

FOOD STANDARDS AGENCY CONSULTATION

DRAFT GUIDE TO COMPLIANCE ON FOOD ADDITIVES LEGISLATION

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
22 April 2013	15 July 2013

Who will this consultation be of most interest to?
Manufacturers and processors; Retailers and caterers; enforcement officers

What is the subject of this consultation?
Draft guide to compliance which provides information about the requirements of revised EU food additives legislation which will apply from 1 June 2013

What is the purpose of this consultation?
To ascertain the relevance and acceptability of the proposed guide to compliance and comment on its content and presentation.

Responses to this consultation should be sent to:

Name GLYNIS GRIFFITHS Division/Branch CSD/FOOD ADDITIVES FOOD STANDARDS AGENCY Tel: 0207 276 8556 Fax: 0207 276 8514	Postal address: Aviation House 125 Kingway, LONDON WC2B 6NH Email: glynis.griffiths@foodstandards.gsi.gov.uk
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Is an Impact Assessment included with this consultation?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/> See Annex A for reason.
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DETAIL OF CONSULTATION

CONSULTATION ON DRAFT GUIDE TO COMPLIANCE ON THE LEGAL REQUIREMENTS OF REGULATION 1333/2008 ON FOOD ADDITIVES

Introduction

This draft guide to compliance sets out the general requirements and scope of revised EU harmonised legislation on food additives (Regulation 1333/2008) which will in the main apply from 1 June 2013, and describes individual provisions within Regulation 1333/2008 in detail.

It also:

- describes the structures and summarises the contents of Annexes II and III of the Regulation;
- explains the key differences between Annex II of the Regulation and the Directives it replaces;
- highlights the restrictions introduced by certain amendments to Regulation 1333/2008;
- clarifies the dates by which compliance with the various elements within the additives legislation is required by reference to transitional provisions.
- explains the EU authorisation procedure for new additives and new uses of permitted additives.

The opportunity has also been taken to draw stakeholders' attention to existing Agency guidance on the labelling of foods which contain the six colours used in the Southampton study and on reformulation of foods that contain the six colours. Reference is also made to EU guidance which aims to help distinguish between food colours and colouring foods.

Existing FSA guidance on nitrites and nitrates in meat and certain sweeteners has been updated and incorporated into the guidance as Appendices 3 and 4.

Background

Harmonised European legislation (Regulation 1333/2008) controls the use of food additives in the European Union. However, until 31 May 2013 the Annexes and associated Articles of the three previous Directives on sweeteners, colours and miscellaneous additives which list permitted additives and their conditions of use in foods will continue to apply. The provisions in these Directives have been largely transferred to Annex II of Regulation 1333/2008 which will apply from 1 June 2013.

In addition controls on additives (including carriers), enzymes, flavourings and nutrients have been incorporated into Annex III of Regulation 1333/2008. Whilst some of these provisions have been transferred from the existing Directive on miscellaneous additives, others are new.

Given that the changeover from the three existing Directives will be completed on 1 June 2013 guidance on the new additives legislation is considered appropriate at this time. There are a number of differences between the old and new legislation and these need to be explained.

Moreover, Regulation 1333/2008 has already been amended on a number of occasions, in most cases to permit new additives or new uses of permitted additives, but in others to restrict the use of permitted additives. The opportunity has also been

taken to remind stakeholders of the various restrictions in additive use that have been introduced, and also to clarify the dates on which various aspects of the legislation will apply.

Finally, all the additives guidance elsewhere on the website has been updated and incorporated into one document, so that stakeholders will find all the information in one place.

Regulation (EC) No 1333/2008 is enforced in England by the Food Additives Regulations 2009 (SI 2009/3238). Parallel but separate Regulations exist in Scotland, Wales and Northern Ireland. However, it is proposed to revoke and re-enact all legislation within the FSA's remit covering food additives, flavourings, enzymes and extraction solvents into a single consolidated statutory 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.

The relevant legislation on which we are currently consulting is the Food Additives, Enzymes, Flavourings and Extraction Solvents Regulations 2013 (SI 2013/xxxx). Please see link below:

<http://www.food.gov.uk/news-updates/consultations/consultations-england/2013/foodadditives-consulteng2013>

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.

Proposals

The key proposal on which this consultation seeks comments is as outlined:

Key proposal:

- **To provide stakeholders with an opportunity to comment on draft guidance on Regulation 1333/2008/EC on food additives, and related food additive issues.**

Impact Assessment

We believe that the guide to compliance will make it easier for all stakeholders to understand the legislation but that there will be no significant incremental impact as a result. We have therefore not produced an Impact Assessment. However, if the consultation identifies any impacts we will reconsider the need for an Impact Assessment.

Consultation Process

The FSA welcomes comments from all interested parties on the draft guide to compliance. We would particularly encourage responses from food manufacturers, food additive suppliers/manufacturers and enforcement authorities.

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

Questions asked in this consultation:

Q1 Do stakeholders consider that the content and presentation of the draft guide to compliance is clear and easily understood?

Q2 Do stakeholders consider that the draft guide to compliance will make it easier for businesses and enforcement officers to understand and interpret food additives legislation?

Q3 Do you agree that there will not be any significant incremental impact as a result of this guide to compliance?

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

Q4 Is the draft guide to compliance deficient in any way?

Please provide evidence to support your views.

Any comments that interested parties are able to provide in relation to the draft guide to compliance would be gratefully received. We are particularly keen to hear from Small and Medium Enterprises (SMEs) and would encourage them to comment as to whether the draft guidance is helpful to them

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

Following the consultation, we will review the responses received and consider whether any changes are required to the draft guide to compliance. 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.

