Food Safety
AUTHORITY OF IRELAND

Guidance on Food Additives

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Summary

Food additives are substances added intentionally to foodstuffs to perform certain technological functions, for example to colour, to sweeten or to preserve.

Food additives are defined in European Union (Community) legislation as "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" (EC Regulation 1333/2008 Article 3).

The Community legislation on food additives is based on the principle that only those additives that are on the list of authorised food additives may be used. An important principle of the legislation is that the consumer should not be misled due to the use of additives in food. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product, including its fruit and vegetable content. Most food additives may only be used in limited quantities (the maximum permitted level (MPL)) in certain foodstuffs. If no quantitative limits or MPLs are foreseen for the use of a food additive, it should be used according to good manufacturing practice, i.e. only as much as necessary to achieve the desired technological effect. This is known as the *quantum satis* principle.

Food additives are divided into categories or functional classes according to their technological function, for example preservatives, anti-oxidants, sweeteners, colours, etc. Foodstuffs are also divided into categories, and specific conditions are laid down regarding which additives or groups of additives may be used in the different food categories. The use of food additives is generally not permitted in certain food categories, e.g. unprocessed foods and foods for infants and young children, including dietary foods for infants and young children for special medical purposes except where specifically provided for in the legislation.

A food additive may only be authorised if:

- Its safety has been evaluated on the basis of the available scientific evidence
- On the basis of this evaluation, it is considered to present no hazard to the health of the consumer at the level of use proposed
- There is a technological need for its use that cannot be achieved by other economically and technologically practicable means
- Its use does not mislead the consumer

Prior to their authorisation, food additives are evaluated for their safety by the European Food Safety Authority (EFSA), the expert risk assessment body that advises the European Commission on questions relating to food safety. Prior to the establishment of EFSA in 2002, this function was carried out by the Scientific Committee on Food (SCF). If the additive is deemed to be safe by EFSA, including (usually) the establishment of an Acceptable Daily Intake (ADI)[1], the Commission will then initiate the process to amend the legislation to add the substance to the list of authorised food additives via a Commission Regulation. In addition to inclusion of the substance on the list, specific conditions are normally laid down under which the additive may be used, in particular the types of food it can be used in and the maximum level of use. Once authorised at EU level, a food additive or foods containing it can be placed on the market in all Member States, as well as Norway and Iceland.

[1] The ADI is defined as *"an estimate of the amount of food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk."*

The Community legislation on food additives comprises Regulation (EC) No 1333/2008 together with a Regulation (Regulation 1331/2008), providing a common authorisation procedure for food additives, flavourings and food enzymes. Regulation (EC) No 1333/2008 together with the parallel Regulations on food enzymes (Regulation 1332/2008), and on flavourings and certain food ingredients with flavouring properties for use in and on foods (Regulation 1334/2008) are collectively known as the Food Improvement Agents Package (FIAP). Regulation 1333/2008 provides for:

(a) A Community list of approved food additives in food and conditions for their use

(b) A Community list of food additives in food additives, food enzymes, food flavourings and nutrients and their conditions of use

(c) Rules on the labelling of food additives sold as such and for foods containing additives

This legislation on food additives replaces the previous Directives 89/107/EEC (the Framework Directive) and Directives 94/35/EC on sweeteners, 94/36/EC on colours and 95/2/EC on food additives other than colours and sweeteners.

Furthermore, all authorised food additives have to fulfil purity criteria which are set out in detail in three Commission Directives:

- Commission Directive 2008/60/EC for sweeteners as amended by Directive 2010/37/EC
- Commission Directive 2008/128/EC for colours
- Commission Directive 2008/84/EC as amended by Commission Directive 2009/10/EC for additives other than colours and sweeteners

The use of food additives must always be labelled on the packaging of food products by their functional class (anti-oxidant, preservative, colour, etc) with either their name or E number. Detailed rules on labelling of additives in foodstuffs, and on additives sold as such to food producers and consumers are laid down in Community legislation (Directive 2000/13/EC and Regulation 1333/2008). Also, where relevant, they must comply with Regulation 1829/2003 and Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food products produced from genetically modified organisms.

Community legislation also requires that Member States monitor food additive intake and usage. The Irish Universities Nutrition Alliance (IUNA) research group in conjunction with the Food Safety Authority of Ireland (FSAI) has produced data on food additive usage and food additive intake to fulfil Ireland's legal obligations in this respect. The use and intake of food additives in the Irish food supply has been monitored using the Irish National Food Ingredient Database (INFID) and the food consumption databases established for the 18-64 year old adult population in the Republic of Ireland and Northern Ireland (the North South Food Consumption Survey (NSFCS), 1997-1999), for children aged between 5-12 years (the National Children's Food Survey (NCFS) 2003-2004) and for teenagers aged between 13-17 years (the National Teen Food Survey (NTFS) 2005-2006). Information is provided in this guidance on (a) food additive usage in foods on the Irish market, (b) the outcome of a recent survey by IUNA on the intake by Irish children and teenagers of certain food colours reported by McCann *et al.*, 2007 (the so-called Southampton study) to be associated with hyperactivity, (c) an analysis of the intake of nitrites by the Irish population.

Introduction

Food additives have been regulated in the European Union for many years under the Framework Directive 89/107/EEC and by Directives 94/35/EC on sweeteners, 94/36/EC on colours and 95/2/EC on food additives other than colours and sweeteners. The EC legislation on food additives was updated in 2008, together with that on flavouring substances. At the same time, new legislative requirements were introduced for enzymes for use in food.

This created a comprehensive legislative package, comprising three individual Regulations on food enzymes (Regulation 1332/2008), food additives (Regulation 1333/2008), and on flavourings and certain food ingredients with flavouring properties for use in and on foods (Regulation 1334/2008). The legislative package also includes a Regulation (Regulation 1331/2008), providing a common authorisation procedure for food additives, flavourings and food enzymes. This legislative package is known as the FIAP. This comprehensive legal structure guarantees the free movement of foodstuffs, ensures a high level of consumer protection and offers the consumer greater freedom of choice between different foodstuffs. The new legislation on food additives replaces and revokes Directives 89/107/EEC, 94/35/EC, 94/36/EC and 95/2/EC. However, the lists of authorised food additives, along with their permitted uses and maximum levels of use, established by the latter Directives plus certain provisions of the legislation remain in force as a transitional measure until such time as new Community lists on food additives are established under Regulation 1333/2008.

In 2001, the FSAI, with the support of its Food Additives, Chemical Contaminants and Residues Sub-committee, published guidance on the legislation, intake and usage of food additives in Ireland, reflecting the requirements of the (EC) legislation in place at that time (FSAI, 2001). This revised guidance has been produced by the FSAI, again with the support of its Food Additives, Chemical Contaminants and Residues Sub-committee, to provide updated information on food additives.

This guidance is aimed at the food industry and at food law enforcement officers. It seeks to clarify issues surrounding food additives including their function, their use, possible implications for health and the legislation by which they are regulated. The guidance covers only the legislation on food additives, together with information on their use in food, their intake by the Irish population and other relevant information. Separate guidance will be published by the FSAI on food enzymes and on flavourings and food ingredients with flavouring properties for use in and on foods.

Chapter 1. Food Additives, Functional Classes, Lists of Authorised Food Additives and the Food Categories to Which They May be Added

1.1 Definition of a Food Additive

Food additives are natural or manufactured substances, added to foods for a variety of reasons - to restore colours lost during processing (i.e. colours), to provide sweetness in low-sugar products (i.e. sweeteners), to prevent deterioration during storage and to guard against food poisoning (i.e. preservatives). A food additive is defined legally in Article 3 of Regulation 1333/2008 (and prior to that in Directive 89/107/EEC) as *"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".*

Whether the additive comes from a natural source or is man-made, the question of safety is central to the decision as to whether or not an additive should be permitted in food. All additives must be authorised at a European level before they can be used in food, a process which involves an assessment of their possible risks to health by EFSA or (in former years) by the EU SCF (see Chapter 3). The risk assessment stage is followed by addition of the additive to the lists of permitted food additives as described in Chapter 3.

Regulation 1333/2008 (Article 3) lists a number of substances that are considered not to be food additives and are not therefore covered by the legislation on food additives; these are as follows:

(i) Monosaccharides, disaccharides or oligosaccharides and foods containing these substances used for their sweetening properties

(ii) Foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect

(iii) Substances used in covering or coating materials, which do not form part of foods and are not intended to be consumed together with those foods

(iv) Products containing pectin and derived from dried apple pomace or peel of citrus fruits or quinces, or from a mixture of them, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts (liquid pectin)

(v) Chewing gum bases

(vi) White or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolitic enzymes

(vii) Ammonium chloride

(viii) Blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten

(ix) Amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts having no technological function

(x) Caseinates and casein

(xi) Inulin

Other substances often thought of as additives also fall outside the scope of the legislation, as they are regulated separately, including: flavourings falling within the scope of Regulation 1334/2008, food enzymes[2] falling within the scope of Regulation 1332/2008, substances added to foodstuffs as nutrients, e.g. minerals, trace elements or vitamins, substances used for the protection of plants and plant products in conformity with European Community rules relating to plant health, e.g. pesticides, herbicides, and substances used for the treatment of water for human consumption falling within the scope of Directive 98/83/EC on the quality of water intended for human consumption.

[2] This exclusion only applies from the date of adoption of the Community list of food enzymes under Regulation 1332/2008; until that time food enzymes will be covered by Regulation 1333/2008.

Processing aids are also not considered as food additives and therefore, are not subject to the requirements of the legislation, although the differentiation of a processing aid from a food additive can be difficult. The definition of a processing aid in Regulation 1333/2008 is *"any substance which is not consumed as a food ingredient by itself, which is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that they do not present any health risk and do not have any technological effect on the finished product".*

1.2 Functional Classes of Food Additives

Additives are placed in different categories dependent on the technological function that the particular additive is intended to have in the food to which it is added. These additive categories (functional classes) are listed in Table 1.1.

Table 1.1. Functional classes of food additives

Acid	Emulsifying salt	Preservative
Acidity regulator	Firming agent	Propellant
Anti-caking agent	Flavour enhancer	Packaging gas
Anti-foaming agent	Flour treatment agent	Raising agent
Anti-oxidant	Foaming agent	Sequestrant
Bulking agent	Gelling agent	Stabiliser
Carrier	Glazing agent	Sweetener
Colour	Humectant	Thickener
Emulsifier	Modified starch	

These functional classes are further defined as follows:

1. **Sweeteners** are substances used to impart a sweet taste to foods or in table-top sweeteners
2. **Colours** are substances which add or restore colour in a food, and include natural constituents of foods and natural sources which are normally not consumed as foods as such and not normally used as characteristic ingredients of food. Preparations obtained from foods and other edible natural source materials obtained by physical and/or chemical extraction resulting in a selective extraction of the pigments relative to the nutritive or aromatic constituents are colours within the meaning of Regulation 1333/2008 on food additives
3. **Preservatives** are substances which prolong the shelf-life of foods by protecting them against deterioration caused by micro-organisms and/or which protect against growth of pathogenic micro-organisms
4. **Antioxidants** are substances which prolong the shelf-life of foods by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes
5. **Carriers** are substances 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)
6. **Acids** are substances which increase the acidity of a foodstuff and/or impart a sour taste to it
7. **Acidity regulators** are substances which alter or control the acidity or alkalinity of a foodstuff
8. **Anti-caking agents** are substances which reduce the tendency of individual particles of a foodstuff to adhere to one another

9. **Anti-foaming agents** are substances which prevent or reduce foaming
10. **Bulking agents** are substances which contribute to the volume of a foodstuff without contributing significantly to its available energy value
11. **Emulsifiers** are substances which make it possible to form or maintain a homogenous mixture of two or more immiscible phases such as oil and water in a foodstuff
12. **Emulsifying salts** are substances which convert proteins contained in cheese into a dispersed form and thereby bring about homogenous distribution of fat and other components
13. **Firming agents** are substances which make or keep tissues of fruit or vegetables firm or crisp, or interact with gelling agents to produce or strengthen a gel
14. **Flavour enhancers** are substances which enhance the existing taste and/or odour of a foodstuff
15. **Foaming agents** are substances which make it possible to form a homogenous dispersion of a gaseous phase in a liquid or solid foodstuff
16. **Gelling agents** are substances which give a foodstuff texture through the formation of a gel
17. **Glazing agents** (including lubricants) are substances which, when applied to the external surface of a foodstuff, impart a shiny appearance or provide a protective coating
18. **Humectants** are substances which prevent foodstuffs from drying out by counteracting the effect of an atmosphere having a low degree of humidity, or promote the dissolution of a powder in an aqueous medium
19. **Modified starches** are substances obtained by one or more chemical treatments of edible starches, which may have undergone a physical or enzymatic treatment, and may be acid or alkali thinned or bleached
20. **Packaging gases** are gases other than air, introduced into a container before, during or after the placing of a foodstuff in that container
21. **Propellants** are gases other than air which expel a foodstuff from a container
22. **Raising agents** are substances or combinations of substances which liberate gas and thereby increase the volume of a dough or a batter
23. **Sequestrants** are substances which form chemical complexes with metallic ions
24. **Stabilisers** are substances which make it possible to maintain the physico-chemical state of a foodstuff. Stabilisers include substances which enable the maintenance of a homogenous dispersion of two or more immiscible substances in a foodstuff, substances which stabilise, retain or intensify an existing colour of a foodstuff and substances which increase the binding capacity of the food, including the formation of cross-links between proteins enabling the binding of food pieces into re-constituted food
25. **Thickeners** are substances which increase the viscosity of a foodstuff
26. **Flour treatment agents** are substances, other than emulsifiers, which are added to flour or dough to improve its baking quality

The allocation of a food additive to a particular functional class does not preclude it from being used for other functions.

1.3 Lists of Authorised Food Additives

The list of currently authorised food additives in the European Union is provided as Appendix 1 to this guidance. The list is presented in order of E number, the E number being the reference number assigned to the additive on its addition to the list. In recent years, the descriptor E number has received some adverse publicity, reflecting concern among consumers regarding the presence of certain food additives in food. In fact, the assignation of an E number to a food additive means that its safety has been assessed and it has been authorised for use throughout the European Union. The presence of an E number should therefore be regarded in a positive, rather than in a negative light.

The current lists of food additives have been compiled over many years. The safety of each food additive has been evaluated by the SCF and latterly by EFSA, followed by the legal process of addition to the list of authorised food additives. As described in more detail in Chapter 3, any new additive which requires approval must go through a lengthy evaluation procedure before addition to the relevant list. Currently, the lists of authorised additives are to be found in the three separate Directives on sweeteners (94/35/EC), colours (94/36/EC) and miscellaneous additives (95/2/EC). Directive 94/35/EC regulates the use and sale of sweeteners, as defined in Article 1 to the Directive. All authorised sweeteners are listed in the Annex to the Directive and may only be used under the conditions specified in that Annex. Directive 94/36/EC on colours for use in foodstuffs regulates the use of colours in or on food and the sale of colours and food containing colours. Permitted colours are listed in Annex 1 of the Directive and their specific use in Annexes II – V. Directive 95/2/EC regulates all food additives other than colours and sweeteners. A list of authorised food additives is set out in the different Annexes to the Directive with a list of the foodstuffs in which they may be used and the conditions of use.

As already indicated, and as described further in Chapter 2, the legislation on food additives was revised in 2008. Regulation 1331/2008 provides for the establishment of Community lists of substances (one each for additives, flavourings and enzymes) that have been authorised to be placed on the Community market (Article 2 of 1331/2008). All the authorised additives listed in Directives 94/35/EC, 94/36/EC and 95/2/EC will be transferred to Annex II of Regulation 1333/2008 on food additives, following a review by the Member States and the Commission of their compliance with Articles 6, 7 and 8 of the Regulation (covering "General conditions for inclusion and use of food additives in Community lists" together with specific conditions for sweeteners and colours). Annex II of Regulation 1333/2008 currently is empty (does not contain any lists of additives). This review will not include a new risk assessment by EFSA but food additives and their uses which are no longer needed will not be entered into Annex II. The review is still ongoing, although the target date for its completion is the end of 2010. Until such time, the lists provided in Directives 94/35/EC, 94/36/EC and 95/2/EC still constitute the official list of authorised food additives within the European Union. The full list of all authorised additives, whether a sweetener, a colour or a miscellaneous additive, is provided in Appendix 1 for the convenience of the reader, in order of E number.

Regulation 1333/2008 also provides for the establishment of a Community list for approved food additives and their conditions of use in food additives, in food enzymes as covered by Regulation 1332/2008, in food flavourings as covered by Regulation 1334/2008 and nutrients or categories thereof to which they may be added. This list will be entered into Annex III of Regulation 1333/2008/EC, which currently is also empty (does not contain any additives).

