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Acronyms

ASA	Advertising Standards Authority
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CSR	Corporate and Social Responsibility
DEFRA	Department for Environment, Food and Rural Affairs
DG SANCO	Directorate-General for Health and Consumers
EC	European Commission*
EFFA	European Flavour Association
EFSA	European Food Safety Authority
EU	European Union
FACET	Flavourings, Additives and Food Contact Materials Exposure Task
FAO	Food and Agriculture Organization
FDA	Food and Drug Administration
FGE	Flavouring Group Evaluation
FIAP	Food Improvement Agents Package
FIR	Food Information Regulation
FSA	Food Standards Agency
GM	Genetically modified
GMO	Genetically modified organism
HFSS	High in fat, sugar and salt
IOFI	International Organization of the Flavor Industry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MSC	Marine Stewardship Council
WHO	World Health Organization

* EC is also used to describe the European Community, which is now known as the European Union.

SUMMARY

Foods have been flavoured for centuries to increase the palatability of diets, and sometimes flavourings can also provide colour or may have anti-microbial or health-promoting properties. Many flavourings originate from plants which have played a significant role in maintaining human health for thousands of years. Culinary herbs and spices have been used to flavour foods since antiquity and in most plants the flavour is provided by the aromatic compounds in their essential oils, which can now be extracted. Recent research suggests that many natural flavourings consumed as intact herbs and spices can provide beneficial antioxidants to the diet and may have a more important role in human health than had been previously known (Tapsell et al, 2006). Flavourings are now predominantly used in food and drink products as cosmetic additives to provide taste and aroma sensations that the basic ingredients are not able to provide on their own.

This review was prompted by new EU-wide regulations and descriptions of flavourings used in food and drink that were published in 2008 and which came into force in 2011. The multinational flavourings industry is dominated by ten companies, is heavily technologised and dynamic research and development underpins market growth. New products and new flavours are crucial to profit making. The industry has grown up alongside the modern, industrialised system that dominates food and beverage supply in the global north and is highly linked to the rapid spread of foods and drinks high in fat, sugar and salt that are known to contribute to the heavy, worldwide burden of chronic disease.

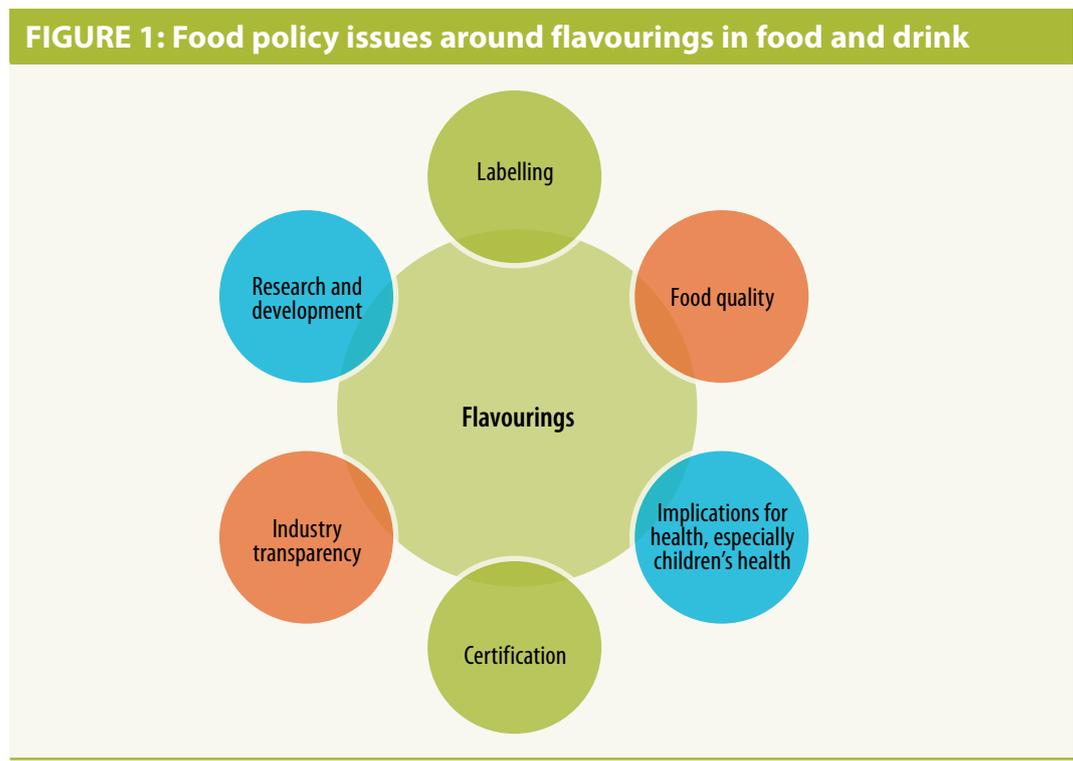
Flavourings is the biggest sector in the global food additives and ingredients market, and there are thousands of flavourings on the market, in a range of forms that are added in various combinations to foods and drinks. They are added to products in order to alter the taste profile of the basic ingredients of the product, to flavour tasteless base materials, to mask 'off-notes', to boost flavour after food processing, to enhance flavours present, or for reasons of economy, as flavourings are generally cheaper than flavourful base ingredients.

