

Food additives

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1. Introduction

The use of food additives is an emotional topic which continues to provoke consumer concern.

Despite modern-day associations food additives have been used for centuries. Food preservation began when man first learned to safeguard food from one harvest to the next and by the salting and smoking of meat and fish. The Egyptians used colours and flavourings, and the Romans used saltpetre (potassium nitrate), spices and colours for preservation and to improve the appearance of foods. Cooks regularly used baking powder as a raising agent, thickeners for sauces and gravies, and colours, such as cochineal, to transform good-quality raw materials into foods that were safe, wholesome and enjoyable to eat. The overall aims of traditional home cooking remain the same as those prepared and preserved by today's food manufacturing methods.

Over the last 50 years, developments in food science and technology have led to the discovery of many new substances that can fulfil numerous functions in foods. These food additives are now readily available and include; emulsifiers in margarine, sweeteners in low-calorie products and a wider range of preservatives and antioxidants which slow product spoilage and rancidity whilst maintaining taste.

2. What are food additives and why are they necessary?

A food additive is defined 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" (Regulation (EC) No 1333/2008). Many food additives are naturally occurring and some are even essential nutrients; it is the technical purpose that leads to these being classified as food additives and given an E number.

Food additives play an important role in today's complex food supply. Never before has the range and choice of foods been so wide either in supermarkets, specialist food shops or when eating out. Whilst a shrinking proportion of the population is engaged in primary food production, consumers are demanding more variety, choice and convenience alongside higher standards of safety and wholesomeness at affordable prices. Meeting these consumer expectations can only be achieved using modern food processing technologies which include the use of a variety of food additives proven effective and safe through long use and rigorous testing.

Additives carry out a variety of useful functions which we often take for granted. Foods are subjected to many environmental conditions, such as temperature changes, oxidation and exposure to microbes, which

can change their original composition. Food additives play a key role in maintaining the food qualities and characteristics that consumers demand, keeping food safe, wholesome and appealing from farm to fork. Food additives are very carefully regulated and the general criteria for their use is that they perform a useful purpose, are safe and do not mislead the consumer.

3. How is the safety of food additives evaluated in Europe?

All food additives must have a demonstrated useful purpose and undergo a rigorous scientific safety evaluation before they can be approved for use. Until the creation of the European Food Safety Authority (EFSA), the safety evaluation of additives in Europe was done by the Scientific Committee on Food (SCF). At present, it is the EFSA Panel on Food Additives and Nutrient Sources Added to Food (ANS Panel), who is in charge of this task. At an international level there is a Joint Expert Committee, from the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO), on Food Additives (JECFA). Assessments are based on reviews of all available toxicological data in both humans and animal models. From the available data, the maximum level of additive that has no demonstrable toxic effect is determined. This is called the "no-observed-adverse-effect level" (NOAEL) and is used to determine the "Acceptable Daily Intake" (ADI) for each food additive. The ADI provides a large safety margin and is the amount of a food additive that can be consumed daily over a lifetime without any adverse effect on health. The SCF before and now the European Food Safety Authority, encourage the lowest possible levels of an additive in a food. To ensure people do not exceed the ADI by consuming too much of, or too many products containing a particular additive, EU legislation requires that studies are done to look at the ranges of intakes across a population and to address any changes in consumption patterns. Occasional intakes over the ADI are unlikely to cause any harm because of the 100-fold safety margin. However, if the ADI might be exceeded by particular sectors of the population, the Commission would assess the need to review levels in foods or reduce the range of foods in which the additive is permitted.

The Codex Alimentarius Commission, a joint FAO/WHO activity which develops guidelines for food safety globally, maintains the "General Standards for Food Additives" (GSFA) database, with the aim of establishing a harmonised, workable and indisputable international standard for world trade. Only those additives that have been evaluated by the JECFA are included.

Thanks to strict regulation and thorough testing, food additives can be considered safe components in our diet that are contributing to the rapid evolution of the food supply in Europe and throughout the world.