Like Annex II to the Regulation, Annex III will be subdivided into a number of parts. Food additives currently authorised as carriers in other food additives in accordance with Directive 95/2/EC and their conditions of use, will be entered into part I of Annex III following a review of their compliance with article 6 of Regulation 1333/2008. Part II of Annex III will comprise a list of food additives other than carriers for use in food additives themselves. Part III will comprise a list of additives and carriers in food enzymes and part IV will comprise a list of authorised additives in food flavourings and their conditions of use. Finally, food additives listed in Annex VI of Directive 95/2/EC on food additives other than colours and sweeteners (food additives permitted for infants and young children) having a function as a food additive in nutrients, have been transferred to Part 5 of Annex III with the same conditions of use.

1.4 EU Food Categories to Which Authorised Food Additives May be Added

In addition to inclusion of a food additive in the lists of authorised food additives, as described in Section 1.3, conditions[3] are normally laid down under which the additive may be used, in particular the types of food it can be used in and the MPL[4]. Currently, these conditions of use are laid down in the Annexes of the three separate Directives on sweeteners (94/35/EC), colours (94/36/EC) and miscellaneous additives (95/2/EC). The European Commission is currently developing a proposal for the establishment of various categories into which the currently authorised food additives, together with their conditions of use, will be placed, the food categorisation system (FCS). When this is agreed (the projected timescale is the end of 2010), the relevant Annexes and corresponding articles in Directives 94/35/EC, 94/36/EC and 95/2/EC will be repealed, as already indicated in Section 1.3.

The categorisation system is based on the established Codex Alimentarius General Standards on Food Additives (GSFA). However, certain amendments were needed to take into account the specificity of the food additive authorisations currently in force within the EU. The categories are created with the sole purpose of listing the authorised additives and their conditions of use. The purpose of the exercise is to minimise the number of categories where possible and to keep the system simple. The food additives will be listed in groups for authorisation in certain foodstuffs. The FCS currently contains seventeen food categories which are further subdivided into one hundred and fifty three subcategories. Currently, authorised additives, which are listed in the Annexes to Directives 94/35/EC, 94/36/EC and 95/2/EC, along with their conditions of use, have been placed into these food categories and sub-categories. The number of additives which may be permitted in the various food categories varies widely, e.g. zero additives permitted in Category 11.3: honey, whilst there are more than 250 additives listed under Category 3: edible ices.

It is envisaged that the FCS will be divided into four parts. The first part will introduce the general provisions concerning the authorisation of food additives and will also include a list of foodstuffs in which no additives may be permitted. Part II will consist of the list of all permitted food additives and these will be listed in accordance with their main functional class. Part III will list all of the additives which may be authorised in groups, whilst part IV will detail the authorised food additives and their conditions of use in the seventeen food categories and one hundred and fifty three subcategories.

Appendix 2 to this guidance lists the food categories to which the authorised food additives may be added, under specific conditions. The conditions of use of the additives have not been included in this Appendix, due to space constraints, and readers are referred to Annex II of Regulation 1333/2008, when adopted, for guidance on this aspect. Until such time as the Annexes II and III of Regulation 1333/2008 are adopted, the conditions of use of the currently authorised food additives are laid down in the Annexes of the three separate Directives on sweeteners (94/35/EC), colours (94/36/EC) and miscellaneous additives (95/2/EC).

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[3] Each authorised food additive is approved on the basis of specific conditions under which the additive may be used, in particular the types of food it can be used in and the maximum permitted level of use, although certain food additives presenting little or no safety concern may used according to the quantum satis principle (i.e. at the amount which is needed) in all foodstuffs.

[4] The MPL is the maximum permitted level of use for a particular additive in a specified foodstuff, as laid down in the legislation

Chapter 2. Food Additive Legislation

2.1 Food Additive Legislation

In the past, differences between national laws relating to food additives and the conditions for their use caused barriers to trade between EU Member States. A true single market for food products could not exist without harmonised rules for the authorisation of food additives and for the conditions for their use. In 1989, the European Community adopted a Framework Directive (89/107/EEC) which set out the criteria by which additives would be assessed and provided for the adoption of three specific technical directives establishing the list of additives which could be used (to the exclusion of all others), the foods in which they could be used and any MPLs. The purity required for these additives is laid down in Directives defining specific purity criteria.

As already indicated, the EC legislation on food additives has recently been updated. The legislative package which replaces the existing directives was published at the end of 2008, and comprises three individual Regulations on food additives, flavourings and food enzymes, and also a Regulation providing a common authorisation procedure for all three types of food additives, as shown in Table 2.1. The Regulations on food additives and food enzymes applied in general from 20th January, 2010, while the Regulation on flavourings will apply from 20th January, 2011. However, the specific obligations under the new legislation are complex in relation to their date of application and are dependent on completion of work to revise and update the Annexes to the existing legislation (see also Section 2.4).

Table 2.1. Legislation on food additives, flavourings and food enzymes, and on the common authorisation procedure

Regulation No. and Title	URL
1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0001:0006:EN:PDF
1332/2008 on food enzymes	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0007:0015:EN:PDF
1333/2008 on food additives	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:EN:PDF
1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0034:0050:EN:PDF

Regulation 1331/2008 provides a common procedure for the assessment and authorisation of food additives, food enzymes and food flavourings. It provides the basis for the Community lists and a mechanism for updating these lists. The main stages of the procedure are laid down in the Regulation, including application for updating the lists, the role of EFSA and the various deadlines in the process. This process is discussed further in Chapter 3.

The core principles and provisions of the existing legislation on food additives are maintained in the new legislation. In addition, new aspects include:

(a) The possibility to update the existing Community list of authorised food additives through the comitology with scrutiny procedure[5] laid down in Council Decision 1999/468/EC, following a proposal from the Commission to the Standing Committee on the Food Chain and Animal Health

(b) A core role for EFSA in risk assessment related to food additives, flavourings and food enzymes

(c) Special labelling provisions for six food colours E110, E104, E122, E129, E102 and E124 (Tartrazine, Quinoline Yellow, Sunset Yellow FCF, Ponceau 4R, Allura Red AC and Azorubine (Carmoisine)) requiring use of the phrase "may have an adverse affect on activity and attention in children" on the label. See also Chapter 4.

[5] The scrutiny procedure refers to the process by which the European Parliament may oppose legislative proposals from the Commission that would normally be adopted by the comitology procedure (voted on by representatives of Member States). This procedure was introduced by Article 5a of Council Decision 2006/512/EC of July 17th 2006 "the European Parliament, acting by a majority of its component members, or the Council, acting by a qualified majority, may oppose the adoption of the said draft by the Commission, justifying their opposition by indicating that the draft measures proposed by the Commission exceed the implementing powers provided for in the basic instrument or that the draft is not compatible with the aim or the content of the basic instrument or does not respect the principles of subsidiarity or proportionality"

2.2 General Requirements of the Legislation

Regulation 1333/2008 lays down rules on additives used in foods with a view to ensuring the effective functioning of the internal market whilst ensuring a high level of protection of human health and a high level of consumer protection, including the protection of consumer interests and fair practices in food trade, taking into account, where appropriate, the protection of the environment.

The Regulation provides for:

(a) Community lists of approved food additives, as already mentioned in Section 1.3 above (these will be set out in Annexes II and III of the Regulation following a review which is due to be completed by 20th January, 2011. In the meantime, the Annexes to the previous Directives apply)

(b) Conditions of use of food additives in foods, including in food additives and in food enzymes as covered by Regulation 1332/2008 (food enzymes), and in food flavourings as covered by Regulation 1334/2008 (flavourings and certain food ingredients with flavouring properties for use in and on foods)

(c) Rules on the labelling of food additives sold as such

(d) Specific rules on the 'carry-over' principle

Existing food additives including colours and sweeteners currently authorised via Directives 94/35/EC, 94/36/EC and 95/2/EC will be contained in Annex II of Reg. No. 1333/2008 on Food Additives. A programme of re-evaluation by EFSA of food additives authorised before the Regulations came into force has been put in place, with an initial emphasis on food colours and sweeteners (see also Chapter 3, Section 3.4,). Additives will only be re-authorised if they present no safety concerns and the consumer is not misled by their use. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product, including its fruit and vegetable content. Additives must also have a technological benefit such as preserving the nutritional quality of the food, enhancing its keeping quality or stability, aiding the manufacture and processing of the product or in its transport or storage. The approval of food additives will also take into account other factors including societal, economic, traditional, ethical and environmental factors, the precautionary principle and the feasibility of controls.

Similarly, positive lists of flavouring substances and food enzymes will be put in place under their respective Regulations. Since the Regulation on food enzymes is a new provision, EFSA is currently developing guidance for potential applicants on the information that should be provided in the technical dossiers to be submitted, and also the criteria to be applied in the EFSA risk assessment. As with food additives, in order to be authorised, food enzymes must not pose a safety concern and there must be a clear technological need for their use, which should not mislead the consumer with regard to the nature, freshness and quality of the food in which the enzyme is used. Enzymes used as processing aids will need to be authorised under Regulation 1332/2008, although they will not need to be labelled on the final product. Enzymes used in the manufacture of additives or processing aids are outside the scope of the legislation, as are processing aids generally.

Regulation 1333/2008 prohibits the placing on the market of a food additive or any food in which such a food additive is present if the use of the food additive does not comply with the requirements set out in the Regulation. Only food additives included in the European Community list in Annex II to the Regulation may be placed on the market as such and used in foods under the conditions of use specified therein. In addition, only food additives included in the Community list in Annex III to the Regulation may be used in food additives, food enzymes, food flavourings and nutrients under the conditions of use specified therein.

A food additive which falls within the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed should be authorised in accordance with that Regulation as well as under Regulation 1333/2008. This means that if the food additive is a genetically modified organism (GMO) or a genetically modified micro-organism (GMM) or is produced by a process which may result in the presence of residues of genetic material from the GMO or GMM in the additive, it must first go through the safety evaluation and authorisation system for GMOs/GMMs (a similar system to that for food additives as described in Chapter 3 of this guidance), before going through the authorisation system for additives.

2.3 'Carry-over' Principle

The presence of a food additive is permitted in the following situations which are covered by the 'carry-over' principle:

(a) In a compound food other than as referred to in Annex II, where the food additive is permitted in one of the ingredients of the compound food

(b) In a food to which a food additive, food enzyme or food flavouring has been added, where the food additive:

  (i) Is permitted in the food additive, food enzyme or food flavouring in accordance with Regulation1333/2008

  (ii) Has been carried over to the food via the food additive, food enzyme or food flavouring

  (iii) Has no technological function in the final food

(c) In a food which is to be used solely in the preparation of a compound food and provided that the compound food complies with Regulation 1333/2008. This latter condition of use is commonly referred to as 'reverse carry-over'

The 'carry-over' principle does not apply to infant formulae, follow-on formulae, processed cereal-based foods, baby foods and dietary foods for special medical purposes intended for infants and young children as referred to the specific legislation referring to these foodstuffs, except where specifically provided for in Regulation 1333/2008 (see also Section 2.4).

Substances not consumed as foodstuffs themselves but used intentionally in the processing of foods, which only remain as residues in the final food and do not have a technological effect in the final product are called processing aids. These substances are not covered by Regulation 1333/2008.

2.4 Use of Food Additives in Certain Foodstuffs

Food additives must not be used in a number of foodstuffs including unprocessed foods[6], and foods for infants and young children as referred to in Directive 2009/39/EC on foodstuffs intended for particular nutritional uses, including dietary foods for infants and young children for special medical purposes, except where specifically provided for in Annex II to Regulation 1333/2008. Table 2.2 lists the full range of foodstuffs for which no additives may be added except when specifically provided for in Annex II to Regulation 1333/2008/EC. There are also a number of food categories for which the use of colours is not permitted unless specifically provided for and these are presented in Table 2.3.

[6] Unprocessed food mean a food which has not undergone any treatment resulting in a substantial change in the original state of the food, for which purpose the following in particular are not regarded as resulting in substantial change: dividing, parting, severing, boning, mincing, skinning, paring, peeling, grinding, cutting, cleaning, trimming, deep freezing, freezing, chilling, milling, husking, packing or unpacking.

Table 2.2. Foodstuffs to which no additives may be added except where specifically provided for in Annex II to Regulation 1333/2008

1	Unprocessed foodstuffs as defined in Article 3 of Regulation 1333/2008
2	Honey as defined in Directive 2001/110/EC
3	Non-emulsified oils and fats of animal or vegetable origin
4	Butter
5	Pasteurised and sterilised (including UHT) milk (including plain, skimmed and semi-skimmed) and plain pasteurised cream
6	Unflavoured, live fermented milk products
7	Natural mineral water as defined in Directive 2009/54/EC and spring water and all other bottled or packed waters
8	Coffee (excluding flavoured instant coffee) and coffee extracts
9	Unflavoured leaf tea
10	Sugars as defined in Directive 2001/111/EC
11	Dry pasta, excluding gluten-free and/or pasta intended for hypoproteic diets, in accordance with Directive 2009/39/EC
12	Plain unflavoured buttermilk (excluding sterilised buttermilk)

Table 2.3. Foodstuffs to which no food colours may be added except where specifically provided for in Annex II to Regulation 1333/2008

1	Unprocessed foodstuffs as defined in Article 3 of Regulation 1333/2008
2	All bottled or packed waters
3	Milk, semi-skimmed and skimmed milk, pasteurised or sterilised (including UHT sterilisation) (unflavoured)
4	Chocolate milk
5	Fermented milk (unflavoured)
6	Preserved milks as mentioned in Directive 2001/114/EC (unflavoured)
7	Butter-milk (unflavoured)
8	Cream and cream powder (unflavoured)
9	Oils and fats of animal or vegetable origin
10	Eggs and egg products as defined in Regulation (EC) 853/2004
11	Flour and other milled products and starches
12	Bread and similar products
13	Pasta and gnocchi
14	Sugar as defined in Directive 2001/111/EC
15	Tomato paste and canned and bottled tomatoes
16	Tomato-based sauces
17	Fruit juice and fruit nectar as mentioned in Directive 2001/112/EC and vegetable juice and vegetable nectars
18	Fruit, vegetables (including potatoes) and mushrooms — canned, bottled or dried; processed fruit, vegetables (including potatoes) and mushrooms
19	Extra jam, extra jelly, and chestnut purée as mentioned in Directive 2001/113/EC; crème de pruneaux
20	Fish, molluscs and crustaceans, meat, poultry and game as well as their preparations, but not including prepared meals containing these ingredients
21	Cocoa products and chocolate components in chocolate products as mentioned in Directive 2000/36/EC
22	Roasted coffee, tea, chicory; tea and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products
23	Salt, salt substitutes, spices and mixtures of spices

24	Wine and other products defined by Regulation (EEC) No 1234/2007
25	Korn, Kornbrand, fruit spirit drinks, fruit spirits, Ouzo, Grappa, Tsikoudia from Crete, Tsipouro from Macedonia, Tsipouro from Thessaly, Tsipouro from Tyrnavos, Eau de vie de marc Marque nationale luxembourgeoise, Eau de vie de seigle Marque nationale luxembourgeoise, London gin, as defined in Regulation (EC) 110/2008
26	Sambuca, Maraschino and Mistra as defined in Regulation (EEC) No 110/2008
27	Sangria, Clarea and Zurra as mentioned in Regulation (EEC) No 1601/91
28	Wine vinegar
29	Foods for infants and young children as mentioned in Directive 2009/39/EC including foods for special medical purposes for infants and young children
30	Honey as defined in Directive 2001/110/EC
31	Malt and malt products
32	Ripened and unripened cheese (unflavoured)
33	Butter from sheep and goats' milk
34	Flavourings, enzymes, additives, nutrients and other substances added for nutritional and/or for other physiological purposes

2.5 Use of Colours for Markings

Only food colours listed in Annex II to Regulation 1333/2008 may be used for the purpose of health marking of fresh meat and other markings required on meat products, as provided for in Council Directive 91/497/EEC (this Directive amends and consolidates Directive 64/433/EEC on health problems affecting intra-Community trade in fresh meat). Similarly, the decorative colouring of eggshells and the stamping of eggshells as provided for in Regulation (EC) No 853/2004, laying down specific hygiene rules for food of animal origin, may only be carried out using these approved food colours.

2.6 Dates of Application of the Provisions of Regulation 1333/2008

Although the Regulations on food additives and food enzymes applied generally from 20th January, 2010, while those of the Regulation on flavourings apply from 20th January, 2011, the specific obligations under the new legislation are complex in relation to their date of application, and the reader is referred to the individual Regulations and/or to the FSAI for further information. The requirement that only authorised food enzymes or flavourings may be used in the manufacture or preparation of foodstuffs will apply from the date of application of the positive list (in the case of food enzymes), and 18 months following the date of application of the positive list (in the case of food flavourings). The positive list of food additives and their permitted uses which currently exist under Directives 94/35/EC on sweeteners, 94/36/EC on colours and 95/2/EC on food additives other than colours and sweeteners will continue to apply until such time as a new list is created under Annex II of Reg. No. 1333/2008.

However, it should be noted that in relation to the warning label required on foodstuffs containing six specific food colours, Sunset Yellow (E 110), Quinoline Yellow (E 104), Carmoisine (E 122), Allura Red (E 129), Tartrazine (E 102) or Ponceau 4R (E 124), pre-packaged foods and drinks containing these colours have had to carry the warning since 20th July, 2010. Any food placed on the market, or labelled before this deadline are allowed to stay on the shelf until the food's date of minimum durability or 'use-by' date. These colours were the subject of the so-called Southampton study (McCann *et al*. 2007), which is discussed further in Chapter 6 of this guidance.

