Food Safety
AUTHORITY OF IRELAND

Guidance on Food Additives

Revision 2, 2015

PREFACE

This guidance document provides an overview of the European Union and National legislation related to additives in food, together with guidance on its interpretation. This document does not purport to be comprehensive or to be a legal interpretation or to constitute legal or other professional advice. Unless otherwise stated, the definitions and terminology used in this report relate to this document only.

References to the applicable legislation are valid, to the best knowledge of the Food Safety Authority of Ireland (FSAI), at the time of publication. Advances in scientific knowledge and changes in legislation can be expected in the future that will necessitate the updating of this document. Further information on all of the legislation covered by this guidance or introduced subsequent to its date of publication (November, 2015) is available from the **fsai website**.

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Summary

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

Food additives are defined in European Union 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 EU 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 or MPL) in certain foodstuffs. If no quantitative limits or MPL 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, e.g. 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

Food additives must also have advantages and benefits for the consumer and therefore, serve one or more of the following purposes:

- Preserving the nutritional quality of the food
- Providing necessary ingredients or constituents for foods manufactured for groups of consumers with special dietary needs
- Enhancing the keeping quality or stability of a food or improving its organoleptic properties, provided that the nature, substance or quality of the food is not changed in such a way as to mislead the consumer
- Aiding in the manufacture, processing, preparation, treatment, packing, transport or storage of food, including food additives, food enzymes and food flavourings, provided that the food additive is not used to disguise the effects of the use of faulty raw materials or of any undesirable practices or techniques, including unhygienic practices or techniques, during the course of any such activities

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). For a new additive or an additive that is being re-evaluated, if it 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.

The Community legislation on food additives comprises Regulation (EC) No 1333/2008 together with 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), 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 for use 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 use in foods

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 Commission Regulation 231/2012/EC.

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 (Regulation 1169/2011/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) which has been superseded by the National Adult Nutrition Survey (NANS) for those over 18 years old (2008-2010), for children aged between 1-4 years (National Pre-School Nutrition Survey (NPNS), 2010-2011), 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 recorded as part of the NANS (b) the outcome of a 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 nitrates, nitrites and sulphites by the Irish adult population.

[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."

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 completely revised in 2008, together with that on flavouring substances. At the same time, new legislative requirements were introduced for enzymes for use in food.

This resulted in a new 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 Food Improvement Agents Package (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 replaced and revoked 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 remained in force as a transitional measure until June 1st 2013. On that date, a revised Union list of approved food additives (Annex II of Regulation 1333/2008/EC), introduced via Regulation 1129/2011/EC came into force. A related Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients (Annex III of Regulation 1333/2008/EC) was introduced via Regulation 1130/2011, which applied from 2nd December 2011.

In 2001, the FSAI, with the support of its Food Additives, Chemical Contaminants and Residues Sub-Committee, published the guidance document *Legislation, Intake and Usage of Food Additives in Ireland*, reflecting the requirements of the (EC) legislation in place at that time (FSAI, 2001). Revised guidance was issued by the FSAI in 2010 to reflect the requirements of the 2008 legislation on food additives and their authorisation (FSAI, 2010), and a further minor revision was published in 2011 (FSAI, 2011). Given that there have been more than 50 amendments to the additives Regulation since it was published in 2008, the current guidance provides a further update to provide information on the most recent Union lists of food additives and other related topics.

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 has been published by the FSAI on flavourings and food ingredients with flavouring properties for use in and on foods (FSAI, 2012) and guidance will be published on food enzymes when the approved list is agreed (still under discussion at EU level).

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 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 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 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 not considered to be food additives and are therefore, outside the scope of the additives legislation.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, e.g. wax coating on cheese

(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, but also falling outside the scope of the legislation, as they are regulated separately, include 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 Union 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. Extraction solvents falling within the scope of EC Directive 2009/32/EC fall also outside the scope of the additives legislation. The use of additives in wine must comply with Regulation 1333/2008/EC and with the provisions in the relevant EU legislation on oenological practises and processes.

[2] This exclusion only applies from the date of adoption of the Union list of food enzymes under Regulation 1332/2008; This list is still under discussion at European level and the Commission has indicated at the working group on enzymes that the list may be published before the end of 2015; until that time food additive enzymes (invertase and lysozyme) will be covered by Regulation 1333/2008/EC.

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. There is no national legislation on processing aids in Ireland nor is there any legally defined list of approved processing aids either within Ireland or the within the EU. 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

Food additives may be assigned to one of the functional classes as laid down in Annex I of Regulation 1333/2008/EC dependent on the technological function of the particular additive in the food to which it is added. These functional classes are listed in Table 1.1.

Table 1.1. Functional classes of food additives

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

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
27. **Contrast enhancers** are substances which, when applied to the external surface of fruit or vegetables following depigmentation of predefined parts, e.g. by laser treatment, help to distinguish these parts from the remaining surface by imparting colour following interaction with certain components of the epidermis

Food additives may exist in more than one functional class, e.g. sodium hydrogen carbonate which is also known as bicarbonate of soda or E-500, is best known as a raising agent but can also function as an anti-caking agent or acidity regulator.

1.3 Lists of Authorised Food Additives

As already indicated, and as described further in Chapter 2, the legislation on food additives was revised in 2008. Regulation 1331/2008/EC provides for the establishment of Union lists of substances (one each for additives, flavourings and enzymes) that have been authorised to be placed on the market of the European Union (Article 2 of 13331/2008/EC). The list of currently authorised food additives in the European Union (Annex II of Regulation 1333/2008/EC) is provided as Appendix 1 to this guidance for the convenience of the reader. This list will however, be amended via further Regulations from time to time, to introduce new additives or to remove additives no longer authorised, and the EU legislation should be consulted to verify the most up-to-date list of authorised additives.

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 list of food additives has been compiled over many years. The safety of each food additive has been evaluated by the SCF and subsequently 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 (authorisation) must go through a lengthy evaluation procedure before addition to the list. The list of all authorised additives is contained in part B of Annex II of Regulation 1333/208/EC, and was introduced via Commission Regulation 1129/2011/EC, which entered into force on the 2nd December 2011, although the list itself was not applicable until 1st of June 2013. This single list of food additives replaced the separate lists of authorised additives that formed part of the three earlier Directives on sweeteners (94/35/EC), colours (94/36/EC) and miscellaneous additives (95/2/EC). The list of additives in Part B of annex II of Regulation 1333/2008/EC is however divided into groups according to whether the authorised additive is (1) a colour, (2) a sweetener or (3) an additive other than a colour or a sweetener (miscellaneous additive), these groupings representing the same grouping found in the earlier Directives on food additives. Part A of Annex II contains a brief introduction to the list and some general provisions related to the listed additives and their conditions of use, including lists of foods in which food additives and food colours are not permitted, even as a result of the carry-over principle as described in Article 18 of Regulation 1333/2008/EC.

The list of approved additives and their conditions of use which is now contained in Annex II of Regulation 1333/2008/EC is also available in the form of an online searchable database on the European Commission's website. This database can serve as a useful tool to inform users about the food additives approved for use in foods within the European Union, and their conditions of use (See section 1.4). Click here for this database.

Regulation 1333/2008 also provides for the establishment of a Union list of additives including carriers that may be used in food additives themselves, in food enzymes, in food flavourings and in nutrients together with their conditions of use. In parallel with the list of authorised additives (Annex II of Regulation 1333/2008/EC), this list was introduced into Annex III of Regulation 1333/2008, via Commission Regulation 1130/2011/EC, which entered into force on 2nd December 2011, although the list itself was not applicable until 1st of June 2013.

Annex III is subdivided into a number of parts. Food additives currently authorised as carriers in food additives themselves and their conditions of use are contained in part I. Part II comprises a list of food additives other than carriers authorised for use in food additives themselves. Part III is a list of additives and carriers authorised for use in food enzymes and part IV is a list of authorised additives in food flavourings and their conditions of use. Finally, food additives that were 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 across to Part V 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 above, conditions[3] are normally laid down under which the additive may be used, in particular the types of food it can be used in (food categories) and the maximum permitted level (MPL)[4]. The food categories and conditions of use are laid down in part D and E respectively of Annex II of Regulation 1333/2008/EC, which was introduced via Commission Regulation 1129/2011/EC, applicable from 1st of June 2013. Although the conditions of use are similar to those previously 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), a new hierarchial food categorisation system (FCS) has been introduced, 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 FCS currently contains 18 food categories which are further subdivided into over 150 subcategories. The current 18 food categories with their subcategories are reproduced in Appendix 2 of this guidance. All currently authorised additives have been placed into one or more of these food categories and sub-categories. The number of additives which may be permitted in the various food categories varies widely, with for example zero additives permitted in Category 11.3: honey, whilst there are more than 250 additives listed under Category 3: edible ices.

As envisaged in Recital 5 of Regulation 1129/2011/EC, guidance has been provided by the European Commission to describe the 18 different food categories and their sub-categories in Annex II of Regulation 1333/2008/EC in order to ensure uniform interpretation of the legislation and to provide clarification on interpretation of the foods that fall (or do not fall) within a particular category. This document is known as the descriptors document and it was elaborated by the Commission Services after consultation with the Member States' experts on food additives and the relevant stakeholders. The descriptions of the categories are useful for all control authorities and the food industry alike to ensure correct implementation of the food additive legislation. Click here for the guidance document.

The conditions of use of the additives specified in Annex II part E of Regulation 1333/2008/EC have not been included in Appendix 2, due to space constraints, and readers are referred to the legal text of the Regulation for these conditions of use.

