Review

Food Additives: Functions, Effects, Regulations, Approval and Safety Evaluation

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Abstract

This article is aimed to review the significance of food additives to the consumers and their regulations on the bases of maximum limits, approval, and safety evaluation, whereby consumers and industries can get know-how which additives are allowed and not allowed to be marketed and added on food and food products. Food additives are substances that are incorporated to food to improve its appearance, flavour and prolong shelf-life, by law are considered as safe with the designated uses in food. All food additives are given labeling codes commonly known as “E-number”. Food additives are subjected to rigorous scientific safety assessment prior to their approval, to render no adverse health effects on consumers. A food additive can provide benefits to the processors and consumers when used as intended. The use of an inappropriate quantity may be deleterious to the food or to the consumer. Approved food additives have effects on different areas of human health like allergies, hyperactivity in children and decrease in human immune response when they are applied over the limit suggested by the regulatory agencies. A major responsibility of the regulatory bodies is to regulate the use and approval of food additives and to evaluate their safety. The most important principles established in food additives regulation 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.

Keywords: Food additives, E-numbers, health effects, regulation, safety evaluation, regulatory bodies.

Introduction

Food additives are defined as substances which are used by being added into food or by other methods in the process of producing food or for the purpose of processing or preserving food (Branen and Haggerty, 2002; Japans External Organization, 2010; Al-Shammari et al., 2014). They can be derivatives of natural products or synthetically produced. Colouring agents are one type of additives routinely added to items such as margarines, soft drinks and confectionery products. Similarly, flavor enhancers such as hydrolysed vegetable protein are often found in desserts. Emulsifiers, like lecithin and mono or diglycerides, are used to enable particles of one substance within a product to disperse into a second substance within the same product, and are found in chocolates, dessert mixes and breads. Similarly, stabilizers, including gelatine and pectin, aid in the creation of a smooth texture and are typically used in the preparation of cream cheeses, baked products and sauces (Vapnek and Spreij, 2005). The Community legislation on food additives is based on the principle that only those additives that are on the list of authorized food additives should be used. An important principle of the legislation is that the consumers should not be misled in use of additives in food. All food additives are advised to be used in limited quantities (the maximum permitted level (MPL)) in foodstuffs. If no quantitative limits or MPLs are foreseen for the use of a food additive, it should be used according to good manufacturing practice that is only as much as necessary to achieve the desired technological effect (Food safety authority of Ireland, 2010). Not only the unapproved food additives, but also, all the approved food additives can cause adverse health effects, once they are consumed in excess of the acceptable daily intake. Some of the pathological adverse effects of food additives include: upper respiratory system symptoms, allergic skin reactions, gastrointestinal disorders, asthma, migraine, and conjunctivitis (Schoenthaler and Doraz, 1986; US Food and Drug Administration, 1993; Al-Shammari et al., 2014). Moreover it has been suggested exposure to some additives like azo are associated with increased risk for hyperactivity effects on child behaviour, or increased attention deficit hyperactivity disorder (Sandler et al., 1999).
Table 1. Functional classes of food additives (adapted from Food safety authority of Ireland, 2010).

<table>
<thead>
<tr>
<th>Class</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acid</td>
<td>Emulsifying salt</td>
</tr>
<tr>
<td>Acidity regulator</td>
<td>Ffirming agent</td>
</tr>
<tr>
<td>Anti-caking agent</td>
<td>Flavour enhancer</td>
</tr>
<tr>
<td>Anti-foaming agent</td>
<td>Flavour enhancer</td>
</tr>
<tr>
<td>Anti-oxidant</td>
<td>Foaming agent</td>
</tr>
<tr>
<td>Bulking agent</td>
<td>Gelling agent</td>
</tr>
<tr>
<td>Carrier</td>
<td>Glazing agent</td>
</tr>
<tr>
<td>Colour</td>
<td>Humectants</td>
</tr>
</tbody>
</table>

Food additives and their functions

According to European legislation, food additives are defined as substances not normally consumed as a food itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to a 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 (Emerton and Choi, 2008; Aderemi et al., 2015). Food additives have several functions when they are incorporated into food. They can be used either to facilitate or complement a wide variety of production methods in the modern food supply. They can make food safer from bacteria by acting as preservatives and preventing oxidation and other chemical changes, or make food look or taste better or feel more pleasing in the mouth (Al-Shammari et al., 2014).