2.5 National Legislation

All legislation agreed in Brussels by the Member States of the European Union has to be transferred into Irish law. Even though an EC Regulation is binding on a Member State it is the transposition into national law that identifies who is responsible for enforcing the legislation and creates the penalties for non-compliance with the regulations. In Ireland, the following Statutory Instruments (S.I.) implement European additives legislation in Irish national law.

European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations, 2000 (S.I. No. 437 of 2000), as amended by:

- European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations, 2001 (S.I. No. 342 of 2001)
- European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations, 2002 (S.I. No. 344 of 2002)
- European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment No.3) Regulations, 2002 (S.I. No. 380 of 2002)
- European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations, 2005 (S.I. No. 61 of 2005)
- European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) (No.2) Regulations, 2005 (S.I. No. 192 of 2005)
- European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) (No.3) Regulations, 2005 (S.I. No. 193 of 2005)
- European Communities (Additives, Colours and Sweeteners in Foodstuffs) (Amendment) Regulations, 2008 (S.I. No.34 of 2008)

Note: The above Irish legislation which remains on the Irish Statute Book transposes the previous legislation which was repealed by Regulation 1333/2008. However, the Annexes will continue to apply until at least January, 2011 and the Department of Health and Children is working on the transposition of this Regulation.

2.6 Purity Criteria

Food additives must comply with the approved specifications, which include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity. The following legislation contains the specifications for the currently approved additives.

2.6.1 Food additives other than colours and sweeteners

EU Legislation

Commission Directive 2008/84/EC (OJ L253, p1, 20/09/2008) of 27 August 2008 laying down specific purity criteria on food additives other than colours and sweeteners, as amended by Commission Directive 2009/10/EC (OJ L44, p62, 14/02/2009) of 13 February 2009

National Legislation

European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) Regulations, 2009 (S.I. No. 277 of 2009)

2.6.2 Colours

Commission Directive 2008/128/EC (OJ L6, p20, 10/01/2009) of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs

2.6.3 Sweeteners

Commission Directive 2008/60/EC of 17 June 2008 laying down specific criteria of purity concerning sweeteners for use in foodstuffs, as amended by Commission Directive 2010/37/EC (OJ L152, 18.6.2010 page 12) of 17 June, 2010

It should be noted however, that the specifications included in the Directives mentioned above, which are codified versions of the previous Directives on specifications, will apply until such time as the additives are transferred into the Annexes II and III to Regulation 1333/2008. At that stage, a new Regulation on specifications will be adopted, containing the purity criteria for all of the additives.

Chapter 3. Food Additive Safety Evaluation

3.1 General Approach to Evaluation of Food Additives

All food additives undergo an exhaustive safety assessment before their inclusion in the list of authorised additives that may be used in the manufacture or preparation of foodstuffs in the European Union. Up to 2002, this safety assessment (also called a risk assessment) was carried out by the EU SCF, a body of independent scientists with expertise in toxicology, food chemistry and exposure assessment. Since 2003, the responsibilities of the SCF have been taken over by EFSA.

The safety evaluation involves examination of the chemical structure and chemical characteristics of the additive, including its specifications, its impurities and potential breakdown products in its intended use. Toxicological data (data derived from tests to determine whether a substance is harmful) are essential to identify and characterise any possible health hazards associated with the additive and to allow extrapolation of the findings in animals and other test systems to humans. In these studies, the additive is administered to laboratory animals, usually mixed with their diet, but at much higher concentrations than would occur in human food.

Such tests are designed to give information on any possible effects from short-term or long-term exposure to the proposed additive, including whether it may have any potential to cause cancer (carcinogenicity), or to affect male or female reproduction or the development of the embryo or the foetus if consumed by a pregnant woman (reproductive or developmental toxicity). Other effects include the genotoxicity (including mutagenicity) potential of the compound; that is its ability to interfere with genetic material in the body, which could lead to the development of cancer or adverse effects in future generations. These toxicological data are used to identify a safe level of intake for consumers, as described below. Finally, data on the potential exposure of consumers from the intended uses are needed in order to determine whether consumer intake could potentially be above the safe level (see also Chapter 5).

If an additive is deemed acceptable for food use, an Acceptable Daily Intake (ADI) is normally set. The ADI is defined as:

"an estimate of the amount of food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk."

The ADI is expressed on a milligram per kilogram bodyweight per day basis (mg/kg bw/day) and is used extensively by regulatory and advisory bodies throughout the world, such as EFSA, the Joint Expert Committee on Food Additives (JECFA)[7], the World Health Organization (WHO) and the UK's Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). The ADI is the maximum daily intake regarded as acceptable by these bodies, and JECFA expresses the ADI in a range from 0 to an upper limit, in order to encourage the lowest levels of use that are technologically feasible. An ADI established by EFSA is expressed as a single figure, e.g. 5 mg/kg bw/day, and is often but not invariably, the same as the upper limit of the JECFA ADI.

In establishing an ADI, the toxicological studies are used to identify the dose levels at which the additive causes effects on the health of the animals (usually rats or mice). The highest level at which no adverse effect on the health of the animals is observed is called the NOAEL (No-Observed-Adverse-Effect-Level). An ADI is derived by dividing the NOAEL obtained from these studies, by an appropriate 'uncertainty' factor, which is intended to take account of differences between the animals on which the additive was tested and humans, in order to reduce further still the possibility of risk to humans. This uncertainty factor is commonly 100 (assuming that human beings are 10 times more sensitive than test animals and that the different levels of sensitivity within the human population is in a 10 fold range), but may be as much as 1,000 (if, for example, the toxic effect in animals is found to be particularly severe) or as low as 10 (where it has been found that humans are less likely than animals to be affected, based on actual data on the additive in humans).

[7] JECFA operates under the aegis of the WHO and the Food and Agriculture Organization of the United Nations and provides international safety assessments of food additives and food contaminants, whereas the assessments produced by EFSA, and previously the SCF, are specific for the European Union. The two expert bodies have in the main assessed the same food additives, and usually the outcome is similar, i.e. the ADI derived by both bodies is usually the same.

3.2 Data Requirements and Administrative Procedures for New Food Additives

The above process for the evaluation of the safety of food additives has been in place since the early 1970's. Food additives already in use at that time were systematically evaluated by the SCF, and as new additives were brought to market, guidelines were developed by the SCF as to the type of data required by the Committee in order to carry out a comprehensive risk assessment. A new additive which requires authorisation must go through a lengthy procedure involving evaluation of its safety followed by the legal process of addition to the list of authorised food additives. The manufacturer of the potential new additive must not only produce evidence that there is a real need for the substance, but also commission research into the safety of that substance in accordance with the guidelines applicable at the time of application.

The SCF initially produced guidelines for the safety assessment of food additives in 1980 (SCF, 1980). These guidelines were updated in 1992 and again in 2001 (SCF, 2001). When EFSA took over responsibility for risk assessment of food additives from the SCF in 2003, the SCF guidance was endorsed by EFSA as their guiding principles for data requirements for new additives. This continues to be the case, although EFSA is currently undertaking a detailed reappraisal of the SCF guidance document in order to reflect the current thinking in risk assessment. A revised guidance is anticipated to be adopted by the relevant EFSA Panel, the Panel on Food Additives and Nutrient Sources added to Food (ANS) by July, 2011.

The SCF/EFSA guidance provides comprehensive guidance to food business operators on the type of information and data needed if they wish to place a new food additive on the EU market. It gives information on the administrative and technical data required on the range of toxicological tests generally required for new food additives and on the format for formal submissions on additives (referred to as "dossiers") to the European Commission. The information submitted is required either for the European Commission and/or for EFSA. Additionally, the European Commission has produced a document outlining the correct procedure that an applicant should follow when applying for the authorisation of a new additive (EC, 2009).

The procedural aspects of the process of assessment and authorisation of food additives are laid down in Regulation 1331/2008 which provides a common procedure for food enzymes and food flavourings as well as food additives. It provides the basis for the Community lists and a mechanism for updating these lists. The main stages of the procedure are laid down in the Regulation, including application for updating the lists, the role of EFSA and the various deadlines in the process. An application for authorisation of a new additive is made to the European Commission, Health and Consumers Directorate-General, and companies requiring approval of new additives should contact the EU Commission in the first instance to check the administrative requirements and the procedure to be followed in submitting a dossier. The address is as follows:

European Commission
Health and Consumer Directorate-General
Directorate E – Safety of the food chain
Unit E3 – Chemicals, contaminants, pesticides
Office B232, 4/49
B-1049 Brussels

If the European Commission agrees that there are legitimate grounds for the use of a new additive, it will request the necessary scientific data from the applicant, unless already submitted with the application. Once submitted, the data will be forwarded to EFSA for a safety evaluation. Under the common procedure laid down in Regulation 1331/2008, EFSA has nine months to issue their opinion following receipt of a valid application. However, in duly justified cases where EFSA requests further information from applicants, this time period of nine months may be extended, and in a complex case which requires additional data/trials etc. the process of assessment could take several years.

If the additive is deemed to be safe by EFSA, including (usually) the establishment of an ADI, the Commission will then initiate the process to add the substance to the list of authorised food additives via a Commission Regulation[8]. Under Regulation 1331/2008, the Commission must submit a draft Regulation containing the necessary measures for the authorisation of the additive to the Standing Committee for the Food Chain and Animal Health (SCoFAH) for vote (the comitology procedure) within 9 months of the EFSA opinion. Following the vote by SCoFAH, the draft is forwarded to the European Parliament, which has a further 3 months to examine the proposal (the scrutiny procedure). As a result of this examination, the European Parliament may oppose legislative proposals from the Commission that would normally be adopted by the comitology procedure. The legal process laid down in Regulation 1331/2008 can thus take a minimum of 21 months before the additive is formally added to the list of authorised additives, at the point at which the Regulation containing the necessary measure has been published in the Official Journal and the date of application has been reached. Only at that time is the substance permitted for food use.

In addition to inclusion of the substance on the list, specific conditions are normally laid down under which the additive may be used, in particular the types of food it can be used in, and the MPL. These conditions reflect in part the uses and use levels sought in the dossier submitted by the applicant, but may also reflect particular concerns that have arisen during the assessment by EFSA. The EFSA assessment includes an estimation of potential exposure of consumers from the intended uses at the use levels sought by the applicant. The MPLs proposed for a particular additive will be determined by the outcome of this exposure assessment; if the outcome is that the ADI proposed by EFSA is likely to be exceeded due to proposed use of the additive in a wide range of foodstuffs at the use levels sought by the applicant, the MPLs ultimately laid down for the additive, together with the use categories may be lower than those originally sought by the applicant.

The legislation on food additives in force until the adoption of Regulation 1333/2008 allowed food business operators to seek a temporary authorisation from a Member State for an additive marketed in the territory of that Member State, rather than going through the centralised application to the European Commission and EFSA described above. The maximum period for such an authorisation was 2 years, after which, if the substance had not been added to the list of authorised additives at European level, sales had to cease. Several such temporary national authorisations were granted in Ireland under this provision. However, with the entry into force of Regulation 1333/2008 on 20th January 2010, it is no longer possible for food business operators to seek such temporary authorisations, and all applications must now be made to the European Commission for EU-wide approval.

3.3 Data Requirements for Changes to Conditions of Use or Production Details for Already Authorised Food Additives

In addition to making an application for a new food additive, a food business operator may also seek a revision of provisions regarding use of an already authorised additive, e.g. use in an additional food category or categories or use at different levels than those laid down in the legislation. He or she may also seek to produce an already authorised additive from a new source or by a new method of production, which could potentially result in different impurities, residues or degradation products than those identified and controlled in the additive via specification, etc. This procedure will require specific data on likely exposure to the additive in the first case and information on the source/manufacturing process/likely impurities, residues or degradation products in the second case, but will not normally require submission of a full technical dossier containing all the toxicological studies on the already authorised additives. Further information is available in the document outlining the procedures that an applicant should follow when applying for the approval of a new additive (EC, 2009) or may be obtained directly from the European Commission at the address given in Section 3.2.

[8] Under the previous legislation on food additives, the list of authorised additives was normally updated via a Commission Directive. In common with other legislative measures introduced by the European Commission in recent years, under Regulation 1333/2008 this will in the future be done via Commission Regulation.

3.4 Re-evaluation of Already Authorised Food Additives

One of the principles established in Regulation 1333/2008 (Recital 14) is that food additives should be kept under continuous observation and must be re-evaluated whenever necessary, in the light of changing conditions of use and new scientific information. The same provision existed under the previous Framework Directive, Council Directive 89/107/EEC. Triggers for re-evaluation, and/or new scientific information, may come from the food industry or academic research and may be conveyed directly to the European Commission or via national authorities in Member States, who are responsible, along with other stakeholders, for the "continuous observation" aspects of this principle. A number of authorised additives have been re-evaluated by the SCF and more recently by EFSA on this basis, e.g. the sweetener aspartame, given continued concerns expressed regarding its safety.

One of the new provisions in Regulation 1333/2008 compared with the previous legislation is that it introduces a requirement that food additives which were permitted before 20 January 2009 shall be subject to a new risk assessment carried by EFSA. To this end the Commission, in consultation with EFSA, has set up a systematic programme for EFSA to re-evaluate the safety of permitted food additives. This is enacted by Commission Regulation (EU) No 257/2010 which was published on 25th March 2010 (EU, 2010). The Regulation defines the priorities for the re-evaluation programme and the procedures that will be followed, and also establishes dates by which the evaluations of specific additives or groups of additives will be completed. The priority list established by the Regulation has been reproduced as Appendix 3 of this guidance.

Food colours were among the first additives to be evaluated by the SCF and many of the evaluations are old. Additionally, new studies have become available on some of these colours. It was decided therefore, that food colours should be given the highest priority for evaluation, and as can be seen from Appendix 3, the evaluation of the synthetic food colours is due to be completed by the end of 2010. Natural food colours have been given a longer deadline of 2015. The order of priorities for the re-evaluation of the remaining permitted food additives is as shown in Appendix 3.

Chapter 4. Labelling of Food Additives

4.1 General Labelling Requirements

In addition to the requirement that all food additives should receive a thorough safety evaluation and that there should be a demonstrated technological need for the additive in food, Regulation 1333/2008 requires that food additives are clearly identified on the packages of foods and beverages which contain them. This addresses one of the most important rule of labelling, namely that the consumer should not be misled regarding the nature and properties of the food they are consuming. Foodstuffs containing additives must comply with both the general labelling provisions for food[9] as laid down in Council Directive 2000/13/EC[10] and with the more specific labelling requirements for food additives as laid down in Chapter IV of Regulation 1333/2008. Also, where relevant, they must comply with Regulation 1829/2003 and Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food products produced from genetically modified organisms.

These labelling requirements may vary dependent on whether the additive is already present in a foodstuff intended for sale to the final consumer, or whether it is in a form intended for sale to and use by industry, e.g. a concentrate or high purity form, but which is not intended for sale to the final consumer. There are also specific requirements for labelling of additives placed on the market in a form, e.g. again a concentrate or high purity form, intended for sale to the final consumer, rather than industry. There are additional specific labelling requirements for foods containing certain sweeteners, e.g. aspartame, and certain food colours. These requirements are described in more detail below.

For additives already present in food intended for sale to the final consumer, the general labelling rules set out in Directive 2000/13/EC apply, including those provisions referring specifically to food additives. Under Directive 2000/13/EC, food additives are considered ingredients and should be listed in the ingredients list using the name of their category followed by their specific name or E number, e.g. Antioxidant: Ascorbic Acid or Antioxidant: E300. The categories of food additives according to their technological function have been described in Section 1.2 of this guidance and are listed in Table 1.1. As already mentioned in Section 1.3, the presence of an E number on the label of a food means that the additive present has been assessed by EFSA or the SCF and has been accepted as safe all across the EU. E numbers have been used for years in order to communicate simply across the range of languages in the EU and to help consumers make informed choices. The presence of an E number on a label should therefore, be regarded in a positive, rather than in a negative light.

Directive 2000/13/EC defines ingredient as *'any substance, including additives and enzymes, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form'*. However, there are certain derogations or exemptions under the Directive for substances that might normally be considered food additives – in that the Directive specifies that the following categories of substances are not considered ingredients:

- Additives whose presence in a given foodstuff is solely due to the fact that they were contained in one or more ingredients of that foodstuff, provided that they serve no technological function in the finished product
- Additives which are used as processing aids
- Substances used in the quantities strictly necessary as solvents or media for additives or flavouring

[9] More information on the general labelling provisions for food can be found on the FSAI website, at: http://www.fsai.ie/legislation/food_legislation/labelling_of_food.html

[10] Council Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

These substances do not have to be declared on the label. Additives present in a food because they were contained in one of the ingredients only need to be indicated in the list of ingredients if they perform a technological function in the final food. Whether or not the additive performs a technological function in the final product will depend both on the ingredient containing the additive and the food to which it is added. For example, preservatives used in fruit puree will not necessarily perform the same function when the fruit is added to a pasteurised yoghurt.

