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Basics of Food Additives

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CHAPTER 1

FOOD ADDITIVES AND WHY THEY ARE USED ?

Introduction

The role of food additives in food manufacture has been much maligned and misunderstood in recent years. Additives fell victim to bad press to the extent that, at the height of the anti-"E" numbers campaign in the 1980s, the word "additive" became almost synonymous with "adulteration", and foods containing additives were as much to be avoided as foods containing genetically modified ingredients have become since their introduction in the late 1990s. Authors whose main objective appeared to be the denigration of the food manufacturing industry, particularly the major multinationals, found this easy meat in an atmosphere of consumer ignorance, and were guaranteed support for their cause by scaring their audience into believing that additives were responsible for a wide range of ill effects from intolerance and hyperactivity to long-term chronic diseases. Constantly prefacing the words "food additive" with "chemical" was sufficiently emotive to result in the perception of "nasty". Alongside this was the implication that ready-prepared, processed food was inherently inferior to, and less wholesome than food prepared in the home.

The catalyst for the 1980s focus on additives was a change in labelling legislation in 1986, which required the detailing of each individual additive in the ingredients list of most pre-packed products. Until that time, the use of additives had been indicated by reference to a generic functional group, such as "preservatives", "antioxidants" and "colours". The new labelling requirements resulted in the appearance on some food labels of some very long lists of additives, including some lengthy chemical names. Some products looked as though they were nothing more than a couple of simple ingredients held together by a dictionary of chemical substances. The "E" number system, intended to assist as a short code for some of the lengthier chemical names and to indicate common European safety approval, became the butt of the criticism against the use of additives, and consumers voted with their feet by leaving products containing long lists of "E" numbers on the shelf.

The interest in, and fear of, what was being put into food spawned a number of books on additives, their use in food, potential (harmful) effects and protocols for their safety approval, along with the author's specific treatise on the subject. Some were informative, intended to assist the consumer in understanding what additives were, how they were produced, why they were used and how to avoid them, if desired. Others were more politically motivated and used the fashionable attack on additives as an illustration of all that was bad about the food industry and the allegedly secretive systems of safety assessment of all chemicals and processes used in food production. The implication was that

any chemicals added to food, either as pesticides in primary production or additives in processing, were suspect.

A generation brought up on convenience foods, removed from the messy business of primary food production, fell easy prey to this suggestion, apparently oblivious to the substances and techniques employed by their grandmothers, when no self-respecting household would have been without baking powder, bicarbonate of soda, cream of tartar, a selection of flavourings and a bottle of cochineal – some of the most common everyday "food additives". These everyday ingredients might well be frowned upon by many a modern shopper uninitiated in the art of cookery, if spotted on the ingredients label of a manufactured product in the form of an "E number" or prefaced, as legislation requires, by its additive class. How many people think of additives when they buy a lemon or a bottle of vinegar? Yet these too are authorised additives (as citric and acetic acid, respectively) and widely used in food manufacture for their preservation properties, as well as their acidic taste, precisely as they are used in everyday cooking. The use of saltpetre as a preservative can be traced back to Roman times, and the controversy over additives use goes back to at least 1925, when the use of boric acid in food was banned under the Preservatives Regulations. However, in recent years the use of boric acid has been accepted under the Miscellaneous Food Additives Regulations 1995 as amended, but only for the treatment of caviar.

Whilst its complexity and scale do not lend modern food manufacture entirely to direct comparison with the traditional kitchen, it is often forgotten that the overall purpose is the same – to prepare, preserve, process and, as the case may be, cook basic raw ingredients to convert them into wholesome, attractive, better tasting and nutritious food, ready to be consumed. Every cook has his or her own techniques, and knows many a trick to prevent peeled vegetables and apples from browning, thicken sauces, brown the gravy, and transform an everyday dish into something special; he or she will also ease dinner party preparations by preparing in advance and storing the part-ready dishes for last- minute completion. Food manufacturers do much the same, and, over years of product development, first on the basis of trial and error and now underpinned by research programmes, have developed the most effective and economical methods of producing a wide range of foods to suit every taste and pocket. In order to achieve this, they need at their disposal a wide range of additives to perform a number of tasks in the process, from cleaning and refining the raw materials, to preserving them in optimal condition throughout further processing or distribution, combining them with other ingredients and ensuring that they appear attractive to the consumer. The types of additive used and some of the functions they perform are explored in greater detail below.

The anti-additives campaign and consequent consumer pressure to remove or minimise the use of

additives inevitably led to changes in manufacturing practice and marketing. In addition, trends towards more "fresh" foods and the growth in market share of chilled foods, together with changes in legislation following completion of the European harmonisation exercise, all had an impact on the use of additives. It is therefore timely to review the place and use of additives in the food supply, whilst bearing in mind that they will always be essential to food preparation, quality and preservation.

What are Food Additives and why are they Used?

The use of food additives is nothing new. Preserving food is an age-old necessity. Many of the techniques that we now take for granted, such as canning, refrigeration and freezing, are relatively new. Even the overwintering of farm animals was rare until the 17th century, when feeding and husbandry techniques became better understood. Any old or weakly livestock such as oxen, cows, sheep, pigs and poultry had to be slaughtered in the autumn, and the meat was dried, salted or pickled to preserve it for the winter months (1). When food shortage ceases to be a problem, greater emphasis is placed on making food look and taste good, and we look beyond food as a survival necessity to food as a pleasure and a treat.

Food additives are used either to facilitate or complement a wide variety of production methods in the modern food supply. Their two most basic functions are that they either make food safer by preserving it from bacteria and preventing oxidation and other chemical changes, or they make food look or taste better or feel more pleasing in the mouth.

The use of additives in food preservation is, not surprisingly, one of the oldest traditions. Our forbears may not have thought of saltpetre, used as a curing agent, or vinegar (acetic acid) as additives, but they would have been the mainstay for ensuring a longer-term supply of precious perishable foods. Salt, though not an additive by the modern definition, was the other essential.

Food additives are defined in European 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 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" (2).

Known as the additives "framework" Directive, this Directive also defines processing aids as "any substance not consumed as a food ingredient by itself, 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 these residues do not present any health risk and do not have any technological effect on the finished product.

Processing aids

Whilst many of the substances used as additives may also be used as processing aids, the latter function is outside the scope of additives legislation. The differentiating criterion, and the question that any manufacturer must ask in terms of regulatory requirements, is "does it continue to function in the final food?" So, for example, sulphur dioxide (E220) may be used to prevent discoloration of fruit destined for pie making, but would have no effect in the fruit pie itself, and indeed would be cooked off during processing. Thus, in this application, it is a processing aid used in the making of a fruit pie, not an additive performing a function in the pie itself. Many of us will be used to similar techniques in the kitchen, such as using lemon juice to prevent discoloration. In the complex world of food manufacture, where production is increasingly specialised and expertise focused at specific sites, it is not unusual for the manufacturer of an end product to buy in many of his supplies as part-processed proprietary ingredients. So additives may be needed at the "intermediate" stage, but would have no function in the final product, and would therefore not appear on the label, unless considered to have the potential to cause an allergenic reaction (see Chapter 2). Thus, anti-caking agents may be required in dry ingredients to prevent them from turning lumpy before being made into a fancy cake, but will have no effect once the cake is baked and decorated, so the anti-caking agent functions as an additive in the dry mix, but is a processing aid as far as the cake is concerned. Other examples of processing aids are release agents used to prevent food from sticking to a mould or, perhaps, slicing equipment. Again, this is part of the process of production, not the composition of the food, even though there may be traces of the "processing aid" left on the product, as there would be on a cake from greasing the cake tin. This, then, is the essential technical difference between a processing aid and an additive.

The "framework" Directive identifies a number of classes of additives,

e.g. sweeteners, colours and "miscellaneous" additives (including additive categories such as preservatives, antioxidants, emulsifiers, stabilisers, thickeners, flavour enhancers etc.), for which more detailed legislation was eventually developed, and lays down general criteria for their use, notably that technological need must be demonstrated that cannot be achieved by other means; that their presence presents no hazard to the consumer; and that they do not mislead the consumer. Their use may be considered only where there is demonstrable benefit to the consumer, namely to preserve the nutritional quality of the food; to provide necessary ingredients or constituents for foods

manufactured for groups of consumers with special dietary needs, or to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that, in doing so, it does not deceive the consumer; and to assist in manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities. These are similar to the principles enshrined in the Codex Alimentarius, the joint FAO/WHO body responsible for international standards in food.

The harmonisation of European legislation was a prerequisite for trade in the Single Market as differences in national legislation constituted barriers to trade. This is explored in greater detail in a later chapter, but it is important to appreciate that the development of a new raft of additives legislation in the late 1980s and through the 1990s was not indicative of an absence of controls before that time, but a recognition that differences in national approaches throughout the Member States were not conducive to the free movement of goods within a single economic entity. The new legislation reinforced the requirement for justification of a case of need in the use of additives and of the importance of not deceiving the consumer.

The primary aim of the food-manufacturing industry is to provide a wide range of safe, wholesome, nutritious and attractive products at affordable prices all year round in order to meet consumer requirements for quality, convenience and variety. It would be impossible to do this without the use of food additives. They are essential in the battery of tools used by the food manufacturer to convert agricultural raw materials into products that are safe, stable, of consistent quality and readily prepared and consumed.

Different types of additive are used for different purposes, though many individual additives perform more than one function. For the purposes of both classification and regulation, they are grouped according to their primary function. The main groupings, or classes, of additives are explained below, together with their functions and some examples of their use.

Preservatives

Preservatives are probably the single most important class of additives, as they play an important role in the safety of the food supply. Despite this fact, any chemical used to counteract the perishability of food raw materials has often become perceived as suspect, and any food containing a preservative has been considered inferior or unsafe. Yet the use of chemical preservatives, such as sulphur dioxide and sulphites, is but a continuation of the age-old practices of using salt, sulphite and spices to preserve perishable foods in the days before refrigeration and modern processing techniques. All

food raw materials are subject to biochemical processes and microbiological action, which limit their keeping qualities. 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. 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. The continued perception of preservatives as undesirable, to which the many labels protesting "no artificial preservatives" testify, is therefore an unfortunate consumer misapprehension.

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 all oxidise spontaneously with oxygen when exposed to air. The rate of deterioration can vary considerably and is influenced by the presence of natural antioxidants and other components, availability of oxygen, and sensitivity of the substance to oxidation, temperature and light, for example. Oxidation can be avoided, or retarded, by a number of means, such as replacing air by inert packaging gases, removal of oxygen with glucose oxidase, incorporation of UV-absorbing substances in transparent packaging materials, cooling, and use of sequestering agents. These may not be possible in all cases, or sufficient for an adequate shelf-life for some foods. Thus antioxidants are used to retard oxidative deterioration and extend shelf-life. 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, BHA and 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. The presence of sequestering agents, such as citric acid, may also have a synergistic effect, by reducing the availability of metallic ions that may catalyse oxidation reactions. The use of the powerful synthetic antioxidants BHA, BHT and the gallic acid esters is very restricted. Tocopherols, which can be either natural or synthetic, are less restricted but are less effective in the protection of processed foods. Antioxidants cannot restore oxidised 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.

Emulsifiers and stabilisers

The purpose of emulsifiers and stabilisers 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 stabilisers. These additives are essential in the production of mayonnaise, chocolate products and fat spreads, for example. The manufacture of fat spreads (reduced-fat substitutes for butter and margarine), has made a significant contribution to consumer choice and dietary change, and would not be possible without the use of emulsifiers and stabilisers. Other reduced- and low-fat versions of a number of products are similarly dependent on this technology. Anyone who has ever made an emulsified sauce, such as mayonnaise or hollandaise, will appreciate the benefits of this technology

– still more so those who have failed miserably in the technique and ended up with an expensive mess of curdled ingredients!

In addition to this function, the term stabiliser is also used for substances that can stabilise, 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.

The increasing awareness of problems with food allergy and intolerance has led to the requirement to state the source of certain emulsifiers on food labelling. For example, lecithin derived from soya is not suitable for an individual with an allergy to soya, therefore clear labelling of the source of the ingredient is vital to aid in consumer choice of products safe for individuals with specific dietary requirements (see Chapter 2).

Colours

Colours are used to enhance the visual properties of foods. Their use is particularly controversial, partly because colour is perceived by some as a means of deceiving the consumer about the nature of the food, but also because some of the most brightly coloured products are those aimed at children. As with all additives, their use is strictly controlled and permitted only where 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. The use of colour in food has a long and noble tradition in the UK. Medieval cooks were particularly fond of it. The brilliant yellow of saffron (from which Saffron Walden derives its name) and the reddish hue of saunders (powdered sandalwood) were used along with green spinach and parsley juice to colour soups in stripes or to give marbleised effects (1). So, whilst adding colour to food may appear to some to be an unnecessary cosmetic, which is not in the consumer's interests, there can be no doubt that the judicious use of colour enhances the attractiveness of many foods. Some retailers tried introducing ranges of canned

vegetables and fruits such as strawberries and peas without adding back the colour leached out by heat processing. They were still trying to dispose of the unsold returns several years later! Colour is important in consumer perception of food and often denotes a specific flavour. Thus, strawberry flavour is expected to be red and orange flavour orange-coloured. Consumer expectation is therefore a legitimate reason for adding colour.

Food colourings, in particular, have long been the scapegoat in the popular press for behaviour problems in children. It has been over 30 years since Feingold suggested that artificial food colours and preservatives had a detrimental effect on the behaviour of children (3).