Additives may also improve nutritional value of foods and improve their taste, texture, consistency or color. In the last 40 years, developments in food science and technology, as well as changes in consumer demand, have led to a substantial increase in the use of food additives (Lawrence, 1998). Lawrence also reported that additives need to be used only in small quantities to be effective, typically less than one percent in the final food. Many additives, e.g. antioxidants, preservatives and flavourings, are effective at levels below 0.1%. Food additives have much significance. For the purpose of both classification and regulation, they are categorized into several functional groups (Table 1).

Preservatives

Preservatives are used to extend the shelf-life of certain products and ensure their safety through that extended period. Most importantly, they retard bacterial degradation, which can lead to the production of toxins and cause food poisoning (Lee, 2012). Thus they offer a clear consumer benefit in keeping food safe over the shelf-life of the product, which itself may be extended by their use and thus meet the demands of modern lifestyles, including infrequent bulk shopping expeditions (Branen and Haggerty, 2002; Emerton and Choi, 2008).

Antioxidants

Antioxidants reduce the oxidative deterioration that leads to rancidity, loss of flavour, colour and nutritive value of foodstuffs. Fats, oils, flavouring substances, vitamins and colours can oxidise spontaneously with oxygen when exposed to air (Branen and Haggerty, 2002). Some antioxidants actually remove oxygen by self-oxidation, e.g. ascorbic acid, whilst others interfere in the mechanism of oxidation, e.g. tocopherols, gallic acid esters, butylated hydroxy anisole (BHA) and butylated hydroxytolene (BHT). All have specific properties, making them more effective in some applications than in others.
Often a combination of two or more antioxidants is more effective than any one used simply because of their synergistic effects (Department of human nutrition, 2010). Antioxidants cannot restore oxidized food; they can only retard the oxidation process. As oxidation is a chain reaction process, it needs to be retarded as early as possible. The most effective use of antioxidants is therefore in the fats and oils used in the manufacturing process (US Food and Drug Administration, 1993). There is a potential health benefits from the use of antioxidants. Recent medical evidence suggests that oxidation reactions in the body could be linked to the incidence of atherosclerosis (blocking of blood vessels) leading to heart attacks (Emerton and Choi, 2008). Ascorbic acid (E 300), Citric acid (E 330), Tocopherols (E 307), Butylated hydroxyanisole (E 320) are some of the common antioxidants.

**Emulsifiers and stabilizers**

The purpose of emulsifiers and stabilizers is to facilitate the mixing together of ingredients that normally would not mix namely fat and water. This mixing of the aqueous and lipid phases is then maintained by stabilizers. These additives are essential in the production of mayonnaise, chocolate, ice cream, homogenized milk products and fat spreads (WHO, 2009). In addition to this function, the term stabilizer is also used for substances that can stabilize, retain or intensify an existing colour of a foodstuff and substances that increase the binding capacity of the food to allow the binding of food pieces into reconstituted food (Jie, 2015; Emerton and Choi, 2008). These types of emulsifiers used in food industries are Clouding agent, Crystallization inhibitor, Density adjustment agent (flavouring oils in beverages), Dispersing agent, Emulsifier, Plasticizer, Surface active agent, and Suspension agent.

**Colourants**

Colourants are used to enhance the visual properties of foods. As with all additives, their use is strictly controlled and permitted only where there is a case of need is proven, e.g. to restore colour that is lost in processing, such as in canning or heat treatment to ensure consistency of colour and for visual decoration. Colour is important in consumer perception of food and often denotes a specific flavour (WHO, 2009; Emerton and Choi, 2008; Jie, 2015).