However, under the requirements introduced by Directive 2003/89/EC, carry-over additives, solvents and carriers for additives or processing aids should be regarded as ingredients where they originate from ingredients listed in Annex IIIa of that Directive. Annex IIIa of Directive 2003/89/EC contains a list of allergenic ingredients such as peanuts and peanut products, sulphur dioxide (SO2) and sulphites, cereals containing gluten, etc. These ingredients or products derived from them must always be indicated on the label with a clear reference to the name of the ingredient from which they originate. In the case of sulphur dioxide/sulphite, in contrast to the usual labelling rules, the E number may not be used as this substance is likely to trigger adverse effects in sensitive individuals and must appear on the label under its full name, where it is present at levels exceeding 10mg/kg or 10mg/l expressed as SO2.

The specific labelling requirements for food additives laid down in Regulation 1333/2008 are outlined in the following sections:

4.2 Labelling of Food Additives not Intended for Sale to the Final Consumer

Food additives not intended for sale to the final consumer, whether sold singly or mixed with each other and/or with food ingredients, must be labelled with the information provided for in Article 22 of Regulation 1333/2008. The labelling must be easily visible, clearly legible and indelible, and in a language easily understandable to purchasers of the product (usually food business operators).

Article 22 of Regulation 1333/2008 requires that the packaging or containers of such food additives must bear the following information:

(a) The name and/or E number of each food additive or a sales description which includes the name and/or E number of each food additive

(b) The statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use

(c) If necessary, the special conditions of storage and/or use

(d) A mark identifying the batch or lot

(e) Instructions for use, if the omission thereof would preclude appropriate use of the food additive

(f) The name or business name and address of the manufacturer, packager or seller

(g) An indication of the maximum quantity of each component or group of components subject to quantitative limitation in food and/or appropriate information in clear and easily understandable terms enabling the purchaser to comply with the Regulation or other relevant EU law. Where the same limit on quantity applies to a group of components used singly or in combination, the combined percentage may be given as a single figure; the limit on quantity shall be expressed either numerically or by the quantum satis principle

(h) The net quantity

(i) The date of minimum durability or 'use-by' date

(j) Where relevant, information on a food additive or other substances listed in Annex IIIa to Directive 2000/13/EC (allergens) as regards the indication of the ingredients present in foodstuffs

The following rules additionally apply:

- Where food additives are sold mixed with each other and/or with other food ingredients, their packaging or containers must bear a list of all ingredients in descending order of their percentage by weight of the total
- Where substances (including food additives or other food ingredients) are added to food additives to facilitate their storage, sale, standardisation, dilution or dissolution, their packaging or containers shall bear a list of all such substances in descending order of their percentage by weight of the total

The information required in points (e) to (g) and in the subsequent two paragraphs need only be provided on the accompanying documents relating to the consignment of the food additive, whether it is sold singly or mixed with other food additives and/or with other food ingredients provided that the indication 'not for retail sale' appears on an easily visible part of the packaging or container of the product in question. Where food additives are supplied in tankers, all of the information may be provided on the accompanying documents relating to the consignment which are to be supplied with the delivery.

It should be noted that foods placed on the market or labelled before 20 January 2010 (the date of application of Regulation 1333/2008) which do not comply with Article 22(1) (i) (requirement to indicate the date of minimum durability or 'use-by' date) and with Article 22 (4) (documents supplied with or prior to the delivery) may be marketed until their date of minimum durability or 'use-by' date. Foods placed on the market after that date should comply fully with the labelling requirements of the Regulation.

4.3 Labelling of Food Additives Intended for Sale to the Final Consumer

In addition to the labelling requirements set out in Directive 2000/13/EC on the labelling, advertising and presentation of foodstuffs, Council Directive 89/396/EEC on indications or marks identifying the lot to which a foodstuff belongs and Regulation (EC) No 1829/2003 on genetically modified food, food additives sold singly or mixed with each other and/or other food ingredients which are intended for sale to the final consumer may be marketed only if their packaging contains the following information:

(a) The name and E number laid down in Regulation 1333/2008 in respect of each food additive or a sales description which includes the name and E number

(b) The statement 'for food' or the statement 'restricted use in food' or a more specific reference to its intended food use.

4.4 Additional Labelling Requirements for Table-top Sweeteners

Regulation (EC) No 1333/2008 grants a derogation from (a) above, if the sales description[11] of a table-top sweetener intended for sale to the final consumer includes the term '… -based table-top sweetener', using the name(s) of the sweetener(s) used in its composition. The E number does not have to be included. Additionally, the labelling of a table-top sweetener containing the food additives polyols and/or aspartame and/or aspartame-acesulfame salt must bear the following warnings:

(a) Polyols: 'excessive consumption may induce laxative effects'

(b) Aspartame/aspartame-acesulfame salt: 'contains a source of phenylalanine'

All the above labelling information for table-top sweeteners must comply with Article 13(2) of Directive 2000/13/EC (general labelling), i.e. it must be easy to understand and marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible. Manufacturers of table-top sweeteners should also make available by appropriate means the necessary information to allow the safe use of such products by consumers.

[11] "Sales description" is not defined in Regulation 1333/2008 or in the general labelling rules under Directive 2000/13/EC, however it is considered to include the sales name and other descriptive information which appears in proximity to the sales name.

4.5 Labelling Requirement for Foods Containing Certain Food Colours

Under Regulation 1333/2008, from the 20th July 2010 the labelling of pre-packaged food and drink containing one or more of the following six food colours - Sunset Yellow (E 110), Quinoline Yellow (E 104), Carmoisine (E 122), Allura Red (E 129), Tartrazine (E 102) or Ponceau 4R (E 124) has been required to display the following warning message:

Name or E number of the colour(s) (e.g. Sunset Yellow): may have an adverse effect on activity and attention in children."

The warning message applies to all pre-packaged food and drink products, with the exception of foods where the colour(s) has been used for the purposes of health or other marking on meat products or for stamping or decorative colouring on eggshells. In addition, alcoholic drinks containing alcohol above 1.2% by volume do not need to carry the warning. The information provided must comply with Article 13(2) of Directive 2000/13/EC (general labelling), i.e. it must be easy to understand and marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.

4.6 Other Labelling Requirements

Additional labelling requirements apply to foodstuffs containing sweeteners, or both a sweetener and an added sugar or sugars. Foodstuffs containing a sweetener or sweeteners (as authorised by Directive 94/35/EC) must be labelled "with sweeteners(s)" near the name of the food, while foodstuffs containing both an added sugar or sugars and a sweetener or sweeteners (as authorised by Directive 94/35/EC) must be labelled "with sugar(s) and sweeteners(s)" near the name of the the food[12].

In addition to the labelling requirements imposed by Directive 2000/13/EC, Regulation 1333/2008 and the other legal instruments mentioned above, there is other potentially applicable EU legislation such as Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures, laws, Regulations or administrative provisions regarding weights and measures or legislation on the transport of chemicals substances and preparations. Food business operators should be aware of these additional requirements and the need to label products for purposes other than food use.

[12] Commission Directive 2008/5/EC(OJ L27, p12, 31/01/2008) of 30 January 2008 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Directive 2000/13/EC of the European Parliament and of the Council (Codified version) http://www.fsai.ie/uploadedFiles/Dir2008_5.pdf

Chapter 5. Monitoring of Food Additives

Member States are legally required to monitor the consumption and use of food additives using a risk-based approach (Article 27 of Regulation 1333/2008). Member States are also required to report their findings to the European Commission at regular intervals. This monitoring programme on the consumption and use of food additives, carried out throughout the European Union, provides the impetus for the re-evaluation programme for food additives (see Section 3.4), based on information from the programme on "changing conditions of use and new scientific information" (Recital 14 of Regulation 1333/2008).

5.1 Surveys of Food Consumption in Ireland

The obligation to monitor consumption and use of food additives was already in place under Directives 94/35/EC, 94/36/EC and 95/2/EC. The Irish Universities Nutrition Alliance (IUNA), which comprises the academic nutrition units of University College, Dublin, University College, Cork, Trinity College Dublin and the University of Ulster, Coleraine, in collaboration with the FSAI has carried out an extensive research programme into food consumption patterns in Irish adults, Irish children and Irish teenagers, via national dietary surveys which inter alia have also generated data on food additive usage and food additive intake. These data have been reported on a regular basis to the European Commission in order to fulfil Ireland's legal obligation to monitor the consumption and use of food additives.

To date, IUNA has published the results of three national dietary surveys. The first, the North/South Ireland Food Consumption Survey (NSIFCS) investigated habitual food and beverage consumption of the 18-64 year old adult population (n=1,379) in the Republic of Ireland and Northern Ireland during 1997-1999 (Harrington *et al.*, 2001; IUNA, 2001). The second survey, the National Children's Food Survey (NCFS) was carried out in the period 2003 – 2004 (IUNA, 2005), and was followed by the National Teen Food Survey (NTFS) in 2005 – 2006 (IUNA, 2007). The NCFS surveyed 594 children aged between 5-12 years and the NTFS surveyed 441 teenagers aged between 13-17 years.

5.2 The Irish National Food and Ingredient Database

In tandem with these dietary surveys, the IUNA developed the Irish National Food and Ingredient Database (INFID). This is a multi-faceted database constructed to record nutrient and ingredient data on foods consumed by adults in the NSIFCS, and to monitor the usage and consumption of food chemicals (Gilsenan *et al*, 2002). INFID was initiated to collaborate with the retail sector and industry to gather food label information on all ingredients used in a generally representative sample of processed Irish foods. The database has multiple uses, one of which is a characterisation of the pattern of food additive usage in branded foods available to Irish consumers. However, the foods consumed in NSIFCS were not recorded at brand level.

Following on from this, another version of the Irish National Food and Ingredient Database (INFID) was developed, in which children and teenagers from the NCFS and the NTFS were asked to collect the packaging of the foods they consumed within the 7-day period. This packaging was collected by the fieldworkers and then forwarded to the coordinating centre in University College, Dublin. By using the information printed on the packaging, much data were recorded about the product, such as brand name, product description, products unit and portion weight, country of origin and manufacturer's details. Furthermore, ingredient lists for each branded food were also recorded from the packaging labels, along with the function of ingredients. Nutritional information for each product was also recorded. A supplementary food and ingredient table also recorded information on the composite ingredients in a product, e.g. ingredients for the cream filling of a biscuit.

All food intake data in the surveys were recorded at brand level. Therefore, unique brand identification codes were allocated to individual branded food products, with codes differing per flavour and per product type. This created 5,551 different brand codes for the children and 4,921 brand codes for the teenagers. These brand id codes are linked to each of the 1806 food items in the most recent version of INFID (2009). Such unique brand codes allowed details of all ingredients per food consumed and recorded in INFID to be connected to the final food consumption databases generated by the surveys.

INFID has multiple uses, including characterisation of the pattern of food additive usage in branded foods available to Irish consumers. Table 5.1 provides an overview of food additive usage in foods in INFID and the most common foods (64 food groups) in which they are found (data were collected during the dietary surveys

2003-2006 and they were updated for certain foods in 2009), while Table 5.2 presents a similar overview, but based on the primary function of the additive, linked to the most common food groups in which they are found.

Table 5.1. Overview of food additive usage as recorded in INFID – percentage of brands within food groups which contain additives

Food group	No. of brands per food group	No. branded foods containing an additive	% branded foods containing additives
Diet carbonated beverages	13	13	100
Meat pies, pastries and sausage rolls	7	7	100
Low fat spreads	5	5	100
Milk puddings, e.g. rice pudding and custards	4	4	100
Other spreading fats	4	4	100
Carbonated beverages	34	33	97.1
Sausages	25	24	96.0
Squashes and cordials	36	34	94.4
Ice-creams	40	37	92.5
Confectionery (chocolate)	117	108	92.3
Cakes, buns and pastries	51	47	92.3
Bacon and ham (including rashers)	46	41	89.1
Non chocolate confectionery	98	87	88.8
Nutritional supplements	16	14	87.5
Processed and homemade potato type products	8	7	87.5
White bread, rolls, white soda type breads	44	38	86.4
Puddings and chilled desserts, excluding milk puddings	22	19	86.4
Wholemeal bread, rolls, brown/wholemeal soda type breads	29	25	86.2
Biscuits (savoury and sweet)	94	79	84.0
Savoury snacks	105	88	83.8
Savouries, e.g. pizza, mixed pasta dishes, quiche	90	74	82.2
Poultry and game dishes	5	4	80.0
Meat products (processed meats, e.g. black pudding)	38	30	79
Soups, sauces and miscellaneous foods	139	107	77.0
Yoghurts	58	44	75.9
Cheeses	43	29	67.4
Fish and fish products (cod, whiting, fish fingers etc.)	21	14	66.7
Coffee	3	2	66.7
Other milks, e.g. processed milk, milk based drinks soya	3	2	66.7
Ready –to- eat breakfast cereals	51	34	66.7
Other breads and scones, bagels, croissants, ethnic breads	43	27	62.8

Food group	No. of brands per food group	No. branded foods containing an additive	% branded foods containing additives
Chicken & turkey	45	28	62.2
Other beverages	53	32	60.4
Potatoes, chipped, fried, roasted	22	12	54.5
Vegetable and pulse dishes, including coleslaw	11	6	54.5
Beef and veal dishes	2	1	50
Tinned or jarred vegetables	17	8	47.1
Burgers (beef and pork)	9	4	44.4
Peas, beans and lentils	25	11	44.0
Sugars, syrups, preserves and sweeteners	28	12	42.9
Fruit juices	57	15	26.3
Creams	4	1	25.0
Tinned fruits	4	1	25.0
Other breakfast cereals, e.g. porridge and ready brek	5	1	20.0
Rice and pasta (plain types), flours, grains and starches	39	7	17.9
Nuts, seeds, herbs and spices	10	1	10.0
Lowfat, skimmed and fortified milks	11	1	9.1
Other fruits, e.g. apples, pears, kiwis	29	2	6.9
Potatoes, boiled, mashed, baked, e.g. milk/ butter added	19	1	5.3
Beef and veal (fresh)	13	0	0.0
Alcoholic beverages	1	0	0
Bananas	3	0	0
Butter	2	0	0
Carrots (including tinned carrots)	8	0	0
Citrus fruit, grapefruit, oranges, tangerines, satsumas etc	5	0	0
Egg and egg dishes	12	0	0
Green vegetables, broccoli, sprouts, green beans, cabbage	13	0	0
Lamb (fresh)	8	0	0
Oils	3	0	0
Other vegetables, e.g. onions, leeks, peppers etc.	21	0	0
Pork (fresh)	2	0	0
Salad vegetables, eaten raw, e.g. lettuce, tomato, cucumber	12	0	0
Tea	6	0	0
Whole milk	15	0	0

Table 5.2. Overview of food additive usage in the Irish food supply as recorded in INFID

Food additive category	Overall additive use		No. of additives to perform function	Most commonly used additive to perform function	No. branded foods containing common additive	No. of food groups in which additive category present	Food groups in which additive category most commonly found	No. times additive category present per food group	No. brands within food group containing additive category (%)
	n	%							
Functional ingredient*	926	19.7	112	E330	262	42	Non chocolate confectionary	135	56 (57)
							Soups, sauces and miscellaneous foods	82	65 (47)
Emulsifier	661	14.1	39	E322	221	28	Confectionery (chocolate)	152	100 (85)
							Cakes, buns and pastries	88	39 (76)
Colour	643	13.7	36	E160a	86	34	Non chocolate confectionary	145	53 (54)
							Confectionery (chocolate)	53	17 (15)
Stabiliser	470	10.0	33	E450	59	33	Ice-creams	91	32 (80)
							Bacon and ham (including rashers)	66	26 (57)
Preservative	424	9.0	36	E202	99	32	Squashes and cordials	68	34 (97)
							Bacon and ham (including rashers)	63	39 (85)
Raising agent	291	6.2	17	E500	97	19	Biscuits (savoury and sweet)	91	53 (56)
							Cakes, buns and pastries	51	30 (59)

Food additive category	Overall additive use		No. of additives to perform function	Most commonly used additive to perform function	No. branded foods containing common additive	No. of food groups in which additive category present	Food groups in which additive category most commonly found	No. times additive category present per food group	No. brands within food group containing additive category (%)
	n	%							
Acidity regulator	238	5.1	24	E331	75	27	Yoghurts	42	23 (40)
							Non chocolate confectionary	29	21 (21)
Flavour enhancer	236	5.0	15	E621	149	16	Savoury snacks	93	60 (57)
							Soups, sauces and miscellaneous foods	79	49 (35)
Antioxidant	208	4.4	21	E300	76	27	Bacon and ham (including rashers)	35	35 (76)
							Sausages	27	23 (92)
Sweetener	198	4.2	14	E951	81	14	Squashes and cordials	62	31 (89)
							Diet carbonated beverages	25	12 (92)
Flour treatment agent	104	2.2	9	E300	71	9	Savouries, e.g. pizza, mixed pasta dishes, quiche	34	28 (31)
							White bread, rolls, white soda type breads	32	28 (64)
Humectant	64	1.4	5	E422	35	7	Non chocolate confectionary	32	22 (22)
							Cakes, buns and pastries	10	9 (18)