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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 be 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. Legislation

2.1 Food Additive Legislation

In the past, differences between national laws relating to food additives and the conditions for their use caused technical 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 their conditions of use. In 1989, the European Union 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 (Directives 94/35/EC, 94/36/EC and 95/2/EC) 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 was laid down in Directives defining specific purity criteria.

As already indicated, the EC legislation on food additives has been substantially updated in recent years. The legislative package which replaced the previous Directives was published at the end of 2008, and comprised three individual Regulations on food additives, flavourings and food enzymes, and also a Regulation providing a common authorisation procedure for all three 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 applied from 20th January 2011. The two primary Regulations enacting Annexes II and III of Regulation 1333/2008/EC are also included in this list. It should be noted however, that at the time of writing Regulation 1129/2011/EC (Annex II) has already been amended over fifty times since its adoption, to add new additives to the list or to amend the conditions of use of already authorised additives. A complete list of amendments with their topics and dates of application is available on the FSAI website, which also provides a consolidated version of Regulation 1333/2008/EC showing all amendments up to November 2015.

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

Regulation No and Title
Regulation 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings
Regulation 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes
Regulation 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
Regulation 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods
Regulation 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives
Regulation 1130/2011/EC of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients

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 Union 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 previous legislation on food additives were maintained in the updated legislation listed above. In addition, new aspects include:

(a) The possibility to update the existing Union 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 (SCoFCAH)[6]

(b) A core role for the European Food Safety Authority (EFSA) in risk assessment related to food additives, flavourings and food enzyme

(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)

(d) Restrictions on the use and maximum permitted levels of the colours Quinoline Yellow (E 104), Sunset Yellow (E110) and Ponceau 4R (E 124) following their evaluation by EFSA in 2009. These measures were introduced in EC Regulation (EU) No 232/2012, which applied from 1 June 2013.

Two significant amendments which have been made to the additives Regulation in recent years include:

- Restrictions on the use of aluminium containing food additives which were introduced via Commision Regulation (EU) No. 380/2012, which came into force on 23 May 2012. These measures were taken as a result of the EFSA opinion in 2008 in which the tolerable weekly intake (TWI) for aluminium was lowered to 1 mg/kg bw/week (EFSA, 2008a). Annex II of Regulation (EC) No 1333/2008 had authorised the use of aluminium-containing food additives in a wide number of foodstuffs, often at very high maximum permitted levels or without any indication of the maximum concentration levels (*quantum satis*). In addition, Annex II to Regulation (EC) No 1333/2008 and Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in the Regulation authorise the use of some colours that may contain aluminium in the form of lakes in a wide number of foodstuffs, in general without any indication of the maximum concentration levels of aluminium in the lakes. As a result it was seen as appropriate to amend the conditions of use and reduce the use levels for aluminium-containing food additives, including aluminium lakes, to ensure that the revised TWI is not exceeded. This was done via Commission Regulation 380/2012/EC.
- When the Union list as set out in Annex II to Regulation (EC) No 1333/2008 was established, meat preparations[7] as defined by Regulation (EC) No 853/2004 were considered as unprocessed meat in which only a restricted number of additives were authorised. However, different interpretations as to what constituted a meat preparation led to the situation where the use of certain additives in particular categories of meat differed between the Member States. The Commission have produced a guidance document on the implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin. This document includes examples of what constitutes meat preparations and meat products.

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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"

6 This committee has changed its name to the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF).

7 Meat preparations are defined as meat that has foodstuffs, seasonings or additives added to it or which has undergone a treatment that is insufficient to modify the cellular structure of the meat and thus to cause the characteristics of the fresh meat to disappear.

- In 2014, following extensive discussions at the EU WG on food additives, it was agreed to authorise as appropriate the use of additional additives in Food Category 8.2, i.e. meat preparations as a result of these historical differences. Irish products such as breakfast sausages and burger meat with a minimum vegetable and/or cereal content of 4% are amongst the products considered to be meat preparations as defined by Regulation (EC) 853/2004. These new provisions include the authorisation of phosphates in burger meat as well as permitting the use of carry-over additives into meat preparations. Further details on these provisions can be found in Regulation 601/2015.

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) Union lists of approved food additives, as already mentioned in Section 1.3

(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

Food additives including colours and sweeteners authorised under Regulation 1333/2008/EC in accordance with the procedures laid down in Regulation 1331/2008 are included in Annex II of Regulation 1333/2008, introduced via Regulation 1129/2011. A programme of re-evaluation by EFSA of food additives authorised before the Regulations came into force has been put in place, (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 have been and food enzymes will be put in place under their respective sector Regulations. EFSA has developed 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 for food additives, enzymes and flavouring substances. As with food additives, in order to be authorised, food flavourings and 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 flavouring or food 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 Union list in Annex II of Regulation 1333/2008 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 Annex III of Regulation 1333/2008 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

1. In accordance with article 18 of the additives Regulation, 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[8] other than as referred to in Annex II of Regulation 1333/2008, where the food additive is permitted in one of the ingredients of the compound food;

   An example of this is biscuits with cereals flakes which belong to food category "fine bakery wares (7.2)". Gallates, TBHQ and BHA (E 310- E 320) are not listed in that category. However these additives are authorised for use in pre-cooked cereals with a maximum level of 200 mg/kg, and therefore their presence in the biscuits is proportionally acceptable

   (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'

   An example of reverse carry-over is the use of Annatto (not normally permitted for use) in seasonings (12.2.2) that is intended solely for use in a snack food (15.1), provided the level of Annatto does not result in the maximum level of Annatto permitted in the snack food being exceeded.

2. 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 covering these foodstuffs, except where specifically provided for in Regulation 1333/2008 (see also Section 2.4).
3. Where a food additive present in a food flavouring, food additive or food enzyme is added to a food via inclusion of the flavouring, additive or enzyme and has a technological function in that food, it shall be considered a food additive of that food and not a food additive of the added flavouring, food additive or food enzyme, and must then comply with the conditions of use for that food as provided.
4. Without prejudice to paragraph 1, the presence of a food additive used as a sweetener shall be permitted in a compound food with no added sugars, in an energy-reduced compound food, in compound dietary foods intended for low-calorie diets, in non-cariogenic compound foods and in a compound food with an increased shelf-life, provided that the sweetener is permitted in one of the ingredients of the compound food.

[8] A compound food means a food that is the product of more than one ingredient.

Table 2.2 below lists the foods in which the presence of an additive may not be permitted by virtue of the carry-over principle as set out in Article 18 (1) (a) of Regulation (EC) No 1333/2008. There are also a number of food categories for which the presence of a colour(s) is not permitted by virtue of the carry-over principle and these are listed in Table 2.3 below.

Table 2.2 Foods in which the presence of an additive may not be permitted by virtue of the carry over principle set out in Article 18(1)(a) of Regulation (EC) No 1333/2008

1	Unprocessed foodstuffs as defined in Article 3 of Regulation 1333/2008, excluding meat preparations as defined by Regulation (EC) No 853/2004
2	Honey as defined in Council Directive 2001/110/EC
3	Non-emulsified oils and fats of animal or vegetable origin
4	Butter
5	Unflavoured pasteurised and sterilised (including UHT) milk and unflavoured pasteurised cream (excluding reduced fat cream)
6	Unflavoured, fermented milk products not heat treated after fermentation
7	Unflavoured buttermilk (excluding sterilised buttermilk)
8	Natural mineral water as defined in Directive 2009/54/EC of the European Parliament and of the Council and spring water and all other bottled or packed waters
9	Coffee (excluding flavoured instant coffee) and coffee extracts
10	Unflavoured leaf tea
11	Sugars as defined in Directive 2001/111/EC
12	Dry pasta, excluding gluten-free and/or pasta intended for hypoproteic diets, in accordance with Directive 2009/39/EC of the European Parliament and of the Council
13	Foods for infants and young children as referred to in Regulation (EU) No 609/2013 (former Directive 2009/39/EC), including foods for special medical purposes for infants and young children

Table 2.3 Foods in which the presence of a food colour may not be permitted by virtue of the carry over principle set out in Article 18(1)(a) of Regulation (EC) No 1333/2008

1	Unprocessed foods as defined in Article 3 of Regulation (EC) No 1333/2008
2	All bottled or packed waters
3	Milk, full fat, 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 Council Directive 2001/114/EC (unflavoured)
7	Buttermilk (unflavoured)
8	Cream and cream powder (unflavoured)
9	Oils and fats of animal or vegetable origin
10	Ripened and unripened cheese (unflavoured)
11	Butter from sheep and goats' milk
12	Eggs and egg products as defined in Regulation (EC) No 853/2004
13	Flour and other milled products and starches
14	Bread and similar products
15	Pasta and gnocchi
16	Sugar including all mono- and disaccharides

17	Tomato paste and canned and bottled tomatoes
18	Tomato-based sauces
19	Fruit juice and fruit nectar as mentioned in Council Directive 2001/112/EC and vegetable juice and vegetable nectars
20	Fruit, vegetables (including potatoes) and mushrooms — canned, bottled or dried; processed fruit, vegetables (including potatoes) and mushrooms
21	Extra jam, extra jelly, and chestnut purée as mentioned in Council Directive 2001/ 113/EC; crème de pruneaux
22	Fish, molluscs and crustaceans, meat, poultry and game as well as their preparations, but not including prepared meals containing these ingredients
23	Cocoa products and chocolate components in chocolate products as mentioned in Directive 2000/36/EC of the European Parliament and of the Council
24	Roasted coffee, tea, herbal and fruit infusions, chicory; extracts of tea and herbal and fruit infusions and of chicory; tea, herbal and fruit infusions and cereal preparations for infusions, as well as mixes and instant mixes of these products
25	Salt, salt substitutes, spices and mixtures of spices
26	Wine and other products covered by Council Regulation (EC) No 1234/2007, as listed in its Annex I, Part XII
27	Spirit drinks defined in Annex II, paragraphs 1-14 of Regulation (EC) No 110/ 2008 of the European Parliament and of the Council, spirits (preceded by the name of the fruit) obtained by maceration and distillation and London gin (Annex II paragraphs 16 and 22 of, respectively) Sambuca, Maraschino, Marrasquino or Maraskino and Mistrà as defined in Annex II, paragraphs 38, 39 and 43 of Regulation (EC) No 110/2008, respectively
28	Sangria, Clarea and Zurra as mentioned in Council Regulation (EEC) No 1601/ 91
29	Wine vinegar covered by Regulation (EC) No 1234/2007, as listed in its Annex I, Part XII
30	Foods for infants and young children as mentioned in Directive 2009/39/EC including foods for special medical purposes for infants and young children
31	Honey as defined in Directive 2001/110/EC
32	Malt and malt products

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[9], 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.