Comments in response to this consultation should be sent to Glynis Griffiths who can be contacted by telephone on 0207 276 8556.. However, comments in response to this consultation should be sent by 15 July 2013:

E-mail to: glynis.griffiths@foodstandards.gsi.gov.uk

Letter to: Glynis Griffiths
Food Additives, Flavourings and Contact Materials Branch
The Food Standards Agency,
Aviation House,
London, WC2B 6NH

Responses

Responses are required by close 15 July 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).

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

Yours, faithfully

Glynis Griffiths
Food Additives, Flavourings and Contact Materials
Chemical Safety Division

Enclosures:

Annex A: Standard Consultation Information
Annex B: Draft guide to compliance on food additives
Annex C: List of interested parties

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 C. 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. A Welsh version of the consultation package can be found at www.food.gov.uk
7. Please contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.
8. Please let us know if you need paper copies of the consultation documents or of anything specified under 'Other relevant documents'.
9. This consultation has been prepared in accordance with HM Government consultation principles¹.
2. An Impact Assessment will normally be published alongside a formal consultation. We have not produced an Impact Assessment for this proposal because we believe that there will be no significant incremental impact as a result of this guidance. If the consultation identifies any impacts we will reconsider the need for an Impact Assessment

¹ <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.



Food additives

July 2013

For all queries about this guide to compliance — including if you require the information in an alternative format such as audio, large print or Braille — please use the number below.

CONTACT TELEPHONE

0207 276 8570

Summary

Intended audience:	<ul style="list-style-type: none"> • Manufacturers and processors • Retailers, caterers and carers • Enforcement officers
Which UK nations does this cover?	England, Scotland, Wales and Northern Ireland
Purpose:	The guide to compliance aims to provide information about the requirements of revised EU food additives legislation, which will apply from 1 June 2013.
Legal status:	Regulatory guide to compliance (Information specifying what food business operators need to do to comply with EU legislation)
Key words	<ul style="list-style-type: none"> • Additives
Review date	July 2014
Sunset date	July 2018

Revision history

This guidance follows the Government [Code of Practice on Guidance](#). If you believe this guidance breaches the Code for any reason, please let us know by emailing betterregulation@foodstandards.gsi.gov.uk. If you have any comments on the guidance itself, please call us using the contact number on page 2 or complete our ongoing [Guidance survey](#): <https://www.surveymonkey.com/s/55QQDCG>

Revision No.	Revision date	Purpose of revision and paragraph number	Revised by

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Purpose and legal status of guidance

1. This guide to compliance has been produced to provide advice on the legal requirements of Regulation 1333/2008 on food additives. It cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances. If you do follow the guide to compliance it will help you to comply with the law. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/environmental health department of the local authority.

Review

2. It is planned to review this guide to compliance in July 2014. We welcome feedback from users of the guidance, including completion and return of the [feedback questionnaire](#)

Contacts

3. For help and advice on this guidance in England please contact the food additives helpline on 0207 276 8570 or foodadditives@foodstandards.gsi.gov.uk .

For Wales contact : 029 2067 8912 Email: food.policy.wales@foodstandards.gsi.gov.uk

For Scotland contact: 01224 285154 Email: Scotland@foodstandards.gsi.gov.uk

For Northern Ireland contact: infofsani@foofstandards.gsi.gov.uk

Introduction

4. A European Union legislative package on “food improvement agents” was published at the end of 2008. This replaced earlier EU legislation and comprised three individual Regulations on food additives, flavourings and enzymes and a Regulation providing a common authorisation procedure for all three. The core principles and provisions of food additives legislation are set out in European Parliament and Council Regulation (EC) No 1333/2008 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:EN:PDF>

Regulation 1333/2008

5. Regulation (EC) No 1333/2008 is enforced in England by the Food Additives (England) Regulations 2009 (SI 2009/3238):

http://www.legislation.gov.uk/ukxi/2009/3238/pdfs/ukxi_20093238_en.pdf
6. Regulation (EC) No 1333/2008 is enforced in Scotland by the Food Additives (Scotland) Regulations 2009 (SI 2009/436).
7. Regulation (EC) No 1333/2008 is enforced in Wales by the Food Additives (Wales) Regulations 2009 (SI 2009/3378).
8. Regulation (EC) No 1333/2008 is enforced in Northern Ireland by the Food Additives (Northern Ireland) Regulations 2009 (SI 2009/416).
9. It is proposed to revoke and re-enact all legislation within the Food Standards Agency's remit covering food additives, flavourings, enzymes and extraction solvents into a single consolidated statutory instrument by Autumn 2013. 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.

General requirements of the legislation

10. The Regulation provides for :
 - a) Community¹ lists of approved food additives which are set out in Annex II and III of the Regulation;
 - b) Conditions of use for food additives used in foods, including in food additives, food enzymes as covered by Regulation 1332/2008, food flavourings as covered by Regulation 1334/2008 and nutrients;
 - c) Rules on the labelling on food additives sold as such;

¹ Following the Treaty of Lisbon, the European Community became the European Union, and references to "Community" in pre-Lisbon legislation are to be read as references to the EU.

- d) specific rules on the “carry-over” principle;
- e) rules on the labelling of the so called “Southampton colours”.
- f) specifications (purity criteria) to be established for permitted food additives.

Substances excluded from the scope of additives legislation (Article 3)

11. The legislation includes a definition of food additive at Article 3 2 (a),

“any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods”.

Any substance, whatever its function, that does not meet this definition, is not controlled by Regulation 1333/2008. Thus, in particular, the Regulation does not apply to normal food/food ingredients, even if they are added to perform a controlled function. The definition includes, for clarification purposes, a list of substances that for the purpose of the Regulation are not considered as food additives.