Food additive category	Overall additive use		No. of additives to perform function	Most commonly used additive to perform function	No. branded foods containing common additive	No. of food groups in which additive category present	Food groups in which additive category most commonly found	No. times additive category present per food group	No. brands within food group containing additive category (%)
	n	%							
Glazing agent	50	1.1	7	E903	27	8	Non chocolate confectionary	21	15 (15)
							Confectionery (chocolate)	15	8 (7)
Thickener	46	<1	14	E412	17	14	Soups, sauces and miscellaneous foods	16	13 (9)
							Non chocolate confectionary	6	5 (5)
Gelling agent	44	<1	5	E440	32	11	Cakes, buns and pastries	11	10 (20)
							Biscuits (savoury and sweet)	7	7 (7)
							Sugars, syrups, preserves and sweeteners	7	7 (25)
Emulsifying salt	22	<1	5	E331c	8	3	Savouries, e.g. pizza, mixed pasta dishes, quiche	14	7 (8)
							Cheeses	7	5 (12)
Anti-caking agent	19	<1	5	E504	11	7	Soups, sauces and miscellaneous foods	8	7 (5)
							Non chocolate confectionary	4	4 (4)
Acid	15	<1	4	E330	10	8	Other beverages	3	3 (6)

Food additive category	Overall additive use		No. of additives to perform function	Most commonly used additive to perform function	No. branded foods containing common additive	No. of food groups in which additive category present	Food groups in which additive category most commonly found	No. times additive category present per food group	No. brands within food group containing additive category (%)
	n	%							
							Savouries, e.g. pizza, mixed pasta dishes, quiche)	3	3 (3)
Flour improver	15	<1	5	E300	10	6	White bread, rolls, white soda type breads	7	6 (14)
							Cakes, buns and pastries	3	2 (4)
Flavouring	14	<1	8	E621	4	5	Savoury snacks	8	6 (6)
							Bacon and ham (including rashers)	3	1 (2)
Firming agent	6	<1	2	E500 & E501	3	1	Savouries, e.g. pizza, mixed pasta dishes, quiche	6	3 (3)
Carrier	1	<1	1	E330	1	1	Sausages	1	1 (4)
Sequestrant	1	<1	1	E415	1	1	Soups, sauces and miscellaneous foods	1	1 (1)

* Functional Ingredient: In cases where an additive was labelled without its function, these additives were entered as functional ingredients

5.3 Use of Data on Food Consumption and on Additive Usage

The early INFID data related to the NSIFCS generated by IUNA provided an initial picture of the use of food additives in the Irish food supply, which was submitted to the EC in the form of a report, "Food additive usage patterns in Ireland and changes in food additive usage over the periods 1995/97 and 1998/99." The results have also been published in the open literature, e.g. Gilsenan *et al.*, 2002; Gilsenan *et al.*, 2003a; Gilsenan *et al.*, 2003b. The data, together with similar data from other Member States, were used as part of an EU Scientific Co-operation (SCOOP) Task to compile a report from the European Commission on dietary food additive intake in the European Union (EC, 1997). The results were used to develop a tiered approach to evaluate dietary intake of food additives by the European population. The tiered approach is described in more detail in Section 5.4.

Since then, the INFID and the food consumption databases have been used for many purposes, including estimation of exposure to food packaging materials (Duffy *et al.* 2006 a, b; Duffy *et al.* 2007; Duffy & Gibney, 2007) and to monitor the intake of pesticides from the Irish diet (Connolly *et al.*, 2009). A more recent publication using the data from INFID was an examination of the intake of certain food colours reported by another study to be associated with hyperactivity by Irish children and teenagers (Connolly *et al.* 2010). As discussed in more detail in Chapter 6, public concern has been expressed regarding the safety of a number of food colours, the so-called Southampton colours, following the publication of a Food Standards Agency UK funded study examining the potential effect of a mixture of these colours and the preservative sodium benzoate on the behaviour of children, which reported some adverse effects due to consumption of these mixtures (McCann *et al.*, 2007).

The study carried out by the IUNA group examined the pattern of intake of the two mixes (A and B) of these target additives used in the Southampton study in Irish children and teenagers using the Irish national food consumption databases for children (n = 594) and teenagers (n = 441) and based on occurrence data in the INFID. The authors found that the majority of additive-containing foods consumed by both the children and teenagers contained only one of the target additives. No food consumed by either the children or teenagers contained all seven of the target food additives. For each additive intake, estimates for every individual were made assuming that the additive was present at the maximum legal permitted level in those foods identified as containing it. For both groups, mean intakes of the food additives among consumers only were below the doses used in the Southampton study on hyperactivity. Intakes at the 97.5th percentile of all food colours fell below the doses used in Mix B, while intakes at the 97.5th percentile for four of the six food colours were also below the doses used in Mix A. However, in the case of the preservative Sodium benzoate, intakes at the 97.5th percentile exceeded the dose used in the Southampton study in both children and teenagers, but mean intakes were lower. Considering the two mixes of additives, no child or teenager achieved the overall intakes used in the Southampton study.

5.4 Estimation of Food Additive Intake

It has generally been agreed by experts in exposure estimation that the process of evaluating food additive intake should start with crude, conservative, easy-to-apply approaches and only proceed to more detailed approaches if the evaluation of the intake, relative to the ADI, indicates that it is necessary to do so (Nutriscan 1994, EC 1997). This has led to the development of "decision tree"/tiered approaches (see Figure 5.1.) which involve a range of exposure assessment methodologies (Nutriscan 1994, EC 1997).

The tiered approach to the estimation of food additive intake is essentially an estimation method that progresses in complexity and data requirements, intended to produce gradually a more accurate estimate of the additive intake. Where results of the estimates in a tier indicate that an ADI is unlikely ever to be exceeded, the additives in question are eliminated from further consideration. Resources can then be focused on the remaining additives for a more refined intake estimate. These tiers are essentially tools to guide Member States, EFSA and the Commission in establishing priorities for further monitoring. The three screening tiers are:

Tier 1: Estimates based on the MPLs for the additive in question, as specified in the legislation, and using the so-called "Budget" method

Tier 2: Estimates based on the MPLs for the additive in question, with adjustment for *quantum satis* usages, and using national individual food consumption data

Tier 3: Estimates based on MPLs and national individual food consumption data

This approach was used in the SCOOP Task on Dietary Food Additive Intake in the European Union carried out in the late 1990s (European Commission, 2001) and also in the IUNA report on Irish data that was submitted to the EC for the SCOOP task. The Tier 1 screening for additives using the budget method highlighted 36 additives or groups of additives which required further screening by Member States. A variety of additional approaches, including portion back calculations, crude food intake data and nutrient-back calculations, were employed by IUNA as a second stage screening to identify additives which require detailed intake estimates.

The IUNA screening carried out in the late 1990's and reported in detail in the first version of this guidance (FSAI, 2001) identified 14 additives for detailed analysis. For these 14 additives a more refined intake assessment was carried out using the North South Ireland Food Consumption Survey (NSIFCS) (Tier 3). This process involved identifying food categories in which each additive is legally permitted according to the relevant EU Directive food categories (see Appendix 2 for the current food categorisation system), and re-grouping foods in the Irish consumption database to correspond to these food categories. For each additive, the appropriate MPL was allocated to each food group. Food additive intake estimates were generated by multiplying the food intake by the MPL and then summing the intake of the additive from each food group for each individual's consumption of the food groups.

The results of the IUNA analysis of additive usage based on the NSIFCS showed that over 160 different additives could be found in foods on the Irish market in 1999, while over 130 of the approved EU additives were not found in any foods examined in the survey. Table 5.3 shows the intake of the 14 additives examined in detail by IUNA in 1999. The results of the detailed intake estimate approach excluded a further 12 additives from the prioritised list and prioritised 2 additives (sulphites and nitrites) for a more detailed assessment or for a revision of the conditions of use.

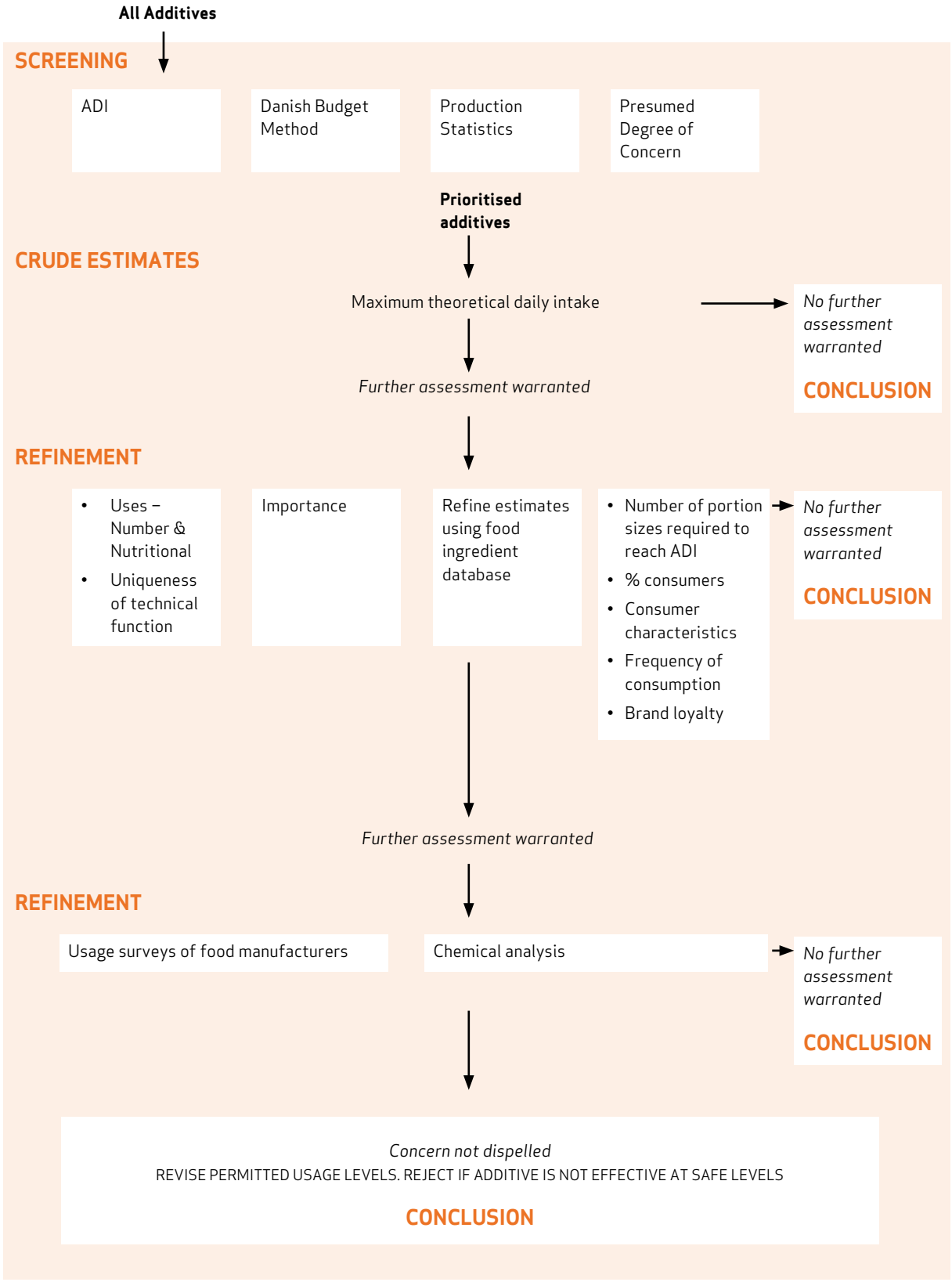
Table 5.3. Detailed intake estimates of the 14 prioritised food additives by Irish adults, based on the north south food consumption survey

Additive	E number	Intake mg/kg bw/day	% ADI	Conclusion
Sunset Yellow	E 110	0.556	22	Unlikely to exceed ADI
Annatto	E 160b	0.055	85	Unlikely to exceed ADI
Sulphites	*E 220 – E 224 E 226 – E 228*	*0.821*	*117*	Could possibly exceed ADI
Butylated Hydroxyanisole (BHA)	E 320	0.373	75	Unlikely to exceed ADI
Carmines	E 120	1.570	31	Unlikely to exceed ADI
Benzoic Acid & Salts	E 210 – E 213	2.878	57	Unlikely to exceed ADI
Polyglycerol Polyricinoleate	E 476	4.327	70	Unlikely to exceed ADI
Polyglycerol Esters of fatty Acids	E 475	23.91	96	Unlikely to exceed ADI
Polysorbates	E 432 – E 436	8.233	80	Unlikely to exceed ADI
Nitrites	*E 249, E 250*	*0.2048*	*205*	Possibility of exceeding the ADI
Gallates	E 310 – E 312	0.384	77	Unlikely to exceed ADI
Stearoyl Lactylates	E 481 – E 482	18.611	20	Unlikely to exceed ADI
Sucrose Esters/ Sucroglycerides	E 473 – E 474	8.926	45	Unlikely to exceed ADI
Butylated Hydroxytoluene (BHT)	E 321	0.0427	85	Unlikely to exceed ADI

It should be noted that results from the NSIFCS demonstrate that some 25% of people consume some form of food supplements, and the IUNA food ingredient databases contains a rather limited range of food supplements. Thus, the potential intake of carmines, benzoates, BHA, BHT, gallates and sunset yellow, from food supplements in this study were not included in their respective exposure assessments. Until such time as a comprehensive database of the additives used in food supplements is obtained, the potential exposure of these additives from food supplements remains to be investigated.

The maximum permitted levels for nitrates/nitrites in foodstuffs were reduced in 2006 (Directive 2006/52/EC), reflecting the fact that results of monitoring throughout the European Union (EC, 2001), in addition to that carried out in Ireland, suggested that the ADI for nitrites was exceeded by a proportion of the EC population. However, a recent reassessment by EFSA of nitrite intake has confirmed that in several European countries, the mean exposure at Tier 2 remains above the ADI (EFSA, 2010a). At Tier 3, the exposure of adult high consumers is just above the ADI, while for high consumer children the exposure is 2.5 times the ADI, and the higher range of the mean exposure of children is close to the ADI. While a specific re-evaluation of nitrite intake by the Irish population has not been undertaken at the time of publication of this guidance, it is likely that the ADI for nitrite is also exceeded by a proportion of the Irish population, despite the reduction in permitted levels introduced via Directive 2006/52/EC.

Figure 5.1. Decision Tree for Monitoring of Food Additives



Chapter 6. Sensitivity or Intolerance to Food Additives

Adverse reactions to food additives occur in a small proportion of the population, although proven cases of sensitivity or intolerance occur less often than supposed by patients (Ortolani, 1999). Reports in the medical literature have been mainly linked to intake of artificial food colours, the sweetener aspartame and the additive monosodium glutamate, although intolerance of common food additives such as benzoates, citrates and sulphites have been widely reported, and some individuals appear to be intolerant to a very wide range of additives in food, e.g. Asero, 2002.

The different causes of adverse reactions to foodstuffs in general can be summarised as follows:

- Toxic reactions: non immune system-mediated reactions, but food poisoning by toxins or by bacterial, viral or parasitic contamination
- Food aversion: non immune system-mediated reactions, but psycho-somatic effects such as panic disorder
- Sensitivity reactions, divided into:
  - Food intolerance: non immune system-mediated reactions, but due to, e.g. enzymatic deficiencies, e.g. lactase intolerance, pharmacological effects, e.g. to caffeine, histamine, tyramine, and still undefined mechanisms,
  - Food allergy: immune system-mediated reactions such as Immediate-Type Hypersensitivity (ITH), which is a Type I, IgE-mediated hypersensitivity, like in the majority of food allergies, e.g. to cow's milk, hen's egg, peanut, tree nuts, soy, fish, shell-fish and seafood etc., or a Delayed-Type Hypersensitivity (DTH), which is a Type IV, effector T cell-mediated reaction, like in the gluten intolerance syndrome (Coeliac disease)

Adverse reactions to food additives, where they have been reported, fall primarily under the broad heading of intolerance. An immune-mediated mechanism is unlikely in the case of the majority of food additives, which are generally small, non-protein-based molecules, and the majority of adverse reactions to food additives fall into the category of food intolerance reactions. Such reactions are however, difficult to demonstrate and are almost certainly much less common than reactions to substances present naturally in food (Ministry of Agriculture, Fisheries and Food (MAFF), 1999). The incidence of intolerance in atopic individuals is much higher than that in a non-atopic population. A MAFF UK survey estimated that the occurrence of intolerance reactions to food additives in the general population is in the range of 0.01-0.23 % (1-23 per 10,000 people) (MAFF, 1999) in contrast to a perceived prevalence of 7.4% for food allergies (Young *et al.*, 1987).