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 Annex II and III of the Regulation. Only food additives included in Annexes II and III of the Regulation may be placed on the market as such and used in foods under the conditions of use specified therein.

[9] Unprocessed food means 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, deepfreezing, freezing, chilling, milling, husking, packing or unpacking.

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. 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 Colouring Foods

Since 2007, the European Commission in consultation with the Member States and industry stakeholders set about the elaboration of a guidance document to address the issue of colouring foods. These colouring foods as their name suggests are foods with colouring properties and are made from edible fruits, vegetables and/or other edible plants. They are manufactured by physical processes resulting in concentrates in which the pigments have not been selectively extracted. This guidance document was adopted by the Standing Committee on the Food Chain and Animal Health (SCoFCAH) at the end of 2013. As a supplement to the exisiting EU legislation on food additives, the objective of the guidance note is to provide simple and practical criteria for the differentiation between foods with colouring properties (so-called colouring foods) and additive food colours within the EU. The guidance describes the criteria that determine the difference between selective and non-selective extraction which is the key to determining whether a substance is a food colour (additive) or a colouring food. Based on an easily applicable decision tree, these criteria serve as an important working and decision tool for the food industry and enforcement authorities of the EU Member States. The document can be found on the Commission website.

2.7 Dates of Application of The Provisions of Regulation 1333/2008

Table 2.4 details the dates of application of the provisions of Regulation 1333/2008/EC as well as the common authorisation procedure, i.e. Regulation 1331/2008/EC.

Table 2.4 Dates of application of the legislation on food additives

Regulation 1333/2008 on food additives	20th January, 2010
Regulation 1331/2008 introducing a common authorisation procedure for food additives, food enzymes and food flavourings	2nd December, 2011
Regulation 1129/2011 amending Annex II of Regulation 1333/2008 by establishing a Union list of food additives	1st June, 2013
Regulation 1130/2011 amending Annex III of Regulation 1333/2008 by establishing a union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients	2nd December, 2011 *31 May, 2013 **2nd December, 2013

* Preparations not complying with Parts 1 and 4 of Annex III could continue to be placed on the market in accordance with the provisions of Annexes I to VI of Directive 95/2/EC until 31 May 2013.

** Preparations not complying with Parts 2, 3 and/or Section A part 5 of Annex III could continue to be placed on the market in accordance with national provisions during a period of 24 months fom the date of entry into force of Regulation 1130/2001, i.e. until 2nd December, 2013.

NB: Foods containining such preparations that have been lawfully placed on the market within these periods may be marketed until stocks are exhausted.

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.

2.8 National Legislation

While the requirements of EU Regulations are binding on the EU Member States and do not have to be transposed word-for-word into national law, legislation is necessary to identify who is responsible for enforcement and to create penalties for non-compliance. In Ireland, the following Statutory Instrument (S.I.) enacts European additives legislation into Irish national law.

European Union (Food Additives) Regulations, 2015 (S.I. No. 330 of 2015)

This S.I. came into effect on 28 July 2015.

These Regulations give further effect to:

- Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives as amended
- Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives
- Commission Regulation (EU) No. 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as amended

And revoke and replace previous statutory instruments covering food additives and their purity criteria such as:

- European Communities (Food Additives) (Purity Criteria Verification) Regulations, 1983 (S.I. No. 60 of 1983)
- European Communities (Purity Criteria on Food Additives other than Colours and Sweeteners) Regulations, 2009 and 2011
- European Communities (Additives, Colours and Sweeteners in Foodstuffs) Regulations, 2000 to 2011
- European Communities (Food Additives other than Colours and Sweeteners) Regulations, 2004 to 2011

2.9 Purity Criteria

Food additives must comply with the approved specifications, which include information to adequately identify the food additive, and to describe the acceptable criteria of purity. Commission Regulation 231/2012 contains the specifications for all currently approved additives (colours, sweeteners and additives other than colours and sweeteners) listed in Annex II of Regulation 1333/2008. This Regulation replaces the previous individual Directives 2008/60/EC, 2008/84/EC and 2008/128/EC establishing purity criteria on sweeteners, food additives other than colours and sweeteners and colours, respectively.

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 following 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 animal studies for example, 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 for example, 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 unit per kilogram bodyweight per day basis, e.g. mg/kg bw/day, and is used extensively by regulatory and advisory bodies throughout the world, such as EFSA and the WHO/FAO Joint Expert Committee on Food Additives (JECFA)[10]. The ADI is the maximum daily intake regarded as acceptable by these bodies, and JECFA often 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 for food additives, EFSA has sought to identify the most sensitive endpoints from a range of toxicological hazards and their dose-response relationships, for identification of a so-called Reference Point or 'Point of Departure' (POD) (EFSA, 2012). This POD is used to establish an ADI, by application of uncertainty factors to account for toxicokinetic and toxicodynamic differences between individuals and species. 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). Typical PODs include the No Observed Adverse Effect Level (NOAEL) or a Bench Mark Dose (BMDL) value. The Benchmark Dose (BMD) approach aims at estimating the dose that corresponds to a low, but measurable change in response. The EFSA Scientific Committee has in recent years endorsed the benchmark

[10] JECFA operates under the aegis of the WHO and the Food and Agriculture Organisation of the United Nations (FAO) 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.

dose procedure as a preferred approach to the NOAEL, to define the POD for deriving health-based guidance values (EFSA, 2005; 2009a). Overall, the BMD approach is considered a more sophisticated and powerful approach for determining a POD as it makes use of a greater number of characteristics of the study under examination.

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 1970s. 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). When EFSA took over responsibility for risk assessment of food additives from the SCF in 2003, an updated version of the SCF guidance from 2001 (SCF, 2001) was endorsed by EFSA as their guiding principles for data requirements for new additives. In June 2012, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), adopted new guidance for the submission of food additive applications, reflecting advances in science and the latest risk assessment principles (EFSA, 2012).

The 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 required must be provided to the European Commission and EFSA before the application can be assessed. 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, which was most recently updated in 2015 (EC, 2015).

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 and it's implementing Regulation 234/2011/EC as amended. It provides the basis for the Union 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 Food Safety 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:

Head of Unit
European Commission
Health and Food Safety Directorate-General
Directorate E – Safety of the food chain
Unit E7 – Food improvement agents
B-1049 Brussels

And further information can be found on the Commission's website.

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 are 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 can take several years.

If the additive is deemed to be safe by EFSA, including (usually) the establishment of an ADI, the Commission then initiates the process to add the substance to the list of authorised food additives via a Commission Regulation[11]. 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 on Plants, Animals, Food and Feed (SCoPAFF) for vote (the comitology procedure) within nine months of the EFSA opinion. Following the vote by SCoPAFF[12], the draft is forwarded to the European Parliament, which has a further three 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 two 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.

11 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 a Commission Regulation.

12 The Standing Committee on Plants, Animals, Food and Feed was set up by Regulation 178/2002 on food law and food safety. The Committee's mandate covers the entire food supply chain - from animal health issues on the farm to the product on the consumer's table - helping the EU deal effectively with health risks at every stage of the production chain. The Standing Committee on Plants, Animals, Food and Feed is divided into 14 different sections, e.g. toxicological safety of the food chain and these committees are made up of representatives from EU Member States and are chaired by a European Commission representative.

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.The food business operator 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, 2015) or may be obtained directly from the European Commission at the address given in Section 3.2 above.

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. The FSAI recently published a factsheet on aspartame.

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 out by EFSA. To this end, the European 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 to be followed, and also establishes dates by which the evaluation of specific additives or groups of additives should 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 was due to be completed by the end of 2010 although an extension of this deadline was given for a small number of these colours. 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 rules 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[13] as laid down in Regulation 1169/2011[14] 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.

Labelling requirements will vary dependent on whether the additive is 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 present in food intended for sale to the final consumer, the general labelling rules set out in Regulation (EU) 1169/2011 apply, including those provisions referring specifically to food additives. Regulation 1169/2011 has been given effect in Irish legislation by S.I. No. 556 of 2014 and is known as the European Union (Provision of Food Information to Consumers) Regulations, 2014. Under Regulation 1169/2011, food additives are considered ingredients and must 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 (functional classes) 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.

