



Food Additives Legislation Guidance to Compliance

November 2013

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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 applied 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	October 2014
Sunset date	October 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 updated guide to compliance has been produced to provide advice on the legal requirements of Council Regulation (EC) No. 1333/2008 (“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/district council.

Review

2. It is planned to review this guide to compliance in October 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@foodstandards.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, which is available at the following website:

<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, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 (SI 2013 No. 2210 available from: www.legislation.gov.uk website).
6. Parallel measures exist in Scotland, Wales and Northern Ireland.
 - [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Wales\) Regulations 2013](#) (WSI 2013 No. 1591 (W255))
 - [The Food Additives, Flavourings, Enzymes and Extraction Solvents Regulations \(Northern Ireland\) 2013](#) (SR 2013 No.220)
 - [The Food Additives, Flavourings, Enzymes and Extraction Solvents \(Scotland\) Regulations 2013](#) (SSI 2013 No. 266)

General requirements of the legislation

7. 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 (EC) No. 1332/2008, food flavourings as covered by Regulation (EC) No.1334/2008 and nutrients;
 - c) rules on the labelling on food additives sold as such;
 - 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.

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.

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

8. 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”.
9. 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. There are a number of substances, such as calcium carbonate or sodium ascorbate, which are used both as food additives and in food supplements or fortified foods. The primary purpose for which these are used will determine the legislation that will apply.
10. Processing aids, including filtration aids and release agents, defined at Article 3.2 (b), are also excluded from the scope of Commission Regulation 1333/2008. In the UK, there is no national legislation on processing aids nor is there any legally defined list of approved processing aids either within the UK or within EU. “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.
11. Other substances falling outside the scope of the Regulation include extraction solvents falling within the scope of EC Directive 2009/32/EC, flavourings falling within the scope of Regulation (EC) No. 1334/2008, and food enzymes falling within the scope of Regulation 1333/2008. 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. The use of additives in wine must comply with Regulation 1333/2008 and with the provisions in the relevant EU legislation on oenological practices and processes.

12. Whether or not governed by specific regulations, the addition of any substance to food is subject to the provisions of Regulation (EC) No. 178/2002 (General Food Law) which prohibits the placing on the market of food that is unsafe, i.e. injurious to health, or unfit for human consumption.

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

13. 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 (EU) No's 1129/2011 and 1130/2011) 'as amended'.
14. 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 are also laid down for colours and sweeteners.
15. 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)

16. 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 requirements 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.
17. Conditions of use for food additives in foods, including restricted uses in specified foods and maximum limits, are set out in Annex II.
18. The maximum limits in the annexes are based on the food as sold unless otherwise specified. However, for dried and/or concentrated foods (including 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.
19. 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)

20. A food additive falling within the scope of Commission Regulation (EC) No. 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 Commission Regulation (EC) No. 1829/2003 and the emulsifier complies with the relevant EU specification.

21. 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. Decisions as to what constitutes a “significant change” are made on a case-by-case basis.

Carry-over rule (Article 18)

22. “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 (Article 18.1 (a) refers).
23. Recital 16 of Regulation 1333/2008 should be taken into account when considering applying the carry-over rule – this states that the level of the additive in the final food should be no greater than would be introduced by the use of the ingredient under proper technological conditions and good manufacturing practice, thus preventing misuse of carry-over. Examples of carry-over are given below:

a) A fruit yoghurt consisting of plain (unflavoured) yoghurt and a fruit preparation would be permitted to contain 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.

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

24. 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” (Article 18 (c) refers). Examples of reverse carry-over are:

- a) 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. The annatto would not be permitted to be added to a seasoning that was intended to be used in a food that is not permitted to contain annatto, such as a minced meat preparation.
- b) Sodium bicarbonate (E 500, a Group 1 additive not normally permitted to be used in self raising flour) could be added to self raising flour that is intended solely for use in bread or fine bakery wares, as Group 1 additives are permitted to be used in these foods.

- 25. 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 (see paragraphs 38-41 below), and has no technological function in the final food (Article 18.1(b) refers). When it has a technological function in the final food it must comply with the relevant provisions of use for that food (Article 18.3) refers.
- 26. Certain foods (listed in tables 1 and 2 of Annex II of Regulation 1333/2008) are not permitted to contain additives by way of carry-over. This includes unprocessed foods. However, if an unprocessed food e.g. a fresh fish fillet, is coated with a batter, the fish and the batter would be considered separate ingredients falling within different food categories. The batter would be permitted to contain all Group 1 additives, even though most Group 1 additives are not permitted in fresh fish.

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, if 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) present 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”.

Specific labelling requirements for six authorised food colours (Article 18)

29. Foods containing Tartrazine (E 102), Ponceau 4 R (E 124), Sunset yellow (E 110), Carmoisine (E 122), Quinoline yellow (E 104) and Allura Red (E 129) 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 FSA has produced guidance to assist them with this. This is published on the FSA’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). The new EU Food Information to Consumers Regulation (EU) No. 1169/2011 will apply in the main from 13 December 2014.