In the case of synthetic food colourings, intolerance reactions are infrequent in the population, and prevalences of 0.14 to around 2 % have been reported (Young *et al.*, 1987; Hannuksela and Haahtela, 1987; Fuglsang *et al.*, 1993, 1994). Reports are often characterised by poorly controlled challenge procedures, and do not therefore, provide definitive proof of an intolerance reaction. None the less colours, such as Tartrazine, do appear to be able to trigger intolerance reactions in a small fraction of the exposed population (EFSA, 2009).

In children, food additive intolerance is primarily found in atopic children with cutaneous symptoms where the additive is aggravating an existing disease. The prevalence in children with atopic symptoms age 5-16 was found to be 1-2% (Madsen, 1994). When children have behavioural problems, an association between ingestion of certain foods or food additives and abnormal behaviour is often suspected by parents. A large number of studies using proper study dosing, including double-blind, placebo-controlled challenge, have been unable to show a significant effect of colouring and preservative free diet on behaviour in children with true hyperkinetic syndrome. The so-called Southampton study conducted by McCann *et al.* has however concluded that exposure to two mixtures of four synthetic colours plus the preservative sodium benzoate in the diet resulted in increased hyperactivity in 3-year old and 8- to 9-year old children in the general population (McCann *et al.* 2007). In an earlier study by the same research team there was some evidence for adverse behavioural effects of a mixture of 4 synthetic colours and sodium benzoate in 3-year old children on the Isle of Wight (Bateman *et al.*, 2004). In the McCann *et al.* (2007) study, the effects of two combinations of Tartrazine (E 102), Quinoline Yellow (E 104), Sunset Yellow FCF (E 110), Ponceau 4R (E 124), Allura Red AC (E 129), Carmoisine (E 122) and sodium benzoate (E211) on children's behaviour were studied.

The EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) published an opinion on this McCann *et al.* study (EFSA, 2008). In this opinion, the AFC Panel also presented an overview of earlier studies that reported effects of food colours in general on child behaviour, the majority of these studies being conducted on children described as hyperactive or with a clinical diagnosis of Attention-Deficit/Hyperactivity Disorder (ADHD). In its opinion, the AFC Panel concluded that the McCann *et al.* study provides limited evidence that the two different mixtures of synthetic colours and sodium benzoate tested had a small and statistically significant effect on activity and attention in some children selected from the general population, although the effects were not observed for all children in all age groups and were not consistent for the two mixtures (EFSA, 2008). The AFC Panel also concluded that the findings may thus be relevant for specific individuals within the population, showing sensitivity to food additives in general or to food colours in particular. However, the AFC Panel, assisted by experts in human behavioural studies in the ad hoc Working group preparing the opinion, also concluded that the clinical significance of the observed effects remains unclear, since it is not known whether the small alterations in attention and activity would interfere with schoolwork and other intellectual functioning.

The AFC Panel also concluded that:

- Since mixtures and not individual additives were tested in the study by McCann *et al.*, it was not possible to ascribe the observed effects to any of the individual compounds, and that
- In the context of the overall weight of evidence and in view of the considerable uncertainties, such as the lack of consistency and relative weakness of the effect and the absence of information on the clinical significance of the behavioural changes observed, the findings of the study could not be used as a basis for altering the ADI of the respective colours

Nonetheless, reflecting public concern regarding these findings, special labelling provisions have been introduced via Regulation 1333/2008 for the six 'Southampton' colours (see Section 4.5).

In the case of aspartame, there are a number of anecdotal reports by individuals who attribute various symptoms and illnesses, including headaches, seizures, memory loss, vision/eye conditions, allergies and gastro-intestinal symptoms directly to aspartame consumption. The SCF Opinion on aspartame of 2002 had in particular considered possible neurological effects of aspartame, in the light of new reports (up to 2002) on the consumption of aspartame in relation to the onset of brain tumours and seizures, headaches, allergies, and changes in behaviour, mood and cognitive function. In a recent evaluation by EFSA (EFSA, 2010b), available as the report of a meeting on the EFSA website but not yet available as a final publication, this was reconsidered. It was provisionally concluded, pending the results of further studies in aspartame-sensitive individuals, that there is still no substantive evidence that aspartame can induce such adverse effects, as earlier concluded by the SCF. Although anecdotal reports in the early 1980s suggested that aspartame might be associated with allergic-type reactions, several clinical studies have shown that when the allergic-type reactions raised in these case reports were evaluated under controlled conditions aspartame is no more likely to cause reactions than placebo. The weight of evidence collected demonstrates that it is not likely that aspartame is associated with allergic-type reactions in experimental models or humans (EFSA, 2010b).

References[13]

Asero, R (2002) Multiple intolerance to food additives. J. Allergy Clin. *Immunol*. 110, 531-532

Bateman B, Warner JO, Hutchinson E, Dean T, Rowlandson P, Gant C, Grundy J, Fitzgerald C, Stevenson J (2004) The effects of a double blind, placebo-controlled, artificial food colourings and benzoate preservative challenge on hyperactivity in a general population sample of preschool children. Arch.Dis. Child. 89, 506-511

Connolly A., Hearty A., Nugent A and Gibney M. J. (2009) The exposure of children (5–12 years) and adults (18–65 years) to pesticide residues in their diets. Proceedings of the Nutrition Society 68 (OCE), E105

Connolly A, Hearty A, Nugent A, McKevitt A, Boylan E, Flynn A, Gibney MJ.(2010) Pattern of intake of food additives associated with hyperactivity in Irish children and teenagers. *Food Addit. Contam.* 27(4):447-56

Duffy, E., Hearty, A. P., Gilsenan, M. B. and Gibney, M. J. (2006a) Estimation of exposure to food packaging materials. 1: Development of a food-packaging database. *Food Addit. Contam.* 23(6): 623–633

Duffy, E., Hearty, A. P., Flynn, A. McCarthy, S. and Gibney, M. J. (2006b) Estimation of exposure to food packaging materials.2: Patterns of intakes of packaged foods in Irish Children aged 5–12 years. *Food Addit. Contam.* 23(7): 715–725

Duffy, E., Hearty, A.P., McCarthy, S. and Gibney, M.J. (2007) Estimation of exposure to food packaging materials. 3: Development of consumption factors and food-type distribution factors from data collected on Irish children. *Food Addit. Contam.* 24(1): 63–74

Duffy E, Gibney MJ. (2007) Use of a food-consumption database with packaging information to estimate exposure to food-packaging migrants: epoxidized soybean oil and styrene monomer. *Food Addit. Contam.* 24(2):216-25

European Commission (1997) Reports on Tasks for scientific co-operation. Task 4.2. Report on Methodologies for the Monitoring of Food Additive Intake across the European Union. DG Industry

European Commission (2001) 542 final. Report from the Commission on dietary food additive intake in the European Union. Accessible via:
http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0542en01.pdf

European Commission (2009) European Commission Administrative guidance for the request of authorisation of a food additive Updated 23-07-2009
http://ec.europa.eu/food/food/chemicalsafety/additives/flav16_en.pdf

European Food Safety Authority (2008) Assessment of the results of the study by McCann *et al*. (2007) on the effect of some colours and sodium benzoate on children's behaviour. Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC). Adopted on 7 March 2008. The *EFSA Journal* (2008) 660, 1-54

European Food Safety Authority (2009) EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the re-evaluation of Tartrazine (E 102) on request from the European Commission. *EFSA Journal*, 2009. 7(11):1331. [52 pp.].doi:10.2903/j.efsa.2009.1331. Available online: www.efsa.europa.eu

European Food Safety Authority (2010a) EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Statement on nitrites in meat products. EFSA Journal 2010; 8(5):1538. [12 pp.]. doi:10.2903/j.efsa.2010.1538. Available online: www.efsa.europa.eu

European Food Safety Authority (2010b) Report of the meetings on aspartame with National Experts
http://www.efsa.europa.eu/en/af100423/docs/af100423-ax1.pdf

European Union (2010) Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of authorised food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives

Food Safety Authority of Ireland (2001) Legislation, Intake and Usage of Food Additives in Ireland

[13] References to Directives and Regulations cited in this guidance have not been included in this Reference list. They may be readily accessed from the legislation section on the FSAI website http://www.fsai.ie/legislation.html

Fuglsang G, Madsen C, Saval P, Osterballe O (1993) Prevalence of intolerance to food additives among Danish school children. *Pediatr Allergy Immunol*. 4(3), 123-9

Gilsenan MB, Lambe J, Gibney MJ. (2002) Irish National Food Ingredient Database: application for assessing patterns of additive usage in foods. *Food Addit Contam*. 19(12):1105-15

Gilsenan MB, Lambe J, Gibney MJ. (2003a) Assessment of food intake input distributions for use in probabilistic exposure assessments of food additives. *Food Addit Contam*. 20(11):1023-33

Gilsenan MB, Thompson RL, Lambe J, Gibney MJ (2003b) Validation analysis of probabilistic models of dietary exposure to food additives. *Food Addit Contam*. 20 Suppl 1:S61-72

Hannuksela M and Haahtela T (1987) Hypersensitivity reactions to food additives. *Allergy* 42(8), 561-75

Harrington KE, Robson PJ, Kiely M, Livingstone MB, Lambe J, Gibney MJ. (2001) The North/South Ireland Food Consumption Survey: survey design and methodology. *Public Health Nutr*. 4(5A):1037-42

Irish Universities Nutrition Alliance (2001) The North/South Ireland Food Consumption Survey (NSIFCS). Available at: http://www.iuna.net/index.php?option=com_content&view=article&id=6&Itemid=18

Irish Universities Nutrition Alliance (2007) The National Teen Food Survey (NTFS). Available at: http://www.iuna.net/index.php?option=com_content&view=article&id=8&Itemid=20

Irish Universities Nutrition Alliance (2005) The National Children's Food Survey (NCFS). Available at: http://www.iuna.net/index.php?option=com_content&view=article&id=7&Itemid=19

Madsen, C. (1994) Prevalence of food additive intolerance. Human & Experimental Toxicology, 14, 393-399

Ministry of Agriculture, Fisheries and Food (1999) Foodsense Factsheet Number 12, Intolerance to foods, food ingredients and food additives

McCann D, Barrett A, Cooper C, Crumpler D, Dalen L, Grimshaw K, Kitchin E, Lok K, Porteous L, Prince E, Sonuga-Barke E, O'Warner J, Stevenson J (2007) Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community a randomized, double-blinded, placebo-controlled trial. *The Lancet*, Vol. 370, Issue 9598, 1560-1567

Nutriscan (1994) Options for the routine collection of data on usage levels of food additives in the European Union. Dublin: Nutriscan Limited, Trinity College, Dublin

O'Brien, Maeve (3 May 2000) Food Additives [email to Maeve O'Brien, Food Unit, Department of Health and Children]

Ortolani, C, Bruijnzeel-Koomen, C, Bengtsson, U, Bindslev-Jensen, C, Björksten, B, Host, A, Ispano, M, Jarish, R, Madsen, C, Nekan, K, Paganelli, R, Poulsen, LK, Wüthrich, B (1999) Controversial aspects of adverse reactions to food. Position Paper of the EAACI Adverse Reactions to Food Subcommittee. *Allergy*, 54, 27-45

Scientific Committee on Food (1980) Guidelines for the safety assessment of food additives (Opinion expressed on 22 February 1980). (Tenth Series (1980) (Cat. N° EUR 6892)

Scientific Committee on Food (2001) Guidance on submissions for food additive evaluations. http://ec.europa.eu/food/fs/sc/scf/out98_en.pdf

Scientific Co-operation Task 4.2 (1997) Report on the methodologies for monitoring of food additive intake across the European Union.

World Health Organization (1987) Principles for the safety assessment of food additives and contaminants in food. IPCS International Programme on Chemical Safety in co-operation with the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Environmental Health Criteria 70. GENEVA

Young, E. Patel, S, Stoneham, M, Rona, R, Wilkins, JD, (1987) The prevalence of reaction to food additives in a survey population. *Journal of the Royal College of Physicians* 21, 241

Appendix 1. List of Authorised Food Additives in the EU with their E Numbers

The list below gives the reference number (the E number) and the English name of all authorised additives in numerical and alphabetical order. It should be noted that some additives are restricted to a very limited number of foods whereas others may be permitted at the level necessary to achieve the desired technical effect ("quantum satis") with no numerical limit stated. Currently, at the time of publication of this guidance Directives 94/35/EC, 94/36/EC or 95/2/EC or the implementing legislation in the Member States should be consulted for actual details. However, when Annexes II and III of Regulation 1333/2008 are completed, the projected date for completion being the end of 2010, these will become the definitive source of information. The numbering system is being adapted for international use by the Codex Alimentarius Commission who is developing an International Numbering System (INS). This will largely use the same numbers (but without the letter E).

This list is correct as of date of final preparation of this guidance (August 2010), but since the Community list under Regulation 1333/2008 will be updated on a regular basis, the legal text should be checked for the most up-to-date version.

E Numbers in Numerical Order	
E100	Curcumin
E101	(i) Riboflavin (ii) Riboflavin-5'-phosphate
E102	Tartrazine
E104	Quinoline Yellow
E110	Sunset Yellow FCF, Orange Yellow S
E120	Cochineal, Carminic acid, Carmines
E122	Azorubine, Carmoisine
E123	Amaranth
E124	Ponceau 4R, Cochineal Red A
E127	Erythrosine
E129	Allura Red AC
E131	Patent Blue V
E132	Indigotine, Indigo carmine
E133	Brilliant Blue FCF
E140	Chlorophylls and Chlorophyllins: (i) Chlorophylls (ii) Chlorophyllins
E141	Copper complexes of chlorophylls and chlorophyllins (i) Copper complexes of chlorophylls (ii) Copper complexes of chlorophyllins
E142	Greens S
E150a	Plain caramel
E150b	Caustic sulphite caramel
E150c	Ammonia caramel
E150d	Sulphite ammonia caramel
E151	Brilliant Black BN, Black PN
E153	Vegetable carbon
E154	Brown FK
E155	Brown HT
E160a	Carotenes: (i) Mixed carotenes (ii) Beta-carotene
E160b	Annatto, bixin, norbixin
E160c	Paprika extract, capsanthin, capsorubin
E160d	Lycopene
E160e	Beta-apo-8'-carotenal (C 30)
E160f	Ethyl ester of beta-apo-8'-carotenic acid (C 30)

E161b	Lutein
E161g	Canthaxanthin
E162	Beetroot Red, betanin
E163	Anthocyanins
E170	Calcium carbonates (i) calcium carbonate (ii) calcium hydrogen carbonate
E171	Titanium dioxide
E172	Iron oxides and hydroxides
E173	Aluminium
E174	Silver
E175	Gold
E180	Litholrubine BK
E200	Sorbic acid
E202	Potassium sorbate
E203	Calcium sorbate
E210	Benzoic acid
E211	Sodium benzoate
E212	Potassium benzoate
E213	Calcium benzoate
E214	Ethyl p-hydroxybenzoate
E215	Sodium ethyl p-hydroxybenzoate
E218	Methyl p-hydroxybenzoate
E219	Sodium methyl p-hydroxybenzoate
E220	Sulphur dioxide
E221	Sodium sulphite
E222	Sodium hydrogen sulphite
E223	Sodium metabisulphite
E224	Potassium metabisulphite
E226	Calcium sulphite
E227	Calcium hydrogen sulphite
E228	Potassium hydrogen sulphite
E234	Nisin
E235	Natamycin
E239	Hexamethylene tetramine
E242	Dimethyl dicarbonate
E249	Potassium nitrite
E250	Sodium nitrite
E251	Sodium nitrate
E252	Potassium nitrate
E260	Acetic acid
E261	Potassium acetate
E262	Sodium acetates (i) Sodium acetate (ii) Sodium hydrogen acetate (sodium diacetate)
E263	Calcium acetate
E270	Lactic acid
E280	Propionic acid

E281	Sodium propionate
E282	Calcium propionate
E283	Potassium propionate
E284	Boric acid
E285	Sodium tetraborate (borax)
E290	Carbon dioxide
E296	Malic acid
E297	Fumaric acid
E300	Ascorbic acid
E301	Sodium ascorbate
E302	Calcium ascorbate
E304	Fatty acid esters of ascorbic acid (i) Ascorbyl palmitate (ii) Ascorbyl stearate
E306	Tocopherol-rich extract
E307	Alpha-tocopherol
E308	Gamma-tocopherol
E309	Delta-tocopherol
E310	Propyl gallate
E311	Octyl gallate
E312	Dodecyl gallate
E315	Erythorbic acid
E316	Sodium erythorbate
E319	Tertiary-butyl hydroquinone (TBHQ)
E320	Butylated hydroxyanisole (BHA)
E321	Butylated hydroxytoluene (BHT)
E322	Lecithins
E325	Sodium lactate
E326	Potassium lactate
E327	Calcium lactate
E330	Citric acid
E331	Sodium citrates (i) Monosodium citrate (ii) Disodium citrate (iii) Trisodium citrate
E332	Potassium citrates (i) Monopotassium citrate (ii) Tripotassium citrate
E333	Calcium citrates (i) Monocalcium citrate (ii) Dicalcium citrate (iii) Tricalcium citrate
E334	Tartaric acid (L(+)-)
E335	Sodium tartrates (i) Monosodium tartrate (ii) Disodium tartrate
E336	Potassium tartrates (i) Monopotassium tartrate (ii) Dipotassium tartrate
E337	Sodium potassium tartrate
E338	Phosphoric acid
E339	Sodium phosphates (i) Monosodium phosphate (ii) Disodium phosphate (iii) Trisodium phosphate
E340	Potassium phosphates (i) Monopotassium phosphate (ii) Dipotassium phosphate (iii) Tripotassium phosphate
E341	Calcium phosphates (i) Monocalcium phosphate (ii) Dicalcium phosphate (iii) Tricalcium phosphate
E343	Magnesium phosphates (i) monomagnesium phosphate (ii) Dimagnesium phosphate
E350	Sodium malates (i) Sodium malate (ii) Sodium hydrogen malate
E351	Potassium malate
E352	Calcium malates (i) Calcium malate (ii) Calcium hydrogen malate