4. How are food additives regulated in Europe?

A true single market for food products could not exist without harmonised rules for authorisation and conditions for the use of additives. In 2008, the EU Regulation (EC) 1333/2008 on food additives which sets out the criteria by which additives are assessed, authorised and listed as approved. This regulation harmonized the European legislation of all food additives, including sweeteners and colours which were previously covered by separate pieces of legislation, and lays out the procedures for authorization, conditions of use and rules for labelling. The list of authorised food additives and their specific conditions of use can be consulted in a [database on the European Commission website](#). Only authorized additives can

be used in the EU with the foods in which they can be used and any maximum levels being described in the list. The purity required for these additives is laid down in a separate regulation defining specific purity criteria

All food additives authorized for use in the EU before 20 January 2009 must undergo a re-evaluation and risk assessment based on the latest available scientific information by EFSA.

5. What are the rules on labelling on food additives in the EU?

In the EU, food additives must be identified as ingredients of the foods in which they are used. The name or E number of the additive (e.g. citric acid or E 330) must be listed on the labels of food products as well as information about the function that the additive performs in the food (i.e. why it is used: e.g. preservative). Some common additives include: colours, preservatives, antioxidants, emulsifiers, stabilisers, thickeners, and sweeteners. These are each discussed in more detail below.

6. What is an E-number?

An E-number signifies approval of an additive by the EU. To obtain an E-number, the additive must have been fully evaluated for safety by the SCF or the European Food Safety Authority. The E-number system also serves as a simple and convenient way to label permitted additives across the range of languages in the European Union.

7. Do food additives cause hyperactivity?

In the 1970s, some researchers suggested that changes in diet had coincided with a rise in the number of children with behaviour problems. The idea that food additives, and food colours in particular, could be linked to hyperactivity generated much interest and considerable controversy.

In 2007, a study by researchers at the University of Southampton linked increased levels of hyperactivity in young children with consuming mixtures of some artificial food colours and the preservative sodium benzoate.

The results of the Southampton study show that when the children were given the drinks containing the test mixtures, in some cases their behaviour was significantly more hyperactive.

In 2008, the European Food Safety Authority (EFSA) evaluated the study against the background of previous studies, going back to the 1970s, on the effect of food additives on behaviour and acknowledged that it was the largest study carried out on a suggested link between food additives and hyperactivity in the general population. The scientific assessment panel was assisted by experts from the fields of behaviour, child psychiatry, allergy and statistics. The panel noted that the majority of the previous studies used children described as hyperactive and these were therefore not representative of the general population.

The EFSA concluded that there was limited evidence that the mixtures of additives tested had an effect on the activity and attention of some children. Although the findings from the study could be relevant for specific individuals showing sensitivity to food additives in general or to food colours in particular, it was found not to be possible at present to assess how widespread such sensitivity may be in the general population.

Professor of Psychology, Jim Stevenson, who led the research noted However parents should not think that simply taking these additives out of food will prevent all hyperactive disorders. We know that many other influences are at work but this at least is one a child can avoid.

8. Can food additives cause allergies or food intolerance reactions?

There has been much public concern that additives cause adverse reactions although careful investigations show that this is often based on misconception rather than on identifiable adverse reactions. Food additives have only rarely been shown to cause true allergic (immunological) reactions. Among the food additives reported to cause adverse reactions are:

Colours

Reactions to tartrazine (E 102, a yellow food colour) and carmine (E 120 or red cochinille) have been reported occasionally in sensitive individuals. Symptoms include skin rashes nasal congestion and hives, although the incidence is very low (estimated to be 1-2 persons per 10,000) and very rare. IgE-mediated allergic reactions have been reported for carmine. Tartrazine has also been reported to cause asthma in sensitive individuals although the incidence is extremely low.