Since then, research into the effect of colours and preservatives in foods on children's behaviour has added fuel to the fire of negative consumer perception of these additives, particularly in products aimed specifically at this age group (4). Significant changes were found in the hyperactivity behaviour of children by removing colorants and preservatives from the diet. There was no gender difference in this result and the reduction of hyperactivity was independent of whether the child was initially extremely hyperactive, or not hyperactive at all. More recently in 2007, a study on the effect of two mixtures of certain artificial food colours together with the preservative sodium benzoate showed an adverse effect on the hyperactive behaviour of children in some age groups in comparison with a placebo, although the increases in the levels of children's hyperactive behaviour were not consistently significant for the 2 mixtures or in the 2 age groups (5). The findings of this new study replicate and extend the findings from an earlier study in preschool children in 2004 (6). The colours used in this study are already included in work of the European Food Safety Authority (EFSA) on the re-evaluation of colours.

Colouring Foodstuffs

The term 'colouring foodstuffs' has been adopted for colourings that are derived from recognised foods and processed in such a way that the essential characteristics of the food from which they have been derived are maintained.

This is a different situation to natural colours that are regarded as additives where the pigment is selectively extracted and concentrated.

A colouring foodstuff can be declared as an ingredient on the label without a requirement for its function to be listed, as legislation only requires this of additives.

These colouring foodstuffs include bright yellow colours derived from turmeric, oleoresin and safflower; golden yellow to natural orange colours from carrots and paprika; toffee brown colour from caramelised sugar syrup; green colours from spinach leaves and stinging nettles, both rich in

chlorophylls; and red, blue and purple colour from concentrates of red and blue fruits, red cabbage and beetroot, rich in anthocyanins.

It is clear that the full spectrum of colour shades is achievable using colouring foodstuffs, although developers should ensure that the colouring foodstuff exhibits the same stability and vibrancy of colour in the final application as a conventional food colouring would.

Sweeteners

Sweeteners perform an obvious function. They come in two basic types – "bulk" and "intense", and are permitted in foods that are either energy-reduced or have no added sugar. They are also sold direct to consumers as "table-top" sweeteners

– well-known to dieters and diabetics. For example the table top sweetener Sunette contains acesulfame-K while Splenda contains sucralose. Intense sweeteners, such as aspartame, saccharin, acesulfame-K and sucralose have, as their name suggests, a very high sweetening property, variable from type to type but generally several magnitudes greater than that of sucrose. (For example, aspartame is approximately 200 times sweeter than sugar, weight for weight; saccharin 300–500 times; and acesulfame-K 130–200 times.) Bulk sweeteners, where the majority are polyols, including erythritol, sorbitol, isomalt and lactitol are less sweet, but provide volume and hence mouthfeel. Amongst the polyols, maltitol is one of the sweetest and xylitol, which is the sweetest, has the same sweetness intensity as sucrose. Due to the reduced sweetness characteristics of the majority of polyols, it is possible to blend them with other polyols or with intense sweeteners to improve the sweetness and taste quality. This property is known as sweetness synergy. Another benefit is the ability to mask the undesired bitter

metallic aftertaste of some intense sweeteners. Commonly used combinations include, saccharin with cyclamate, acesulfame-K with aspartame, erythritol with acesulfame-K and there are many more. Both types of sweetener (bulk or intense) are useful in low-calorie products, and are increasingly sought after by many consumers, and for special dietary products such as for diabetics. The absence of sucrose also lowers the cariogenic properties of the product.

Flavour enhancers

This is a group of additives that has attracted adverse attention, in particular monosodium glutamate (MSG:E621), which is widely blamed for an intolerance reaction that became known as "Chinese Restaurant Syndrome".

Flavour enhancers are substances that have no pronounced flavour or taste of their own but which

bring out and improve the flavours in the foods to which they are added. Although salt has a distinctive taste of its own and is not classed as a food additive, it is in fact the most widely used flavour enhancer. The next best known is glutamic acid and its salts, most commonly found in the form of monosodium glutamate, which has been used for several centuries in the Far East as a condiment in savoury products. It is a normal constituent of all proteins, an essential amino acid and present in the body. The alleged intolerance reaction was never confirmed in sound scientific studies. Anyone showing a reaction to MSG used as an additive would necessarily also react to foods that contain it naturally in high quantities, such as tomatoes and cheese.

Some sweeteners have also been found to have flavour-enhancing properties and have been authorised for use as such. For example, neohesperidine DC (E959) can enhance the flavour of meat products and margarine, and acesulfame K, aspartame and thaumatin are used to enhance the flavour of chewing gum and desserts.

Flavourings

Although flavour enhancers are categorised as additives, flavourings are technologically different and regulated separately, even though they are often considered by the general public to be the same thing. Flavourings are defined as imparting odour and/or taste to foods and are generally used in the form of mixtures of a number of flavouring preparations and defined chemical substances. These do not include edible substances and products intended to be consumed as such, or substances that have exclusively a sweet, sour or salty taste, i.e. ordinary food ingredients such as sugar, lemon juice, vinegar or salt. The latest draft of the proposed new EC Regulation on Flavourings would also exclude from the

definition of flavourings raw foods and non-compound foods, and mixtures of spices or herbs, mixtures of tea provided they are not used as food ingredients. In addition to the types of flavouring such as process flavours or smoke flavours, there are three distinct classes of flavouring substances: natural, e.g. citral; nature- identical, e.g. vanillin; and artificial, e.g. ethyl vanillin. Some 2700 substances were identified and included in a European register following Commission Decision (EC) 1999/217/EC as amended. Then there are flavouring preparations,

e.g. vanilla extract. Many flavourings are sold as a complex mixture of individual preparations and flavouring substances, generally confidential to the company that has produced the flavouring. Legislation has been designed to protect commercial confidentiality in registering on the EC list newly discovered flavouring substances. Because of the complexity of the flavouring used in a food, labels generally indicate simply “flavourings” in the ingredients list. This is all that is legally

required, as to list every individual substance would often be extremely lengthy and virtually incomprehensible to the consumer, although the manufacturer may be more specific if he wishes. Any flavourings labelled as "natural" must meet the legal definition. The Food Standards Agency has issued criteria for the use of the term "natural" in product labelling. The new proposal for an EC Regulation on flavourings and certain food ingredients with flavouring properties for use in and on foods means that in future there are likely to be stricter controls for the labelling of natural flavourings (7).

As with additives, some flavourings are sold direct to the consumer for domestic culinary use. Vanilla and peppermint are amongst the best known, as well as the popular brandy and rum essences. Anyone who has ever added too much flavouring to a home-made cake or a batch of peppermint creams will appreciate the minute quantities in which they are used. Similarly, in commercial manufacture, the quantity of flavouring used is extremely small in relation to that of other ingredients. Most flavourings are developed from substances naturally present in foods. Citrus and orange oils, for example, are amongst the most common natural source materials used in flavouring preparations and substances.

Other additives

Colours and sweeteners are very specific, well-defined classes of additives and, because of the nature of their function, are subject to specific legislation. All other classes of additive now fall under the general heading of "miscellaneous". In addition to the larger groups mentioned above, there are other categories within this more general grouping – namely thickeners, acids, acidity regulators, anti-caking agents, anti-foaming agents, bulking agents, carriers, glazing agents, humectants, raising agents and sequestrants.

The function of most of these is obvious from the name, with the possible exception of sequestrants. These are substances that form chemical complexes with metallic ions. They are not widely used and this is a class of additives rarely seen on a food label. Thickeners, on the other hand, are amongst the most commonly used additives, as they exert an effect on the texture and viscosity of food and drinks products. Much as various types of flour are used extensively in the kitchen to thicken sauces, soups, stews and other dishes with a high liquid content, most commercial thickeners are starch- or gum-based and serve much the same purpose.

One class of additive that has no domestic equivalent is that of packaging gases. These are the natural atmospheric gases now widely used in certain types of pre-packed products, such as meat, fish and seafood, fresh pastas and ready-prepared vegetables found on the chilled food counters in

sealed containers. The “headspace” of the container is filled with one or a combination of the gases, depending on the product, to replace the air and modify the atmosphere within the pack to help retard bacteriological deterioration, which would occur under normal atmospheric conditions – hence the term “packaged in a protective atmosphere”. Arguably, the gases do not have an additive function as they are not detectable in the food itself and function only to preserve the food for longer in its packaged state, but for regulatory purposes they were deemed to be additives and must therefore be labelled. Carbon dioxide will, of course, also be familiar as an ingredient in many fizzy drinks - an illustration of the many different functions and uses of additives.

Current EC legislation on additives does not cover the use of enzymes apart from invertase and lysozyme. However, in July 2006, the European Commission published a package of legislative proposals to introduce harmonised EU legislation on food enzymes for the first time and upgrade current rules for food flavourings and additives to bring them into line with the latest scientific and technological developments. The proposals were amended in October 2007 and are discussed further in the next chapter.

Safety of Additives

The safety of all food additives, whether of natural origin or synthetically produced, is rigorously tested and periodically re-assessed. In the UK, the responsible authority is the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), a Government-appointed expert advisory committee, which provides advice to the Food Standards Agency, the Department of Health and other Government Departments and Agencies on matters concerning the toxicity of chemicals, including food additives. At

European level, all additives approved for use in legislation have been evaluated by the Scientific Committee on Food (SCF) or, since May 2003, by its replacement the European Food Safety Authority (EFSA). Therefore, EFSA's Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC panel) is now responsible for the safety evaluation of new food additives (8,9).

Only additives evaluated in this way are given an “E” number; thus the “E” number is an indication of European safety approval, as well as a short code for the name of the additive.

In evaluating an additive, EFSA allocates an “Acceptable Daily Intake” (ADI), the amount of the substance that the panel considers may be safely consumed, daily, throughout a lifetime. This assessment is used to set the maximum amount of a particular additive (or chemically related group of additives) permitted in a specific food, either as a specified number of grams or milligrams per

kilogram or litre of the food or, if the ADI is very high or "non- specified", at *quantum satis*, i.e. as much as is needed to achieve the required technological effect, according to Good Manufacturing Practice.

In establishing the ADI, a safety factor is always built in, usually 100- fold, to ensure that intake of any additive is unlikely to exceed an amount that is anywhere near toxicologically harmful. To ensure that consumers are not exceeding the ADI by consuming too much of or too many products containing a particular additive, the EU legislation requires that intake studies be carried out to assess any changes in consumption patterns.

The UK has carried out a number of intake surveys involving specific additives. None has culminated in results that have given cause for concern, except that in its 1994 survey of artificial sweeteners, consumption by some toddlers was considered to be excessive, given their high consumption of fruit squash. This potential problem was resolved by advice to add extra water to squash given to toddlers. It also raised questions about the establishment and application of the ADI, given that it is intended to cover changes in patterns of eating throughout a lifetime, from weaning to old age, but that is a separate scientific debate in itself.

At international level, there is a further level of evaluation of food additives, contaminants and residues of veterinary drugs in food by the Joint Expert Committee on Food Additives (JECFA), which advises the UN's Food and Agriculture Organization (FAO) and World Health Organization (WHO) Codex Alimentarius, which sets international standards. This has become increasingly important in recent years as World Trade Organisation (WTO) arrangements specify that Codex standards will apply in any dispute over sanitary and phytosanitary standards, i.e. the safety and composition of foods. For this reason,

the Codex General Standard for Food Additives (GSFA), was adopted to recommend usage levels of food additives in all products traded internationally.

As part of EFSA's role in the area of food additives, it is involved in the re-evaluation of all authorised food additives in the EU.

In September 2004, EFSA issued an opinion on the safety of parabens (E214-219) used as preservatives in foods following a risk assessment of its use in foods. As a result, Directive 2006/52/EC amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs, deleted the preservatives, E216 propyl p-hydroxybenzoate and E217 sodium propyl p-hydroxybenzoate from the list of permitted preservatives in Annex III (10).

In the area of sweeteners, the safety of aspartame was considered controversial, especially following

a long-term study on its carcinogenicity in 2005. Hence, EFSA evaluated findings from this study, and, in this case, confirmed that there was no need to revise the previously established ADI (11).
On the other hand, in re-evaluating the colour E128, Red 2G, in 2007, EFSA decided that there was a safety concern, and later the Commission suspended its use (12,13).

Intolerance

Additives have often been blamed for causing intolerance or allergic reactions, especially hyperactivity in children. Whilst there is no doubt that certain foods and food ingredients, including additives, are responsible for intolerance reactions, the prevalence of such reactions has often been greatly exaggerated. Genuine intolerance to food additives is extremely rare. It has been estimated that the true prevalence of intolerance to foods is about 2% in adults and up to 20% in children, and for food additives from 0.01 to 0.23%. The substantial overestimation of such reactions by the general public probably owes itself to the adverse media coverage and anti-additives campaigning of the 1980s, when popular belief was that additives were responsible for harmful behavioural effects and hyperactivity was attributed solely to the consumption of tartrazine (E102). The result was that tartrazine, an azo (synthetic) colour, was removed from a wide range of products, especially sweets and soft drinks that were likely to be consumed by children, as consumers in their droves ceased to buy anything that was labelled as containing it. Manufacturers are still reluctant to use this colour, unless there is nothing else in the palette of yellow colours authorised for the product. Such is the power of consumer choice, be it informed or otherwise.
Food intolerance, and especially allergy, is again under the spotlight, not now because of alleged hyperactivity in children, but, far more seriously, because
of the seemingly growing prevalence of severe allergic reactions, particularly to peanuts. Since the mid-1990s, there have been a number of widely reported incidents, including several tragic deaths as a result of anaphylactic shock, a severe allergic reaction to specific proteins, most commonly those found in tree nuts and peanuts and a small number of other foods, including milk, wheat, eggs, soya, fish and shellfish. The reasons for such reactions are not yet fully understood and are still under investigation, as are the causes of this apparently growing problem, but the need to address the issue and do everything possible to assist the small but significant number of people affected by this most severe form of allergy caused the European Commission to task its former Scientific Committee for Food (SCF) with identifying the scope of the problem and the foods and ingredients associated with it. This 1996 Report reaffirmed the SCF's earlier (1982) estimation of intolerance to additives as affecting from 0.01 to 0.02% of the European population (14). More specifically, the prevalence of

intolerance to food additives in the population was put at 0.026%, or about 3 people per 10,000 of the population. This compares with the prevalence of adverse reactions to cows' milk of 1 to 3%. The most commonly observed reaction is now to sulphur dioxide (E220) and sulphites, especially in asthma sufferers, again growing in number or perhaps being more frequently reported.