12. Processing aids, including filtration aids and release agents, defined at Article 3.2 (b), are also excluded from the scope of Regulation 1333/2008.

“Processing aid” means any substance which:

- (i) is not consumed as a food by itself;
- (ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and
- (iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risks and do not have any technological effect on the final product. In the UK there is no national legislation on processing aids and as such there is no legally defined list of approved processing aids.

13. Other substances falling outside the scope of the Regulation include extraction solvents falling within the scope of Directive 2009/32/EC, flavourings falling within the scope of Regulation 1334/2008, and food enzymes falling within the scope of Regulation 1332/2008. Food additives legislation will however continue to regulate the use of food additive enzymes (e.g. invertase and lysozyme) until such time as the positive list of food enzymes is established. Also excluded are substances added to foods as nutrients e.g. minerals, trace elements or vitamins, substances used for the protection of plants and plant products in conformity with European Union rules on plant health e.g. pesticides, herbicides and substances used for the treatment of water
14. Whether or not governed by specific regulations, the addition of any substance to food is subject to the provisions of Regulation (EC) 178/2002 (General Food Law) which prohibits the placing on the market of food that is unsafe, ie injurious to health, or unfit for human consumption.

EU lists of foods additives (Articles 4, 7 and 8)

15. Lists of permitted food additives (including colours and sweeteners and miscellaneous additives such as preservatives and antioxidants) can be found in Annexes II and III of Regulation 1333/2008. Annexes II and III have been populated by way of separate Regulations (Commission Regulations 1129/2011 and 1130/2011) [and subsequent amendments to these or 'as amended'].
16. To be included in the approved list, additives must comply with the conditions set out in Regulation 1333/2008, which state that they should not present safety concerns, should be technologically justified, and should not mislead the consumer. Additives should also have advantages and benefits for the consumer such as preserving the nutritional quality of food, enhancing its keeping quality or stability, aiding the manufacture and processing of the product or in its transport or storage. Additional specific conditions for colours and sweeteners are also laid down.
17. The functional classes of food additives are defined in Annex I. Some additives have multiple technological functions. For example, Sodium Hydrogen Carbonate, which is also known as Bicarbonate of Soda, or E 500, is best known as a raising agent but can also function as an anti-caking agent or acidity regulator.

Conditions of use for additives in foods, including maximum limits, prohibition of additives in unprocessed foods etc. (Articles 4, 5, 11, 15 and 16)

18. Regulation 1333/2008 prohibits the placing on the market of a food additive or any food containing food additives if the use of the additive does not comply with the requirement in the Regulation. This includes additives which are used for a technological function not listed in Annex I. In this case, an appropriate new function will be assigned to the additive and added to the list in Annex I when the additive is undergoing the authorisation process.
19. Conditions of use for food additives in foods, including restricted uses in specified foods and maximum limits, are set out in Annex II.
20. The maximum limits in the annexes are based on the food as sold unless otherwise specified. However, for dried and/or concentrated food and drinks, the maximum limits apply to the food as reconstituted following manufacturers' instructions, taking into account the minimum dilution factor. It is recognised that certain substances, for example phosphates and glutamates, are naturally present in certain foods. The quantitative limits apply to the amount of additive added. There is however an exception in the case of sulphites, as the legislation requires that the specified quantitative limits include sulphites available from all sources and therefore take into account any natural occurrence of the substance.
21. There are instances in the legislation where no numerical limit is set for additive use. This is because there is no need on safety grounds to set a maximum level. Rather a level of *quantum satis* (QS) is set. QS is defined in the legislation and means that additives shall be used in the food concerned in accordance with good manufacturing practice. This means that it must not be used at a level higher than is necessary to achieve the intended purpose and must not be used in a way that misleads the consumer.

GM additives, additives produced from new sources or different processes (e.g. nano technology) (Articles 12 and 13)

22. A food additive falling within the scope of Regulation 1829/2003 on genetically modified food will need to be covered by an authorisation under that Regulation before it can be added to the list of permitted additives. e.g. an emulsifier made from GM soya oil

would be permitted provided that the GM soya is permitted under Regulation 1829/2003 and the emulsifier complies with the relevant EU specification.

23. If there is a significant change to the production methods or starting materials, including particle size through nanotechnology, of an approved additive, it will be considered a different additive and will need to undergo re-evaluation.

Carry-over rule (Article 18)

24. “Carry-over” provisions apply to most foods permitted to contain food additives, but not to those specially prepared for infants and young children. These provisions permit the presence of a permitted food additive in a compound food, to the extent that the food additive is allowed by the provisions of Annex II of Regulation 1333/2008 in one of the ingredients of the compound food. Certain foods (listed at tables 1 and 2 of Annex II of Regulation 1333/2008) are not permitted to contain additives by way of carry-over.

Examples of carry-over:

A fruit yoghurt consisting of plain (unflavoured) yoghurt and a fruit preparation would be permitted to contain sorbates, due to the fact that sorbates are permitted in fruit preparations, even though they are not permitted in plain yoghurts. The level used must not exceed the maximum level for the fruit preparation element of the yoghurt.

If a non-heat treated meat product is used as an ingredient in a compound food (e.g the cooked bacon in a BLT sandwich), the presence of nitrate would be permitted in the BLT sandwich up to the limit permitted for the cooked bacon

25. The carry-over rule also provides for permitted food additives to be present in foods (such as intermediary products) in which they would not otherwise be permitted, provided that those foods are to be used solely in the preparation of a compound food that will conform to the provisions of Annex II. The latter is commonly referred to as “reverse carry-over”.

Example of reverse carry-over:

Annatto (not normally permitted to be used in seasonings) could be added to a seasoning that is intended solely for use in a snack food, provided the level of annatto does not result in the maximum level of annatto permitted for the snack food being exceeded.