**Flavor enhancers**

Flavor enhancers enhance a food’s existing flavors. They may be extracted from natural sources (through distillation, solvent extraction, maceration, among other methods) or created artificially (Japan’s External Organization, 2010; Jie, 2015). They can be incorporated in to different types of food and food products.

Some of common flavor enhancers used are Dioctyl sodium-sulfosuccinate-used in processed foods, Disodium guanylate-used in canned meats, meat based foods, Hydrolyzed vegetables-used in mixes, stock, processed meats and Monosodium glutamate (MSG)-used in Chinese food, dry mixes, stock cubes, and canned, processed, and frozen meats.

**Roles of food additives**

Food additives play a vital role in today’s food supply. They allow the people to have a variety of foods year-round. And, they make possible an array of convenience foods without the inconvenience of daily shopping. Food additives perform a variety of useful functions in foods that are often taken for granted. Since, most people no longer live on farms, additives help keep food wholesome and appealing while en route to markets sometimes thousands of miles away from where it is grown or manufactured. Additives also improve the nutritional value of certain foods and can make them more appealing by improving their taste, texture, consistency or colour (U.S. Food and Drug Administration, 1993).

**Effects of food additives**

The side effect of food additives is a hot issue at this time. The effects raised are different for people with age, immune response, frequency and other factors. It has been suggested that the exposure to some additives like azo are associated with increased risk for hyperactivity effects on child behavior, or increased attention deficit hyperactivity disorders (Sandler et al., 1999; Gil, 2014). Branen and Haggerty (2002) have reported that avoiding or minimizing toxins in a diet is an important step toward enhancing the health and lowering risk of disease. Foods, amongst other things (cosmetics and medications), represent a source of these toxins. Effects of food additives may be immediate or may be harmful in the long run if consumers have constant exposure. Immediate effects may include headaches, change in energy level and alterations in mental concentration, behavior, or immune response. Long-term effects may increase the risk of cancer, cardiovascular disease and other degenerative conditions (US Food and Drug Administration, 1993). Although additives and preservatives are essential for food storage, they can give rise to certain health problems (Tuormaa, 1994). They can cause different allergies and conditions such as hyperactivity and attention deficit disorder in some people who are sensitive to specific chemicals. Gil (2014) found in his research that the foods containing additives can cause asthma, hay fever and certain reactions such as rashes, vomiting, headache, tight chest, hives and worsening of eczema.
Some of the known dangers of food additives and preservatives are as follows: Benzoates can trigger the allergies such as skin rashes and asthma as well as believed to be causing brain damage. Bromates destroy the nutrients in the foods. It can give rise to nausea and diarrhea. Butylates are responsible for high blood cholesterol levels as well as impaired liver and kidney function. Caffeine is a colourant and flavourant that has diuretic, stimulant properties. It can cause nervousness, heart palpitations and occasionally heart defects. Saccharin causes toxic reactions and allergic response, affecting skin, gastrointestinal tract and heart. It may also cause tumors and bladder cancer.

To minimize the risk of developing health problems due to food additives and preservatives, researchers recommend avoiding the foods containing additives and preservatives. Before purchasing the canned food, consumers must check its ingredients. They should buy organic foods, which are free from artificial additives.

Safety evaluation of food additives

The safety evaluation involves examination of the chemical structure and chemical characteristics of the additive, including its specifications, its impurities and potential breakdown products in its intended use (Gil, 2014). Toxicological data (data derived from tests to determine whether a substance is harmful) are essential to identify and characterize any possible health hazards associated with the additive and to allow extrapolation of the findings in animals and other test systems to humans (Food safety authority of Ireland, 2010). According to the safety evaluation protocol, the additive should be administered to laboratory animals, usually mixed with their diet, but at much higher concentrations than would occur in human food. European Food Safety Authority (2007) reported that studies on safety evaluation should be done for long term and re-evaluated for authorized additives; additives may have the consequence of short or long term effects to the people.