Sulphites

One group of additives that can cause problems in sensitive individuals is the sulfiting agents. This group includes several inorganic sulphite additives (E 220-228), including sodium sulphite, potassium bisulphite and metabisulphite containing sulphur dioxide (SO₂). These preservatives are used to control microbial growth in fermented beverages and they have been widely used in wines, beers and fruit products for over 2000 years. In sensitive (asthmatic) individuals, sulphites may trigger asthma characterised by breathing difficulties, shortness of breath, wheezing and coughing.

Monosodium glutamate (MSG) and aspartame

MSG is made up of sodium and glutamic acid. Glutamic acid is an amino acid found naturally in high protein foods such as meats and dairy products like Camembert cheese. MSG is also a flavour enhancer used in prepared meals, some Chinese food, certain sauces and soups. MSG has been "blamed" for a variety of side effects including headaches and body tingling, however scientific studies show no link between MSG and these reactions suggesting that some other component of the meal, or even psychological responses, may be responsible for any adverse effects.

Similarly, the high-intensity sweetener aspartame (another substance made from naturally occurring amino acids, aspartic acid and phenylalanine) has been blamed for a wide variety of adverse effects, none of which have been validated by scientific studies.

While food additives pose no problems for most people, a small number of people with specific allergies may be sensitive to certain food additives. It appears that where food additives have an adverse effect, they exacerbate a pre-existing condition rather than induce it. These adverse reactions, which are rarely allergic, and the foods or food components responsible, should be validated by a health professional or dietician to ensure that unnecessary dietary restrictions are not imposed. As all food additives are clearly labelled, those with specific sensitivities and those who believe they have sensitivity to a food additive, can readily avoid any that may pose problems.

9. What food additives are used in Europe?

Food additives that are commonly added to foods in Europe include:

9.1 Additives that maintain freshness and prevent deterioration

Some food additives help to keep foods fresh and safe. They help increase shelf-life by protecting foods against deterioration caused by oxidation or by micro-organisms. They can be divided into two categories based on their principal function.

9.1.1. Antioxidants

Antioxidants prevent the oxidation of foods that results rancidity or discoloration. They are used in baked foods, cereals, fats, oils and salad dressings. The major fat soluble antioxidants are:

- Tocopherols (E 306-309), BHA (butylated hydroxyanisole or E 320) and BHT (butylated hydroxytoluene or E 321) - these protect edible fats, vegetable oils and salad dressings from turning rancid.
- Ascorbic acid (E 300) and citric acid (E 330) - which preserve the colour of freshly cut fruits and vegetables.

9.1.2. Preservatives

Preservatives limit, retard or arrest the growth of micro-organisms (e.g. bacteria, yeast, mould) that are present in or gain entry to the food, preventing spoilage or food poisoning. They are used in baked foods, wine, cheese, cured meats, fruit juices and margarine among others. Examples include:

- Sulphur dioxide and sulphites (E 220-228) - these help to prevent colour changes in dried fruits and vegetables. Sulphites also inhibit the growth of bacteria in wine and fermented foods, some snack

foods and baked goods. Sulphites also have antioxidant properties.

- Calcium propionate (E 282) - prevents bread and baked foods from turning mouldy.
- Nitrates and nitrites (sodium and potassium salts) (E 249-252) - are used as a preservative in processed meats such as ham and frankfurters to keep the products safe by preventing the growth of botulinum bacteria, *Clostridium botulinum*, which is highly pathogenic.

9.2 Additives that amplify or promote sensory qualities

Additives are also useful for imparting certain characteristics to foods, improving texture or helping in food processing.

9.2.1. Taste and texture modifiers

Examples are:

- Emulsifiers and stabilisers - The purpose of these food additives is to maintain consistent texture and to prevent the separation of ingredients in such products as margarine, low-fat spreads, ice cream, salad dressings and mayonnaise. Many reduced-fat and low-fat versions of common foods are dependent on this technology. Any recipe that requires the mixing of ingredients that normally do not mix, such as fat and water, need emulsifiers and stabilisers to impart and maintain the desired consistency. Examples include lecithin, mono- and diglycerides.
- Thickeners - these substances help increase the viscosity of foodstuffs. They are added to foods such as salad dressings and flavoured milk. Gelatin or pectin are often used as thickening agents.
- Sweeteners - Both "bulk" and "intense" sweeteners impart a sweet taste to foodstuffs and are useful in low-calorie products and for special dietary products, such as those for diabetics. Intense sweeteners, such as acesulfam K (E 950), aspartame (E 951) and saccharin (E 954) are 130-200 times, 200 times and 300-500 times sweeter, respectively, than sugar-and they have zero calories. Thaumatin (E 957), a naturally sweet protein extracted from the fruit of the plant *Thaumatococcus danielli*, is 2500 times sweeter than sugar and is used at very low levels for its flavouring properties. Bulk sweeteners include sorbitol (E 420), isomalt (E 953) and maltitol (E 965) and these can be incorporated into "table-top" sweeteners and in energy-reduced foods, in which they provide volume and mouth feel. These substances have reduced caloric value, providing 2.4 kcal/gram compared with 4 kcal/gram for other carbohydrates.
- Flavour enhancers - Probably the best known is monosodium glutamate (MSG; E 621), which is used to bring out and enhance the flavours in the foods to which it is added. It is used mainly in savoury products and in a wide variety of oriental dishes.

- Others - this group includes acids, acidity regulators (used to control acidity and alkalinity in various types of food products), anti-caking agents (used to keep powders flowing freely), anti-foaming agents (reduce foams, e.g. when jams are boiled), and packaging gases (used in certain types of sealed packages, such as for meat, fish, seafood and ready-prepared vegetables and salads found in chill cabinets).

9.2.2. Colours

Colour is one of the first and most important sensory qualities and it helps us to accept or reject particular foods. Whilst adding colour may appear to some to be purely cosmetic, there is no doubt that colour is important in consumer perception of a food and it is often associated with a specific flavour and intensity of flavour. Colours are used to add or restore colour in a food in order to enhance its visual appeal and to match consumer expectations. The processing of peas and the preparation of jams can lead to loss of colour, and hence food colours can compensate for these losses. Some colours are used purely for visual decoration on cakes and confectionery items. Masking or disguising inferior quality, however, are unacceptable uses of colours

The primary reasons for adding colours to foods include:

- To offset colour loss due to exposure to light, air, extremes of temperature, moisture and storage conditions
- To compensate for natural or seasonal variations in food raw materials or the effects of processing and storage to meet consumer expectations (Masking or disguising inferior quality, however, are unacceptable uses of colours.).
- To enhance colours that occur naturally but at levels weaker than those usually associated with a given food.

Annex 1: Questions and Answers about Acceptable Daily Intakes (ADIs)

1. What is an ADI?

The Acceptable Daily Intake (ADI) is defined as an estimate of the amount of a food additive, expressed on a bodyweight basis that can be ingested on a daily basis over a lifetime without appreciable risk to health. "Without appreciable risk" means based on the current knowledge, certainty that no harm will result, even after a lifetime of exposure to the chemical additive concerned. The ADI is usually given as a range of 0-x milligrams per kilogram of bodyweight per day.

2. What is the purpose of an ADI?

ADIs serve to protect the health of consumers and to make international trade in food easier. The ADI is a practical approach to determining the safety of food additives and is a means of achieving some harmonisation of regulatory control. The advantage of regulatory and advisory bodies setting ADIs for food additives is that they are universally applicable in different countries and to all sectors of the population.

3. Who determines the ADI?

Basically, expert scientific committees advise national and international regulatory authorities. The safety assessments of food additives have developed along similar lines in individual Member States in the European Union and in the wider international community.

The main international body that addresses the safety of food additives is the Joint Expert Committee on Food Additives (JECFA) of the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). The setting of international standards has become increasingly important in recent years as the World Trade Organisation arrangements specify that Joint FAO/WHO and Codex Alimentarius Commission (Codex) standards will apply to the safety and composition of foods worldwide. A standard called the [General Standard for Food Additives \(GSFA\)](#) has been established by Codex, with the aim of developing a harmonised, workable and indisputable international standard for world trade. Only those additives that have been evaluated by the JECFA and found to meet the necessary standards of use in foods are included.