32. Guidance has also been drawn up which aims to assist businesses who want to remove these 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 describes the criteria that determine the difference between selective and non-selective extraction for the classification of food extracts/concentrates as food colours or colouring foods and proposes a decision tree and checklist to facilitate this classification. The guidance is aimed at industry and enforcement authorities/regulators and is expected to be available at the end of 2013 on the European Commission's food additives database which can be accessed at:

https://webgate.ec.europa.eu/sanco_foods/main/?sector=FAD

Annex II of Commission 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 (EC Directives 95/2/EC, 94/35/EC and 94/36/EC) and populating Annex II of Commission 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:

- a) Category 05 – confectionery
- b) Sub-category 05.1 – cocoa and chocolate products as covered by Directive 2000/36/EC
- c) Sub-category 05.2 – other confectionery including breath freshening micro sweets

d) 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 that 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 (EU) No. 1129/2011 entered into force on 2 December 2011 and applied 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 Appendix 2 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
- 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). The use of these additives in foods must comply with the provisions in Part E of Annex II.

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. There are 18 food categories, including category 0, which covers food additives (i.e. gases) that 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, it was decided to include 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. Some additives are approved for use across the broader food category whereas others are permitted in specific food products only e.g. Group 1 additives are permitted in all foods in category 8.2.1 (non-heat-treated-processed meat) whereas E 100 curcumin is permitted only in sausages and pasturmas.

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 (EU) No. 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 2.

Structure of Annex III

Part 1 - covers carriers used in other additives. Carriers are defined in Regulation 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.

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

40. Food additives must comply with the approved specifications set out in EC Regulation (EU) No. 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>

41. EC Regulation (EU) No. 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

42. 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, EC Regulation (EU) No. 1131/2011, which came into force on 2 December 2011, permits steviol glycosides to be used in certain specified foods at maximum specified levels.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0205:0211:EN:PDF>

43. EC Regulation (EU) No. 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>

44. EC Regulation (EU) No. 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 are now 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. EC 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 (EC 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>

45. 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 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

46. 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>

47. 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

48. 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

49. All currently permitted food additives are subject to a re-evaluation by EFSA in accordance with Regulation (EU) No. 257/2010 that sets out a programme for their re-evaluation in order of priority. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:080:0019:0027:EN:PDF>
50. 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 EC Commission Directives 95/2/EC, 94/35/EC and 94/36/EC

51. The provisions in Annex II reflect, in the main, those in the Annexes of EC Directives 95/2/EC, 94/35/EC and 94/36/EC. However, some unintended 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.
52. 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 EC 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.

53. 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.
54. The restrictions on the use and levels for aluminium-containing food additives referred to in paragraph 43 and set out in Regulation (EU) No. 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 with effect from 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.
55. 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 EC 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 18 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 EC Directive 94/36/EC, previously allowed in most processed foods, are only permitted to be used in the food categories specified.
56. 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.

Meat preparations

57. 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 (EC) No. 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 (EC) No. 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.
58. A number of additives that are not in conformity with the provisions of the old Directives nor with Annex II have been used in meat preparations in several Member States due to historical differences in interpretation of the legislation. There has therefore been a need to amend the legislation to permit certain current practices where appropriate. These amendments will permit a number of additional additives in specific meat preparations, will clarify the definitions within the legislation and will amend the carry-over rule to permit additives to be used in food ingredients used in unprocessed meat preparations, including the use of phosphates in the seasonings used with burgers.
59. In compound foods such as Cordon Bleu chicken, in which a fresh meat preparation is coated with cheese and breadcrumbs, the whole product should be considered a food consisting of several components i.e. a meat preparation which is not permitted to be coloured, cheese which can contain certain colours and a breadcrumb coating which can also contain colours. The note in EC Directive 94/36 which had clarified this principle will be re-instated in Table 2 of Annex II.
60. European Commission Guidance on Regulation (EC) No. 853/2004 includes guidance on the definitions of “meat preparations” and “meat products” (at Section 5.9) which can be used to determine which additives are permitted in individual products; please see link below:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/guidance_doc_853-2004_en.pdf

Food category descriptors

61. In order to ensure uniform interpretation of the food categories in Annex II of Regulation 1333/2008 the Commission has published descriptors. These should be used for informal interpretation of the legislation only. A copy of the Commission's draft document is available on request from: foodadditives@foodstandards.gsi.gov.uk
62. Stakeholders will be able to access the finalised document by the end of 2013 on the Commission's food additives database.
63. 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

64. 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 EC Directive 94/35/EC, Article 2 (1) to (6) and (8) to(10) of EC Directive 94/36/EC and Article 2 and 4 of EC 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

65. 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 EC Directive 95/2/EC. Preparations not complying with the requirements of Parts 1 or 4 or with Section B of Part 5 were permitted to continue to be marketed in accordance with the provisions of EC Directive 95/2/EC until 31 May 2013.

66. 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) No. 178/2002 (General Food Law). Preparations not complying with the requirements of Parts 2 or 3 or with Section A of Part 5 may continue to be marketed in accordance with national provisions where they exist until 2 December 2013.

Commission Regulation (EU) No. 380/2012

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

Appendix 3

Nitrites and nitrates in meat products

68. 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.
69. 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

70. The traditional meat products for which derogations have been agreed include categories for six traditional UK meat products. These are listed in italics, which indicate 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)
71. 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.
72. 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

73. 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”

74. 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.
75. 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

76. 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

77. 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 microorganisms 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

78. 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

79. 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.
80. 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.
81. 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).
82. 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'

83. 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

84. 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
85. 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. In addition, 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

86. 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

87. 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).
88. 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

89. 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 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**