The Scientific Committee on Food (SCF) organization, which acts as an expert composed mainly of toxicologists, has issued guidelines setting out the tests that must be carried out on food additives in order to demonstrate their safety. The guidelines require an extensive range of test animals and other tests to assess every conceivable risk to the consumer: metabolic studies (to understand how the body absorbs, distributes, metabolizes and eliminates the substance); genetic toxicity (the potential for gene and chromosome damage); reproduction and teratogenicity studies (life-time studies, including the potential for fertility and birth defects); chronic and carcinogenicity studies (the potential for causing cancer) (Branen and Haggerty, 2002). Sandler et al. (1999) reported that everything is toxic if consumed at a high enough dose, and everything is safe, with a few exceptions, if taken at a low enough dose. To put it another way, a threshold level exists above which consumption is unsafe and below which consumption is safe. The plan of testing is the identification of an adverse effect caused by the additive (Rulis and Levitt, 2008). The target is to test at three different dosages: the top dose should show an effect and both mid- and low doses show no effect. This being the case, the mid-dose becomes the no observable effect level (NOEL). This is considered to be a safe level for humans since there were no effects in animals. The toxicologist takes this level and applies a safety factor which recognizes, amongst other things, that humans are not just big rats. The safety factor is usually, but not always, too. The value then obtained by dividing the NOEL by 100 is called the Allowable/Acceptable Daily Intake (ADI). So, for instance, a NOEL of 5000 mg/kg gives an ADI of 50 mg/kg for humans (Branen and Haggerty, 2002; Emerton and Choi, 2008). Branen and Haggerty (2002) have also suggested three categories of food additive intake: Those below 30% of the ADI are certainly safe for whole population. Those between 30 and 100% of the ADI indicate concern for the safety of extreme consumers, often children in particular. Those greater than 100% are unsafe for all population. Current evidence suggests that additive intakes do not often exceed their ADI, but that in the cases where they do, additive usage and the regulations should be altered.

FDA use three principal factors to determine the estimated daily intake, namely: (a) the amount of the additive to be added to particular foods; (b) the frequency with which consumers will eat those foods; and (c) the amounts of those foods consumed by individuals across the various subpopulations of consumers stratified by age groups (Rulis and Levitt, 2008). ADI is different among different targeted consumers such as adults, children, infants, old people immune suppressed consumers. Food safety authority of Ireland conducted a survey on the acceptable daily intake some authorized and approved food additives (Table 2).

Approval of food additives

Prior to their authorization, food additives are evaluated for their safety by the European Food Safety Authority (EFSA) and other organizations, the expert risk assessment body that advises the European Commission on questions relating to food safety (FDA, 2014). The FDA evaluates new additive petitions to determine if substances are considered safe for addition to the food supply and maintains a database for evaluation and monitoring of these substances (FDA, 1998). This petition of additives must specify all pertinent information concerning the additive including the chemical identity and composition; its physical, chemical, and biological properties; and information regarding possible byproducts or impurities.
Table 2. Detailed intake estimates of the 14 prioritized food additives by Irish adults based on the north south food consumption (adapted from Food safety authority of Ireland, 2010).

