i>Subject matter</i>
Article 10.1 (as read with Article 11)	Requirements for labelling of food enzymes and preparations not intended for sale to the final consumer.
Article 12.1	Requirements for labelling of food enzymes and preparations intended for sale to the final consumer.

## SCHEDULE 5

Regulation 21

### Revocations

<i>Name of instrument</i>	<i>Extent of revocation</i>
The Extraction Solvents in Food Regulations 1993 (S.I. 1993/1658)	The whole Regulations
The Extraction Solvents in Food (Amendment) Regulations 1995 (S.I. 1995/1440)	The whole Regulations
The Extraction Solvents in Food (Amendment) Regulations 1998 (S.I. 1998/2257)	The whole Regulations
The Food (Suspension of the Use of E128 Red 2G as a Food Colour) (England) Regulations 2007 (S.I. 2007/2266)	The whole Regulations
The Extraction Solvents in Food (Amendment) (England) Regulations 2011 (S.I. 2011/1738)	The whole Regulations
The Smoke Flavourings (England) Regulations 2005 (S.I. 2005/464)	The whole Regulations
The Food Enzymes Regulations 2009 (S.I. 2009/3235)	Regulations 3, 4, 5 and 6
The Food Additives (England) Regulations 2009 (S.I. 2009/3238)	All provisions except regulations 1, 2, 18 and 19
The Food Additives (England) (Amendment) Regulations 2011 (S.I. 2011/258)	The whole Regulations
The Food Additives (England) (Amendment) (No.2) Regulations 2011 (S.I. 2011/1456)	The whole Regulations
The Food Additives (England) (Amendment) and the Extraction Solvents in Food (Amendment) (England) Regulations 2012 (S.I. 2012/1155)	The whole Regulations
The Flavourings in Food (England) Regulations 2010 (S.I. 2010/2817)	All provisions except regulations 1, 2 and 7.

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

1. These Regulations *(to be completed following consultation)*

## List of interested parties - Annex D

A F Suter and Company Limited  
A H Allen Limited  
Abbott Laboratories Limited  
Action Against Allergy  
Additives Survivors Network  
AEA Technology plc  
Alcontrol Laboratories UK Limited  
Allied Bakeries Ltd  
Allied Technical Centre  
Amano Enzyme Europe Limited  
Ambersil Ltd  
Arla Foods UK  
Arthur Branwell and Company Ltd  
Artisan Foods  
Asia Food Products Ltd  
Association for the International Promotion of Gum  
Association of Cereal Food Manufacturers  
Association of Convenience Stores  
Association of Port Health Authorities  
Association of Public Analysts  
Association of the British Pharmaceutical Industry  
Augustus Oils Ltd  
Bahia Corp Ltd  
Basildon Chemical Company Ltd  
Bernard Matthews Farms Ltd  
Berry Ottaway and Associates Limited  
Bespoke Foods Ltd  
Biocatalysts Ltd  
Biozyme Laboratories Ltd  
Birds Eye Iglo Group Ltd  
Boehringer Ingelheim Limited  
Booker Ltd  
Botanix  
Bottle Green Drinks Company  
Bowmans Milling Ltd  
Brewing Research International  
British Aerosol Manufacturers' Association  
British Beer and Pub Association  
British Cheese Board  
British Dietetic Association  
British Frozen Food Federation  
British Hospitality Association  
British Meat Processors Association  
British Medical Association  
British Plastics Federation  
British Retail Consortium  
British Soft Drinks Association  
British Specialist Nutrition Association  
Brunel Healthcare Manufacturing Limited  
Burson-Marsteller EMEA  
Bush Boake Allen  
Cambridge Health Plan Ltd  
CAMedica Consulting  
Campden BRI  
Cantox Health Sciences International  
Centre for Pregnancy Nutrition  
Chartered Institute of Environmental Health  
Chilled Food Association Ltd