Regulation 1169/2011 defines ingredient as *'any substance or product, including flavourings, food additives and food enzymes and any constituent of a compound ingredient used in the manufacture or preparation of a food and still present in the finished product, even if in altered form; residues shall not be considered as ingredients'*. However, there are certain derogations or exemptions under the Regulation for substances that might normally be considered food additives in that the Regulation specifies that the following categories of substances are not considered ingredients:

- Food additives whose presence in a given food is solely due to the fact that they were contained in one or more ingredients of that food, in accordance with the 'carry-over' principle referred to in points (a) and (b) of Article 18 (1) of Regulation 1333/2008, provided that they serve no technological function in the finished product
- Additives which are used as processing aids
- Carriers and substances which are not food additives but are used in the same way and with the same purpose as carriers and which are used in the quantities strictly necessary

13 Information on the general labelling provisions.

14 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. This Regulation is available on the FSAI website.

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, e.g. preservatives used in fruit puree will not necessarily perform the same function when the fruit is added to pasteurised yoghurt.

However, under the requirements of Regulation 1169/2011/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 II of the Regulation. Annex II of Regulation 1169/2011 contains a list of allergenic ingredients such as peanuts and peanut products, sulphur dioxide (SO_2) 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 10 mg/kg or 10 mg/l expressed as SO_2[15].

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 (normally 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 laid down in the Regulation 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 II to Regulation 1169/2011 (allergens) as regards the indication of the ingredients present in foodstuffs

[15] Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO_2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;

In addition, 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
- 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 must 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) above 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 have been marketed until their date of minimum durability or 'use-by' date. Foods placed on the market after that date must comply fully with the labelling requirements of the Regulation.

4.2.1 Specific conditions for some colours and nitrites

It should also be noted that in accordance with Annex II part A of Regulation 1333/2008/EC the following colours may not be sold directly to the consumer: E 123 (amaranth), E 127 (erythrosine), E 160b (annatto, bixin, norbixin), E 161g (canthaxanthin), E 173 (aluminium) and E 180 (litholrubine BK). In addition, when labelled 'for food use', nitrite may be sold only in a mixture with salt or a salt substitute.

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

In addition to the labelling requirements set out in Regulation 1169/2011 on the provision of food information to consumers, Council Directive 2011/91/EC 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 labelling 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 as laid down in point (a) above, if the sales description[16] 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'.

[16] "Sales description" is not defined in Regulation 1333/2008 or in the labelling rules under Regulation 1169/2011/EC, however it is considered to include the sales name and other descriptive information which appears in proximity to the sales name.

All the above labelling information for table-top sweeteners must comply with Article 13 (1) of Regulation 1169/2011 (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 where appropriate indelible. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material. 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.

4.5 Labelling Requirement for Foods Containing Certain Food Colours

Under Regulation 1333/2008, since 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) are required to be labelled with the following additional information: *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(1) of Regulation 1169/2011, 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 where appropriate indelible.

4.6 Other Labelling Requirements

Additional labelling requirements apply to foods packaged in certain gases or foods containing sweeteners, or both a sweetener and an added sugar or sugars and these requirements are laid down in Annex III of Regulation 1169/2011/EU and are listed below:

- Foods whose durability has been extended by means of packaging gases (authorised by Regulation 1333/2008/EC) must be labelled with the statement "packaged in a protective atmosphere"
- Foods containing a sweetener or sweeteners (as authorised by Regulation 1333/2008/EC) must be labelled "with sweeteners(s)" and this statement must accompany the name of the food
- Foods containing both an added sugar or sugars and a sweetener or sweeteners (as authorised by Regulation 1333/2008/EC) must be labelled "with sugar(s) and sweeteners(s)" and again this statement must accompany the name of the food
- Foods containing aspartame/aspartame-acesulfame salt authorised by Regulation 1333/2008/EC must be labelled with the following statement: "contains aspartame (a source of phenylalanine)" in cases where aspartame/aspartame-acesulfame salt is designated in the list of ingredients only by reference to the E-number. For foods containing aspartame/aspartame-acesulfame salt which is designated in the list of ingredients by its specific name, these foods must be labelled with the statement "contains a source of phenylalanine"
- Foods containing more than 10% added polyols (as authorised by Regulation 1333/2008/EC) must be labelled with "excessive consumption may produce laxative effects"

In addition to the labelling requirements imposed by Regulation 1169/2011/EU, 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.

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). The Commission in conjunction with the Member States of the European Union are currently working on the development of a common methodology for gathering information on the consumption and use of food additives and flavourings across the European Union.

5.1 Surveys of Food Consumption In Ireland

The obligation to monitor consumption and use of food additives was already in place under the old additives Directives. 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 of Ireland 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.

In recent years, IUNA[17] has completed a number of comprehensive national nutrition surveys. The information collected during these surveys is used to develop evidence-based nutrition policies and health promotion campaigns in Ireland and to assess the safety of the food supply. The surveys conducted to date are: The North/South Ireland Food Consumption Survey (2001) of adults aged 18-64 years; The National Children's Food Survey (2005) of children aged 5-12 years; The National Teens Food Survey (2008) of teenagers aged 13-17 years and The National Adult Nutrition Survey (NANS) (2011) of adults aged 18-90 years and the National Pre-School Nutrition Survey (NPNS) (2012) of children aged 12 to 59 months inclusive.

5.2 The Irish National Food and Ingredient Database

In tandem with these dietary surveys, the IUNA developed the Irish National Food & Ingredient Database (INFID). This is a multi-faceted database constructed to record nutrient and ingredient data on foods consumed by all of the population groups subject to the national consumption surveys as listed above in Section 5.1. It is also used to monitor the usage and consumption of food chemicals (Gilsenan *et al*, 2002; Connolly *et al*., 2010). 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. Subsequent versions of INFID were compiled from information printed on the packaging of foods consumed during the national food surveys using unique brand identification codes. Such information includes, but is not limited to, nutritional composition data and a full listing of ingredients and their functions (including those of composite ingredients). As all food intake data were recorded at brand level in the national food surveys and entered into INFID using these brand level codes, this means that food consumption data can be directly linked to the data collected in INFID. Hence, the INFID database has multiple uses, one of which is the 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 as recorded INFID version 3 and reported to the FSAI in November 2012), 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.

[17] All surveys are available at www.iuna.net

Table 5.1 General overview of food additive usage in brands consumed by Irish adults (age 18+) as recorded in INFID Version 3

Food group	Total no. of brands in food group	Number of brands with all ingredients	No. of brands containing an additive	% branded foods containing additives
Low-fat spreads	17	16	16	100
Other spreading fats	11	10	10	100
Oils	2	2	2	100
Bacon and ham (including rashers)	48	46	46	100
Sausages	22	22	22	100
Diet carbonated beverages	6	6	6	100
Confectionery (chocolate)	159	155	151	97.4
Ice-creams	26	25	24	96.0
Carbonated beverages (non-diet)	17	17	16	94.1
Cakes, buns and pastries	84	81	73	90.1
Non chocolate confectionery	74	70	62	88.6
Puddings and chilled desserts, excluding milk puddings	9	8	7	87.5
Burgers (beef and pork)	8	8	7	87.5
White bread, rolls, white soda type breads	47	44	38	86.4
Wholemeal bread, rolls, brown/wholemeal soda type breads	89	88	76	86.4
Savoury snacks	86	84	71	84.5
Biscuits (savoury and sweet)	117	114	96	84.2
Squashes, cordials and fruit juice drinks	18	18	15	83.3
Meat products (processed meats, e.g. black pudding)	73	71	59	83.1
Nutritional supplements	37	37	30	88.1
Yoghurts	208	198	158	79.8
Savouries, e.g. pizza, mixed pasta dishes, quiche	100	93	71	76.3
Other breads and scones, bagels, croissants, ethnic breads	85	80	61	76.3
Milk puddings, e.g. rice pudding and custards	10	10	7	70.0
Soups, sauces and miscellaneous foods	199	193	131	67.9
Processed and homemade potato type products	11	11	7	63.6
Poultry and game dishes	20	19	12	63.2
Peas, beans and lentils	30	30	18	60.0
Fish dishes only (mixed fish dishes)	5	5	3	60.0
Sugars, syrups, preserves and sweeteners	21	20	12	60.0
Other milks, e.g. processed milk, milk-based drinks soya	13	12	7	58.3
Cheeses	75	72	42	58.3
Meat pies, pastries and sausage rolls	24	24	14	58.3

Table 5.1 General overview of food additive usage in brands consumed by Irish adults (age 18+) as recorded in INFID Version 3

Food group	Total no. of brands in food group	Number of brands with all ingredients	No. of brands containing an additive	% branded foods containing additives
Tinned or jarred vegetables	15	15	8	58.3
Vegetable and pulse dishes, including coleslaw	41	40	20	50.0
Lamb, pork and bacon dishes	6	6	3	50.0
Potatoes, chipped, fried, roasted	18	18	8	44.4
Tinned fruits	19	18	8	44.4
Other beverages	41	39	17	43.6
Fish and fish products (cod, whiting, fish fingers etc.)	94	86	30	34.9
Coffee	30	26	9	34.6
Nuts, seeds, herbs and spices	31	31	9	29.0
Other breakfast cereals, e.g. porridge and ready brek, ready brek	20	20	5	25.0
Chicken, turkey, game, pheasant, rabbit	13	13	3	25.0
Ready-to-eat breakfast cereals	61	60	14	23.3
Pork (fresh)	5	5	1	20
Fruit juices	60	59	10	16.9
Carrots (including tinned carrots)	12	12	2	16.7
Low-fat, skimmed and fortified milks	28	27	4	14.8
Rice and pasta (plain types)	60	60	8	13.3
Egg and egg dishes	26	25	3	12.0
Creams	9	9	1	11.1
Other vegetables, e.g. onions, leeks, peppers etc.	44	44	4	9.1
Other fruits, e.g. apples, pears, kiwis, fruit salads	50	50	3	6.0
Potatoes, boiled, mashed, baked, e.g. milk/ butter added	33	32	1	3.1
Teas	38	36	1	2.8
Whole milk	20	20	0	0.0
Butter	7	7	0	0.0
Green vegetables, broccoli, sprouts, green beans, cabbage	17	17	0	0.0
Salad vegetables, eaten raw, e.g. lettuce, tomato, cucumber	28	27	0	0.0
Bananas	8	8	0	0.0
Citrus fruit, grapefruit, oranges, tangerines, satsumas etc.	8	8	0	0.0
Beef and veal (fresh)	26	26	0	0.0
Lamb	4	4	0	0.0
Beef and veal dishes	6	5	0	0.0
Alcoholic beverages	20	11	0	0.0