It must be understood that the incidence of genuine intolerance to additives is very low. Accurate labelling is the key to avoiding unnecessary suffering of an adverse reaction, such as urticaria, asthma or atopic symptoms, in the case of sensitised consumers, or adverse publicity in the case of food producers, and for this reason the EC Labelling Directive 2000/13/EC was amended in 2002, 2003, 2006 (to establish a list of potential allergens that must be declared by name on food labels) and in 2007 (see Chapter 2).

Myths and Fallacies

Nothing is guaranteed to fill column inches and dominate the airwaves more than a good food scare. Additives have seen their share of these, though not on the scale of the 1996 BSE crisis or the more recent controversy over genetic modification: though equally long-running and bearing similarities to the latter issue, additives were never the butt of a concerted campaign by environmentalists and others dedicated to the downfall of a specific technology. Anti-additives campaigns would either target a specific additive or class of additives, for whatever reason, or cite the use of additives as part of a general thrust to disparage the modern food-manufacturing industry and seek to encourage a "back to basics" trend towards good old-fashioned home cooking and away from the purported less healthy foods produced by industrial processing for the UK's largely urbanised society.

Hence the periodic targeting of preservatives, antioxidants, azo colours, sweeteners and monosodium glutamate. The evidence of such "scares" still abounds on the labels of countless products that claim to be free from "artificial" preservatives, colours and additives in general. This is indicative of the susceptibility of both marketing men and consumers to perceived adverse effects of particular additives. Such a response is unhelpful; whilst it is understandable that consumer concern in response to a media scare may result in a company removing an additive, or indeed any other ingredient, from a product for reasons of short-term expediency, the options and alternatives will inevitably become reduced every time something is removed from the range of ingredients, and the controversy left unresolved. It would be far better to address the issue through appropriate scientific investigation and seek to ensure that evidence of safety and absence of adverse effects are given at least some airing in the public domain to explode the myth engendered by the original controversy.

This, of course, is not easy, as good news is, generally speaking, no news at all and certainly unlikely

to make the headlines. The tabloid newspapers had a field day with the Food Commission's stories that "Cyclamates 'may cause testicular atrophy'" (15) and "Aspartame 'may cause brain tumours'" (16). Refuting such headlines is not easy; the full barrage of scientific evidence generally needs to be brought out in defence of any food ingredient or additive placed under the media spotlight and accused of causing some adverse effect. Often the "evidence" produced in support of the story needs to be pulled apart under the microscope and any deficiencies, such as in the research protocols or the way in which any experimentation was conducted, identified. The motivation for publishing such "research", and any exaggeration of the findings, also need to be examined.

All this takes time and will not protect any company using the additive or additives concerned from a barrage of enquiries from worried customers who, not unnaturally, seek reassurances that they have not already been harmed or will not be if they continue to consume the product. Again, a sense of proportion is important. The "problem" needs to be placed in context, given perspective against the wide range of risk factors to which all of us are exposed in daily life, and consumers assisted and encouraged to develop their own sense of risk assessment and risk management. This will become all the more important as communication becomes ever more global and instantaneous. The internet offers both threats and benefits: threats in that anyone can rapidly set off a scare by posting adverse information about, say, a specific sweetener. This may be a genuine concern that some possible risk to, perhaps, a certain sector of the population has been found,

maybe to people suffering from a specific condition. It may also be that an unscrupulous company seeking to target that group with a new product decides to set off a scare shortly before launching its product, which is marketed as "free from" that additive or ingredient. The benefit lies in being able to expose such scares equally quickly, and the opportunity to post true and accurate information about food production for those who want to know.

Clean Labels

The growing demand from health-conscious consumers is for the replacement of artificial food additives with 'natural' ingredients, which perform similar technological functions. Thus, food processors are continuously seeking natural alternatives to food additives as, when these are listed on labels as the named ingredients rather by E-number, it gives the food product a 'clean label' declaration.

Clean label declarations are not regulated; however, the Food Standards Agency in the UK has issued "Criteria for the use of the terms Fresh, Pure, Natural etc." which could be used as guidance. In addition, when incorporating new substances into foods one would also need to comply with the

EC Regulation 258/97 concerning Novel Foods and Novel Food Ingredients.

A number of ingredients are now being manufactured that claim to give foods a clean label status e.g. emulsifiers such as lecithin and soya protein; antioxidants including grape seed, chestnut and olive leaf extracts; colours for example, lycopene, anthocyanin and chlorophyll; and preservatives including cinnamic acid, carvacol, chitosan, and lysozyme.

Some bacterial cultures, known as 'protective cultures', able to inhibit the growth of pathogenic bacteria and mycotoxin-producing mould are being used as inhibitors of foodborne microorganisms. These protective cultures produce antimicrobial metabolites like organic acids (lactic and acetic acid), and bacteriocins (nisin and natamycin), and are substitutes for conventional additives, helping manufacturers make the 'Clean Label' claim.

It will be some time before we see a complete shift to clean label products, and in some situations this may not be possible due to a lack of suitable natural alternatives.

Conclusions

Much has happened to and in the food industry and the market for food since the great focus on additives in the 1980s. The popular books produced on the subject at that time focused largely on the potential adverse effects of additives; the

potential misleading of consumers about the food they were eating; and the profit- driven nature of the industry motivated to use additives in their products (17,18,19). But not all of this criticism was without justification, and there were undoubtedly bad practices in place in some sectors of the industry, where unscrupulous traders saw opportunities for quick profit. The use of phosphates in reconstituted meat and fish products to make them appear as better-quality cuts and fillets or to add weight to a chicken was a dodge that trading standards officers rightly pursued with some zeal. This is not a criticism of the legitimate use of phosphates in meat products such as hams, but of the instances of false description of reconstituted products as prime cuts, and frozen "scampi" that disintegrated on defrosting. Any business will always have its unscrupulous operators, but strict regulation and enforcement now make this increasingly difficult in the food industry.

The 1990 Food Safety Act provided the framework of primary legislation for the food industry in the UK. The raft of legislation on food additives developed as part of the European Single Market, and explored in detail in a later chapter, strictly controls the use of all additives.

The establishment of the Food Standards Agency, with its dual role of protecting and informing the consumer, may well influence both trends in the use of additives and public perceptions of their worth.

Furthermore, the market has changed considerably in recent years, partly as a result of European integration and partly because consumers have become more sophisticated, more knowledgeable, and more affluent. Overseas travel has greatly broadened the British palate and increased demand for a wide range of exotic and adventurous foods that have been sampled overseas. Our increasingly cosmopolitan society has also led to the availability of more and more "ethnic" foods, both in restaurants and for domestic consumption, while busy lifestyles, and the increasing number of working women have led to more and more food being consumed outside the home.

Never has the range and choice of foods been so great, in terms of availability in the supermarkets and specialist food shops, or through the catering trade. This is not to say that additives are less widely used or less relevant – far from it. But those who wish to avoid them, either as manufacturers or consumers, should find it possible to do so, and those who do use them need have no concerns, except to obey the law in the case of manufacturers, and to understand the meaning of the ingredients list in the case of consumers. Astute consumers now notice that it is not only pre-packed foods that contain additives: foods sold "loose" at delicatessen counters are now also labelled to indicate the content of additives – or should be. And it has not escaped the notice of public health analysts that the greatest use of food colours is in ethnic restaurants. Public protection is ensured and additives cannot be used to deceive, but we would be deceiving ourselves if we thought that we could continue to enjoy the choice, ease and convenience of our food supply without them.

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Chapter 2

WHAT SHOULD BE DECLARED ON THE LABEL

Introduction

The primary legislation that needs to be examined when looking at labelling of food additives is the Food Safety Act 1990, which stipulates that it is illegal to sell food that is 'injurious to health' or to falsely describe it. Similar provisions are set in the General Food Regulations 2004. Other legislation that also needs to be considered is the Trade Descriptions Act 1968, the Weights and Measures Act 1985, and the Food (Lot Marking) Regulations 1996. The main regulations that relate specifically to labelling of food additives are the Food Labelling Regulations 1996 (as amended) and the Food Additives Labelling Regulations 1992.

This chapter gives a basic outline of what should be on the label of a pre- packed food, as specified in the Food Labelling Regulations. Details are given on what should be declared, including the name of the food, the list of ingredients, the appropriate durability indication, a quantitative ingredients declaration, storage conditions, place of origin and instructions for use. The requirements of the Food Additives Labelling Regulations are outlined and relevant areas that define food additives and prescribe requirements for labelling of food additives for business and consumer sale are highlighted. Please note that the actual legislation should be consulted when constructing or checking label copy.

Food Safety Act 1990

It is worth noting that, although the Food Safety Act does not contain details of labelling requirements, it does set an overarching provision prohibiting labelling of food with a false description or a description that may mislead the consumer as to the nature, substance or quality of the food.

The Act makes it an offence for anyone to sell, or possess for sale, food

that:

- has been rendered injurious to health;
- is unfit or so contaminated that it would be unreasonable to expect it to be eaten;
- is falsely described, advertised or presented;
- is not of the nature, substance or quality demanded.

The General Food Regulations 2004 (S.I. 2004 No. 3279)

These regulations enforce certain provisions of Regulation (EC) No. 178/2002 laying down the

general principles and requirements of food law.

- Article 14 specifies food safety requirements and prohibits the placing of unsafe food on the market
- Article 16 states that the labelling/advertising/presentation of food should not mislead consumers
- Article 18 states that the traceability of food/any other substance to be incorporated into a food shall be established at all stages of production, processing and distribution and sets obligations to food business operators.
- Article 19 places an obligation on food business operators to take responsibility and initiate the withdrawal of food if it does not comply with food safety requirements.

Trade Descriptions Act 1968

The Trade Descriptions Act 1968 makes it an offence for a trader to

- apply a false trade description to any goods;
- supply or offer to supply any goods to which a false trade description is applied.

Parts of the Trade Descriptions Act will soon be amended or repealed by virtue of the UK implementation of the Unfair Commercial Practices Directive 2005/29/EC. This Directive harmonises unfair trading laws in all EU member states and its provisions must have been applied in member states by 12 December 2007.

In the UK, it is expected that the regulation implementing this Directive, the Consumer Protection from Unfair Trading Regulations 2007, will come into force by April 2008.

Weights and Measures Act 1985

This Act provides for regulations to be drawn up on the expression of net quantity on prepacked food. The Act also provides for the 'average' system of quantity control for prepacked goods. Most foods and additives prepacked in quantities greater than 5 g or 5 ml need a quantity mark.

Food (Lot Marking) Regulations 1996 (S.I. 1996 No. 1502)

The aim of these Regulations is to establish a framework for a common batch or lot in order to facilitate the tracing and identification of product along the food chain.

Food Labelling Regulations 1996 (S.I. 1996 No. 1499 as amended by S.I. 1998 No. 1398, S.I. 1999 No. 747, S.I. 1999 No. 1483, S.I. 2003 No. 474, S.I.

2004 No. 1512, S.I. 2004 No. 2824, S.I. 2005 No. 899, S.I. 2005 No. 2057, S.I. 2005 No. 2969 and S.I. 2007 No. 3256.)

The general requirements laid down by the Food Labelling Regulations 1996 are set out below in more detail.

The Regulations stipulate that all prepacked foods that will be supplied to the ultimate consumer or to a catering establishment must be labelled with:

Name of the food

If there is a name prescribed by law for a food it must be used as the name of the food. If there is no name, a customary name may be used. If there is neither a name prescribed by law nor a customary name, the name must inform the buyer of the true nature of the food and, if necessary, must include a description of use. Trademarks or brand names may be used but these may not substitute for the name of the food. If necessary, the name must include an indication of the physical condition of the food or any treatment that it has undergone.

List of ingredients

All labels must include a list of ingredients, and all ingredients in the food must be declared in the list, unless there are specific exemptions. The title 'Ingredients' must be contained in the heading for the list.

The names given to these ingredients must be the same as if they were being sold as a food. If the ingredient has been irradiated in any way, its name must be accompanied by the word 'irradiated' or the phrase 'treated with ionising radiation'.

Ingredients must be listed in descending order of weight as used during the preparation of the food. The exception is water and volatiles, which should be listed in order of weight in the final product. Ingredients that are reconstituted during preparation may be included in the list of ingredients in the order of their weight before concentration or drying. However, if the food is a dehydrated or concentrated food, which will be reconstituted with water, then the ingredients may be listed as reconstituted.

If the food contains mixed fruit, vegetables, or mushrooms present in variable proportions but of similar weight, these ingredients may be grouped together in one place in the list of ingredients by their designation of 'fruit', 'vegetables' or 'mushrooms' and labelled with the words 'in variable proportions' followed by a list naming all the fruit, vegetables or mushrooms present.