Christan Hanson UK Ltd  
CMS Cameron McKenna LLP  
Colorcon Limited  
Consensus Action on Salt and Health  
Cott Beverages Ltd  
Covington and Burling LLP  
CTPA - cosmetic toiletry and perfumery association  
Cullinane Associates Ltd  
Cultor Food Science  
Custom Pharmaceuticals Limited  
Dairy Crest Group plc  
Dairy UK Ltd  
Dawn Foods (UK) Ltd  
Decision News Media  
Department for Environment, Food and Rural Affairs  
Department for Business, Innovation and Skills  
Department of Health  
Diabetes UK  
East End Foods plc  
Edme Ltd  
European Snacks Association / SNACMA  
Exova UK Limited  
F I Data Services Ltd  
FBE Services Limited  
Federation of Bakers  
FIPRA International Ltd  
Firmenich UK Ltd  
Flavour Craft  
Food Additives and Ingredients Association  
Food and Drink Federation  
Food and Environment Research Agency  
Food Commission  
Food Industry Environmental Network LLC  
Food Law Monthly  
FR Benson & Partners Ltd  
Good Relations Limited  
Goodman Fielder Limited  
Greencell Ltd  
Halal Food Authority  
Haribo Dunhills (Pontefract) plc  
Hays Albion Chemicals Group  
Healan Ingredients Limited  
Health Care Products Ltd  
Health Food Manufacturers' Association  
Hermes Sweeteners Ltd  
Holland & Barrett Retail Limited  
Huntingdon Life Sciences  
Hyperactive Children's Support Group  
Hyperama  
Ice Cream Alliance Ltd  
Icefresh Foods Limited  
Ingredion UK Limited  
Innovia Films Ltd  
Institute of Food Science and Technology  
Institute of Grocery Distribution  
International Pectin Producers' Association  
International Rayon and Synthetic Fibres Committee  
International Speciality Products  
International Sweeteners Association  
Isotron Limited

J Ralph Blanchfield Consultancy  
Kapajo Group  
Keller & Heckman LLP  
Kingfisher Colours Ltd  
Kraeber (UK) Ltd  
LAURENS PATISSERIES  
Leatherhead Food International  
LGC Limited  
Local Authority in England  
Local Government Association  
London Port Health Authority  
London Port Health Authority  
Lycored Ltd  
Margaret Anderson & Associates  
Marinalg International  
Marlin Chemicals Ltd  
Mars UK  
Masonline Ltd  
McCormick (UK) Ltd  
MH Foods Limited  
Mitsubishi-Kagaku Foods Corporation  
NATCOL  
National Association of British and Irish Millers  
National Association of Master Bakers  
National Childbirth Trust  
National Consumer Federation  
National Farmers Union  
National Federation of Women's Institutes  
National Office of Animal Health Ltd  
National Society for Phenylketonuria  
Nestle UK Limited  
Neville Craddock Associates  
Novelfoods Consultancy Ltd  
Nutragen Ltd  
Office of Fair Trading  
Omya UK Limited, Technical Centre  
P & B ( Foods) Ltd  
PepsiCo UK & Ireland  
PQ Corporation  
Proprietary Association of Great Britain  
Provision Trade Federation  
Public Analyst Scientific Services Ltd.  
R. Twining and Company Limited  
Regulatory Solutions (Scotland) Ltd  
Rhodia Ltd  
Rocol  
Royal College of Physicians  
Royal Environmental Health Institute of Scotland  
Royal Pharmaceutical Society of Great Britain  
Royal Society for Public Health  
Salt Association  
Scotch Whisky Association  
Sea Fish Industry Authority  
Seed Crushers & Oil Producers Association  
Sensient Flavours  
Sensient Food Colours UK  
SHS International Limited  
Society of Dyers and Colourists  
Society of Independent Brewers  
Soda Club Ltd

Soil Association  
Sugarflair Colours Ltd  
Sustain  
Sweet and Maxwell London  
Tata Chemicals Europe  
Tazaki Foods Ltd  
The National Association of Cider Makers  
The Wine & Spirits Trade Association  
Thorntons plc  
TMC Ventures Inc.  
Townswomens' Guilds  
UK Flavour Association  
UKLPG  
Unilever UK Limited  
United Kingdom Vineyards Association  
Vegetarian Economy and Green Agriculture  
Verner Wheelock Associates Limited  
Vitrition UK Limited  
West Country Farmhouse Cheesemakers Ltd  
Westler Foods Ltd  
Which  
Whitehouse Consultancy Ltd  
Whitworths Limited  
William Blythe Limited  
Wimpy UK  
Witwood Food Products Ltd  
Worldwide Fruit Ltd  
Xyrex Ltd  
Zeelandia Ltd

## Transposition of EU Extraction Solvents Directive - Annex E

### Background

European legislation on extraction solvents has existed since the late 1980s - Directive 88/344/EEC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. This was transposed into national legislation in 1993.