At EU level, additives approved for use in current legislation are listed in Annex 1 of the EU regulation on food additives (EC 1333/2008) after agreement by each of the Member States. All those additives have all been evaluated by the former Scientific Committee on Food (SCF) and since the creation of the European Food Safety Authority (EFSA) by the EFSA Panel on Food Additives and Nutrient Sources Added to Food (ANS) (post 2008) or the EFSA Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC Panel) (pre-2008). These expert advisory groups usually set an ADI, or in the absence of an ADI, may stipulate other limitations on use. Only additives evaluated by the SCF and/or EFSA are given an E-number, as an indication of European safety approval. The concept of ADI and the JECFA safety evaluations have been widely adopted by EFSA, the US Food and Drug Administration and other authorities worldwide.

4. How is the ADI determined?

The general criteria for the use of food additives set out in the EU regulation stipulate that additives can be approved only if they present no hazard to human health at the level of use proposed based on the scientific evidence available. The safety evaluation is based on a scientific review of all pertinent toxicological data on the specific additive—both observations in humans and mandatory tests in animals. In the EU, all the evidence is reviewed by the European Food Safety Authority.

The toxicological tests required by the regulatory authorities include lifetime feeding studies and multigenerational studies that determine how the additive is handled by the body in order to assess any possible harmful effects of the additive or its derivatives. The starting point for establishing the ADI is the

determination of the "No Observed Adverse Effect Level" (NOAEL) for the most sensitive adverse effect relevant to human health in the most sensitive species of experimental animal. The NOAEL is, therefore, the highest dietary level of an additive at which no adverse effects were observed in the studies and it is expressed in milligrams of the additive per kilogram of bodyweight per day (mg/kg bodyweight/day). The NOAEL is then divided by a safety factor, usually 100, which results in a large margin of safety.

5. Why is a safety margin necessary?

Firstly, the NOAEL is determined in animals, not humans. It is therefore prudent to adjust for possible differences by assuming that man is more sensitive than the most sensitive test animal. Secondly, the reliability of toxicity tests is limited by the number of animals tested. Such tests cannot represent the diversity of the human population, subgroups of which may show different sensitivities (e.g. children, the old and the infirm). Again, it is prudent to adjust for these differences.

6. What safety margin is normally used when determining levels of food additives?

Traditionally, the World Health Organisation has used a safety or uncertainty factor of 100, based on a 10-fold factor to allow for differences between animals and an average human, and a 10-fold factor to allow for differences between average humans and sensitive subgroups (pregnant women, the elderly). However, this may be varied according to the characteristics of the additive, the extent of the toxicology data and the conditions of use.

7. Is it acceptable for an individual to exceed the ADI on any given day?

The consumption of an additive above its ADI on a given day is not a cause for concern because the ADI has a large built-in safety factor and in practice, consumption above the ADI on one day is more than accounted for by consumption below the ADI on most other days. However, if an intake figure indicates that the ADI may be regularly exceeded by certain sectors of the population, it may be necessary for the European Food Safety Authority to advise a reduction of levels in foods consistent with the amount needed to achieve its function, or to reduce the range of foods in which the additive is permitted for use. Because of the large safety margin used in setting the ADI, it is likely that an ADI for a given additive would have to be exceeded by some considerable amount for there to be any risk of harm to human health.

8. How are dietary intakes of food additives monitored?

The monitoring of food additives is carried out by individual Member States on advice from the European Food Safety Authority. The ADI is compared with "average" and "extreme" consumption estimates in the population as whole or in particular subgroups of the population. Provided that intakes for average and extreme consumers are within the ADI, it is unlikely that any harm will result because the ADI is based on a no-observed adverse effect level, to which a large safety margin has been applied. To ensure that consumers are not exceeding the ADI by consuming too much or too many products containing a particular additive, EU legislation requires that intake studies be carried out to assess any changes in intake patterns.

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