If the food contains a mixture of herbs and spices and these are in equal proportion, these ingredients

may be listed in any order and labelled with the words ‘in variable proportions’.

Ingredients that constitute less than 2% of the finished product may be listed in a different order after the other ingredients. Similar or mutually substitutable ingredients and those used in the preparation of a food without altering its nature or its perceived value (excluding additives and allergenic ingredients) that make up less than 2% of the finished product may be referred to by the phrase 'contains...and/or…' where at least one of no more than two such ingredients is present in the finished product.

The Labelling Regulations include a list of permitted generic names that may be used to name an ingredient provided it meets the specified conditions, for example for oils the generic name ‘vegetable oil’ or ‘animal oil’ may be used rather than the specific source of the oil, provided an indication that the oil has been hydrogenated is given where appropriate.

If water constitutes more than 5% of the finished product, it must be included on the ingredients list.

For a list of foods that are exempt from ingredients listing, see Appendix

A. It is important to note that the allergen labelling requirements detailed later override these exemptions.

Compound ingredients

If a compound ingredient (an ingredient composed of two or more ingredients, including additives) is used in the food, the names of the ingredients in the compound ingredient must be given in the list of ingredients either instead of the name of the compound ingredient or in addition to it.

If the name of the compound ingredient is given, its ingredients must immediately follow the name.

The names of the ingredients of a compound ingredient do not need to be listed if the compound ingredient:

- is a food that if sold by itself would not require a list of ingredients;
- is an ingredient which is identified by a permitted generic name;
- constitutes less than 2% of the finished product and its composition is defined in Community legislation (e.g. that on chocolate, fruit juice, jam, fat spreads); or
- constitutes less than 2% of the finished product and consists of a mixture of spices and/or herbs.
- If they are exempt when the compound food is sold as such.

It is important to note that the allergen labelling requirements detailed later override these exemptions.

If an ingredient of a compound ingredient has been irradiated, it must be listed and accompanied by the word 'irradiated' or words 'treated with ionising radiation' except in the case of food prepared for patients needing sterile diets under medical supervision.

Additives

Additives added to or used in a food to serve the function of one of the categories of additives listed below must be identified in the ingredients list by the name of the category followed by the specific name or serial number ('E number').

If an additive serves more than one function, it is only necessary to indicate the category that represents the principal function served by the additive in the food. If an additive serves none of these functions, it must be declared by its specific name in the ingredients list.

The following list shows the categories of additives that must be identified in a list of ingredients by their category name (Schedule 4 Food Labelling Regulations).

Acid[1]	Flour treatment agent
Acidity regulator	Gelling agent
Anti-caking agent	Glazing agent
Anti-foaming agent	Humectant
Antioxidant	Modified starch[2]
Bulking agent	Preservative
Colour	Propellant gas
Emulsifier	Raising agent
Emulsifying Salts	Stabiliser
Firming agent	Sweetener
Flavour enhancer	Thickener

Flavourings

If a flavouring is added to or used in a food, it should be described in the ingredients list using the word 'flavouring' or, where more than one flavouring ingredient is used, the word 'flavourings'. A more specific name or description of the flavouring may be used.

Use of the word 'natural'.

The word 'natural' or any word having substantially the same meaning, may be used for an

[1] In the case of an additive that is added to or used in food to serve the function of an acid and whose specific name includes the word 'acid', it is not necessary to use the category.

[2] Neither the specific name nor the serial number need be indicated. However, if the modified starch may contain gluten, the vegetable origin must be indicated, e.g. 'modified wheat starch'.

ingredient being a flavouring only where the flavouring component of such an ingredient consists exclusively of:

- A flavouring substance (a defined chemical substance) that is obtained by physical (e.g. distillation and solvent extraction), enzymatic or microbiological processes, from material of vegetable or animal origin, which is either raw or subjected only to a normal process used to prepare food for human consumption; or
- A flavouring preparation, i.e. other products, possibly concentrates, obtained by physical, enzymatic or microbiological processes from material of vegetable or animal origin.

Processes normally used in preparing food for human consumption include drying and fermentation.

If the nZame of the flavouring refers to the vegetable or animal nature or origin of the material contained in it, 'natural' or similar words, may be used only if the flavouring components have been isolated solely or almost solely from that vegetable or animal source.

The proposed regulation on flavourings and certain food ingredients with flavouring properties for use in and on foods sets tighter controls for the use of the term 'natural' in the labelling of flavourings which is discussed later in this chapter.

Sweeteners

Foods that contain sweeteners must be labelled with the indication 'with sweetener(s)', and those that contain sugars and sweeteners with the indication 'with sugar(s) and sweetener(s)'. These statements must accompany the product name.

Foods that contain aspartame must be labelled with the words 'contains a source of phenylalanine'.

Foods that contain more than 10% added polyols must carry the indication 'excessive consumption may produce laxative effects'.

Exemptions from Ingredient Listing

Ingredients which need not be named:

- constituents of an ingredient which have become temporarily separated during the manufacturing process and are later re-introduced in their original proportions
- any additive whose presence in the food is due only to the fact that it was contained in

an ingredient of the food, provided it does not serve any significant technological function in the finished product

- any additive that is used solely as a processing aid
- any substance other than water that is used as a solvent or carrier for an additive and is used in an amount that is no more than that which is strictly necessary for that purpose.
- Any substance which is not an additive but which is used in the same way and for the same purpose as a processing aid.

However, the allergen labelling requirements detailed later override the above exemptions.

Appropriate durability indication

All foods must be date marked unless specifically exempt from this requirement (see Appendix B for list of exemptions). Highly perishable foods with the potential to endanger human health must be labelled with a 'use by' date, for other foods a minimum durability date must be given.

The date and any storage conditions that need to be observed may be placed apart from the 'best before' or 'use by', as long as there is a reference to the place where the date appears, e.g. 'best before end - see lid'.

Labelling of minimum durability

The words 'best before' must be used to indicate the minimum durability. It must be followed by the date, shown as the day, month and year. For foods that will keep for 3 months or less, the label may state 'best before' with the day and the month only.

Foods that will keep for more than 3 months but not more than 18 months may be labelled with 'best before end' with the month and the year only. For foods that will last longer than 18 months, the label may state 'best before end' plus month and year only, or year only.

Labelling of 'use by' date

If 'use by' is required, it must be followed by the day and month or the day, month and year in that order.

Quantitative Ingredients Declaration (QUID)

The aim of QUID labelling is to help consumers differentiate between similar products and so be

able to make a more informed choice.

It is required that the quantity of an ingredient or category of ingredients used in the manufacture or preparation of a foodstuff is declared where the ingredient:

i) appears in the name under which the food is sold, or is usually associated with that name by the consumer; or
ii) is emphasised in the labelling, either by words or by the use of pictorial representations; or
iii) is essential to characterise the food and to distinguish it from products with which it could be confused because of its name or appearance; or
iv) in other cases, as determined.

QUID is not required if:

i) the drained net weight of the food is indicated;
ii) the quantity of the ingredient is already required to be given;
iii) the ingredient is used in small quantities for the purpose of flavouring;
iv) the name of the ingredient appears in the name under which the food is sold, but where the variation in its quantity does not distinguish the food from similar products.

The quantity must be expressed as a percentage and must correspond to the quantity of the ingredient at the time of use. The declaration must appear either in or immediately next to the name under which the food is sold or in an appropriate place in the list of ingredients.

QUID declarations are not triggered by:

- 'with sweeteners' or 'with sugars and sweeteners', in the name of the food;
- references to vitamins and minerals, as long as these are indicated in nutrition labelling.

<u>QUID calculations</u>

QUID declarations should be calculated on the finished product for foodstuffs that have lost moisture following heat treatment or other treatment. If the resultant

% exceeds 100%, then it is to be replaced by the weight of ingredient used in the preparation of 100 g of the finished product.

In the case of volatile ingredients, QUID should be calculated on the finished product.

Dehydrated or concentrated ingredients, which are reconstituted during manufacture, may be declared on the basis of ingredient weight prior to concentration or dehydration. Alternatively, for concentrated or dehydrated foods that are intended to be reconstituted with water, QUID may be given on the basis of the reconstituted product.

Storage conditions

Any special storage conditions or conditions of use need to be included on the label.

Name and address

The business name and address of the manufacturer or packer, and/or seller established within the European Community needs to be included on the label.

Place of origin

Details of the place of origin of the food must be given if the failure to provide such information would mislead as to the true origin of the food.

Instructions for use

These need to be included if it would be difficult to use the food without instructions.

Additional labelling

There are additional labelling requirements for the following types of food:

- Food sold from vending machines Prepacked alcoholic drinks
- Raw milk
- Products that contain skimmed milk with non-milk fat Foods packaged in certain gases

Certain foods with compositional standards (e.g. jams, chocolate, infant formulae) also have additional labelling requirements specified within the appropriate compositional regulation.

There are labelling requirements for some cheese varieties, cream types, milk, ice cream and indication of specific flavours, which aim to prevent misleading descriptions set in Schedule 8 to the Food Labelling Regulations.

Allergens

EC Directive 2000/13/EC as amended states that foods containing allergenic ingredients or ingredients originating from an allergenic ingredient listed below must be marked with a declaration of these ingredients in the ingredients list, unless they have already been mentioned in the product name.

This means that even if an ingredient meets the criteria for which it wouldn't usually need to be

declared in an ingredients list, or could have been declared by a generic name, if it contains an allergenic ingredient or originated from one, the ingredient must be declared.

The current list of allergens is:

- Cereals containing gluten: wheat, rye, barley, oats, spelt, kamut and their hybridised strains
- Crustaceans
- Eggs
- Fish
- Peanuts
- Soybeans
- Milk
- Nuts - specific varieties
- Celery
- Mustard
- Sesame seeds
- Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/l, expressed as SO2
- Lupin*
- Molluscs*

*Lupin and molluscs were added to the list of allergens under Commission Directive 2006/142/EC and member states were required to transpose this Directive into national legislation by 23 December 2007. For example, in the UK, this Directive is implemented through the Food Labelling (Declaration of Allergens) (England) Regulations 2007.

All products must comply with the requirements of this Directive by 23 December 2008.

Directive 2007/68/EC (amending Annex IIIa to Directive 2000/13/EC) has been published following a review by EFSA of dossiers submitted for highly processed ingredients derived from the allergens listed in Annex IIIa, to allow exemption from labelling with reference to the allergen.

The exemptions are set out below:

(a) wheat-based glucose syrups including dextrose [1];

(b) wheat-based maltodextrins [1];

(c) glucose syrups based on barley;

(d) cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

(e) fish gelatine used as carrier for vitamin or carotenoid preparations;

(f) fish gelatine or Isinglass used as fining agent in beer and wine;

(g) fully refined soybean oil and fat [1];

(h) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D- alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources;

(i) vegetable oils derived phytosterols and phytosterol esters from soybean sources;

(j) plant stanol ester produced from vegetable oil sterols from soybean sources;

(k) whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages;

(l) lactitol;

(m) nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.

[1] And products thereof, insofar as the process that they have undergone is not likely to increase the level of allergenicity assessed by the EFSA for the relevant product from which they originated.

Alcoholic drinks which have an alcoholic strength by volume of more than 1.2% and contain any allergenic ingredient listed need to be labelled with the word 'contains' followed by the name of the allergenic ingredient.

Prescribed nutrition labelling

When a claim is made and/or food is fortified, prescribed nutrition labelling is triggered; otherwise nutritional labelling is voluntary. The only exceptions are natural mineral waters and food supplements, which are exempt from prescribed nutrition labelling as set in the Food Labelling Regulations but are subject to product specific controls. There are several different criteria for nutrition labelling, depending on the type of claim being made.

Prescribed nutrition labelling must include either Group 1 (a) or Group

(a) energy and the amounts of protein, carbohydrate and fat; or

(b) energy and the amounts of protein, carbohydrate, sugars, fat, saturates, fibre and sodium (this format should be used if a claim is being made for sugars, saturates, fibre or sodium).

Where a nutrition claim is made for polyols, starch, monounsaturates, polyunsaturates, cholesterol, vitamins or minerals, the amount/s must be included in the prescribed nutrition labelling. Where no claim is made, these nutrients may be optionally included.

The nutrients need to be listed in the following order and in the same style:

energy	[x] kJ and [x] kcal
protein	[x] g
carbohydrate	[x] g of which:
sugars	[x] g
polyols	[x] g
starch	[x] g
fat of which:	
- saturates	[x] g
- monounsaturates	[x] g
- polyunsaturates	[x] g
- cholesterol	[x] mg
fibre	[x] g
sodium	[x] g
[vitamins]	[x units]
[minerals]	[x units]

Where monounsaturates and/or polyunsaturates are included, saturates must also be included.

All amounts must be expressed per 100 g or 100 ml of the food. In addition, they may be given per quantified serving of food or per portion of food. The use of nutrition claims is controlled through Regulation (EC) No.

1924/2006 on nutrition and health claims made on foods which was applied from 1 July 2007 and is directly applicable in England through the Nutrition and Health Claims Regulations 2007. Making a claim is voluntary and the regulation details this information to include conditions for their use. Any foods which do not meet the requirements stated in the regulations would be subject to transitional measures. A health claim triggers group 2 nutrition declaration and other additional labelling requirements.

As well as this, Regulation (EC) 1925/2006 on the Addition of Vitamins and Minerals and of certain other substances to foods requires that foods to which vitamins and minerals have been added

(covered by Regulation (EC) 1925/2006) must contain nutrition labelling and be of the Group 2 format as described previously in this section.