26. In addition, an additive may be present in a food to which a food additive, food enzyme, food flavouring or nutrient has been added, provided that the additive is permitted in accordance with the provisions of Annex III of Regulation 1333/2008 and has no technological function in the final food.

Rules on the labelling of food additives sold as such to other businesses and to consumers (Articles 21- 23)

27. Labelling requirements for business-to-business sales of food additives are set out in Articles 21 – 22. By way of derogation from these rules, certain specified aspects of the required information may be shown on the documents relating to the consignment supplied with or prior to delivery rather than on label, provided that it is made clear that the product is not for retail sale. In addition, the required information on food additives supplied in tankers may be shown on the accompanying document.
28. Labelling requirements for sales of additives sold to consumers are set out in Article 23 which apply without prejudice to labelling rules for food in general.. There are a number of additional labelling requirements for table top sweeteners requiring that the sweetener(s) presented is indicated in the sales description (e.g. x based table sweetener) Table top sweeteners containing polyols must carry the warning “excessive consumption may induce laxative effects”, and table top sweeteners containing aspartame or aspartame-acesulfame salt must be marked with the indication “contains a source of phenylalanine” .

Foods containing six colours used in the study by Southampton University (Article 24)

29. Foods containing Tartrazine (E102), Ponceau 4 R (E124), Sunset yellow (E110), Carmoisine (E122), Quinoline yellow (E104) and Allura Red (E129) are required to be labelled with the following additional information;

‘name or E number of the colour(s)’: may have an adverse effect on activity and attention in children’.

30. For those businesses who retained these colours and have to label their products with the required warning notice, the Agency has produced guidance to assist them with this. This is published on the Agency’s website at:

<http://www.food.gov.uk/multimedia/pdfs/labellingcoloursreg13332008.pdf>

31. The use of food additives in food is covered by the general labelling rules as set out in Directive 2000/13/EC which is implemented in GB by the Food Labelling Regulations 1996 (and equivalent in NI)

Guidance on reformulation of foods containing the six colours used in the study by Southampton University

32. Guidance has also been drawn up which aims to assist businesses who want to remove the six colours and replace them with alternatives. This is aimed specifically at assisting small and medium sized businesses and is available on the Food Standard Agency's website at the following link:

<http://www.food.gov.uk/news/newsarchive/2011/sep/colourguidance>

“Colouring” foods

33. EU guidance has been drawn up to distinguish between food colours, which are subject to EU food additives legislation and colouring food extracts, which are not. The guidance is aimed at industry and enforcement authorities/regulators and can be accessed here: (to be added when available)

Annex II of Regulation 1333/2008

34. Following the adoption of Regulation 1333/2008, the European Commission was tasked with transferring the existing food additives authorisations in the food additives legislation being phased out (Directives 95/2/EC, 94/35/EC and 94/36/EC) and populating Annex II of Regulation 1333/2008. Following extensive consultation with Member States and stakeholders, a Food Categorisation System (FCS) was developed similar to that in the Codex General Standard for Food Additives, but adapted to the EU market and to EU principles.

An example of a food category and its sub-categories in Annex II is set out below:

Category 05 – confectionery

Sub-category 05.1 – cocoa and chocolate products as covered by Directive 2000/36/EC

Sub-category 05.2 – other confectionery including breath freshening micro sweets

Sub-category 05.3 – chewing gum

35. All additives (colours, sweeteners and miscellaneous additives) permitted in each sub-category of food are listed, together with conditions of use. In general, additives not listed are not permitted to be used. However, category 0 covers food additives (i.e. gases) which are permitted in all categories of food, and additives such as silicates which are permitted in all dried powdered foods, and category 18 covers processed foods not covered by categories 1 – 17.
36. Annex II was published as Commission Regulation 1129/2011, entered into force on 2 December 2011 and applies from 1 June 2013. However, transitional provisions were included to permit products complying with the previous Directives on colours, sweeteners and miscellaneous additives to continue to be marketed up to 31 May 2013, details of which can be found in the Appendix II below.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0001:0177:En:PDF>

Structure of Annex II

Part A – this includes:

- An introduction to the Annex and general provisions on listed additives and conditions of use;
- Lists of colours that may not be sold directly to the consumer and the requirement for nitrites to be sold in a mixture of salt or salt substitute,
- Lists of foods which are not permitted to contain additives or colours by way of the carry-over principle.

Part B – this includes lists of all authorised additives (colours, sweeteners and additives other than colours and sweeteners)

Part C – For ease of reference, certain additives are grouped together in Part E of Annex II and the groupings are defined in Part C. Group I comprises generally permitted additives, Group II comprises food colours authorised at quantum satis level, Group III covers food colours with a combined maximum limit and Group IV covers polyols. In addition, other additives that have a common reporting basis e.g. sorbates or sulphites are grouped together.

Part D – a list of all the food categories and sub-categories within the FCS are set out in Part D. A full list of these and descriptors are set out in the Appendix. There are 18 food

categories, including category 0 which covers food additives (i.e. gases) which are permitted in all categories of food, and additives such as silicates which are permitted in all dried powdered foods. Category 18 covers processed foods not covered by categories 1-17. As additives can only be used in the food categories listed, there was considered to be a need for a category that would cover any foods that may have been overlooked when the FCS was created.

Part E - comprises food categories and authorised additives. The additives (where appropriate grouped together) are listed against the 153 sub-categories by E number and name with conditions of use (including the maximum limit) indicated. Also indicated are any restrictions or exceptions on the additive use in that sub-category, and footnotes are included where appropriate.