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

Food additive category	No. of times additive use recorded in INFID	% of overall additive occurrence recorded in INFID	No. of additives recorded in INFID to perform function	Most commonly used additive in INFID 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
Emulsifier	1,105	18.1	49	E322	278	38	Confectionery (chocolate)	267	146
Functional ingredient*	828	13.6	104	E330	29	49	Nutritional supplements	85	28
Colour	810	13.3	34	E160a	152	28	Biscuits (savoury and sweet)	41	25
Stabiliser	660	10.8	44	E412	102	40	Yoghurts	141	83
Preservative	567	9.3	25	E202	214	27	Yoghurts	58	57
Raising agent	536	8.8	21	E500(ii)	187	25	Biscuits (savoury and sweet)	168	86
Acidity regulator	438	7.2	34	E330	145	39	Yoghurts	188	113
Sweetener	216	3.5	7	E951	99	17	Yoghurts	118	77
Flavour enhancer	216	3.5	5	E621	112	11	Soups, sauces and miscellaneous foods	105	53
Antioxidant	210	3.4	20	E301	85	9	Bacon and ham (including rashers)	40	40
Flour treatment agent	1	2.7	7	E300	145	166	Wholemeal bread, rolls, brown/ wholemeal soda type breads,	47	34
Thickener	79	1.3	12	E412	27	17	Soups, sauces and miscellaneous foods	19	18
Gelling agent	73	1.2	11	E440	47	16	Cakes, buns and pastries	15	11

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

Food additive category	No. of times additive use recorded in INFID	% of overall additive occurrence recorded in INFID	No. of additives recorded in INFID to perform function	Most commonly used additive in INFID 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
Humectant	66	1.1	3	E422	53	7	Confectionery (chocolate)	23	20
Acid	47	0.8	7	E330	24	13	Non chocolate confectionary	11	11
							Soups, sauces & miscellaneous foods	6	6
Anti-caking agent	36	70.6	9	E551	17	15	Nutritional supplements	11	8
Glazing agent	28	0.5	11	E903	9	5	Non chocolate confectionary, Yoghurts	10	8
Bulking agent	13	0.2	4	E460, E1200	5, 5	3	Nutritional supplements	8	5
Firming agent	10	0.1	4	E509	4	7	Savouries	2	1
							Cakes, buns and pastries	2	2
							Savoury snacks	2	1
Carrier	2	0	1	E420	2	1	Nutritional supplements	2	3
Carrier	2	0	1	E420	2	1	Nutritional supplements	2	3
Sequestrant	1	0	1	E452	1	1	Non chocolate confectionery (chocolate)	1	1

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

5.3 Estimation of Food Additive Intake

The data contained in INFID in conjunction with the IUNA surveys on food consumption for the various population groups can be used to provide estimates of food additive intake by the Irish population, in other words the population's exposure to additives in their food. This exposure estimate can be compared with the ADI for the particular additive established by EFSA, SCF, JECFA or other standard-setting body (see Chapter 3). If the exposure estimate is higher than the ADI, there may be a risk to the health of the consumer, and appropriate action may need to be taken to reduce exposure to the additive in question. This process of risk assessment can be carried out at national level, by the FSAI in conjunction with IUNA using data collected during the national food surveys and/or from INFID data. In some cases, a more refined exposure assessment maybe needed to determine whether there is a risk to health or not.

EFSA also carries out risk assessments for food additives, combining the results of their evaluations of the possible toxicological effects of the additive with an assessment of the exposures of individual groups, i.e. infants, toddlers, children, adolescents, adults, the elderly, of the European population. Data from Ireland contribute to these exposure assessments as appropriate through the submission of analytical data on food additives found as part of the national chemical monitoring programme as well as the submission of national food consumption data which is included in the EFSA comprehensive European food consumption database.

5.3.1 Estimation of food additive intake at European level

Assessment of exposure to food additives and other food ingredients at European level is carried out by EFSA using the EFSA Comprehensive European Food Consumption Database (Comprehensive Database). This database is based on food consumption information from a total of 32 dietary surveys carried out in 22 Member States including Ireland and covering more than 67 000 individuals (EFSA, 2011). The Comprehensive Database includes individual food consumption data for infants, toddlers, children, adolescents, adults, the elderly and very elderly. These data can be combined with the concentration of the particular additive in the foods in which it is permitted, in order to arrive at a total intake of the additive on a daily basis. The concentration of the additive used in the derivation of the daily intake can be the Maximum Permitted Level (MPL) in each food as laid out in Annex II of Regulation 1333/2008, giving a worst case estimate of exposure, or can be the actual level reported to be used in the food by industry. Alternatively, it could be based on the average (and range) of a number of analytical measurements of the concentration of the additive in the foods in which it is permitted. Actual use levels are usually lower than MPLs and give a more realistic estimate of exposure for comparison with an ADI.

In the risk assessments of food additives carried out by EFSA, an exposure estimate derived from the Comprehensive Database is normally expressed as a mean intake for an average European consumer derived in turn from the average intakes for each of the populations in the individual Member States providing the food consumption data held in the database.This can be done for the various sub-populations in the Comprehensive Database where data are available. The exposure estimates may also be expressed as a range, the lower end of the range being that for the Member State having the lowest average intake of the additive in question and the higher end of the range representing the Member State with the highest average intake. Exposure estimates are also derived for high level consumers (normally the 95th percentile) of the population and are routinely the ones that are compared with the ADI in order to determine whether the population may be potentially at risk of exceeding the ADI. If this is the case, the European Commission may instigate risk management measures such as reducing the MPL or the number of foods in which the additive is permitted.

An exposure assessment tool, the 'Food additives intake model' (FAIM)[18] template, was specifically developed by EFSA, to support the calculation by applicants of estimates of exposure to new or modified food additive applications and its by-products and to harmonise the submission of the related data.

[18] Food Additive Intake Model

5.3.2 Estimation of food additive intake in Ireland

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. The IUNA screening of additive intake carried out in the late 1990s, 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. 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 identified two additives (sulphites and nitrites) for a more detailed assessment.

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 and 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

The maximum permitted levels for nitrates/nitrites in foodstuffs were reduced in 2006 (Directive 2006/52/EC)[19], 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 EU population. However, a recent reassessment by EFSA of nitrite intake has confirmed that in several European countries, the mean exposure at Tier 2[20] remains above the ADI (EFSA, 2010a). At Tier 3[21], 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. Dietary intake assessments for nitrates, nitrites and sulphites for the Irish adult population are given below. Under the re-evaluation programme for food additives set out in Regulation 257/2010/EC the preservatives nitrates, nitrites and sulphites are to be re-evaluated by EFSA with a deadline of 31 December 2015. The re-evaluation of these additives will include a detailed exposure assessment which will include Irish data and hence, provide an updated indication of the exposure of the Irish population to these additives.

In 2014, IUNA carried out a dietary exposure assessment in order to estimate the intake of nitrates, nitrites and sulphur dioxide in Irish adults (18–90 years) using the Irish National Adult Nutrition Survey (NANS) and chemical concentration data supplied by the FSAI as a result of the national chemical monitoring programme from 2008-2012. Three separate exposure scenarios were developed to deal with non-detects in the additive concentration data. Supplementary to the NANS survey, the Irish National Food and Ingredient Database (INFID) (Version 3) was utilised to calculate the probability of the three target additives being present in the recorded IUNA food groups. This was possible as all data in INFID are recorded at brand level. By recording information on the occurrence of additives in branded food items, this facilitated the development of a presence probability of occurrence for nitrates, nitrites and sulphur dioxide in a number of IUNA food groups. These data, when incorporated into the exposure assessments, refined results for these food groups, as it removed the assumption that because an additive was legally permitted in a certain food group, it was always present, e.g. if nitrate was recorded in 6 out of 12 branded foods in the 'Savouries' food group within INFID (Version 3), a presence probability of 0.5 (or 50%) was applied for this additive to this food group in the exposure assessment. In the case where none of the additives were detected in INFID (Version 3), food groups but additive concentration data were supplied, the assumption remained that if an additive was permitted in this food group, it was present in all foods within the food group. Creme Global software (Creme Food)[22] was utilised to conduct all exposure assessments.

A number of unquantifiable concentration levels were recorded in the additive concentration data, i.e. non-detects. Therefore, three separate exposure scenarios were developed to conduct the exposure analyses for the study:

- Scenario 1: Exposure analyses were conducted using all available concentration data. Data below the limit of detection (<LOD) were assigned a value of zero
- Scenario 2: Exposure analyses were conducted using all available concentration data. Data below the limit of detection (<LOD) were assigned a value of 0.5 x LOD
- Scenario 3: Exposure analyses were conducted using all available concentration data. Data below the limit of detection (<LOD) were assigned the value of the LOD

All concentration values were recorded in milligrams/kilograms. Therefore, all results presented in the tables below are presented in terms of milligrams/kilograms body weight/day (mg/kg/bw/d). Exposure results are presented in terms of 'total population' for all three exposure scenarios.