At time of publication, EU food labelling legislation is being reviewed by the European Commission; it is likely that the current food labelling directive will be superseded by a directly applicable regulation.

The Commission published a draft proposal for a Regulation on the provision of food information to consumers at the end of 2007. The draft proposal includes a new requirement to provide mandatory nutrition labelling for the energy value and the amount of fats, saturated fats, sugars and salt, and requires this information to be given in the principal field of vision of a food label and in this order. It is anticipated that this regulation will be adopted by the European Parliament and Council by 2010. The national provisions of the Food Labelling Regulations 1996 (as amended) are being reviewed by the Food Standards Agency with the intention of either removing or seeking to retain specific provisions for inclusion at European level.

Food Additives Labelling Regulations 1992 (S.I. 1992 No. 1978)

These Regulations relate to business and consumer sales of food additives sold as such. They define food additives, list excluded substances including processing aids, a definition of which is given, and prescribe requirements for labelling.

These Regulations do not apply to

i) Processing aids
   ii) Substances used in the protection of plants and plant products.
   iii) Flavourings within the meaning of the Flavourings in Food Regulations 1992.
   iv) Substances added to foods as nutrients.

Definition

A food additive must fall within a category or categories listed below:

- Colours
- Antioxidants
- Preservatives
- Emulsifiers
- Emulsifying salts

- Thickeners
- Gelling agents
- Stabilisers
- Flavour enhancers
- Acids
- Acidity regulators
- Anti-caking agents
- Modified starch
- Sweeteners
- Raising agents
- Anti-foaming agents
- Glazing agents
- Flour bleaching agents: any substance primarily used to remove colour from flour
- Flour treatment agents: any substance that is added to flour or dough to improve its baking quality
- Firming agents
- Humectants
- Enzyme preparations: any substance that contains a protein capable of catalysing a specific chemical reaction
- Sequestrants
- Bulking agents
- Propellants
- Packaging gas
- Carriers and carrier solvents

An additive is normally neither consumed as a food in itself or used as a characteristic ingredient of food, whether or not it has nutritive value, and is intentionally added to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of that food, and results, or could result, in it or its by-products becoming directly or indirectly a component of the food.

A processing aid is defined as a substance that is not consumed as a food ingredient by itself; is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil

technological purposes during treatment or processing; and is capable of resulting in the unintended but technically unavoidable presence of its residues or its derivatives in the finished product, and the residues of which do not present any risk to human health and do not have any technological effect on finished products.

Labelling requirements for business sale of food additives

The container of the food additive must bear the information listed under 1 or 2 below, and it must be clearly legible, conspicuous and indelible.

1.

(a) The label must have the correct EC name and number, or in the absence of such name, a description of the food additive that will distinguish it from any other that it could be confused with. If there is more than one food additive present, the information must be given in descending order of the proportion by weight.

If there is any supplementary material, (substances to facilitate storage, sale, standardisation, dilution or dissolution of a food additive), each component of the supplementary material must be labelled in descending order of the proportion by weight of the components.

(b) The label must state that the food additives are 'for use in food' or 'restricted use in food' or a more specific reference to its intended food use.

(c) If there are any special storage conditions for the food additive, or if there are any special conditions of use, this needs to be labelled.

(d) Instructions for the use of the food additive must be given if it would be difficult to use the food additive without them.

(e) An identifying batch or lot mark.

(f) The name and address of the manufacturer or packer, or EC seller of the food additive must be stated on the label.

(g) If it is prohibited to exceed a specified quantity of the food additive in a food, the percentage of each component of the food additive must be stated. Alternatively, enough information must be given to enable the purchaser to decide whether, and to what level, he could use such food additives in food sold by him.

or

2. The label needs to include 1(a), (c), (d) and (e) (above) and in an obvious place the words 'intended for manufacture of foodstuffs and not for retail sale'. Relevant trade documents must be supplied to the purchaser and must include the remainder of the information given in section 1(b), (f), (g) and (h).

Labelling requirements for consumer sale of food additives

The container must bear the following information, which must be clearly legible, conspicuous and indelible.

- The name of the product. A description of food additives specified in Community provisions and the EC number. If there is no EC name or EC number, a description must be given to identify it from any other product with which it may be confused.
- In addition, the label must include all the information stated in section 1. (a)–(g) in 'Labelling requirements for business sale', above.
- The minimum durability of the product must be stated.

Exemption:

These regulations do not apply to any food additive that is part of another food.

Additive numbers

Where the serial number of the additive is to be given in the ingredients list:

- The number used should be one that appears in the column headed 'EC No.' in the relevant schedule (e.g. E150b, E420).

Additive names

Where the specific name of the additive is to be given in the ingredients list:

- The name used should be one that appears in the column headed 'Colour' or 'Permitted sweetener' or 'Name' in the relevant schedule (e.g. Cochineal, Aspartame).
- A summary name that appears in the column headed 'Colour' or 'Permitted sweetener' or 'Name' in the relevant schedule may be used in place of a more specific name, provided that the latter does not

have its own serial number (e.g. carotene may be used for 'mixed carotenes', 'sorbitol' may be used for 'sorbitol syrup').

- If the name in the column headed 'Colour' or 'Permitted sweetener' or 'Name' in the relevant schedule is preceded by a bracketed letter or Roman numeral (e.g. (ii) Beta carotene), this need not be given as part of the name.
- In the case of miscellaneous additives, where an alternative to the specific name is given in brackets in the column headed 'Name' in the relevant schedule, this may be used in place of the specific name (e.g. 'polysorbate 20' instead of 'polyoxyethylene sorbitan monolaurate').
- In the case of miscellaneous additives being phosphates, the names, 'diphosphates', 'triphosphates' and 'polyphosphates' are acceptable as specific names for the phosphates covered by the serial numbers E450, E451 and E452, respectively. They should not be used for the phosphates covered by serial numbers E338, E339, E340 and E341.
- Synonyms or acronyms that are not included in the relevant schedule should not be used as alternatives to the specific name.

Flavourings in Food Regulations 1992 (S.I. 1992 No. 1971, as amended by S.I. 1994 No. 1486)

Definition

A flavouring is a material used or intended for use in or on food to impart odour, taste or both.

Labelling requirements for business sale of relevant flavourings

The container must be labelled with the following information.

(a) The name and business name and address of the manufacturer or the packer, or of the EC seller.

(b) The word 'flavouring' or more specific names or descriptions of the relevant flavourings.

(c) The words 'for foodstuffs' or a more specific reference to the food for which the relevant flavouring is intended.

(d) A list, in descending order of weight, using the following classifications:

- 'natural flavouring substances' – for flavouring substances obtained by physical, enzymatic or microbiological processes from appropriate material of vegetable or animal origin;

- ‘flavouring substances identical to natural substances’ – for flavouring substances obtained from chemical synthesis or isolated by chemical processes and chemically identical to a substance naturally present in appropriate material of vegetable or animal origin;
- ‘artifical flavouring substances’ – for flavouring substances obtained by chemical synthesis;
- ‘flavouring preparations’ – for flavouring preparations;
- ‘process flavourings’ - for process flavourings;
- ‘smoke flavourings’ - for smoke flavourings.

In the case of other substances or materials, their names or EC numbers.

(e) The quantity of any material in or on the relevant flavourings where the sale of food containing excess of such quantity would be prohibited by the Food Safety Act.

The information must be visible, legible, and indelible, and must be expressed in terms easily understood by the purchaser.

Use of the word ‘natural’

The word ‘natural’ or any similar word may not be used to describe the relevant flavouring unless it is used in compliance with the labelling requirements above; or the flavouring components of the relevant flavouring comprise flavouring substances obtained by physical, enzymatic or microbiological processes from appropriate material of vegetable or animal origin or flavouring preparations or both.

The word ‘natural’ or any similar word shall not be used to qualify any substance used in its preparation unless the relevant flavouring is a permitted flavouring, the flavouring component of which has been isolated solely, or almost solely, from that substance by physical processes, enzymatic or microbiological processes, or processes normally used in preparing food for human consumption. The conditions governing the use of the word 'natural flavouring' in labelling will be amended by the proposed regulation on flavourings and certain food ingredients with flavouring properties for use in and on foods as discussed later in this chapter. According to this proposed regulation, the term ‘natural’ may only be used for the description of flavouring if the flavouring component
comprises only flavouring preparations and/or natural flavouring substances.

A ‘natural flavouring substance’ shall mean a flavouring substance obtained by appropriate

physical, enzymatic or microbiological processes from material of vegetable, animal or microbiological origin either in the raw state or after processing for human consumption by one or more of the traditional food preparation processes as listed in the regulation. They are:

- Chopping Coating
- Cooking, baking, frying (up to 240 °C) Cooling
- Cutting
- Distillation / rectification
- Drying Emulsification Evaporation
- Extraction, including solvent extraction Fermentation
- Filtration Grinding Heating Infusion Maceration
- Microbiological processes Mixing
- Peeling Percolation Pressing
- Refrigeration/freezing Roasting/grilling Squeezing
- Steeping

For 'flavouring preparation' it is natural under the conditions that it is a product, other than a flavouring substance which is obtained from food by appropriate physical, enzymatic or microbiological processes either in the raw state of the material or after processing for human consumption by one or more of the traditional food preparation processes listed above and/or appropriate physical processes.

The term 'natural' may only be used in combination with a reference to a food, food category or a vegetable or animal flavouring source, if at least 95% (by w/w) of the flavouring component has been obtained from the source material referred to.

The flavouring component may contain flavouring preparations and/or natural flavouring substances.

Labelling requirements for consumer sale of relevant flavourings

The container must include the following information:

(a) The name and business name and address of the manufacturer or the packer, or of the EC seller. The word 'flavouring' or more specific names or descriptions of the relevant flavourings.

(b) The words 'for foodstuffs' or a more specific reference to the food for which the relevant flavouring is intended.

(c) An indication of minimum durability.

(d) Any special storage conditions or conditions of use.

(e) Instructions for use, where omission would prevent appropriate use of the flavouring.

(f) Where the relevant flavouring contains other substances or materials, a list in descending order of weight:

- in respect of components of the relevant flavouring, the word 'flavouring' or more specific names or descriptions of the relevant flavourings;
- in respect of each other substance or material, its name or, where appropriate, its E number.

The information must be visible, legible and indelible, and must be expressed in terms easily understood by the purchaser.

Sale of food containing flavourings:

Generally no food shall be sold which has in it or on it any added relevant flavouring other than a permitted flavouring (complying with general purity criteria).

Smoke Flavourings Regulations 2005 (S.I. 2005 No. 464)

Definition

'Smoke flavouring' means a smoke extract used in traditional foodstuffs smoking processes.

The following definitions are also given:

- 'primary smoke condensate' shall refer to the purified water-based part of condensed smoke and shall fall within the definition of 'smoke flavourings';
- 'primary tar fraction' shall refer to the purified fraction of the water-insoluble high-density tar phase of condensed smoke and shall fall within the definition of 'smoke flavourings';
- 'primary products' shall refer to primary smoke condensates and primary tar fractions;
- 'derived smoke flavourings' shall refer to flavourings produced as a result of the further processing of primary products and which are used or intended to be used in or on foods in order to impart smoke flavour to those foods.

Smoke flavourings need to be indicated as such, see the previous section on Flavourings in food.

Colours in Food Regulations 1995 (S.I. 1995 No. 3124, as amended by S.I. 2000 No. 481, S.I. 2001 No. 3442, S.I. 2005 No. 519 and S.I. 2007 No. 453)

Definition

A food colour is a food additive used or intended to be used primarily for adding or restoring colour to a food. This includes:

- any natural constituent of food and any natural source not normally consumed as food as such and not normally used as a food ingredient; and
- any preparation obtained from food or any other natural source material by physical and/or chemical extraction resulting in selective extraction of the pigment relative to the nutritive or aromatic constituent.

For labelling of colours in foods see the Food Labelling Regulations - Additives section. See section on Food Additives Labelling Regulations, for business/consumer sale of food additives.

Sweeteners in Food Regulations 1995 (S.I. 1995 No. 3123, as amended by S.I. 1996 No. 1477, S.I. 1997 No. 814, S.I. 1999 No. 982, S.I. 2001 No. 2294,

S.I. 2002 No. 379, S.I. 2003 No. 1182, S.I. 2004 No. 3348 and S.I. 2007 No.

1778)

Definition

A sweetener is a food additive used or intended to be used to impart a sweet taste to food, or as a table-top sweetener.

For labelling of sweeteners, see sections on:

i) Food Additives Labelling Regulations, for business/consumer sale of food additives.

ii) The Food Labelling Regulations - both Additives and Sweeteners.

Miscellaneous Food Additives Regulations 1995 (S.I. 1995 No. 3187, as amended by S.I. 1997 No. 1413, S.I. 1999 No. 1136, S.I. 2001 No. 60, S.I.

2001 No. 3775, S.I. 2003 No. 1008, S.I. 2003 No. 3295, S.I. 2004 No. 2601,

S.I. 2005 No. 1099 and S.I. 2007 No. 1778)

Definition

The term 'miscellaneous additive' refers to any food additive that is used or intended to be used primarily as an acid, acidity regulator, anti-caking agent, anti- foaming agent, antioxidant, bulking agent, carrier, carrier solvent, emulsifier, emulsifying salt, firming agent, flavour enhancer, flour treatment agent, foaming agent, gelling agent, glazing agent, humectant, modified starch, packaging gas, preservative, propellant, raising agent, sequestrant, stabiliser or thickener; but does not include use as a processing aid or any enzyme except invertase or lysozyme.