<table>
<thead>
<tr>
<th>Additives</th>
<th>E number</th>
<th>Intake (mg/kg.bw/day)</th>
<th>% ADI</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sunset Yellow</td>
<td>E 110</td>
<td>0.556</td>
<td>22</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Annatto</td>
<td>E 160b</td>
<td>0.055</td>
<td>85</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Sulphites</td>
<td>E220-E 224, E 226-E 228</td>
<td>0.821</td>
<td>117</td>
<td>Could possible exceed ADI</td>
</tr>
<tr>
<td>Butylated Hydroxyanisol (BHA)</td>
<td>E 320</td>
<td>0.375</td>
<td>75</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Carmines</td>
<td>E 120</td>
<td>1.570</td>
<td>31</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Benzoic Acid &amp; Salts</td>
<td>E 210-E 213</td>
<td>2.878</td>
<td>57</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Polylglycerol Polycrinoiate</td>
<td>E 476</td>
<td>4.327</td>
<td>70</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Polyglycerol Esters of fatty Acid</td>
<td>E 475</td>
<td>23.91</td>
<td>96</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Polysorbates</td>
<td>E 432-E 436</td>
<td>8.233</td>
<td>80</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Nitrites</td>
<td>E 249, E 250</td>
<td>0.2048</td>
<td>205</td>
<td>Possibility of exceeding the ADI</td>
</tr>
<tr>
<td>Callates</td>
<td>E310-E312</td>
<td>0.384</td>
<td>77</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Stearoyl Lactylates</td>
<td>E 481-E482</td>
<td>18.611</td>
<td>20</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Sucrose Ester/Sucroglycerides</td>
<td>E 473-E474</td>
<td>8.926</td>
<td>45</td>
<td>Unlikely to exceed ADI</td>
</tr>
<tr>
<td>Butylated Hydroxyltolune</td>
<td>E 321</td>
<td>0.0427</td>
<td>85</td>
<td>Unlikely to exceed ADI</td>
</tr>
</tbody>
</table>

Other information that must be included relates to method of preparation, identify of the manufacturer, determination of stability, proposed uses or concentrations of use, and methods of analysis or recovery (Branen and Haggerty, 2002). To be included in the approved list, additives must comply with the conditions set out in regulation whereby should not present safety concerns, should be technologically justified, and should not mislead the consumer. Additives should also have advantages and benefits for the consumer such as preserving the nutritional quality of food, enhancing its keeping quality or stability, aiding the manufacture and processing of the product or in its transport or storage (Food Additive Unit, 2002; Food Standard Agency, 2015). If the additive is deemed to be safe by EFSA, including (usually) the establishment of an Acceptable Daily Intake (ADI), the Commission will then initiate the process to amend the legislation to add the substance to the list of authorized food additives via a Commission Regulation. Vapnek and Spreij (2005) also reported that assessments must be based on all toxicological data and other relevant available information in order to determine the Acceptable Daily Intake (ADI). The ADI must provide a large safety margin and is the amount of each food additive that can be consumed daily over a lifetime without any adverse effect on human health (Branen and Haggerty, 2002). 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 (Jie, 2015). Once authorized at EU level, a food additive or foods containing it can be placed on the market. Food additives must comply with the approved specifications, which include information to adequately identify the food additive, including origin, and to describe the acceptable criteria of purity (Food safety authority of Ireland, 2010).

Food additive which has identified and approved has the code as, E-number (European Union legislation, 2016). According to the conditions and feeding habits of people, some of food additives may not have acceptability even if used in other country.

**E-numbering**

The regulatory agency has developed several lists of additives. The E-system, developed by the European Economic Community, is a list of food additives that is updated on a regular basis, including additives that are considered safe, and allows foods to move from country to country within the common market (Al-Shammari et al., 2014). To regulate these additives and inform consumers, each additive is assigned a unique number, termed as “E-numbers”, which is used in all over the world for all approved additives (European Union legislation, 2016). This numbering scheme has now been adopted and extended by the Codex Alimentarius Commission to internationally identify all additives, regardless of whether they are approved for use (CAC, 2001).