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19 This Directive has been subsequently repealed and provisions for nitrates and nitrites are included in annex II of Regulation 1333/2008/EC on food additives.

20 Tier 2 estimates of exposure are calculated by using data on actual food consumption and the maximum intended use level of the food additive. For Tier 1 exposure assessments, these are based on theoretical food consumption data and maximum permitted use levels (MPLs) for the additives as permitted by Regulation 1333/20078/EC.

21 Tier 3 estimates of exposure are a further refinement of exposure when compared to estimates at Tier 2. In the case of tier 3 exposure estimates these are calculated using data on actual food consumption and normal use levels of the food additive.

22 Creme Global Software. Creme Food Client.

Dietary exposure levels of Irish adults to nitrates are presented in Table 5.4 below. Nitrates were detected in 15 out of the 68 IUNA food groups, the majority of these being processed meats and food groups listing processed meats as an ingredient, e.g. the ham on a ham and mushroom pizza. All exposure levels were below the ADI of 3.7 mg/kg/bw/d in 14 out of the 15 food groups. However, the ADI was exceeded in 2.5% of the total population in the food group 'Salad Vegetables', with exposure levels reaching 116% of the ADI (P97.5 intake for total population for Scenarios 1 and 2). Regarding nitrates, vegetables are the major source for the human intake of nitrate and maximum permitted levels are also laid down for nitrates in lettuce and spinach under the EU contaminants legislation (Regulation 1881/2006/EC). Since climatic conditions have a major influence on the levels of nitrate in certain vegetables especially lettuce, different maximum levels are fixed depending on the season.

Dietary exposure levels of Irish adults to nitrites are presented in Table 5.5. Nitrites were detected in 8 out of the 68 IUNA food groups, the majority of these being processed meats and food groups listing processed meats as an ingredient. All exposure levels were below the ADI of 0–0.07 mg/kg/bw/d for the total population.

Dietary exposure levels of Irish adults to sulphur dioxide are presented in Table 5.6. Sulphur Dioxide was detected in 20 out of the 68 IUNA food groups, primarily including beverages, processed meats and processed fruit and vegetables. In terms of the total population the ADI of 0–0.7 mg/kg/bw/d was exceeded across all three scenarios for high consumers (P95 and P97.5) in the food groups 'alcoholic beverages' and 'other fruits'. 'Other fruits' included dried fruits and sultanas. The ADI was exceeded most notably in the 'other fruits' food group, with P95 intakes among the total population exceeding the ADI by up to 174%-186% across the three scenarios tested. However, mean exposure levels for the total population in the remaining 18 other food groups were below the ADI of 0–0.07 mg/kg bw/d.

Overall, the safety levels of nitrates and sulphites were exceeded on a number of occasions for the total population. In the case of both of these additives, the exceedances for the total population were typically only at the higher levels of the exposure distribution (P95 and P97.5 values for sulphites and at the P95 level for nitrates). This may be attributable to a number of factors. Firstly, a number of the additive concentrations detected in the analysed foods returned particularly high concentration levels. These high levels naturally increase the overall distribution of exposure. Secondly, presence probabilities, i.e. additive occurrence data, were not applied to every food group, as some food groups did not record the presence/absence of the additives within the INFID database.If such information had been known and applied to every food group for which additive concentration data was available, the exposure assessments could have been further refined by not assuming the additives are present in all foods recorded in the food group. The benefits of applying additive occurrence data to an additive exposure assessment have been discussed by Connolly *et al.*, in 2010. By addressing these two factors, dietary exposure levels of Irish adults to nitrates and sulphur dioxide is likely to further decreased from these reported conservative values. The exposure levels for nitrites were all below the ADI for the total population.

Table 5.4 Dietary exposure levels of nitrates (E250, E251) among Irish adults (18–90 years) (total population) for all three exposure scenarios (mg/kg bw/day)

Nitrate Exposure Levels in Irish Adults (Total Population), mg/kg/bw/d ADI: 0 - 3.7 mg/kg/bw/day												
	Scenario 1				Scenario 2				Scenario 3			
	Mean	SD	P95	P97.5	Mean	SD	P95	P97.5	Mean	SD	P95	P97.5
Bacon & ham	0.01	0.02	0.06	0.09	0.01	0.02	0.06	0.08	0.01	0.02	0.05	0.08
Beef & veal	0.08	0.10	0.30	0.36	0.08	0.10	0.30	0.36	0.08	0.10	0.30	0.36
Beef & veal dishes	0.02	0.04	0.12	0.16	0.02	0.04	0.12	0.16	0.02	0.04	0.12	0.15
Lamb, pork & bacon dishes	0.005	0.02	0.02	0.07	0.01	0.02	0.02	0.05	0.004	0.02	0.02	0.06
Meat pies & pastries	0.003	0.01	0.02	0.04	0.003	0.01	0.02	0.04	0.002	0.01	0.02	0.04
Meat products	0.001	0.01	0	0	0.0007	0.009	0	0	0.0004	0.006	0	0
Other beverages	0.03	0.04	0.12	0.16	0.04	0.05	0.14	0.17	0.04	0.05	0.15	0.19
Other breakfast cereals	0.03	0.07	0.21	0.26	0.03	0.07	0.20	0.26	0.03	0.07	0.20	0.26
Pork	0.002	0.01	0	0.03	0.00	0.02	0.02	0.05	0.01	0.01	0.03	0.05
Poultry & game dishes	0.01	0.03	0.1	0.14	0.01	0.03	0.10	0.13	0.01	0.04	0.10	0.15
Rice & pasta, flours, grains & starch	0.03	0.05	0.13	0.17	0.03	0.05	0.13	0.17	0.03	0.05	0.13	0.16
Salad vegetable	0.78	1.18	3.25	4.28	0.82	1.24	3.3	4.28	0.81	1.2	3.24	4.17
Sausages	0.0009	0.005	0.004	0.01	0.0006	0.003	0.002	0.009	0.001	0.005	0.006	0.01
Savouries	0.0002	0.003	0	0	0.0004	0.004	0	0	0.002	0.003	0	0
Vegetable & pulse dishes	0.02	0.05	0.12	0.18	0.02	0.06	0.14	0.20	0.02	0.06	0.14	0.20
Scena rio 1: All '<' values in the concentration data were entered into assessment as 0 va l ues												
Scenario 2: All '<' values in the concentration data were entered into assessment as 0.5 x LOR												
Scenario 3: All '<' values in the concentration data were entered into assessment as LOR												

Table 5.5 Dietary exposure levels of nitrites (E249, E250) among Irish adults (18–90 years) (total population) for all three exposure scenarios (mg/kg bw/day)

Nitrite Exposure Levels in Irish Adults (Total Population) mg/kg/bw/d ADI: 0 - 0.07 mg/kg/bw/day

	Scenario 1				Scenario 2				Scenario 3			
	Mean	**SD**	**P95**	**P97.5**	**Mean**	**SD**	**P95**	**P97.5**	**Mean**	**SD**	**P95**	**P97.5**
Bacon & ham	0.008	0.01	0.02	0.04	0.009	0.01	0.03	0.04	0.010	0.01	0.03	0.04
Beef & veal	0.01	0.01	0.04	0.05	0.01	0.01	0.04	0.05	0.01	0.01	0.04	0.05
Chicken, turkey & game	0.01	0.02	0.04	0.05	0.01	0.01	0.04	0.05	0.01	0.01	0.04	0.05
Lamb	0.002	0.007	0.02	0.02	0.002	0.007	0.02	0.02	0.002	0.007	0.02	0.02
Meat products	0.001	0.005	0.01	0.01	0.001	0.003	0.009	0.01	0.001	0.004	0.01	0.01
Pork	0.003	0.010	0.02	0.03	0.004	0.01	0.02	0.03	0.004	0.01	0.02	0.03
Sausages	0.0003	0.001	0.002	0.006	0.0003	0.001	0.001	0.004	0.0003	0.001	0.001	0.004
Savouries	0.0004	0.005	0	0	0.0003	0.005	0	0	0.0003	0.006	0	0

Scenario 1: All '<' values in the concentration data were entered into assessment as 0 values

Scenario 2: All '<' values in the concentration data were entered into assessment as 0.5 x LOR

Scenario 3: All '<' values in the concentration data were entered into assessment as LOR

Table 5.6 Dietary exposure levels of Sulphur Dioxide (E220) among Irish adults (18–90 years) (total population) for all three exposure scenarios (mg/kg bw/day)