Extraction Solvents in Food Regulations 1993 (S.I. 1993 No. 1658, as amended by S.I. 1995 No. 1440 and S.I. 1998 No. 2257)

Definition

An extraction solvent is any solvent used or intended to be used in an extraction procedure, including, in any particular case further to its use in such a procedure, any substance other than such a solvent derived exclusively from such a solvent.

Labelling of permitted extraction solvents

- The name of the permitted extraction solvent that is stated in the list of Permitted Extraction Solvents.
- A clear statement that the permitted extraction solvent is of suitable quality for use in an extraction procedure.
- An identifying batch or lot mark.
- The name or business name and address of the manufacturer or packer, or of an established EC seller.
- The net quantity or volume, in metric units, of the permitted extraction solvent in any container or other packaging in which it is to be sold or imported.
- Any special storage conditions or conditions of use.

The information must be easily visible, clearly legible and indelible.

The information must be given on the packaging, container or label of the permitted extraction solvent to which it relates.

The Genetically Modified Food (England) Regulations 2004 (S.I. 2004 No. 2335)

This Regulation makes provisions for the enforcement of EC Regulation No. 1829/2003 on genetically modified food and feed which harmonises procedures for the scientific assessment and authorisation of genetically modified organisms (GMOs) and genetically modified food and feed and lays down labelling requirements.

The EC Regulation applies to the whole of the UK although the S.I. 2004 No. 2335 applies only in England. Similar legislation has been made in Scotland, Wales and Northern Ireland as follows:

- The Genetically Modified Food Regulations (Northern Ireland) 2004 (Statutory Rule 2004 No. 385)
- The Genetically Modified Food (Scotland) Regulations 2004 (Scottish Statutory Instrument 2004 No. 432)
- The Genetically Modified Food (Wales) Regulations 2004 No. 3220 (W.276)

The Genetically Modified and Novel Foods (Labelling) (England) Regulations 2000 have been revoked.

The Food Standards Agency was designated as the national competent authority to receive applications for the authorisation of:

- new genetically modified organisms for food use
- food containing or consisting of GMOs or
- food produced from or containing ingredients produced from GMOs.

The Genetically Modified food (England) Regulations sets labelling requirements for:

- food containing or consisting of genetically modified organisms (GMOs) or
- food produced from or containing ingredients produced from GMOs.

The labelling requirements apply regardless of whether or not the final product contains DNA or protein resulting from genetic modification.

The labelling requirements of this regulation do not apply to foods containing material which contains, consists of or is produced from GMOs that have an EU authorisation in a proportion <0.9% of the food ingredients, where the presence is adventitious or technically unavoidable. This

unintentional presence is subject to the operator being able to supply evidence to satisfy the competent authorities that they have taken appropriate steps to avoid the presence of such material.

GM material that has not been authorised in the EU cannot be present at any level in food products.

The Regulation requires that:

- If the food consists of more than one ingredient, the words 'genetically modified' or 'produced from genetically modified X', are to appear in the ingredient list in parentheses immediately after the ingredient name (or in a prominent footnote linked to indicate this) in the ingredients list.
- If the ingredient is designated by a category name, the words 'contains genetically modified Y', or 'contains X produced from genetically modified Y', are to appear in the ingredients list.
- For a food without an ingredient list, the words 'genetically modified' or 'produced from genetically modified Y' are to appear on the label.

where, X = name of ingredient, where Y = name of organism

In the case of non-prepackaged products or pre-packaged food in small containers of which the largest surface has an area of less than 10 cm2, the information required under this paragraph must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

In addition to the labelling requirements given above, the labelling should also mention any characteristic or property, as specified in the authorisation where a food or ingredient has changed in respect to its composition, nutritional value/nutritional effects, intended use, implications for the health of certain sections of the population as well as any ethical/religious concerns.

Also, genetically modified food must not:

- have adverse effects on human health, animal health or the environment

mislead the consumer

- differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

Note: Legally there are no controls for 'GM free' labelling for food ingredients other than rules on misleading claims. Consumers should check with the company/retailer as to the criteria that are being employed in using the term.

The Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004 (S. I. 2004 No. 2412)

This Regulation provides for the enforcement in England of EC Regulation No. 1830/2003 on the traceability and labelling of GMOs and GM food and feed. It requires the identification of GM products throughout the supply chain in order to facilitate accurate labelling in accordance with Regulation (EC) 1829/2003 for:

- food consisting or containing GMOs
- food produced from GMOs

Unique identifier codes on GMOs can be found in a register and are used in traceability documentation. These codes must be used for the traceability of products consisting of or containing GMOs (e.g. maize) but not of foods produced from GMOs (e.g. maize gluten).

The EC Regulation applies to the whole of the UK and similar legislation has been made in Scotland, Wales and Northern Ireland.

Package of proposals for new legislation on food additives, flavourings and enzymes

In July 2006, The European Commission published a package of legislative proposals to introduce harmonised EU legislation on food enzymes for the first time and upgrade current rules for food flavourings and additives to bring them into line with the latest scientific and technological developments. The proposals were amended in October 2007.

The package includes four proposals on food improvement agents as follows:

1. Establishing a common authorisation procedure for food additives, food enzymes and food flavourings
2. Food additives
3. Food enzymes
4. Flavourings and certain food ingredients with flavouring properties for use in and on foods

1. Proposal for a Regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings

   http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0672en01.pdf

   The safety of additives, enzymes and flavourings used in foodstuffs for human consumption must be assessed before they can be placed on the community market.

   Currently, the general criteria for the use of food additives is given in the Framework Directive 89/107/EEC concerning food additives authorised for use in foodstuffs intended for human consumption, which is discussed further in the next chapter. The authorisation procedure for a food additive at Community level currently involves a two-step procedure. Therefore, firstly the additive is included in the relevant Directive, and then the Commission would adopt a specification for that additive after this is agreed by the Standing Committee on the Food Chain and Animal Health.

   The proposed Regulation lays down a common assessment and authorisation procedure for food additives, food enzymes, food flavourings and sources of food flavourings used or intended for use in or on foodstuffs.

   Under Regulation (EC) 178/2002 laying down procedures in matters of food safety, the placing of substances on the market must be authorised only after an independent scientific assessment by the European Food Safety Authority of the risks that they pose to human health. This is followed by a risk management decision taken by the Commission. Food additives, food enzymes, food and flavourings must be included in the positive list for each respective regulation in order for them to be marketed for human consumption. These positive lists will be created, maintained and published by the Commission.

2. Proposal for a Regulation of the European Parliament and of the Council on food additives

   http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0673en01.pdf Currently, food additives are governed by the following:

- Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption. Official Journal of the European Communities L40, 11.02.89,27- 33, as amended.
- European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs. Official Journal of the European Communities. L237, 10.9.94, 3-12, as last amended.

- European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs. Official Journal of the European Communities. L237, 10.9.94, 13-29.
- European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. Official Journal of the European Communities. L61, 18.3.95, 1-40, as last amended.
- Decision No 292/97/EC of the European Parliament and of the Council of 19 December 1997 on the maintenance of national laws prohibiting the use of certain additives in the production of certain specific foodstuffs
- At present, the authorisation of a food additive at community level is based on a co-decision procedure. If the new proposal is adopted, the provisions on additives in the different existing Directives will be brought together in one regulation. This single Regulation will harmonise the use of food additives in foods in the Community.
- The regulation will include the principles for the use of food additives, and a positive list of approved food additives, as well as covering the use of food additives in food additives and food enzymes, and carriers for nutrients. The regulation will be based on a comitology approach since the package was adopted around the time of entry into force of Decision 2006/512/EC, amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission.
- The inclusion of food additives onto a positive list will be based on their safety when used, a technological need and their usage must be of benefit to the consumer. Their use must not mislead the consumer and this would include issues related to the quality of ingredients used, naturalness, nutritional quality of the product or its fruit and vegetable content. The European Food Safety Authority (EFSA) will be responsible for carrying out all safety evaluations.
- The additives present in the positive list will have specifications including purity criteria and origin.
- Producers or users of additives should provide the Commission with information on their use which may affect the assessment of the safety of the food additive.

When a food additive is already included in a Community list but there is a significant change in the production methods or the starting materials, the food additive prepared by these new methods or materials shall be considered as a different additive and a new entry in the Community lists or change in the specifications shall be required before it can be placed on the market.

Additionally, any GM-containing additives must be authorised following Regulation (EC) No 1829/2003 on genetically modified food and feed.

Food Additives currently included in Directives 95/2/EC, 94/35/EC and 94/36/EC will be entered into Annex II of the proposal following a review undertaken by the Standing Committee on Food Chain and Animal Health (SCFCAH). The SCFCAH will evaluate the compliance of existing authorisations for food additives and their conditions of use with general criteria i.e. technological needs, and consumer aspects. However, Annex III will be completed with other food additives used in food additives and food enzymes as well as carriers for nutrients and their conditions for use as follows:

Annex III:

Part I: Carriers in food additives (transferred from Annex V of Directive 95/2/EC on food additives authorised for use in food additives as permitted carriers/carrier solvents)

Part 2: Additives other than carriers in food additives Part 3: Additives including carriers in food enzymes

Part 4: Additives including carriers in food flavourings (transferred from Directive 95/2/EC on food additives authorised for use in food flavourings)

Part 5: Carriers in nutrients

3. Proposal for a Regulation of the European Parliament and of the Council on food enzymes

http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0670en01.pdf

Currently, Council Directive 95/2/EC on food additives other than colours and sweeteners allows two enzymes to be used as food additives. (In addition, Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption, Council Directive 83/417/EEC relating to certain lactoproteins intended for human consumption and Council Regulation 1493/1999/EC on the common organisation of the market in wine, regulate the use of certain food enzymes in these specific foods.) Other uses of enzymes aren't regulated at all or are regulated as processing aids under the national legislation of the Member States; however, requirements differ significantly between each Member State.

The proposed regulation on enzymes would establish a positive list of approved enzymes, conditions for their use in foods and rules on labelling of food enzymes sold as such.

Hence, the regulation will apply to all enzymes including enzymes used as processing aids and miscellaneous additives, although the regulation will not apply to enzymes for nutritional or digestive purposes. Likewise, microbial cultures traditionally used in the production of food (e.g.

cheese) that may contain enzymes but aren't specifically used to make them will not be considered as food enzymes.

The proposed regulation also defines the terms 'enzyme', 'food enzyme' and 'food enzyme preparation'.

In the positive list, the entry of a food enzyme shall specify:

- The description of the food enzyme (including its common name)
- Specification (including origin, purity criteria etc)
- Foods in which it may be used
- Conditions for its use
- If there any restrictions for the enzyme when sold directly to consumers
- Any specific labelling requirements (in the food where the enzyme has been used to ensure the physical condition of the food and specific treatment is indicated if necessary)

The proposed regulation lays down labelling requirements of food enzymes and food enzyme preparations whether or not they are intended for sale to the final consumer.

Enzymes that are already on the market can be transferred onto the positive list if EFSA accepts the previous safety assessment done at community level. The proposal states there is an initial two-year authorisation period during which EFSA must evaluate all applications for food enzymes.

Novel foods falling within the scope of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients should be excluded from the scope of this proposed regulation on food enzymes.

Enzymes produced from genetically modified organisms will be subject to the scope of Regulation (EC) 1829/2003 on genetically modified food and feed in relation to the safety assessment of the genetic modification, whereas other aspects of safety and the final authorisation shall be covered under the proposed regulation on food enzymes.

4. Proposal for a Regulation of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods

http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0671en01.pdf

Currently, flavourings are regulated through Council Directive 88/388/EEC relating to flavourings for use in foodstuffs and to source materials for their production. Within this, flavourings can be divided into the following categories:

- Flavouring substances (which describes natural, nature identical and artificial flavourings)
- Flavouring preparations

- Process flavourings
- Smoke flavourings

Council Directive 88/388/EEC also sets maximum limits for certain undesirable substances obtained from flavourings and other food ingredients with flavouring properties. The proposed regulation on flavourings sets new maximum limits for the presence of these undesirable substances in foods. It also introduces a new annex (Annex IV) which lists source materials to which restrictions apply for their use in the production of flavourings and food ingredients with flavouring properties. EFSA is responsible for the risk assessment of flavourings.

The proposed regulation on flavourings aims to establish a positive list of flavourings and source materials approved for use in and on foods with their conditions of use in and on foods, as well as setting rules on the labelling of flavourings.

The positive list shall be established by placing the list of flavouring substances referred to in Article 2(2) of Regulation (EC) No 2232/96 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs, into Annex I of the proposed regulation on flavourings, at the time of its adoption.

The current register of flavouring substances (as adopted by Decision (EC) 1999/217/EC, as amended, adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96), is valid for the whole of the EU and includes about 2700 flavouring substances.

The new proposed regulation defines and contains the following categories of flavourings:

- Flavouring substances (defining natural flavouring substances only)
- Flavouring preparations
- Thermal process flavourings*
- Smoke flavourings
- Flavour precursors*
- Other flavourings or mixtures thereof*

*A new category of flavouring introduced by the proposal

The definition of a 'natural flavouring substance' has been amended by this proposal as discussed earlier in this chapter. Given that the chemical structure of the molecules is identical, it was sensible to remove the distinction between ‘natural’ and ‘nature identical’ flavouring substances because as far as human consumption is concerned, it is the safety of the substance that is important, not its origin.