Annex III to Regulation 1333/2008

37. Annex III to Regulation 1333/2008, the content of which was amended and substantially populated by Commission Regulation 1130/2011, lists the additives that are permitted for use in additives, including carriers, in food enzymes, in food flavourings and in nutrients.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0178:0204:EN:PDF>

Dates of application

38. Commission Regulation 1130/2011 entered into force and became applicable on 2 December 2011. However, transitional provisions have been included to permit products complying with preceding legislation to be marketed up to specified deadlines, details of which can found in Appendix II below.

Structure of Annex III

Part 1 - covers carriers used in other additives. Carriers are defined in 1333/2008 as substances which are used to:

“Dissolve, dilute, disperse or otherwise physically modify a food additive or a flavouring, food enzyme, nutrient and/or other substance added for nutritional or physiological purposes to a food without altering its function (and without exerting any technological effect themselves) in order to facilitate its handling, application or use”.

39. Some of the carriers listed in Part 1 can be used in all additives, and others are restricted to certain categories of additives only, e.g. anti-foaming agents, sweeteners and glazing agents for fruit. Most are permitted at *quantum satis* level. The maximum limit is based on the additive preparation itself, except in the case of E 1520 where the limit relates to the carry-over level in the final food.
40. **Part 2** - covers additives (except carriers) used in other additives. Additives listed in Table 1 of Part 6 can be used in all additive preparations at *quantum satis* level, the other listed additives are restricted to certain categories of additives only. Maximum permitted levels are based on the additive preparation in the case of phosphates and silicates; in all other cases, limits are set for the food additive preparation and for the final food.

Part 3 - covers additives (including carriers) used in food enzymes. Additives listed in Table 1 of Part 6 of the Regulation can be used in food enzyme preparations at *quantum satis* level. Maximum permitted levels are based on the enzyme preparation in the case of phosphates and silicates; in all other cases, limits are set for the enzyme preparation and for the final food. Only specified ones can be used as carriers.

Part 4 - covers additives (including carriers) used in food flavourings. Additives listed in Table 1 of Part 6 of the Regulation can be used in flavourings at *quantum satis* level. Maximum permitted levels are based on the flavouring preparation in most cases, but in specified cases, limits are set for the flavouring preparation and for the final food.

Part 5 (Section A) - covers additives (including carriers) used in nutrients, except those added to nutrients to be used in foods for infants and young children.

Part 5 (Section B) - covers additives added to nutrients to be used in foods for infants and young children listed in Category 13.1 of Part E of Annex II.

Part 6 (tables 1– 7) - sets out the various groupings of food additives.

Specifications

41. Food additives must comply with the approved specifications set out in Commission Regulation 231/2012. The specifications comprise information which adequately identifies the food additive, including origin and description of the manufacturing

process, and establish acceptable purity criteria for each additive, such as maximum limits for undesirable impurities.

<http://eur-lex.europa.eu/JOIndex.do?year=2012&serie=L&textfield2=83&Submit=Search&submit=Search&ihmlang=en>

42. Regulation 231/2012 laying down specifications for food additives listed in Annexes II and III of Regulation 1333/2008 was adopted on 9 March 2012. The new Regulation, which consolidates and repeals the three previous purity criteria Directives, includes a number of technical changes and clarifications whilst specifications for additives which are no longer permitted have been removed (e.g. Red 2G). It applied from 1 December 2012

Amendments to Annexes II and III

43. A number of Regulations amending Annexes II and III to Regulation 1333/2008 have already been published. Some of these restrict the permitted uses of authorised additives whilst others permit the use of newly approved additives or new uses of existing additives. In particular:
44. Regulation 380/2012, which came into force on 23 May 2012, amends Annex II to restrict the use and levels for aluminium-containing food additives. The measures restrict the use of aluminium silicates (commonly used as anti-caking agents), aluminium lakes (a base for certain food colours), and limit the raising agent E541 Sodium Aluminium Phosphate (SALP) to one product only, Battenburg-style cakes. Transitional arrangements have been agreed to allow industry to adapt to the proposed changes. Details of these are set out in Appendix II below.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:119:0014:0038:EN:PDF>

45. Regulation 232/2012, which came into force on 23 May 2012, amends Annex II to restrict the use and levels for three colours – E 104 Quinoline Yellow, E 110 Sunset Yellow and E 124 Ponceau 4R. The levels of these colours will be restricted in a number of food categories, including soft drinks, confectionery, sauces and seasonings and in some cases (for example Ponceau 4R in sauces and seasonings) no longer permitted. The Regulation includes a use level of 20 mg/l for Sunset Yellow in soft drinks. Regulation 232/2012 is directly applicable in Member States' legislation and applied from 1 June 2013. Foods placed on the market that comply

with the provisions of the previous legislation (Directive 94/36/EC) can continue to be marketed until stocks are exhausted.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:078:0001:0012:en:PDF>

46. The European Commission's food additives database includes links to all the food additives legislation and can also be used to access the additives and approved conditions. Whilst not a legal document it is a useful reference source as it is updated by the European Commission to reflect the changes to the Annexes in Regulation 1333/2008.

https://webgate.ec.europa.eu/sanco_foods/main/?event=display

Approval for new additives, new uses of already authorised additives

47. Commission Regulation (EU) No 234/2011 sets out the authorisation procedure for food additives as well as for food enzymes and food flavourings:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:064:0015:0024:EN:PDF>

48. All applications for new additives and new uses of permitted additives should be sent to the European Commission. Guidance regarding the submission of an application and the procedures involved in such an application are available on the Commission's website, via the link below:

http://ec.europa.eu/food/food/FAEF/authorisation_application_en.htm

Guidance on scientific requirements and data submission

49. EFSA have produced guidance on submissions for food additives, detailing specific scientific approaches and data requirements for food additives evaluations:

<http://www.efsa.europa.eu/en/efsajournal/doc/2760.pdf>

European Food Safety Authority re-evaluation of food additives

50. All currently permitted food additives are subject to a re-evaluation by EFSA in accordance with Regulation 257/2010 that sets out a programme for their re-evaluation in order of priority. [http://eur-](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:080:0019:0027:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:080:0019:0027:EN:PDF](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:080:0019:0027:EN:PDF)

51. Additives are being evaluated by functional groups and priority. The re-evaluation started with colours, which generally have the oldest evaluations and ending with sweeteners, which have the most recent. However, if new scientific evidence emerges that indicates a possible risk for health or casts doubt on the safety of an additive, this will trigger an immediate re-evaluation of the relevant additive. Food business operators producing or using food additives are obliged under Article 26 of Regulation 1333/2008 to inform the Commission of any new scientific or technical information that might affect the assessment of the safety of the food additive.

Appendix 1

Differences between Annex II and Directives 95/2/EC, 94/35/EC and 94/36/EC

52. The provisions in Annex II reflect, in the main, those in the Annexes of Directives 95/2/EC, 94/35/EC and 94/36/EC. However, some inconsistencies have been noted, and the Commission will be issuing a number of amending Regulations that will correct these and permit current authorisations to continue where appropriate after 1 June 2013.
53. Nevertheless, a number of currently permitted food additives uses have been restricted since 1 June 2013. These include the restrictions on Quinoline Yellow, Sunset Yellow and Ponceau 4R mentioned above following re-evaluation by EFSA in September 2009. The use of the food colour lycopene has also been restricted following an EFSA opinion in January 2008. In addition, as a result of information from stakeholders that a number of colours in Annex V Part 2 of Directive 94/36/EC are no longer being used, the colours permitted in the following food categories have been reduced: flavoured processed cheese, preserves of red fruit, fish paste and crustacean paste, precooked crustacean and smoked fish.
54. Following its suspension in 2007, Red 2G (E 128) is no longer listed as a permitted colour, nor are Brown FK (E 154) and Ethyl ester of beta-apo-8-carotenic acid (E 160f) as industry indicated that these colours are no longer used.
55. The restrictions on the use and levels for aluminium-containing food additives referred to in paragraph 38 and set out in Regulation 380/2012, have resulted in significant changes to the permitted use of aluminium lake versions of colours (i.e. the process whereby water-soluble food colours are precipitated with an aluminium salt to form water-soluble pigments called lakes). At present aluminium lake versions

of all colours are permitted but wef 1 August 2014 these will be restricted to certain specified colours set out in Table 3 to Annex II of Regulation 1333/2008. In addition, where aluminium lake colours are used in food there will be a limit to the aluminium permitted to be present in the food as a result of the aluminium lake.

56. Annex II is structured by food category, and only the additives listed against a specific food can be used, in accordance with the relevant provisions. There is no scope for additives to be permitted by default as was the case in Directives 95/2/EC and 94/36/EC which permitted certain additives/colours to be used in most processed foods at quantum satis level. Whilst category 0 in Annex II permits processed foods not covered by categories 1 – 17 (excluding foods for infants and young children) to contain Group 1 additives, the colours in Annex V Part 1 of Directive 94/36/EC, previously allowed in most processed foods, are only permitted to be used in the food categories specified.
57. Certain food additives have been restricted as a result of interpretations agreed within the EU. In particular, flour, originally considered a processed food in the UK, is now deemed to be an unprocessed food following agreement of EU Member States at the Commission's Working Group on Food Additives, with only a small number of group 1 additives permitted. However, self-raising flour is considered to be a bakery pre-mix, consisting of flour and raising agents. As the pre-mix is to be used in the preparation of for instance sponge cakes, Group 1 additives (including sodium bicarbonate) are permitted to be present in the pre-mix by way of the "reverse carry-over" provision in Regulation 1333/2008.
58. The scope of the "meat preparations" category (08.1.2) has been the subject of extensive discussion in EU food additives working group. UK products such as breakfast sausages and burger meat with a minimum vegetable and/or cereal content of 4% are amongst those considered to be meat preparations as defined by Regulation 853/2004, in which are permitted only a restricted number of additives; a much wider range of additives is permitted in the processed meat category (08.2). Burgers and breakfast sausages were commonly considered to be meat products under the earlier additives Directives which preceded Regulation 853/2004 and thereby permitted to contain a range of additives including phosphates. Under their new classification as meat preparations, breakfast sausages, but not burgers, have been permitted to contain phosphates after 1 June 2013.

Food category descriptors

59. In order to ensure uniform interpretation of the food categories in Annex II of Regulation 1333/2008, the Commission has published descriptors that will be made available at a later date (in the meantime a draft will be sent on request). The descriptors should be used for informal interpretation of the legislation only.
60. Responsibility for enforcement and interpretation of the law within the UK rests with local enforcement authorities and ultimately the law courts. Within the EU, Article 19 of Regulation 1333/2008 provides for decisions over specific interpretation issues (for example over unresolved queries over the interpretation of food categories) to be made by the Standing Committee on the Food Chain and Animal Health.

Appendix 2

Transitional provisions

Annex II of Regulation 1333/2008

61. In the main Annex II did not apply until 1 June 2013. Until 31 May 2013, the provisions in Article 2 (1), (2) and (4) of Directive 94/35/EC, Article 2 (1) to (6) and (8) to (10) of Directive 94/36/EC and Article 2 and 4 of Directive 95/2/EC, together with the Annexes of all three remained in force. This was to enable manufacturers to adapt to the new provisions, some of which are more restrictive than those in the legislation being phased out.