Directive 88/344/EEC (as amended) was repealed and recast in 2009 by 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. Directive 2009/32/EC was simply a recast of the existing rules therefore no changes were required to the national implementing legislation.

In the proposed draft SI, the drafting of the provisions on extraction solvents have been simplified and there is now closer textual alignment with Directive 2009/32/EC. However, the requirements on food business operators remain the same.

In addition, to avoid unnecessary duplication between domestic and EU text and in order to gain the advantages of ambulatory references, regulations in the SI have been drafted to refer directly to Annex I of the European Directive (as amended) with the effect that any changes to the list of permitted extraction solvents (including any new permitted solvents) or their conditions of use will directly apply.

Certain Articles of Directive 2009/32/EC do not need to be transposed into national law as they relate to general obligations on Member States or administrative provisions or deal with historical issues such as entry into force and the repeal of previous legislation.

### Transposition table

Article in Directive 2009/32/EC	Copy out	If no – Reason for Elaboration	National Provision
<p><b>Article 1</b></p> <p>General article covering scope of Directive.</p> <p><i>Article 1 (1) para 2</i> States what is outside the scope of the Directive.</p> <p><i>Article 1 (2)</i> Defines 'solvent' and 'extraction solvent'.</p>	Yes		<p><b>Regulation 10 (a)</b> states when the provisions do not apply as set out in Article 1 (1) para 2</p> <p>The definitions for 'solvent' and 'extractions solvent' apply by way of <b>Regulation 2(2)</b>.</p>
<p><b>Article 2</b></p> <p>Regarding authorised extraction solvents.</p> <p>Article 2 (1) &amp; (2) relates to Annex I which lists the authorised extraction solvents</p>	Yes		<p><b>Regulation 11 (a) (i) and (ii)</b> as read with regulations 12 and 13 and with Annex I to the Directive transposes Article 2(1) &amp; (2)</p> <p><b>Regulation 11 (b) and (c)</b> transpose Article 2 (3)</p>

and sets conditions of use.  Article 2 (3) authorises as an extraction solvent, water and other food substances with solvent properties.			
<b>Article 3 and Annex I</b>  Covers purity criteria for extraction solvents	Yes		<b>Regulation 11 (a) (iii), (iv) and (v)</b> as read with regulations 12 and 13 transposes Article 3.
<b>Article 4</b>  Applies to requirements that the Commission should adopt e.g. amendments to Annex I, methods of analysis.	No	No transposition required	N/A
<b>Article 5</b>  Refers to Member States' ability to temporarily suspend or restrict the use of a permitted extraction solvent and the associated actions required by the European Commission.	No	No transposition required	N/A
<b>Article 6</b>  Relates to EC administrative elements in updating the legislation.	No	No transposition required	N/A
<b>Article 7</b>  Covers labelling provisions	Yes		<b>Regulation 14</b> covers all the labelling provisions stated in Article 7.
<b>Article 8</b>  <i>Article 8 (1)</i> States Directive also applies to extraction solvents used in the production of foods which are imported into the EU.  <i>Article 8 (2)</i> States the Directive does not apply to extractions solvent or foods exported outside the EU.	Yes		<b>Regulation 13 (b)</b> (restriction on placing on the market) will apply equally to products imported from outside the EU  <b>Regulation 10 (b)</b> states the provisions do not apply if intended for export outside the EU
<b>Articles 9-11</b>  Article 9 - repeals Directive 88/344/EEC and associated amendments Article 10 – specifies the entry into force date of the Directive. Article 11 – states the Directive is addressed to Member States.	No	No transposition required	N/A