A ‘thermal process flavouring’ is defined as a product obtained after heat treatment from a mixture

of ingredients not necessarily having flavouring properties themselves, of which at least one contains nitrogen and another is a reducing sugar; the ingredients for the production of thermal process flavourings may be:

(i) food; and/or

(ii) source material other than food

In Annex V of the proposed regulation on flavourings, conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavourings are specified.

A 'flavour precursor' is defined as a product, not necessarily having flavouring properties itself, intentionally added to food for the sole purpose of producing flavour by breaking down or reacting with other components during food processing; it may be obtained from:

(i) food; and/or

(ii) source material other than food;

A flavouring or source material that falls within the scope of Regulation (EC) 1829/2003 on genetically modified food and feed can only be included in the positive list of flavourings under the new proposal if it has been covered by an authorisation in accordance with the Regulation (EC) No 1829/2003.

Appendix A: Exemptions from Food Ingredients Listing

Foods that are exempt from ingredients listing are:

1. Fresh fruit and vegetables, which have not been peeled or cut into pieces.
2. Carbonated water that contains only carbon dioxide, and whose name indicates that it has been carbonated.
3. Vinegar obtained by fermentation from a single product with no additions.
4. Cheese, butter, fermented milk and fermented cream containing only lactic products, enzymes and microorganism cultures essential to manufacture, or cheese (except curd cheese and processed cheese) containing salt for manufacture.
5. Flour to which no substances have been added other than those required to be present in flour by the Bread and Flour Regulations 1998.
6. Drinks with an alcoholic strength by volume of more than 1.2%.
7. Foods consisting of a single ingredient, where the name of the food is identical to the name of the ingredient, or the name of the food enables the nature of the ingredient to be clearly identified.

Appendix B: Exemptions from Durability Indication

1. Fresh fruit and vegetables, which have not been peeled or cut into pieces.
2. Wine, liqueur wine, sparkling wine, aromatised wine and any similar drink obtained from fruit other than grapes.
3. Any drink made from grapes or grape musts and coming within specified codes of the Combined Nomenclature.
4. Any drink with an alcoholic strength by volume of 10% or more.
5. Any soft drink, fruit juice or fruit nectar or alcoholic drink, sold in a container containing more than 5 litres and intended for supply to catering establishments.
6. Any flour confectionery and bread that, given the nature of its content, is normally consumed within 24 hours of its preparation.
7. Vinegar.
8. Cooking and table salt.
9. Solid sugar and products consisting almost solely of flavoured or coloured sugars.
10. Chewing gums and similar products.
11. Edible ices in individual portions.

Appendix C: Permitted Extraction Solvents

1. Propane
2. Butane
3. Ethyl acetate
4. Ethanol
5. Carbon dioxide
6. Acetone
7. Nitrous oxide
8. Methanol
9. Propan-2-ol
10. Hexane
11. Methyl acetate
12. Ethylmethylketone
13. Dichloromethane
14. Diethyl ether
15. Butan-1-ol
16. Butan-2-ol
17. Propan-1-ol
18. Cyclohexane
19. 1,1,1,2-Tetrafluoroethane

Chapter 3

SAFETY OF FOOD ADDITIVES

Introduction

The objective of European Union (EU) legislation on food additives is to ensure protection of public health within a harmonised EU internal food market. The legislation on food additives has been developed following the approach laid down by the European Commission in 1985 (1). This approach limited the requirement for legislation to those areas that were justified by the need to protect public health, to provide consumers with information and protection in matters other than health, to ensure fair trading and to provide for the necessary public controls. This chapter focuses on the mechanisms to ensure the safety of food additives covered by EU legislation.

European Directives

Framework Directive on Food Additives

The general framework Directive 89/107/EEC on food additives was adopted by the European Economic Community in 1988 (2). This Council Directive:-

- gives a definition of 'food additive'
- sets out a framework for adoption of lists of permitted additives
- gives general criteria for the inclusion of food additives on such lists
- provides for the adoption of purity criteria (specifications)
- gives Member States powers to temporarily suspend or restrict the use of a permitted additive if new information gives grounds for thinking it might endanger health
- gives Member States powers to provisionally authorise new additives at the national level for up to 2 years
- provides for consultation of the Scientific Committee on Food or, since May 2003 by its replacement the European Food Safety Authority (EFSA) in matters concerning public health,
- provides for labelling of traded food additives and of foods sold to the consumer.

The definition of a food additive in 89/107/EEC is as follows:-

"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".

The definition excludes processing aids, including enzymes and extraction solvents, flavourings,

substances added as nutrients, such as vitamins and minerals, and substances migrating from food-packaging materials that do not exert a technological function in the food. All substances falling under this definition are called food additives in the EU, and there is no distinction, as there is in the USA, into 'direct' and 'indirect' food additives. Substances defined as food additives in the EU are the equivalent of direct additives in US terminology. Indirect food additives in the US are pesticide residues and substances derived from food-packaging materials. Pesticides and food-packaging substances are covered by separate legislation in the EU and will not be further discussed here. Similarly, extraction solvents and flavourings are also covered by separate EU legislation and will not be further discussed.

Specific Directives on classes of additives

Between 1994 and 1995, three specific Directives stemming from 89/107/EEC were adopted (3-5). They are widely known as the "sweeteners Directive", the "colours Directive" and the "miscellaneous additives Directive". These Directives and their subsequent amendments list the individual permitted additives (now 15 sweeteners, 42 colours and over 280 miscellaneous additives) and the general and specific food categories in which each additive is permitted, and lay down any necessary maximum levels of use. Additives are also grouped into Annexes in the Directives, which broadly define how widely they may be used. All three Directives also require Member States to set up systems to monitor consumer consumption of additives and, in the case of sweeteners, to establish consumer surveys that will include monitoring of 'table-top' sweetener usage (6). Results of such monitoring are to be reported to the Commission and ultimately to the European Parliament.

The new proposal for an EC Regulation on food additives as discussed in the previous chapter would bring together the framework directive, colours, sweeteners and miscellaneous additives directives into one regulation. Therefore once the proposed regulation on food additives is in force, the framework directive, colours, sweeteners and miscellaneous additives directives will be repealed.

Origin of 'E' numbers

Each permitted additive is assigned an 'E' number, signifying that it has been approved as safe for food use by the EC Scientific Committee on Food (SCF), or, since May 2003 by its replacement EFSA, and its inclusion in the relevant directive has been agreed by the Member States. Each E number has a separate specification, which lays down purity criteria for the additive (7-9). Labels on processed foods may list additives by their E numbers and/or by their common name.

Safety Testing and Evaluation of Food Additives

Requirements of the EC Framework Directive on safety assessment

The general criteria for use of food additives set out in Directive 89/107/EEC stipulate that additives

can be approved only if they present no hazard to the health of the consumer at the level of use proposed, so far as can be judged on the scientific evidence available (2). To assess the possible harmful effects of a food additive or its derivatives, it must be subject to toxicological testing. All food additives must be kept under observation after approval so that they can be re- evaluated if there are changing conditions of use, or if new scientific information emerges on safety aspects.

Under the new proposal for an EC Regulation on food additives and that of the proposal for an EC regulation establishing a common authorisation procedure for food additives, food enzymes and food flavourings as discussed in the previous chapter, EFSA will be responsible for carrying out all safety evaluations for food additives, whilst the Commission will create, maintain and publish the positive lists for food additives, food enzymes and food flavourings.

General approach of advisory and regulatory bodies

The safety assessment of food additives has developed along similar lines in individual countries, in the EU and in the wider international community. The main international body that has addressed the issue of food additive safety is the Joint FAO/WHO Expert Committee on Food Additives (JECFA). This Committee was set up in 1956 and over the years has drawn on expertise from around the world for its changing membership. Over the first 5 years of its existence, JECFA set out principles for the assessment of food additives, which have been collated and updated in subsequent years (10). The general principles of the JECFA approach have been widely adopted by other national and international bodies, including the SCF or, since May 2003 by EFSA.

Derivation of an acceptable daily intake

The JECFA approach is based on assessment of a usually extensive series of toxicological tests, identification of any critical toxic effects, their dose-response relationships, the doses at which they do not cause any adverse effects, and the setting of an Acceptable Daily Intake (ADI). The ADI is defined by JECFA as an estimate of "the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk" (10). The ADI is derived by applying a safety or uncertainty factor to (usually) the lowest no-observed-adverse-effect level (NOAEL) in the toxicity studies. The safety factor most commonly used is 100, comprising a factor of 10 to take account of possible inter-species differences when extrapolating from animal experiments to humans and a further factor of 10 to take account of possible inter-individual differences between humans. The ADI is expressed as a range from 0 to an upper limit in mg/kg body weight. For some food additives, an "ADI not specified" is allocated. This is because a number of additives, in contrast to, say, pesticides or drugs, are of very low toxicity and no toxic effects are seen during animal testing when large amounts are given in the diet. In some instances, they may be

the same as normal food ingredients (e.g. citric acid) or human metabolites (e.g. carbon dioxide, lactic acid). For some additives, EFSA may make their own decision in relation to setting maximum permitted levels for food additives irrespective of JECFA's opinions. For example, in the case of starch aluminium octenyl succinate, JECFA did not set any ADI levels as no toxicity data was available in 1997 and also as it was considered that the intake of aluminium from this source would be low and hence would not pose a safety concern (11). However in 2006, starch aluminium octenyl succinate became a newly permitted miscellaneous additive within the EU, up to a maximum level of 35 g/kg permitted in encapsulated vitamin preparations in food supplements.

On the other hand, there may be considerable evidence of safe human use of an additive from a country outside the EU. An example here would be in the case of Stevioside which is extracted and refined from *Stevia rebaudiana Bertoni* leaves and is used as a sweetener. It is permitted for use in certain countries including Japan, however it is not permitted on the market as a food or food ingredient in the EC or the US due to insufficient data on its safety (12).

Structurally related additives, with a common mechanism of action or effect, may be assigned a Group ADI. The summed intakes of all additives in a group should not exceed the figure for the Group ADI.

Toxicological tests required

The range of toxicological tests generally required for a proposed new food additive has been set out by various bodies, including JECFA (10), the SCF (13) and the US FDA (14). While these various guidelines differ in some aspects of detail, the core requirements are very similar. The SCF guidelines for submissions for food additive evaluations have been endorsed by EFSA (2nd meeting of AFC Panel, 9 July 2003) (13) and these guidelines replace those given by the SCF in 1980 on the toxicological tests generally required for additives.

Acute toxicity studies

Acute toxicity studies are not mandatory for the safety assessment of food additives although such data will often exist because of their necessity for occupational safety assessments in manufacturing. Hence, if such studies have been conducted for other purposes then they should be submitted. Similarly, studies on eye and skin irritation and skin sensitisation may also be available for occupational reasons but are of little use in the safety evaluation of food additives as consumed, hence they are not required. Skin sensitisation, for example, is not predictive of oral sensitisation, for which no validated animal models currently exist.

Absorption, distribution, metabolism and excretion

Studies on absorption, distribution, metabolism and excretion are usually conducted following single

and short-term repeat dosing. These can greatly aid in the design of subsequent toxicity tests, indicate whether harmful metabolites may be produced, or whether the parent compound or its metabolites may accumulate in the body, and help in the interpretation of adverse findings in toxicity tests. Information on metabolism in humans is desirable. This occasionally becomes available for food additives after they have been approved and marketed. More such data could be safely generated prior to approval by the use of very small doses of radiolabelled compound, as is done in human volunteers for therapeutic drugs. Only when such comparative data are available can a definitive judgement be made on whether appropriate species have been selected for toxicity testing. *In vitro* studies can also give additional useful information.

Sub-chronic, repeat-dose toxicity studies

Sub-chronic studies in rodent and non-rodent species (usually 13-week studies in the rat and dog) for a period of at least 90 days are generally required. Ideally, exposure to the test compound should be via the oral route, usually given at fixed concentrations in the diet, but sometimes by gavage. For non-toxic substances, use of upper concentrations in the diet greater than 5% are not encouraged, since such concentrations tend to cause nutritional problems, which may then give rise to secondary toxicity. These studies yield important information on any food consumption and body weight changes, haematological changes, effects on blood and urine biochemistry which provide indications of damage to organs such as the liver and kidney, organ weight changes, and pathological changes in organs and tissues at the gross, macroscopic and microscopic levels.

Reproductive and developmental toxicity studies

Reproductive and developmental toxicity studies are also usually required. These generally comprise a multigeneration study in the rat and developmental toxicity studies in two species. Multigeneration studies assess any effects on male or female fertility, and the ability to maintain pregnancy, deliver offspring and maintain successful lactation; they also indicate any adverse effects on survival, growth and development of the offspring. Nowadays, such studies are likely to include not only assessment of the postnatal physical development of the offspring but also measures of motor and behavioural development. Such studies usually extend for either two or three generations so that the reproductive function of offspring themselves exposed to the test compound in utero can be assessed. This is currently regarded as very important, since critical aspects of the development of the reproductive system in rats occur in the late prenatal and early postnatal period – a developmental window in which there may be particular vulnerability to endocrine disrupter-induced effects.

In developmental toxicity studies (formerly known as teratology studies), the growth and development of the embryo and foetus are assessed, with emphasis on embryonic and foetal survival,

foetal weight and the occurrence of any malformations. The dosing period for such studies was formerly during embryogenesis only (e.g. day 6–15 in the rat or 6–28 in the rabbit), but now it is recommended to continue dosing throughout embryogenesis and up to term (e.g. to day 21 in the rat). This is in order to cover important periods of brain and reproductive system development, which continue beyond the classical period of organogenesis for other systems. Dosing is normally via the diet or by gavage.