Annex III of Regulation 1333/2008

62. The provisions in Parts 1 (carriers in additives) and 4 (additives in flavourings) and Section B of Part 5 (additives in nutrients to be used in foods for infants and young children) of Annex III largely reflect those in Directive 95/2/EC. Preparations not complying with the requirements of Parts 1, 4 and Section B of Part 5 were permitted to continue to be marketed in accordance with the provisions of Directive 95/2/EC until 31 May 2013.
63. The provisions in Parts 2 (additives in additives) and 3 (additives used in enzymes) and Section A of Part 5 (additives used in nutrients) have only recently been

harmonised within the EU. Prior to this, national rules applied. In the UK there was no specific legislation in these areas, though the addition of any substance to food is subject to the provisions of Regulation (EC) 178/2002 (General Food Law).

Preparations not complying with the requirements of Parts 2, 3 and Section A of Part 5 may continue to be marketed in accordance with national provisions (General Food Law) until 2 December 2013.

Regulation 380/2012

64. Foods containing aluminium lake colours which comply with the provisions of Directive 94/36/EC will be able to continue to be marketed until 1 August 2014.

Appendix 3

Nitrites and nitrates in meat products

65. Authorised levels for nitrites and nitrates in meat and other food products take account of the opinion of the European Food Safety Authority (EFSA), published on 26 November 2003, which aims to keep levels of nitrosamines as low as possible whilst maintaining the microbiological safety of food products. In addition, in line with EFSA's recommendations, controls on the level of nitrites and nitrates in meat products, are usually based on added rather than residual amounts. However, a degree of compromise has been introduced in the legislation in order to allow the continued production of certain traditional products. These compromises include provisions which permit traditional UK meat products such as Wiltshire cured ham, bacon and similar products to be produced based on residual amounts.
66. Other than certain traditional products, the legislation limits the use of potassium and sodium nitrite in meat products to a maximum amount added of 150 mg/kg, and in sterilised meat products ($F_0 > 3$), to 100 mg/kg. The use of potassium and sodium nitrate is permitted only in non-heat-treated meat products, to a maximum amount added of 150 mg/kg, although nitrates may be present in some heat treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment. The limits for both nitrites and nitrates relate to the maximum amount that may be added during the manufacture of the product i.e. ingoing limits.

Traditional meat products

67. The traditional meat products for which derogations have been agreed include categories for six traditional UK meat products. These are listed in italics, which indicates they are Member States' national products. In Annex II of Regulation 1333/2008 they are grouped in food category 0.8.2.4 under three sub-headings:
- traditional immersion cured meat products, including Wiltshire bacon and Wiltshire ham and similar products and cured tongue (category 08.2.4.1);
 - traditional dry cured meat products, including dry cured bacon and dry cured ham and similar products (category 08.2.4.2) ; and
 - other traditionally cured meat products, which includes jellied veal and brisket (category 08.2.4.3)
68. For traditional products, the limits for both nitrites and nitrates relate to the maximum residual levels permitted in finished products. The manufacturing method for each of these traditional products is described in the legislation.
69. When interpreting the legislation, the information for each specific product should be read in conjunction with the general description for the type of product. For example, to meet the specification for Wiltshire bacon, the product would need to comply with: the description for traditional immersion cured meat products set out at 08.2.4.1 (i.e. it would need to be immersed in a curing solution containing nitrites and/or nitrates, salt and other components); AND the manufacturing process for Wiltshire bacon described in the relevant row under category 08.2.4.1; (i.e. it would need to be injected with curing solution followed by immersion curing for 3 to 10 days with an immersion brine solution including microbiological starter cultures).

Traditional Products Which Do not Fit Into Any Named Category

70. Only certain types of traditional products are specifically referred to in the legislation. If a product does not meet the requirements for any named product (allowing for "similar products" explained below), it then defaults to a general category e.g. "meat product" or "non-heat-treated meat product" and the maximum ingoing permitted levels should be used.

“Similar products”

71. The legislation contains the words “and similar products” against many, but not all, of the categories for which derogations have been granted. The legislation does not define similar products and currently there are no decisions by the EU Standing Committee or by a Court. The overall intention of the legislation is to reduce the use of nitrites and nitrates. During the negotiation of the legislation which introduced these restrictions, the Council and European Parliament saw the derogations for certain traditional products as being of a limited nature, and the Parliament in particular wished to see specifications which limit the named derogations. With this background, we consider that a similar product will closely resemble the product named (but may obviously have a different name); In addition, it must have been traditionally produced and produced using the same stages as described in the manufacturing process though there may be some variation in the times and temperatures cited.
72. To be 'traditionally produced' we consider a product needs to have been produced for more than 25 years at the time EC Directive 2006/52 came into force (i.e. since before September 1981). Traditional is not defined within EU food additives legislation and it is ultimately for a Court to decide the interpretation. We have suggested it should be taken to be of the order of 1 generation / 25 years, which would be in line with Regulation (EC) No 509/2006 of 20 March 2006 on Agricultural Products and Foodstuffs as Traditional Specialities Guaranteed, that introduced a legal definition of the term “traditional”, specifically for the purpose of the regulation. This definition requires a period of 25 years for production/recipe for a traditional food that is registered under the Scheme.

Dry cured ham

73. The ‘dry cured ham’ produced in the UK, which is different to that produced elsewhere in the EU, is defined by way of the manufacturing process specified against the product listed within category 08.2.4.2. The process used must comply with that stipulated; otherwise the product will default into the relevant general meat product category.