The use of flavourings in processed foods and drinks is ubiquitous as the only products they are excluded from are infant formulae. The available evidence suggests that the heaviest sectoral users are alcoholic drinks, soft drinks, confectionery, and dairy products such as ice cream and flavoured yoghurts. Heavy consumers of these products are likely to consume significant amounts of flavour components without any knowledge of what they are consuming, and often without knowledge of what additional substances might have been used as solvents or encapsulators to deliver the flavours.

In light of the dynamic, global nature of the industry, the EC adopted new legislation in 2008 designed to bring 'harmony' to the regulation of the industry throughout the Member States. Regulation EC 1334/2008 was designed to ensure that, throughout the EU, risk assessments of flavourings are done by uniform, specifically designed procedures and that the flavourings that are on sale have been approved after appropriate risk assessment and categorisation. The regulation also aims to ensure that the labelling systems in place are uniform and offer consumers some information about the nature of the flavourings that products contain. It aims to ensure uniform monitoring systems of flavourings are put in place in each Member State, but this depends on sufficient local capacity.

The regulation may bring harmony, but it was also designed to update the systems for an industry that had grown beyond its controls. The information needs of consumers, new perspectives in risk assessment, and concerns over the nature of diets have all arisen to challenge the status quo that had grown up alongside an industry that itself grew dynamically from more humble beginnings. The regulation is still new, and none of its measures to provide EU-wide lists of flavourings, new risk assessments of all flavourings, monitoring systems and labelling systems are yet in place. There are still questions about the procedures and systems enacted by the regulation, and the degree to which they will satisfy critics of the flavourings, and processed food, industries.

There are a number of food policy areas to consider relating to flavourings in foods and drinks (see Figure 1), and this review reflects on all of these areas in light of information currently available.



However, debate as to whether consumers' interests are adequately protected by regulatory controls, and whether consumers' health could be affected by exposure, is on-going. Outside of the scientific and regulatory spheres there are broader social and environmental questions about the role of flavourings as a central component of a globalised and industrialised food system. There is a need for more reflection on the role of flavoured foods in moving human beings further and further away from diets that promote optimum health, and on what is lost when we seek to consume foods that taste familiar but which have lost some of the basic, nutritious ingredients.

This report only touches the surface of some of the wider issues of toxicology and safety, and the lack of data acceptable to safety authorities reviewing flavourings is a key problem in discussion of these issues. There remains debate over the safety of a number of flavouring compounds and whether methods to assess intakes are sufficiently robust. We hope to revisit some of these issues in the months to come.

The discussion of flavour components in this report focuses on what they are and how they are classified, regulated and monitored. The report makes recommendations for research, legislative review, and consumer awareness measures in the interest of ensuring consumers are offered the high level of protection and involvement in informed choice-making that the UK government says they deserve. These recommendations are timely, as many companies become more aware of their responsibility to both human health and the health of the planet.

We hope this report will enliven the debate about flavourings and other additives in food and encourage more investigation and transparency around how consumers can be supported to choose a health-promoting diet which minimises any potential risk to health.

RECOMMENDATIONS

Issue to be addressed	By whom
RESPONSIBILITY TOWARDS CHILDREN	
To investigate the potential impact on child health of the supportive role of flavourings in marketing and selling foods of low nutritional value, and the potential for taste standardisation at a young age, we would like to see:	
<ul style="list-style-type: none"> • A consideration by all players of the special vulnerabilities and health needs of children, and a move towards an overall reduction in the use of flavourings in foods and drinks. 	Regulators and industry
<ul style="list-style-type: none"> • A greater awareness of how flavourings are being used via the regular gathering of industry-wide data on the type of flavoured foods and drinks consumed by children, and the potential impact this may have on their health. 	Industry
<ul style="list-style-type: none"> • The UK's Food Standards Agency should explore 'action' research with food companies to progress the reduction of the use of flavourings in food and drink products, aimed at children. 	Food Standards Agency
MONITORING FLAVOURING USE AND INTAKES	
Government should ensure that it is able to monitor the use and intake of flavourings following the EU legislative change in 2011, and should report on this annually.	National and international authorities
Government should properly fund the services of public analysts and trading standards officers to ensure they can monitor the food supply effectively and make their results known.	National authorities

Issue to be addressed	By whom
<p>SAFETY</p> <p>Industry must prioritise producing toxicology data that are acceptable to EFSA (the European Food Safety Authority) on the 400 flavourings that have not yet been fully reviewed before the deadline of December 2014. The Commission and EFSA must strictly enforce this deadline so that any flavourings for which data are still lacking by the deadline are removed from use immediately.</p>	Industry
<p>TRANSPARENCY AND TECHNOLOGICAL PROGRESS</p> <p>Concerns about the secrecy and lack of monitoring and data on the flavourings industry should be addressed by:</p> <ul style="list-style-type: none"> • Gathering annual data on usage and sharing this with international trade organisations with a view to publishing this and allowing regulators and the public to know what is being used. • The development by industry of methodologies which simplify flavouring recipes and enable a far greater use of natural as opposed to synthetic ingredients. 	Industry Industry
<p>FOOD QUALITY</p> <p>The use of flavourings in food and drink products that are high in fat, salt and sugar is likely to contribute to poor dietary intakes and chronic disease. Manufacturers should consider the quality of the food and drink they produce, to ensure that they do not use flavourings to improve the appeal of poor-quality foods.</p>	Industry