Genotoxicity studies

Genotoxicity studies assess the ability of a substance to interfere with DNA by induction of single gene mutations, chromosome aberrations, or other forms of DNA damage. Such effects on DNA are of significance because they indicate the potential for carcinogenic effects or induction of heritable mutations in germ cells. A battery of three *in vitro* genotoxicity tests are required (two for gene mutations and a chromosome aberration test), using bacterial systems such as *Salmonella typhimurium* and mammalian cells in culture from rodents or human lymphocytes. *In vivo* tests may also be required, especially if positive results are obtained in any *in vitro* studies, so that the genotoxic potential of the substance in the context of its *in vivo* metabolism and kinetics can be assessed. Substances that are genotoxic *in vitro* but not *in vivo* (e.g. because they are readily broken down into non-genotoxic compounds) are not generally regarded as hazardous to humans. For food additives, carcinogenicity studies (see below) will also normally be available to provide corroborating data for any genotoxic activity.

Chronic toxicity/carcinogenicity studies

Chronic toxicity/carcinogenicity studies in two species, usually rat and mouse, are also required for most food additives. Dosing commences when the animals are in the juvenile period of rapid growth, at about 6 weeks of age, and continues for most of the animal's lifetime (2 years or more for rats and mice). Dosing is almost invariably via the diet. The emphasis in these studies is on body weight, organ weight and pathological changes in tissues and organs. Examination of haematological and clinical chemistry parameters may also be included in satellite groups killed at intervals before the termination of the study at 2 years. Combined chronic toxicity/carcinogenicity studies are also considered acceptable.

Other studies

The core studies are designed to give clear information on the nature of any toxicity and NOAELs for most toxicological end points. However, for some less common aspects of toxicity, they are designed only to indicate a potential problem, and further studies may be required to elucidate these

properly. Depending on the findings in these core tests, further special studies may sometimes be needed – for example, to clarify the mechanism of toxicity, in order to determine its relevance to humans, or to better define the (cellular, subcellular, biochemical) NOAEL. Similarly, if the core studies indicate, for example, that there may be effects on the immune, nervous or endocrine systems, further special studies designed to answer specific questions on these aspects may be required.

Test protocols and EC submissions

For the core tests, standard protocols are available, which have been developed and are widely accepted internationally. Studies conducted to OECD Guidelines

(15) or EC Guidelines (16-18), the latter being essentially the same as OECD's, are acceptable for the testing of food additives for applications made to the EC. Further information on the presentation of applications to the EC for use of a new food additive has been published by the Commission (19).

Interpretation of toxicity tests

The toxicity of most food additives is generally low in comparison with that of other classes of chemical, such as pesticides, drugs and some industrial chemicals. The majority of effects observed in toxicity studies on food additives, usually confined to the higher levels of administration, are effects on body weight, with or without accompanying reductions in food consumption. Effects on the liver and kidney are also seen because these are the major organs of metabolism and elimination, so are often exposed to the highest concentrations of the additive and its metabolites. In reproductive and developmental toxicity studies, effects on the offspring, such as death and reductions in birth weight and postnatal growth, have to be assessed in light of whether the substance causes any maternal toxicity, since maternal toxicity can induce secondary effects on the offspring; this can often be a difficult judgement to make. In chronic toxicity/carcinogenicity studies, the maximum dose of a substance used should not cause undue mortality but should provide some evidence of toxicity (e.g. a reduction in body weight of up to 10% in comparison with controls). In this way, the maximum tolerated dose is given but the general toxicity should not interfere unduly with interpretation of the results with respect to carcinogenicity.

Relevance of effects observed for humans

In reviewing all the available toxicity studies, a judgement has to be made about which effects are adverse and which are not. For example, the feeding of large amounts of poorly absorbed materials, such as polyols, to rats is known to cause caecal enlargement, disturb calcium homeostasis, cause pelvic nephrocalcinosis and perhaps result in the development of adrenal phaeochromocytomas (20).

However, this would not be taken as indicative of the same adverse effects occurring in humans if the additive were used in small amounts. On the other hand, the feeding of lower amounts of poorly absorbed bulk sweeteners, such as the polyols, can also cause an osmotic diarrhoea – an effect that is transient but which also occurs in humans, and this effect is taken into account in deciding in what foods such additives should be used and in setting maximum levels of use (20). There are also effects that occur in rodents that are not of significance for man, such as kidney damage and tumours via a mechanism involving a-2m- globulin – a protein formed only in male rat liver, which binds with certain hydrocarbons and accumulates in the kidney (21).

Effects may also be observed that are not regarded as being of toxicological significance, such as staining of tissues when high amounts of colours are fed to animals, or increases in liver weight and liver enzyme induction in response to metabolic overload when high amounts of some substances are fed. Similarly, sporadic but statistically significant changes in biochemical or haematological parameters, inevitable in any series of repeat-dosing studies, that are not accompanied by corroborating pathological changes may be disregarded.

Genotoxicity and carcinogenicity

The interpretation of genotoxicity and carcinogenicity studies is of special significance for food additives. Any substance that is genotoxic *in vivo* would not be regarded as acceptable for use as a food additive, since such effects may be without a threshold and thus could occur at very low daily exposures over a lifetime. Carcinogenicity bioassays often confirm the adverse consequences of genotoxic activity *in vivo*. If a substance is non-genotoxic *in vivo* but does show evidence of carcinogenicity in lifetime rodent studies (e.g. the sweetener sodium saccharin), it may still be acceptable as a food additive, provided a mechanism of toxicity and a threshold for its action can be identified (20). Such substances may act by inducing tissue damage and necrosis, resulting in enhanced cell division during repair, and tumour development. Provided a repeat-dose causing no tissue damage can be identified, an ADI may be set by applying an uncertainty factor to the NOAEL for tissue damage. For example, the antioxidant butylated hydroxyanisole (BHA) causes forestomach tumours in the rat when fed at 1 and 2% in the diet, via prolonged stimulation of the stomach epithelium causing hyperplasia. Hyperplasia, but not tumours, are also seen at 0.5% in the diet, but there is a NOAEL for hyperplasia of 0.125% in the diet.

Setting the ADI

In the setting of ADIs for food additives, it is often long-term, chronic toxicity studies or

multigeneration studies that are critical in determining the lowest NOAELs and hence the ADI. This is due to the long periods of administration and the fact that they cover a number of critical periods in the lifetime.

To determine the ADI, a default safety or uncertainty factor of 100 is usually applied to the lowest NOAEL, unless other considerations intervene. If, for example, the critical study is one involving human subjects, then a reduced safety factor of perhaps 10 may be applied. Such is the case, for example, with the colour erythrosine. This affects the human and rat thyroid, ultimately causing tumours in the rat due to excessive production of thyroid stimulating hormone (TSH). Its mechanism of action is well understood and a no-effect level for increases in thyroid hormone levels in humans has been established and used, in conjunction with a 10-fold rather than a 100-fold safety factor to set the (low) ADI (23).

The majority of ADIs set nowadays by EFSA are full ADIs, but temporary ADIs are sometimes set by EFSA and by JECFA. A temporary ADI may be set when the data are sufficient to determine that no harm is likely to result from consumption of the additive over a short period of time, but that some further piece of information is needed to complete the database or to answer a specific question, in order to provide reassurance about lifetime exposure. A deadline is usually set for the submission of the required data. In such cases, an additional safety factor of 2 or more may be employed in setting the temporary ADI to take account of the residual additional uncertainty. If there are large gaps in the database, the AFC panel does not allocate an ADI, either temporary or full. Higher overall safety factors than 100 are also sometimes applied to take account of the severity or irreversibility of a critical effect (e.g. if teratogenicity or non- genotoxic carcinogenicity are the effects determining the ADI), the rationale being to err on the side of caution. An additional safety factor of 10 may also be applied if there is a minimal toxicity level apparent but no clear NOAEL from the toxicity studies.

Comparing Intakes with ADIs

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. The one exception to this is in the case of food additives for infant formulae, for which EFSA considers it may be necessary to conduct specially designed additional tests and perhaps to set a different ADI (24). This is because standard toxicity testing protocols do not adequately model artificial feeding in the neonatal phase.

Methods for estimating food additive intake

To assess the health significance, if any, of intakes of food additives, the ADI can be compared

against average and extreme consumption estimates in the population as a whole, or in particular subgroups of the population (e.g. sweetener intakes in diabetics). There are a large number of practical problems in estimating dietary intakes of food additives, and obtaining reliable estimates of average and extreme consumption amongst various sub-groups of the population with differing dietary habits is both time-consuming and expensive (25). It is therefore more usual for food additive intakes to be estimated initially using relatively crude approaches and for these to be further refined if necessary.

A very rough estimate of food additive intake on a national scale can be made by dividing the total weight of a food additive made annually, or the disappearance annually of a food additive into the food chain, by the number of individuals in the population as a whole. However, the annual per capita consumption figure generated by this means may be misleading in that it usually does not take account of imports and exports of food, and it assumes that all food sold is consumed. Overall, it is thought to considerably underestimate the actual exposure of individuals because it assumes consumption is even across the entire population, which is rarely the case. Such per capita estimates are rarely useful for providing reassurance that ADIs are not being exceeded. One way of reducing the likely underestimate is to assume that only 10% of the population are consumers. This method is being used by JECFA to estimate intakes of flavouring substances (26).

An initial screening method that has gained popularity in Europe is known as the (Danish) Budget Method (27). It relies on assumptions regarding physiological requirements for energy and liquid and on energy density of foods, instead of on detailed food consumption surveys. It assumes that all foods contributing to energy intake and all beverages contributing to liquid intake will contain the additive at the maximum permitted use levels. The resulting intake estimation is clearly an overestimate, but if such an overestimate is below the ADI for the additive concerned, no further refinement of the intake estimate is necessary.

A more refined method is to use surveys of food consumption that are representative of the population as a whole, and which provide information on average and extreme consumption of a wide range of foods. It is then assumed that all foods that may contain any particular additive do, and that they do so at the maximum level permitted or maximum level needed to achieve the desired technological effect. Combining these two types of information results in estimated intakes for average and extreme consumers that are thought to be conservative in that the assumptions made about food additive content are likely to overestimate actual intakes (28). If a highly refined estimate of intake is needed, detailed individual intake data can be gathered by means of food diary studies or duplicate diet studies. In food diary studies, estimates of intake may be made from the self-reported

record of the individual's food consumption and information on the additive content of each food, obtained either from the manufacturer of the food or from knowledge of the maximum likely additive content of particular types of food. In duplicate diet studies, more accurate estimates of intake may be made by analysing exact replicates of the food eaten by an individual for the additive content. The latter method is particularly costly, and both of these methods are limited by the number of individuals that can be surveyed.

Estimates generated for food additive consumption are then compared with the ADI. Since most food additives are regularly ingested and not of any direct health benefit to the consumer, it is important to make this comparison not only for average consumers, but also for extreme consumers, to ensure that they are protected. Different regulatory authorities may use differing cut-off points to define "extreme" consumers. None uses the most extreme consumer since, within any population, there are likely to be one or two individuals with bizarre dietary habits, whose intakes are completely unrepresentative of intakes among the vast majority of the population. Extreme consumers are therefore usually defined as those having the 90th, 95th or 97.5th percentile of intake for the population as a whole.

Significance of exceeding the ADI

Provided that intakes for average and extreme consumers are within the ADI, it is reasonable to assume that there is very unlikely to be any risk to health. Even if intakes occasionally exceed the ADI, it is unlikely that any harm will result, since the ADI is based on a no-effect level and not on an effect level, to which a large safety factor has also been applied. Moreover, ADIs are often derived from long- term studies in which the additive is administered daily over a lifetime and prolonged administration at the toxic dose was required to elicit an effect.

If, however, intake figures indicate that the ADI may be regularly exceeded by certain sectors of the population, it may be necessary to reduce levels in foods or reduce the range of foods in which the additive is permitted for use. Since levels in foods are determined by what is needed to achieve the desired

technological effect, the option to reduce levels in foods may not be available. It can, however, be considered when there are several additives within a class (e.g. colours, sweeteners, antioxidants) that perform the same function and which may be used in combination with each other.

Even when intake, by for example the 97.5th percentile of consumers, is within the ADI, it may be necessary to consider those individuals exceeding it to determine whether they represent a discrete population subgroup with atypical dietary behaviour (e.g. diabetics), which predisposes them to exceed the ADI. Action such as specific targeted advice or modification of particular products may

then be necessary.

In cases where the ADI is determined by an irreversible effect that can occur following short-term rather than long-term exposure, particular care may be necessary to ensure that the ADI is not exceeded, even on an occasional basis (29). This would be the case, for example, if the ADI were determined by a developmental effect, since compounds affecting embryonic and foetal development can do so after exposure of only a matter of days. However, even in these cases, because large safety margins are usually built into the ADI for such serious, irreversible effects, it is likely that the ADI would need to be exceeded by some considerable margin for there to be any risk of harm to human health. A more comprehensive discussion of the significance of excursions of intake above the ADI is available (30).

Conclusions

The use of additives in foods traded within the EU is strictly controlled by legislation, which can be amended to include newly approved additives or (more rarely) to delete additives that are no longer approved. Food additives can be approved for inclusion in EU 'positive lists' only after full consideration of safety aspects by EFSA, which advises the Commission. The AFC Panel usually sets an ADI or, in the absence of an ADI, may stipulate other limitations on conditions of use. Once marketed, the monitoring of consumer intakes of food additives by the Members States enables checks to be carried out to ensure that Acceptable Daily Intakes are not regularly exceeded.

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