**Positive and negative lists of food additives**

Food additives are specifically categorized in two systems according to the regulation, positive list system, which can be used (toxicologically cleared), and negative list system, prohibited to use either absolutely, maximum content or with certain conditions, according to their effects to the people (Post, 2003). Additives which do not have any adverse effect after consumption are being listed under the positive list. Approved food additive by the regulatory organization is allowed to be available in the market and to use (Feng, 208; Japans External Organization, 2010). On the other case, food additives which does adverse health effect for human consumption are listed under the negative list and should not be marketed (Morgan et al., 2014).
Lee (2012) explained that negative list of food additives are described in Food Additive Code, in Korea. Approval and tolerance level should be established on product basis and usually it takes about a year to get a new additive to the approved list upon petition by a producer.

**Regulations and limits of food additives**

Food additive safety regulation is one of the core areas of public health regulation, which in turn is a chief activity of the world (Post, 2003). Food additives are regulated and controlled by European Union (EU), Food and Drug Administration (FDA), Food and Agricultural Organization (FAO) and World health Organization (WHO) (Barroso, 2012). Regulations on food additives, which usually appear as subsidiary instruments under the main food legislation, should list the minimum requirements for their composition and quality, the additives which may be used (to the exclusion of others), the foods in which they may be used and the maximum levels (Vapnek and Spreij, 2005; Jie, 2015). The relevant directive clearly states that food additives are allowed only if: they present no hazard to health at the level proposed; a reasonable technological need can be demonstrated; they do not mislead the consumer. The directives also state that all food additives must be re-evaluated wherever necessary in the light of changing conditions of use and new scientific observation (Food Additive Unit, 2002; Emerton and Choi, 2008; Feng, 2008). There are three directives on food additives, one on colours, a second on sweeteners and a third on remaining categories of additives, e.g. preservatives, stabilisers, emulsifiers, the so-called 'miscellaneous additives'. All have now been implemented into the national laws in each member state, which means the same additives are now allowed in the same foods in every country in the Union. A total of 297 additives are now approved for use in food across the Union (43 colours, 12 sweeteners and 242 'miscellaneous additives') (Emerton and Choi, 2008). The directive on colours (94/36/EC) and sweeteners (94/35/EC) were both adopted in 1994. The directive on the miscellaneous additives (95/12/EC) was adopted in 1995. Each directive contains a list of permitted additives, the foods in which each of the additives may be used, and permitted levels of use (Emerton and Choi, 2008; Barroso, 2012).

In Europe, a total of 43 colours with E-numbers are permitted according to European Community (EC) directive. The directive also lists the foods which may be used and the maximum levels of colour added to those foods. The large number of colours allows many different shades to be produced. The levels allowed in a product are very low. Synthetic colours have a strong hue and are allowed at typical concentrations of 0.01 g/kg to 0.02 g/kg (0.001%-0.002%). Levels of natural/nature identical colours are from 0.05-10 g/kg of food product (Branen and Haggerty, 2002; Emerton and Choi, 2008).

**Conclusion**

Food additives are chemicals which are intentionally added to food during its preparation or storage to fulfill a specific technological function. Food additives preserve the freshness and appeal of food between the times it is manufactured and when it finally reaches the market. All food additives approved for use in the organizations and nation wise are carefully regulated by the authorities to ensure that foods are safe to eat. Today, food and color additives are more strictly regulated than at any time in history after incorporating in foods for the technological purpose. The Food and Agriculture Organization (FAO), however, recognizes additives as any substance whose intended use will affect, or may reasonably be expected to affect, the characteristics of any food. The law and regulation (FAO, FDA) of food additives prohibits the use of any additive that has been found to cause health problem such as cancer in humans or animals. To market any food additive, a manufacturer or industry must first petition the FAO for its approval. The safety evaluation, short and long term effects are the main criteria for approval food additives. Some food additives like boric acid, citric acid and sodium metabisulphite have potential risks for human health. Thus, all additives should subject to ongoing safety review as scientific understanding and methods of testing continue to improve, whereby health of consumers will be secured. The Food additive regulatory bodies have a responsibility to ensure that the additives which are added to foods are not harmful to consumers. The agency has enjoyed a level of trust on the part of consumers who rightfully see it as a competent and impartial arbiter of food safety.

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