Wiltshire bacon/ham

74. Whilst no definition of Wiltshire cure has been included in the legislation, the manufacturing process for Wiltshire cured ham and bacon is defined by way of the

manufacturing process specified against the product listed within category 08.2.4.1. The use of 'live' immersion brines is the main distinguishing factor between Wiltshire and other cures. The criteria within the manufacturing process state that the immersion brine solution includes microbiological starter cultures. We do not consider it is necessary for a culture to be added prior to each immersion; the culture may well be present, as it traditionally was, from previous use of the immersion solution. The micro-organisms present perform the function of reducing added nitrate to nitrite which then goes on to become the active curing compound.

Cure-in-the-bag products

75. Cure-in-the-bag products are injected with curing solution, and not immersed, and it is possible to accurately regulate the ingoing amount of curing solution. This type of product therefore falls under the general meat products category (08.2.1 or 08.2.2) and not in the derogations for traditional immersion cured meat products.

Non-heat-treated meat products

76. Sodium and potassium nitrates are permitted to be added to non-heat treated products. The European Commission considers that the use of nitrate is not necessary in products which have been heat treated to the extent that any bacteria have been destroyed. It follows therefore that the relevance of any heat treatment and the use of nitrates needs to take into account the stage in which the heat treatment is applied and the effectiveness of any heat treatment (temperature and time). For example, a piece of bacon or ham is cooked before consumption (and possibly before purchase); however, this level of heat treatment could not be considered to negate the need for nitrates at the earlier stages of preparation.
77. Cooked bacon and ham should therefore be classified as "non heat-treated products". In the case of bacon, this would apply to both heat set bacon (briefly cooked at circa 50 °c in order to partially heat-set some of the protein in order to aid slicing) and to cured bacon that is cooked prior to addition to a sandwich.
78. Permitted levels of nitrates will depend on whether the product in question falls into the general (non-heat treated) meat product category (08.2.1) (permitted up to 150 mg/kg) or into one of the traditional categories (08.2.4.1) e.g. Wiltshire bacon/ham (permitted up to 250 mg/kg) or cured tongue (permitted up to 10 mg/kg).
79. Products that should be considered as "heat treated" and fall within category 08.2.2 include many products which are cooked after canning.

‘Bacon, filet de bacon’

80. The entry for ‘Bacon, Filet de bacon’ in category 08.2.4.1 refers to a traditional French product and is not the same as standard bacon. Hence, the maximum permitted level (250 mg/kg residual, without added E249 or E250) only applies to this and similar products.

Conversion factor for potassium salts

81. All levels given in the legislation are for the sodium salts. Conversion factors for the equivalent potassium salts are:
- To convert sodium nitrite to potassium nitrite: multiply by 1.23
 - To convert sodium nitrate to potassium nitrate: multiply by 1.19
82. For example, the maximum amount of sodium nitrite which can be added to sterilised meat products is 100 mg/kg, which is equivalent to 123 mg/kg potassium nitrite. And the maximum amount of sodium nitrate which can be added to non-heat treated meat products is 150 mg/kg, which is equivalent to 178 mg/kg potassium nitrate.

Vegetable extract nitrites

83. The indirect addition of nitrates to foods via nitrate rich extracts of vegetables such as spinach or celery should be considered an additive use, and not a food use. In such cases the extract is being added for preservation as it contains a standardised level of nitrate and consequently such use would not be permitted by Regulation 1333/2008 as these extracts have not been approved as preservatives.

Appendix 4

Maximum usable doses for salt of aspartame-acesulfame

84. The salt of aspartame-acesulfame (E 962) is only permitted for use in food categories established for both of its constituent components; aspartame (E951) and acesulfame K (E950).
85. Maximum usable doses for the salt are expressed in annex II as either aspartame (E951) and acesulfame K (E950) as indicated in the footnote to the relevant entry. The maximum usable doses for both aspartame (E951) and acesulfame K (E950) are not to be exceeded by use of the salt of aspartame-acesulfame, either alone or in combination with E950 or E951.

Method of calculating permitted levels of salt of Aspartame-acesulfame

86. The maximum usable dose for the salt of aspartame-acesulfame in a particular food can be calculated by firstly multiplying the maximum usable dose (in the food concerned) expressed as either the acesulfame K or aspartame equivalent by the molecular weight of salt of aspartame-acesulfame. This figure should then be divided by the molecular weight of either the acesulfame K or aspartame as appropriate to obtain the final figure. Examples of this calculation are shown below.

Molecular weight of salt of aspartame-acesulfame = **457.46**

Molecular weight of acesulfame K = **201.24**

Molecular weight of aspartame = **294.31**

Examples

Acesulfame K

Category 14.1.4 “Flavoured drinks, energy-reduced or with no added sugar” – where the

maximum usable dose for the salt is expressed as for acesulfame K = **350 mg/l**

350 multiplied by **457.46** = **160111**

160111 divided by **201.24** = **795.62**

The equivalent permitted level of salt of aspartame-acesulfame is **796 mg/l**.

Aspartame

Category 15 “Ready to eat savouries and snacks” – where the maximum usable dose for the salt is expressed as aspartame = **500** mg/kg

500 multiplied by **457.46** = **228730**

228730 divided by **294.31** = **777.17**

The equivalent permitted level of salt of aspartame-acesulfame is **777** mg/kg

Interested parties list

Provision Trade Federation
Which?
Food Additives and Ingredients Association
British Essence Manufacturers Association
Biocatalysts Ltd
Campden BRI
Food and Drink Federation
International Sweeteners Association
British Hospitality Association
Chilled Food Association Ltd
Food and Drink Federation
British Retail Consortium
Food Additives and Ingredients Association
Berry Ottaway and Associates Limited
British Soft Drinks Association Ltd
Wine and Spirit Trade Association
Procter & Gamble UK and Ireland
British Meat Processors Association
Britvic plc