E353	Metatartaric acid
E354	Calcium tartrate
E355	Adipic acid
E356	Sodium adipate
E357	Potassium adipate
E363	Succinic acid
E380	Triammonium citrate
E385	Calcium disodium ethylene diamine tetra-acetate (Calcium disodium EDTA)
E392	Extracts of Rosemary
E400	Alginic acid
E401	Sodium alginate
E402	Potassium alginate
E403	Ammonium alginate
E404	Calcium alginate
E405	Propan-1,2-diol alginate
E406	Agar
E407	Carrageenan
E407a	Processed eucheuma seaweed
E410	Locust bean gum
E412	Guar gum
E413	Tragacanth
E414	Acacia gum (gum arabic)
E415	Xanthan gum
E416	Karaya gum
E417	Tara gum
E418	Gellan gum
E420	Sorbitol (i) Sorbitol (ii) Sorbitol syrup
E421	Mannitol
E422	Glycerol
E425	Konjac (i) Konjac gum (ii) Konjac glucomannane
E427	Cassia gum
E431	Polyoxyethylene (40) stearate
E432	Polyoxyethylene sorbitan monolaurate (polysorbate 20)
E433	Polyoxyethylene sorbitan monooleate (polysorbate 80)
E434	Polyoxyethylene sorbitan monopalmitate (polysorbate 40)
E435	Polyoxyethylene sorbitan monostearate (polysorbate 60)
E436	Polyoxyethylene sorbitan tristearate (polysorbate 65)
E440	Pectins (i) pectin (ii) amidated pectin
E442	Ammonium phosphatides
E444	Sucrose acetate isobutyrate
E445	Glycerol esters of wood rosins
E450	Diphosphates (i) Disodium diphosphate (ii) Trisodium diphosphate (iii) Tetrasodium diphosphate (iv) Dipotassium diphosphate (v) Tetrapotassium diphosphate (vi) Dicalcium diphosphate (vii) Calcium dihydrogen diphosphate
E451	Triphosphates (i) Pentasodium triphosphate (ii) Pentapotassium triphosphate

E452	Polyphosphates (i) Sodium polyphosphates (ii) Potassium polyphosphates (iii) Sodium calcium polyphosphate (iv) Calcium polyphosphates
E459	Beta-cyclodextrine
E460	Cellulose (i) Microcrystalline cellulose (ii) Powdered cellulose
E461	Methyl cellulose
E462	Ethyl cellulose
E463	Hydroxypropyl cellulose
E464	Hydroxypropyl methyl cellulose
E465	Ethyl methyl cellulose
E466	Carboxy methyl cellulose, Sodium carboxy methyl cellulose
E468	Crosslinked sodium carboxymethyl cellulose
E469	Enzymically hydrolysed carboxy methyl cellulose
E470a	Sodium, potassium and calcium salts of fatty acids
E470b	Magnesium salts of fatty acids
E471	Mono- and diglycerides of fatty acids
E472a	Acetic acid esters of mono- and diglycerides of fatty acids
E472b	Lactic acid esters of mono- and diglycerides of fatty acids
E472c	Citric acid esters of mono- and diglycerides of fatty acids
E472d	Tartaric acid esters of mono- and diglycerides of fatty acids
E472e	Mono- and diacetyl tartaric acid esters of mono- and diglycerides of fatty acids
E472f	Mixed acetic and tartaric acid esters of mono- and diglycerides of fatty acids
E473	Sucrose esters of fatty acids
E474	Sucroglycerides
E475	Polyglycerol esters of fatty acids
E476	Polyglycerol polyricinoleate
E477	Propane-1,2-diol esters of fatty acids
E479b	Thermally oxidized soya bean oil interacted with mono- and diglycerides of fatty acids
E481	Sodium stearoyl-2-lactylate
E482	Calcium stearoyl-2-lactylate
E483	Stearyl tartrate
E491	Sorbitan monostearate
E492	Sorbitan tristearate
E493	Sorbitan monolaurate
E494	Sorbitan monooleate
E495	Sorbitan monopalmitate
E500	Sodium carbonates (i) Sodium carbonate (ii) Sodium hydrogen carbonate (iii) Sodium sesquicarbonate
E501	Potassium carbonates (i) Potassium carbonate (ii) Potassium hydrogen carbonate
E503	Ammonium carbonates (i) Ammonium carbonate (ii) Ammonium hydrogen carbonate
E504	Magnesium carbonates (i) Magnesium carbonate (ii) Magnesium hydroxide carbonate (syn. Magnesium hydrogen carbonate)
E507	Hydrochloric acid
E508	Potassium chloride
E509	Calcium chloride
E511	Magnesium chloride
E512	Stannous chloride

E513	Sulphuric acid
E514	Sodium sulphates (i) Sodium sulphate (ii) Sodium hydrogen sulphate
E515	Potassium sulphates (i) Potassium sulphate (ii) Potassium hydrogen sulphate
E516	Calcium sulphate
E517	Ammonium sulphate
E520	Aluminium sulphate
E521	Aluminium sodium sulphate
E522	Aluminium potassium sulphate
E523	Aluminium ammonium sulphate
E524	Sodium hydroxide
E525	Potassium hydroxide
E526	Calcium hydroxide
E527	Ammonium hydroxide
E528	Magnesium hydroxide
E529	Calcium oxide
E530	Magnesium oxide
E535	Sodium ferrocyanide
E536	Potassium ferrocyanide
E538	Calcium ferrocyanide
E541	Sodium aluminium phosphate, acidic
E551	Silicon dioxide
E552	Calcium silicate
E553a	(i) Magnesium silicate (ii) Magnesium trisilicate
E553b	Talc
E554	Sodium aluminium silicate
E555	Potassium aluminium silicate
E556	Calcium aluminium silicate
E558	Bentonite
E559	Aluminium silicate (Kaolin)
E570	Fatty acids
E574	Gluconic acid
E575	Glucono-delta-lactone
E576	Sodium gluconate
E577	Potassium gluconate
E578	Calcium gluconate
E579	Ferrous gluconate
E585	Ferrous lactate
E586	4-Hexylresorcinol
E620	Glutamic acid
E621	Monosodium glutamate
E622	Monopotassium glutamate
E623	Calcium diglutamate
E624	Monoammonium glutamate
E625	Magnesium diglutamate

E 626	Guanylic acid
E627	Disodium guanylate
E628	Dipotassium guanylate
E629	Calcium guanylate
E630	Inosinic acid
E631	Disodium inosinate
E632	Dipotassium inosinate
E633	Calcium inosinate
E634	Calcium 5'-ribonucleotides
E635	Disodium 5'-ribonucleotides
E640	Glycine and its sodium salt
E650	Zinc acetate
E900	Dimethyl polysiloxane
E901	Beeswax, white and yellow
E902	Candelilla wax
E903	Carnauba wax
E904	Shellac
E905	Microcrystalline wax
E907	Hydrogenated poly-1-decene
E912	Montanic acid esters
E914	Oxidized polyethylene wax
E920	L-Cysteine
E927b	Carbamide
E938	Argon
E939	Helium
E941	Nitrogen
E942	Nitrous oxide
E943a	Butane
E943b	Isobutane
E944	Propane
E948	Oxygen
E949	Hydrogen
E950	Acesulfame K
E951	Aspartame
E952	Cyclamic acid and its Na and Ca salts
E953	Isomalt
E954	Saccharin and its Na, K and Ca salts
E955	Sucralose
E957	Thaumatin
E959	Neohesperidine DC
E961	Neotame
E962	Salt of aspartame-acesulfame
E965	Maltitol (i) Maltitol (ii) Maltitol syrup
E966	Lactitol

E967	Xylitol
E968	Erythritol
E999	Quillaia extract
E1103	Invertase
E1105	Lysozyme
E1200	Polydextrose
E1201	Polyvinylpyrrolidone
E1202	Polyvinylpolypyrrolidone
E1203	Polyvinyl alcohol (PVA)
E1204	Pullulan
E1404	Oxidized starch
E1410	Monostarch phosphate
E1412	Distarch phosphate
E1413	Phosphated distarch phosphate
E1414	Acetylated distarch phosphate
E1420	Acetylated starch
E1422	Acetylated distarch adipate
E1440	Hydroxy propyl starch
E1442	Hydroxy propyl distarch phosphate
E1450	Starch sodium octenyl succinate
E1451	Acetylated oxidised starch
E1452	Starch aluminium octenyl succinate
E1505	Triethyl citrate
E1517	Glyceryl diacetate (diacetin)
E1518	Glyceryl triacetate (triacetin)
E1519	Benzyl alcohol
E1520	Propan-1,2-diol (propylene glycol)
E1521	Polyethylene glycols

Appendix 2. EU Food Categorisation System

To date, the following 17 food categories have been created:

1 Dairy
2 Fats and Oils
3 Edible Ice
4 Fruit and Vegetables
5 Confectionery
6 Cereals and Cereal Products
7 Bakery Wares
8 Meat and Meat Products
9 Fish and Fish Products
10 Eggs and Egg Products
11 Sugars and Table Top Sweeteners
12 Salt, Spices, Seasonings, Sauces etc.
13 PARNUTS
14 Beverages
15 Snacks
16 Desserts
17 Food Supplements

As indicated in Section 1.4 of this guidance and also in Chapter 2, the European Commission is currently finalising its proposal for the establishment of the categories into which the currently authorised food additives, together with their conditions of use, will be placed, the food categorisation system (FCS). The projected timescale is the end of 2010, and the information provided in the following tables should not be taken as final. The legal text of Annexes II and III should be consulted for the final version of the food categorisation system and the conditions of use of the permitted food additives. The electronic version of this guidance will provide a link to this information when the EC legislation is published in 2011.

The following table provides the provisional current subcategories (August, 2010) into which these main food categories have been further divided.

EU Food Categorisation System with Subcategories	
1.	**Dairy products** This category covers all types of dairy products that are derived from the milk of any milking animal, e.g., cow, sheep, goat, buffalo, including analogues, excluding products of Category 2 Fats and Oils, Category 14 and Category 16. In this category, a "plain" product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients (including sweeteners), unless otherwise specified. This category contains also corresponding lactose free products.
01.1	**Plain fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk)** Milk is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing.

01.2	**Plain fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non heat treated after fermentation** Fermented milk products are produced by fermentation, either by spontaneous souring by the action of lactic acid-forming bacteria or flavour forming- bacteria, or by inoculation of lactic acid-forming or flavour-forming bacteria. Buttermilk is the nearly milk fat-free fluid remaining from the butter-making process, e.g., the churning fermented or non-fermented milk and cream.
01.3	**Plain fermented products, heat-treated after fermentation**
01.4	**Flavoured fermented milk products including heat treated products** This category covers heat-treated and non-heat-treated products.
01.5	**Dehydrated milk as defined by Directive 2001/114/EC**
01.6	**Cream**
01.6.1	**Unflavoured pasteurised plain cream (excluding reduced fat creams)**
01.6.2	**Unflavoured live fermented cream products and substitute dairy products with a fat content of less than 20%**
01.6.3	**Other creams** This category covers creams which have undergone a higher heat treatment than pasteurisation, e.g. sterilised and UHT creams. Also including clotted cream, whipping and whipped creams, reduced-fat creams and flavoured creams.
01.7	**Cheese**
01.7.1	**Unripened cheese excluding products falling into Category 16** This category covers cheeses which are ready for consumption soon after manufacture, e.g. fresh cheese, unripened cheeses in brine.
01.7.2	**Ripened cheese** Ripened cheese including cheeses which are not ready for consumption soon after manufacture, but are held under such time and temperature conditions so as to allow the necessary biochemical and physical changes that characterise the specific cheese. Ripened cheese may be soft, semihard, hard or extra-hard.
01.7.3	**Edible cheese rind** The rind of the cheese is the exterior portion of the cheese mass that initially has the same composition as the interior portion of the cheese, but which may dry after brining and/ or ripening.
01.7.4	**Whey cheeses** This category covers solid or semi-solid products obtained by concentration of whey with or without the addition of milk, cream or other materials of milk origin, and moulding of the concentrated product. Including also whey protein cheeses which are principally made by coagulation of whey proteins which are extracted from the whey component of milk e.g. ricotta cheese
01.7.5	**Processed cheeses** This category covers spreadable or solid products with a very long shelf life obtained by melting and emulsifying cheese, mixtures of cheese, milk fat, milk protein, milk powder, and water in different amounts. Products may contain other added ingredients, such as flavours, seasonings and fruit, vegetables and/or meat.
01.8	**Dairy analogues, including beverage whiteners** This category covers products in which milk-proteins or milk-fat have partially or wholly been replaced by proteins, fats or oils of non dairy origin. This category covers also beverage whiteners including milk or cream substitutes consisting of a vegetable fat-water emulsion in water with milk protein and lactose or vegetable proteins for use in beverages such as coffee and tea.

2.	**Fats and Oils, and Fat Emulsions** This category covers all fat-based products that are derived from vegetable, animal or marine sources, or their mixtures
2.1	**Fats and oils essentially free from water (excluding anhydrous milkfat)**
2.2	**Fat and oil emulsions mainly of type water-in-oil**
2.2.1	**Butter and concentrated butter and butter oil and anhydrous milkfat** This category covers other fat and oil emulsion including spreads as defined by Article 115 and Annex XV of Council Regulation (EC) No 1234/2007 and liquid emulsions.
2.2.2	**Other fat and oil emulsions including spreads as defined by Council Regulation (EC) No 1234/2007 and liquid emulsions** This category covers other fat and oil emulsion including spreads as defined by Article 115 and Annex XV of Council Regulation (EC) No 1234/2007 and liquid emulsions.
2.3	**Vegetable oil pan spray**
3.	**Edible Ices**
4.	**Fruit and Vegetables**
04.1	**Unprocessed fruit and vegetables**
04.1.1	**Entire fresh fruit and vegetables**
04.1.2	**Peeled, cut and shredded fruit and vegetables** This category covers unprocessed fruit and vegetables which have undergone a cutting treatment such as peeling, cutting, trimming, shredding.
04.1.3	**Frozen fruit and vegetables**
04.2	**Processed fruit and vegetables** This category covers dried, canned, bottled fruit and vegetables; fruit and vegetables in vinegar, oil, or brine; fruit and vegetable preparations and jam, jellies and marmalades and similar products
04.2.1	**Dried fruit and vegetables**
04.2.2	**Fruit and vegetables in vinegar, oil, or brine** Vegetables in brine have a salt concentration is contributes significantly to the stability of the food.
04.2.3	**Canned or bottled fruit and vegetables** This category covers fully preserved products in cans, jars or retort pouches.
04.2.4	**Fruit and vegetable preparations** This category covers preparations such as pulp, purees, compote and similar products.
04.2.4.1	**Pulp, purees, and similar products** This category includes coconut milk.
04.2.4.2	**Compote**
04.2.5	**Jam, jellies and marmalades and similar products** This category covers products defined by Directive 2001/113/EEC and other fruit or vegetable spreads including low-calorie products.
04.2.5.1	**Extra jam and extra jelly as defined by Directive 2001/113/EEC**
04.2.5.2	**Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC**
04.2.5.3	**Other similar fruit or vegetable spreads**
04.2.5.4	**Nut butters and nut spreads** This category excludes sweetened chestnut puree covered by 2001/113/EC
04.2.6	**Processed potato products**

5.0	**Confectionery**
05.1	**Cocoa and Chocolate products as covered by Directive 2000/36/EC**
05.2	**Other confectionery** This category covers a sugar-based, starch-based, cocoa-based confectionary, hard and soft confectionery, liquorice, nougats, imitation chocolate, chocolate substitute products and cocoa-based products not covered by Directive 2000/36/EC. Products from categories other than 5.2 are not covered.
05.3	**Decorations** This category covers decorations e.g., for fine bakery wares, candy and confections. It includes non-fruit toppings, glazing, coatings, syrups, sweet sauces and fillings. Excluded are chocolate products covered by, unflavoured and non-coloured products covered by category 11 and fruit-based toppings within category 4 fruits and vegetables.
05.4	**Micro sweets for throat and breath freshening** This category covers throat and breath freshening pastilles, strips and similar products.
05.5	**Chewing gum** This category covers products which are made from natural or synthetic gum base containing flavourings, sugars and/or sweeteners.
6.	**Cereals and Cereal Products** This category covers unprocessed and processed products derived from cereal grains, from roots and tubers, pulses and legumes, excluding products from food category 7 bakery wares.
06.1	**Whole, broken, or flaked grain** This category includes barley, corn (maize), oats, sorghum, soybeans, wheat, and rice
06.2	**Flours and starches** This category includes soybean powder.
06.2.1	**Flours** In this category premixes are considered as compound food.
06.2.2	**Starches**
06.3	**Breakfast cereals** This category covers products that are primarily manufactured from cereal grains (such as maize, wheat, barley, rye, oats and rice), including rolled oats.
06.4	**Pasta** This category covers products consisting of a dough prepared with wheat or cereal flours. Other ingredients like eggs and vegetables may be added.
06.4.1	**Fresh pasta** This category covers products that are untreated (i.e., not heated, boiled, steamed, cooked, pre-gelatinized or frozen, excluding heat treatments for conversation and hygenic purposes) and are not dehydrated. Including gnocchi
06.4.2	**Dried pasta** This category covers dehydrated pasta with a humidity content of not more than 13% on dry solids.
06.4.3	**Potato-gnocchi** Small balls or cylindrical rods with or without typical line-drawn surfaces, obtained from a dough using potatoes, wheat four, starch and salt. Sometimes eggs, milk and a small quantity of fat can be added.
06.4.4	**Fillings of stuffed pasta (ravioli and similar)** Mixture of fresh, cooked or seasoned meat and fish, vegetables, cheese, ricotta-cheese and various other ingredients suitably minced and mixed with salt, breadcrumbs, potato flakes and spices.