	Sulphur Dioxide Exposure Levels in Irish Adults (Total Population), mg/kg/bw/d ADI: 0 - 0.7 mg/kg/bw/d											
	Scenario 1				Scenario 2				Scenario 3			
	Mean	SD	P95	P97.5	Mean	SD	P95	P97.5	Mean	SD	P95	P97.5
Alcoholic beverages	0.22	0.42	1.11	1.51	0.22	0.41	1.05	1.38	0.23	0.43	1.13	1.54
Beef & veal	0.004	0.03	0.006	0.04	0.008	0.003	0.02	0.04	0.010	0.02	0.04	0.07
Burgers	0.005	0.03	0	0.06	0.004	0.02	0.01	0.06	0.005	0.03	0.01	0.06
Cakes, pastries & buns	0.00004	0.0006	0	0	0.00004	0.0004	0	0	0.005	0.009	0.02	0.03
Carbonated beverages	0.0007	0.006	0	0	0.002	0.007	0.01	0.02	0.003	0.01	0.02	0.03
Fish & fish products	0.001	0.01	0.009	0.02	0.003	0.01	0.01	0.01	0.005	0.01	0.01	0.02
Fruit juices & smoothies	0.03	0.06	0.16	0.21	0.03	0.07	0.16	0.24	0.03	0.06	0.16	0.23
Lamb	0.002	0.01	0.02	0.04	0.002	0.01	0.01	0.03	0.004	0.01	0.02	0.05
Meat pies & pastries	0.0007	0.01	0	0	0.0006	0.01	0	0	0.0009	0.01	0	0
Meat products	0.00005	0.001	0	0	0.0001	0.002	0	0	0.00009	0.001	0	0
Non-chocolate confectionary	0.01	0.05	0.11	0.17	0.01	0.04	0.11	0.18	0.01	0.05	0.11	0.18
Other fruits	0.25	0.49	1.22	1.62	0.27	0.50	1.30	1.73	0.26	0.51	1.26	1.72
Other vegetables	0.04	0.10	0.25	0.36	0.04	0.11	0.27	0.35	0.04	0.11	0.23	0.35
Pork	0.004	0.01	0.03	0.06	0.004	0.01	0.03	0.06	0.005	0.01	0.04	0.07
Potatoes (boiled/baked/ mashed)	0.04	0.06	0.17	0.23	0.04	0.06	0.18	0.24	0.05	0.06	0.2	0.25

Table 5.6 Dietary exposure levels of Sulphur Dioxide (E220) among Irish adults (18–90 years) (total population) for all three exposure scenarios (mg/kg bw/day)

	Sulphur Dioxide Exposure Levels in Irish Adults (Total Population), mg/kg/bw/d ADI: 0 - 0.7 mg/kg/bw/d											
	Scenario 1				Scenario 2				Scenario 3			
	Mean	SD	P95	P97.5	Mean	SD	P95	P97.5	Mean	SD	P95	P97.5
Processed & homemade potato products	0.003	0.01	0.01	0.03	0.002	0.01	0.01	0.02	0.003	0.01	0.01	0.03
Sausages	0.01	0.04	0.10	0.15	0.01	0.04	0.11	0.16	0.01	0.04	0.11	0.14
Soups, sauces & miscellaneous foods	0.001	0.03	0	0	0.003	0.004	0.0006	0.002	0.001	0.01	0.001	0.007
Squashes, cordials & fruit juice drinks	0.004	0.02	0.02	0.05	0.004	0.01	0.02	0.05	0.005	0.02	0.02	0.05
Tinned fruits	0.01	0.09	0.03	0.20	0.01	0.09	0.02	0.15	0.01	0.08	0.04	0.18
Scena rio 1: All '<' values in the concentration data were entered into assessment as 0 va l ues												
Scenario 2: All '<' values in the concentration data were entered into assessment as 0.5 x LOR												
Scenario 3: All '<' values in the concentration data were entered into assessment as LOR												

Another publication using the data from INFID was an examination of the intake by Irish children and teenagers of certain food colours reported to be associated with hyperactivity (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.

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). Most population-based studies estimate the prevalence of reactions to food additives at less than 1% in adults and up to 2% in children (Wilson and Bahna, 2005). 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, and
  - 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 cows' milk, hens' 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. Such reactions are however, difficult to demonstrate and are almost certainly much less common than reactions to substances present naturally in food (MAFF, 1999). The incidence of intolerance in atopic[23] individuals is much higher than that in a non-atopic population. A UK Ministry of Agriculture, Fisheries and Food 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. Nonetheless, colours such as Tartrazine, do appear to be able to trigger intolerance reactions in a small fraction of the exposed population (EFSA, 2009b). The frequency of Tartrazine intolerance has been estimated to be <1 % in subjects with food-induced urticaria and angioedema. Only few cases of intolerance reactions to Tartrazine and Ponceau 4R, and to a lesser extent to Sunset Yellow FCF and Amaranth, in sensitive individuals have been reported following double-blind placebo-controlled food challenge (DBPCFC) procedures after exclusion diets. These reactions include urticaria, angioedema, wheezing, and leukoclastic vasculitis (an allergic inflammation of blood vessels), (EFSA, 2010c). No data on sensitivity to Brown FK, Brown HT, Litholrubine BK, Brilliant Black BN, Carmoisine, and Allura Red AC are available, and no well-documented cases of intolerance reactions after oral exposure have been reported.

[23] Atopic: A predisposition toward developing certain allergic hypersensitivity reactions. Atopy may have a hereditary component, although contact with the allergen must occur before the hypersensitivity reaction can develop.

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 three year old and eight to nine 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 four synthetic colours and sodium benzoate in three 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, 2008b). 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, 2008b). 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 Chapter 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 2010, EFSA concluded that there is still no substantive evidence that aspartame can induce such adverse effects, as earlier concluded by the SCF. In a more recent evaluation by EFSA (EFSA, 2013), the Panel concluded that there was no evidence that aspartame affects behaviour or cognitive function in children or adults. 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 however; EFSA could not exclude the possibility that in rare instances individuals could be susceptible to allergic reactions following aspartame ingestion (EFSA, 2013). The EFSA National Expert Group assessed anecdotal data of spontaneous reports of cases with symptoms imputed to be related to aspartame (EFSA, 2010b). The anecdotal reports explored were largely self-reported, and the information was not structured and was without medical confirmation. The expert group noted that the number of cases is low when compared with the widespread use and that the effects were mild to moderate (EFSA, 2010b).

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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. At the time of publication of this guidance, Regulation 1333/2008/EC and its annexes should be consulted as 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 (November, 2015), 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	Riboflavins
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
E141	Copper complexes of chlorophylls and chlorophyllins
E142	Greens S
E150a	Plain caramel
E150b	Caustic sulphite caramel
E150c	Ammonia caramel
E150d	Sulphite ammonia caramel
E151	Brilliant Black PN
E153	Vegetable carbon
E155	Brown HT
E160a	Carotenes
E160b	Annatto, bixin, norbixin
E160c	Paprika extract, capsanthin, capsorubin
E160d	Lycopene
E160e	Beta-apo-8'-carotenal (C 30)
E161b	Lutein
E161g	Canthaxanthin*
E162	Beetroot Red, betanin
E163	Anthocyanins

E170	Calcium 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[1]
E211	Sodium benzoate[1]
E212	Potassium benzoate[1]
E213	Calcium benzoate[1]
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
E243	Ethyl Lauroyl arginate
E249	Potassium nitrite
E250	Sodium nitrite
E251	Sodium nitrate
E252	Potassium nitrate
E260	Acetic acid
E261	Potassium acetates[2]
E262	Sodium acetates
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
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
E332	Potassium citrates
E333	Calcium citrates
E334	Tartaric acid (L(+)-)
E335	Sodium tartrates
E336	Potassium tartrates
E337	Sodium potassium tartrate
E338	Phosphoric acid
E339	Sodium phosphates
E340	Potassium phosphates
E341	Calcium phosphates
E343	Magnesium phosphates
E350	Sodium malates
E351	Potassium malate
E352	Calcium malates
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	Gum Arabic (acacia gum)
E415	Xanthan gum
E416	Karaya gum
E417	Tara gum
E418	Gellan gum
E420	Sorbitols
E421	Mannitol
E422	Glycerol
E423	Octenyl succinic acid modified gum arabic
E425	Konjac
E426	Soybean hemicellulose
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
E442	Ammonium phosphatides
E444	Sucrose acetate isobutyrate
E445	Glycerol esters of wood rosins
E450	Diphosphates
E451	Triphosphates
E452	Polyphosphates
E459	Beta-cyclodextrin

E460	Cellulose
E461	Methyl cellulose
E462	Ethyl cellulose
E463	Hydroxypropyl cellulose
E464	Hydroxypropyl methyl cellulose
E465	Ethyl methyl cellulose
E466	Sodium carboxy methyl cellulose, Cellulose gum
E468	Crosslinked sodium carboxy methyl cellulose, cross linked cellulose gum
E469	Enzymatically hydrolysed carboxy methyl cellulose, Enzymatically hydrolysed cellulose gum
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
E499	Stigmasterol-rich plant sterols
E500	Sodium carbonates
E501	Potassium carbonates
E503	Ammonium carbonates
E504	Magnesium carbonates
E507	Hydrochloric acid
E508	Potassium chloride
E509	Calcium chloride
E511	Magnesium chloride
E512	Stannous chloride
E513	Sulphuric acid
E514	Sodium sulphates

E515	Potassium sulphates
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	Magnesium silicate
E553b	Talc
E554	Sodium aluminium silicate
E555	Potassium aluminium silicate
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
E626	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
E641	L-Leucine
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
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	Cyclamates
E953	Isomalt
E954	Saccharins
E955	Sucralose
E957	Thaumatin
E959	Neohesperidine DC
E960	Steviol glycosides
E961	Neotame
E962	Salt of aspartame-acesulfame
E964	Polyglycitol syrup
E965	Maltitols
E966	Lactitol
E967	Xylitol
E968	Erythritol
E969	Advantame

E999	Quillaia extract
E1103	Invertase
E1105	Lysozyme
E1200	Polydextrose
E1201	Polyvinylpyrrolidone
E1202	Polyvinylpolypyrrolidone
E1203	Polyvinyl alcohol (PVA)
E1204	Pullulan
E1205	Basic methacrylate copolymer
E1206	Neutral methacrylate copolymer
E1207	Anionic methacrylate copolymer
E1208	Polyvinylpyrrolidone-vinyl acetate copolymer
E1209	Polyvinyl alcohol-polyethylene glycol-graft-co-polymer
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

* Canthaxanthin is not authorised in the food categories listed in Part D and E of Regulation 1333/2008. The substance is in the positive list of food additives because it is used in medicinal products in accordance with Directive 2009/35/EC of the European Parliament and of the Council.