06.5	**Noodles and similar products** This category covers treated (i.e., heated, boiled, steamed, cooked, pre-gelatinized or frozen) products consisting of a dough prepared mainly of cereals and water. Including instant noodles
06.6	**Batters including pre-dusts, cereal-based coatings and breaders** This category includes pre-dusts and breaders for, e.g. fish or poultry.
06.7	**Pre-cooked and processed cereals** This category covers pre-cooked and processed rice products, including rice cakes (oriental type only) and other pre-cooked cereals.
7.	**Bakery Wares** This category covers products which are prepared mainly with flour or cereals and may have undergone a heat treatment, e.g. baking, steaming.
07.1	**Breads and rolls** This category covers all ordinary bakery wares like bread, e.g., wheat bread, rye bread, whole meal bread, multi-grain bread, rolls, bagels, pita, English muffins, rusks and steamed breads. This category includes bread-based products, e.g. croutons, bread stuffing, prepared doughs (excluding pre-dusts, cereal- based coatings and breaders in Category 6).
07.1.1	**Bread prepared solely with wheat flour, water, yeast or leaven, salt**
07.1.2	**Pain courant francais: Friss búzakenyér, fehér és félbarna kenyerek** Pain courant français: bread prepared solely with the following ingredients: wheat flour, water, yeast or leaven, salt. Other food ingredients such as flour of bean or soya or malted wheat can be added for a technological purpose. Friss búzakenyér, fehér és félbarna kenyerek: fehér kenyerek - white breads: White bread, consisting of 100% of wheat-flour, produced with yeast or yeast substitute, manufactured through kneading, forming, rising and baking of the dough.
07.2	**Fine bakery wares** This category covers products such as cookies, cakes, biscuits, agglomerated cereal bars, pastries, pies, scones, cornets, wafers and crackers. In this category, a cracker is a thin crisp wafer usually unsweetened, e.g. soda crackers, rye crisps, mathozns. Flavoured crackers are covered by Category 15.1: Snacks - potato-, cereal-, flour- or starch-based
8.	**Meat**
8.1	**Unprocessed meat** 'Unprocessed' means not having undergone any treatment resulting in a substantial change in the original state of the foodstuffs. However, they may have been, e.g. divided, parted, severed, boned, minced, skinned, pared, peeled, ground, cut, cleaned, trimmed, deep-frozen, frozen, chilled, milled or husked, packed or unpacked
8.2	**Meat preparations** Fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat.
8.3	**Processed meat** Processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat. Processing means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes
8.3.1	**Non heat treated processed meat**
8.3.2	**Heat treated processed meat**
8.3.3	**Casings and coatings**

9.	**Fish and Fishery Products**
	This category covers fish and fisheries products, including molluscs, crustaceans and echinoderms.
9.1	**Unprocessed fish and fisheries products**
	This category covers unprocessed products. The products may be cleaned, gutted, headed, filleted, peeled, cut into pieces etc. The products can be chilled, frozen and deep frozen.
9.1.1	**Unprocessed fish**
9.1.2	**Unprocessed molluscs, crustaceans**
9.2	**Processed fish and fisheries products including crustaceans and molluscs**
	This category includes smoked, fermented, dried and/or salted fish and fisheries products, including molluscs and crustaceans. These products may be sold canned or in vinegar, brine, oil etc. This category covers also surimi and similar products which are obtained from fish proteins and processed into various shapes.
9.3	**Fish roe**
10.	**Eggs and Egg Products**
10.1	**Unprocessed eggs**
	This category covers unprocessed eggs in their shell
10.2	**Processed eggs and egg products**
	This category covers egg products which may have been frozen, dehydrated, dried or concentrated, as well as boiled eggs.
11.	**Sugars, Syrups, Honey and Table-top Sweeteners**
11.1	**Sugars and syrups as defined by Directive 2001/111/EC**
11.2	**Other sugars and syrups**
	This category covers sugars and syrups not covered by Directive 2001/111. Excluded are flavoured syrups from Category 5 confectionery.
11.3	**Honey**
11.4	**Table-top Sweeteners**
	This category covers products that are preparations of intense sweeteners, which may contain polyols or other food additives and/or food ingredients and which, when compared on a weight-for-weight basis, are significantly sweeter than sucrose. Includes blends with sugar, deriving their sweetness intensity predominantly from intense sweeteners. These products, which are sold to the final consumer as a substitute for sugar, may be in powder, solid, e.g. tablets or cubes, or liquid form
12.	**Salts, Spices, Soups, Sauces, Salads and Protein Products**
12.1	**Salt and salt substitutes**
	This category covers food-grade sodium chloride. Includes table salt, including fluoride iodized salt and similar products. Salt substitutes are seasonings with reduced sodium content intended to be used on food in place of salt.
12.2	**Herbs, spices, seasonings and condiments**
12.2.1	**Herbs and spices**
	Herbs and spices are edible parts of plants which are traditionally added to foodstuffs for their natural flavouring, aromatic and visual properties. This category includes mixtures which only contain herbs and spices and, if necessary, permitted anti-caking agents.
12.2.2	**Seasonings**
	A seasoning is a blend of permitted food ingredients added as necessary to achieve an improvement of taste, eating quality and/or functionality of a food. It may have additional functional properties such as thickening, emulsifying, preserving, tenderising, colouring. It typically contains one or more herbs and/or spices and other flavour-enhancing or flavour-imparting ingredients.

12.3	**Vinegar** Liquid produced from fermentation of ethanol from a suitable source, e.g., wine, cider.
12.4	**Mustard** Condiment sauce prepared from ground, often defatted, mustard seed that is mixed into a slurry with water, vinegar, salt, oil and other spices and refined.
12.5	**Soups and broths** This category covers ready-to-eat soups and concentrated products to be reconstituted before consumption.
12.6	**Sauces and similar products** This category covers sauce, gravy, mayonnaise, ketchup, salad cream, dressing and similar products. Emulsified sauces are based, at least in part, on a fat- or oil-in water emulsion. Non-emulsified sauces include barbecue sauce, tomato ketchup, cheese sauce, Worcestershire sauce, chilli sauce, sweet and sour dipping sauce.
12.7	**Salads and sandwich spreads** This category covers prepared and spreadable salads, as macaroni salad, potato salad and Feinkostsalat.
12.8	**Yeast and yeast products** This category includes baker's yeast and leaven used in the manufacture of baked goods and alcoholic beverages. It also covers yeast derivatives such as yeast extracts and cell walls.
12.9	**Protein products** This category covers protein analogues or substitutes for standard products, such as meat, fish or milk from other animal or vegetable origin, including gelatine.
13.	**Foodstuffs Intended for Particular Nutritional Uses as Defined by Directive 2009/39/EC**
13.1	**Foods for infants and young children** This category covers infant and follow-on formulae as defined by Directive 2006/141/EC, processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC and other foods for young children.
13.1.1	**Infant formulae as defined by Directive 2006/141/EC**
13.1.2	**Follow-on formulae as defined by Directive 2006/141/EC**
13.1.3	**Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC**
13.1.3.1	**Processed cereal-based foods including cereals, biscuits and rusks**
13.1.3.2	**Fruit- and vegetable-based drinks, juices and baby foods**
13.1.3.3	**Desserts and puddings**
13.1.4	**Other foods for young children including food supplements for young children** This category covers foods for young children not covered by Directive 2006/125/EC such as milk based products for young children.
13.1.5	**Dietary foods for infants and young children for special medical purposes as defined by Directive 1999/21/EC and special formulae for infants**
13.1.5.1	**Dietary foods for infants for special medical purposes and special formulae for infants** This category covers premature infant formulae, hospital discharge formulae, low birth and very low birth weight formulae, and human breast milk fortifiers.
13.1.5.2	**Dietary foods for babies and young children for special medical purposes**
13.2	**Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from Food Category 13.1.5)**
13.3	**Dietary foods for weight control diets intended to replace total daily food intake or an individual meal**
13.4	**Foodstuffs suitable for people intolerant to gluten as defined by Regulation (EC) 41/2009**

14.	**Beverages** Excluding the Category 1.1 Unflavoured milk
14.1	**Non-alcoholic beverages**
14.1.1	**Water** This category includes natural mineral waters, spring waters, table waters and soda waters.
14.1.2	**Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices**
14.1.3	**Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars**
14.1.4	**Flavoured drinks** This category covers water-, dairy- and fruit-based flavoured drinks, including "sport," "energy," and "electrolyte" drinks, excluding products covered by categories 14.1.1, 14.1.2, 14.1.3 and 14.1.5.
14.1.5	**Coffee, tea, and similar hot beverages (excluding cocoa)**
14.1.5.1	**Coffee, coffee extracts and unflavoured tea**
14.1.5.2	**Other hot beverages** This category covers coffee-based drinks, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages.
14.2	**Alcoholic beverages, including alcohol-free and low-alcohol counterparts**
14.2.1	**Beer and malt beverages**
14.2.2	**Wine and partially fermented grape must defined by Annex XI b of Council Regulation (EC) 1234/2007**
14.2.3	**Cider and perry**
14.2.4	**Fruit wine and made wine** This category includes products obtained by fermentation of ingredients/substances other than grape.
14.2.5	**Mead**
14.2.6	**Distilled alcoholic beverages**
14.2.6.1	**Spirit drinks as defined by Regulation (EC) 110/2008**
14.2.6.2	**Spirituous beverages containing less than 15 % of alcohol**
14.2.7	**Aromatised wine-based products as defined by Regulation (EEC) No 1601/91**
14.2.7.1	**Aromatised wines**
14.2.7.2	**Aromatised wine-based drinks**
14.2.7.3	**Aromatised wine-product cocktails**
14.2.8	**Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine**
15.	**Ready-to-eat Savouries** This category covers potato-, cereal-, flour- or starch-based snacks and processed nuts.
15.1	**Potato-, cereal-, flour- or starch-based snacks** In this category, the starch originates from roots and tubers, pulses and legumes.
15.2	**Processed nuts** This category includes marinated and/or coated nuts and nut mixtures with, e.g. dried fruit.
16.	**Desserts**
17.	**Food Supplements as Defined in Directive 2002/46/EC**
17.1	**Food supplements supplied in a solid form including capsules and tablets and similar forms** This category includes supplements to be dissolved in liquid before consumption, e.g. effervescent tablets. The amount of sweeteners applies for the prepared product.
17.2	**Food supplements supplied in a liquid form**
17.3	**Food supplements based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form**

Appendix 3. Specific Priorities for Assessment of Certain Food Additives by EFSA

(within the functional classes of food additives as referred to in Article 3(1) and (2) of Regulation 1333/2008 (Annex II of the Regulation)

Part 1. Food Colours

Within the overall deadline of 31.12.2015 set for the re-evaluation of food colours in Article 3(1) the following specific deadlines are set for the following food colours:

1. The following food colours shall be evaluated by 15.4.2010

E 123 Amaranth
E 151 Brilliant Black BN, Black PN
E 154 Brown FK
E 155 Brown HT and
E 180 Litholrubine BK

2. The following food colours shall be evaluated by 31.12.2010

E 100 Curcumin
E 127 Erythrosine
E 131 Patent Blue V
E 132 Indigotine, Indigo carmine
E 133 Brilliant Blue FCF
E 142 Green S
E 150a Plain caramel
E 150b Caustic sulphite caramel
E 150c Ammonia caramel
E 150d Sulphite ammonia caramel
E 161b Lutein
E 161g Canthaxanthin
E 170 Calcium carbonate

3. The following food colours shall be evaluated by 31.12.2015

E 101 (i) Riboflavin (ii) Riboflavin-5'-phosphate
E 120 Cochineal, Carminic acid, Carmines
E 140 Chlorophylls and Chlorophyllins: (i) Chlorophylls (ii) Chlorophyllins
E 141 Copper complexes of Chlorophylls and Chlorophyllins: (i) Copper complexes of chlorophylls (ii) Copper complexes of chlorophyllins
E 153 Vegetable carbon
E 160b Annatto, bixin, norbixin
E 160a Carotenes: (i) mixed carotenes, (ii) beta-carotene
E 160c Paprika extract, capsanthin, capsorubin
E 160e Beta-apo-8'-carotenal (C30)
E 160f Ethyl ester of beta-apo-8', -carotenoic acid (C30)
E 162 Beetroot red, betanin
E 163 Anthocyanins
E 171 Titanium dioxide
E 172 Iron oxides and hydroxides
E 174 Silver
E 175 Gold

Part 2. Food Additives Other Than Colours and Sweeteners

Within the overall deadline of 31.12.2018 set for the re-evaluation of food additives other than colours and sweeteners in Article 3(1), the following specific deadlines are set for certain food additives and groups of food additives:

1. Preservatives and antioxidants E 200-203; E 210-215, E 218-252, E 280-285; E 300-E 321 and E 586 shall be evaluated by 31.12.2015

With higher priority within this group on:

E 310-312 Gallates
E 320 Butylated hydroxyanisole (BHA)
E 321 Butylated hydroxytoluene (BHT)
E 220-228 Sulphur dioxide and sulphites
E 304 Fatty acid esters of ascorbic acid: (i) Ascorbyl palmitate (ii) Ascorbyl stearate
E 200-203 Sorbic acid and sorbates
E 284 Boric acid
E 285 Sodium tetraborate (borax)
E 239 Hexamethylene tetramine
E 242 Dimethyl dicarbonate
E 249 Potassium nitrite
E 250 Sodium nitrite
E 251 Sodium nitrate
E 252 Potassium nitrate
E 280-283 Propionic acid and its sodium, calcium and potassium salts
E 306 Tocopherol-rich extract
E 307 Alpha-tocopherol
E 308 Gamma-tocopherol
E 309 Delta-tocopherol

2. Emulsifiers, stabilisers, gelling agents E 322, E 400-E 419; E 422-E 495; E 1401-E 1451 shall be evaluated by 31.12.2016

With higher priority within this group on:

E 483 Stearyl tartrate
E 491-495 Sorbitan esters
E 431 Polyoxyethylene (40) stearate
E 432-436 PolysorbatesE 444 Sucrose acetate isobutyrate
E 481 Sodium stearoyl-2-lactylate
E 482 Calcium stearoyl-2-lactylate
E 414 Acacia gum (gum arabic) (*)
E 410 Locust bean gum (*)
E 417 Tara gum (*)
E 422 Glycerol
E 475 Polyglycerol esters of fatty acids

3. **E 551 Silicon dioxide, E 620-625 Glutamates, E 1105 Lysozyme and E 1103 Invertase shall be evaluated by 31.12.2016**

4. **The remaining food additives other than colours and sweeteners shall be evaluated by 31.12.2018**

With higher priority on:

E 552 Calcium silicate
E 553a Magnesium silicate and trisilicate
E 553b Talc
E 558 Bentonite
E 999 Quillaia extract
E 338-343 Phosphoric acid and phosphates
E 450-452 Di-, tri- and polyphosphates
E 900 Dimethyl polysiloxane
E 912 Montan acid esters
E 914 Oxidised polyethylene wax
E 902 Candellila wax
E 904 Shellac
E 626-629 Guanylic acid, Disodium guanylate, Dipotassium guanylate and Calcium guanylate
E 630-633 Inosinic acid, Disodium inosinate; Dipotassium inosinate and Calcium inosinate
E 634-635 Calcium 5'-ribonucleotides and Disodium 5'-ribonucleotides
E 507-511 Hydrochloric acid, Potassium chloride, Calcium chloride, Magnesium chloride
E 513 Sulphuric acid

Appendix 4. Members of the FSAI Sub-committee on Food Additives, Chemical Contaminants and Residues

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