[1] Benzoic acid may be present in certain fermented products resulting from the fermentation process following good manufacturing practice.

[2] Period of application: From 6 February 2013

Appendix 2. EU Food Categorisation System

The following 18 food categories have been created to date:

0 All Categories of Food
1 Dairy Products and Analogues
2 Fats and Oils and Fat and Oil Emulsions
3 Edible ices
4 Fruit and Vegetables
5 Confectionery
6 Cereals and Cereal Products
7 Bakery Wares
8 Meat
9 Fish and Fisheries Products
10 Eggs and Egg Products
11 Sugars, Syrups, Honey and Table-top Sweeteners
12 Salt, Spices, Soups, Sauces, Salads and Protein Products
13 Foods intended for particular nutritional uses as defined by Directive 2009/39/EC
14 Beverages
15 Ready-to-Eat Savouries and Snacks
16 Desserts Excluding Products Covered in Categories 1, 3 and 4
17 Food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children[25]
18 Processed foods not covered by Categories 1 to 17, excluding foods for infants and young children

As indicated in Chapter 1.4 of this guidance and also in Chapter 2, the European Commission has established these food categories into which the currently authorised food additives, together with their conditions of use, are placed, the food categorisation system (FCS). The list allows easy identification of the additives authorised for use in a certain foodstuff, offering greater transparency. The new list is more accessible for all persons involved in any component of the food chain, be it as a consumer, the control authorities or the food industry. The improved transparency allows correct and therefore, safer use of food additives.

The following Table provides the current subcategories, at the time of publication of this guidance, into which these main food categories have been further divided.

[25] A list of authorised additives in food supplements intended for infants and young children is currently under discussion at EU level between the Commission and the Member States.

EU Food Categorisation System with Subcategories

Number	Name
0	**All categories of foods excluding foods for infants and young children, except where specifically provided for**
01.0	**Dairy products and analogues**
01.1	**Unflavoured pasteurised and sterilised (including UHT) milk**
01.2	**Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation**
01.3	**Unflavoured fermented milk products, heat-treated after fermentation**
01.4	**Flavoured fermented milk products including heat-treated products**
01.5	**Dehydrated milk as defined by Directive 2001/114/EC**
01.6	**Cream and cream powder**
01.6.1	Unflavoured pasteurised cream (excluding reduced fat creams)
01.6.2	Unflavoured live fermented cream products and substitute products with a fat content of less than 20%
01.6.3	Other creams
01.7	**Cheese and cheese products**
01.7.1	Unripened cheese excluding products falling in Category 16
01.7.2	Ripened cheese
01.7.3	Edible cheese rind
01.7.4	Whey cheese
01.7.5	Processed cheese
01.7.6	Cheese products (excluding products falling in Category 16)
01.8	**Dairy analogues, including beverage whiteners**
02.0	**Fats and oils and fat and oil emulsions**
02.1	**Fats and oils essentially free from water (excluding anhydrous milkfat)**
02.2	**Fat and oil emulsions mainly of type water-in-oil**
02.2.1	Butter and concentrated butter and butter oil and anhydrous milkfat
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1234/2007 and liquid emulsions
02.3	**Vegetable oil pan spray**
03.0	**Edible ices**
04.0	**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
04.1.3	Frozen fruit and vegetables

Number	Name
04.2	**Processed fruit and vegetables**
04.2.1	Dried fruit and vegetables
04.2.2	Fruit and vegetables in vinegar, oil, or brine
04.2.3	Canned or bottled fruit and vegetables
04.2.4	Fruit and vegetable preparations, excluding products covered by 5.4
04.2.4.1	Fruit and vegetable preparations excluding compote
04.2.4.2	Compote, excluding products covered by Category 16
04.2.5	Jam, jellies and marmalades and similar products
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EC
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EC
04.2.5.3	Other similar fruit or vegetable spreads
04.2.5.4	Nut butters and nut spreads
04.2.6	Processed potato products
05.0	**Confectionery**
05.1	**Cocoa and chocolate products as covered by Directive 2000/36/EC**
05.2	**Other confectionery including breath refreshening microsweets**
05.3	**Chewing gum**
05.4	**Decorations, coatings and fillings, except fruit based fillings covered by Category 4.2.4**
06.0	**Cereals and cereal products**
06.1	**Whole, broken, or flaked grain**
06.2	**Flours and other milled products and starches**
06.2.1	Flours
06.2.2	Starches
06.3	**Breakfast cereals**
06.4	**Pasta**
06.4.1	Fresh pasta
06.4.2	Dry pasta
06.4.3	Fresh pre-cooked pasta
06.4.4	Potato gnocchi
06.4.5	Fillings of stuffed pasta (ravioli and similar)
06.5	**Noodles**
06.6	**Batters**
06.7	**Pre-cooked or processed cereals**
07.0	**Bakery wares**
07.1	**Bread and rolls**
07.1.1	Bread prepared solely with the following ingredients: wheat flour, water, yeast or leaven, salt
07.1.2	Pain courant français; Friss búzakenyér, fehér és félbarna kenyerek
07.2	**Fine bakery wares**

Number	Name
08.0	**Meat**
08.1	**Fresh meat, excluding meat preparations as defined by Regulation (EC) No 853/2004**
08.2	**Meat preparations as defined by Regulation (EC) No 853/2004**
08.3	**Meat products**
08.3.1	Non-heat-treated meat products
08.3.2	Heat-treated meat products
08.3.3	Casings and coatings and decorations for meat
08.3.4	Traditionally cured meat products with specific provisions concerning nitrites and nitrates
08.3.4.1	Traditional immersion cured products (meat products cured by immersion in a curing solution containing nitrites and/or nitrates, salt and other components)
08.3.4.2	Traditional dry cured products (dry curing process involves dry application of curing mixture containing nitrites and/or nitrates, salt and other components to the surface of the meat followed by a period of stabilisation/maturation)
08.3.4.3	Other traditionally cured products (immersion and dry cured processes used in combination or where nitrite and/or nitrate is included in a compound product or where the curing solution is injected into the product prior to cooking)
09.0	**Fish and fisheries products**
09.1	**Unprocessed fish and fisheries products**
09.1.1	Unprocessed fish
09.1.2	Unprocessed molluscs and crustaceans
09.2	**Processed fish and fishery products including molluscs and crustaceans**
09.3	**Fish roe**
10.0	**Eggs and egg products**
10.1	**Unprocessed eggs**
10.2	**Processed eggs and egg products**
11.0	**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**
11.3	**Honey as defined in Directive 2001/110/EC**
11.4	**Table-top sweeteners**
11.4.1	Table-top sweeteners in liquid form
11.4.2	Table-top sweeteners in powder form
11.4.3	**Table-top sweeteners in tablets**
12.0	**Salts, spices, soups, sauces, salads and protein products**
12.1	**Salt and salt substitutes**
12.1.1	Salt
12.1.2	Salt substitutes
12.2	**Herbs, spices, seasonings**
12.2.1	Herbs and spices
12.2.2	Seasonings and condiments
12.3	**Vinegars**
12.4	**Mustard**
12.5	**Soups and broths**

Number	Name
12.6	**Sauces**
12.7	**Salads and savoury based sandwich spreads**
12.8	**Yeast and yeast products**
12.9	**Protein products, excluding products covered in Category 1.8**
13.0	**Foods intended for particular nutritional uses as defined by Directive 2009/39/EC**
13.1	**Foods for infants and young children**
13.1.1	Infant formulae as defined by Commission 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 Commission Directive 2006/125/EC
13.1.4	Other foods for young children
13.1.5	Dietary foods for infants and young children for special medical purposes as defined by Commission 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
13.1.5.2	Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC
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 (the whole or part of the total daily diet)**
13.4	**Foods suitable for people intolerant to gluten as defined by Commission Regulation (EC) No 41/2009**
14.0	**Beverages**
14.1	**Non-alcoholic beverages**
14.1.1	Water, including natural mineral water as defined in Directive 2009/54/EC and spring water and all other bottled or packed waters
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products
14.1.4	Flavoured drinks
14.1.5	Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products
14.1.5.1	Coffee, coffee extracts
14.1.5.2	Other
14.2	**Alcoholic beverages, including alcohol-free and low-alcohol counterparts**
14.2.1	Beer and malt beverages
14.2.2	Wine and other products defined by Regulation (EEC) No 1234/2007, and alcohol-free counterparts
14.2.3	Cider and perry
14.2.4	Fruit wine and made wine
14.2.5	Mead
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008

Number	Name
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	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol
15.0	**Ready-to-eat savouries and snacks**
15.1	**Potato-, cereal-, flour- or starch-based snacks**
15.2	**Processed nuts**
16.0	**Desserts excluding products covered in Categories 1, 3 and 4**
17.0	**Food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children**
17.1	**Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms**
17.2	**Food supplements supplied in a liquid form**
17.3	**Food supplements supplied in a syrup-type or chewable form**
18.0	**Processed foods not covered by Categories 1 to 17, excluding foods for infants and young children**

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 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 Polysorbates
E 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

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