Issue to be addressed	By whom
<p>CERTIFICATION</p> <p>Those who provide certification schemes for foodstuffs (for example, organic certification or fair trade certification) should place a priority on re-considering their rules on the use of flavourings to ensure that these fit in with their ethics and purpose.</p>	Certifiers
<p>LABELLING</p> <p>Any encapsulating agent used in the placement of flavourings in foods should be named on the food label as an ingredient. This is particularly important where this might be from an animal source that would be unacceptable to some consumers.</p>	Regulators and Industry
<p>Any flavouring component which may be unacceptable to some consumers and which is not labelled specifically as an allergenic ingredient should be highlighted on food and drink products, with special attention paid to ensuring foods that may not be suitable for those who avoid animal products are clearly labelled as such.</p>	Regulators and Industry
<p>Until such labelling above becomes a legal requirement, food manufacturers should follow best practice voluntarily.</p>	Industry
<p>Where products are sold without labels or consumed outside the home and not labelled, information should be easily available about the composition of that food or drink on menus, on panels at point of sale, and on a consumer-facing company website.</p>	Industry and Retailers
<p>A reconsideration of the language used in naming flavourings should be made so that the difference between the terms used for the various categories of flavourings and their source materials is made much easier to understand.</p>	National and international authorities

Issue to be addressed	By whom
<p>CONSUMER AWARENESS</p>	
<p>There is a need for research into what the term ‘natural flavourings’ means to consumers and their awareness of the use of flavourings in food and drink.</p>	<p>Food Standards Agency</p>
<p>A campaign such as Action on Additives should promote awareness of the use of flavourings in foods and drinks and highlight the high potential intakes among children and young people and the impact this may have on food and drink choice, long-term dietary habits, and the quality of the diet.</p>	<p>Campaigners</p>
<p>CORPORATE SOCIAL RESPONSIBILITY</p>	
<p>Public assurance should be given that flavour companies are not involved in the following negative practices. They should have monitoring systems in place throughout their organisations to report on this:</p>	<p>Industry</p>
<ul style="list-style-type: none"> • Biopiracy • Land grabs • Exploitation of endangered species. 	
<p>All flavour companies should publish comprehensive Corporate Social Responsibility reports explaining how they will offer greater transparency to consumers about their products, work towards more sustainable manufacturing, and support worldwide efforts for healthier, more sustainable diets.</p>	<p>Industry</p>

INTRODUCTION

Aim and objectives of this review

The **aim** of this report is to provide a review of the role, use, safety and regulation of flavourings in the UK food supply.

The **objectives** are:

- to review why and how flavourings are used in foods and drinks
- to summarise current legislation and monitoring arrangements for the safe use of flavourings in food and drink
- in particular, to consider the role of flavourings in foods and drinks which may be consumed by children, and
- to make recommendations for campaigners and consumers about the labelling of flavourings in food and drinks, and how the use of flavourings may be better regulated and monitored.

Who the review is for

The main audiences for this review are:

- those agencies responsible for the regulation of flavourings in foods
- those who are responsible for ensuring that clear and fair information about food is available to consumers and that food labelling is fit for purpose
- those who campaign for safe food and transparent food labelling
- health professionals and others who advise consumers
- members of the public, and
- industry, food manufacturers and food retailers.

How the review was compiled

This report is not a systematic review. The research for each section has involved consideration of the available legal, scientific, corporate and academic literature, informed by conversations with stakeholders from those fields. The focus of the review is broad, and the available relevant literature is enormous in quantity, so pragmatic judgements have been made about the scope of the review.

1 FLAVOURINGS IN FOOD AND DRINK

The taste of food is important. Humans have sensitive taste receptors which allow them to appreciate a wide variety of flavours in the food they eat, and the fact that foods taste good is fundamental to how we choose our diets. Flavours in foods have been used for thousands of years to enhance the sensory quality of foods, and ingredients used to flavour it often had other properties too, such as adding colour, adding texture or preserving it. The spice trade is probably the most ancient trade in the world and the annual global spice trade today is estimated to be in the order of \$2,000 million a year (Srinivasan, 2005). Similarly, herbs have been used as food and medicine for centuries. There are known to be a wide variety of active phytochemicals in herbs including many with antioxidant properties (Craig, 1999), and recent evidence suggests that they may play an important role in adding small but significant amounts of health-promoting nutritive and non-nutritive components to diets (Craig, 1999; Srinivasan, 2005; Tapsell et al, 2006).

However, today's technically-led food industry no longer relies solely on herbs, spices and whole foodstuffs to add flavour to food. The globalisation of the food supply has led to an ever-increasing desire for easily available foods and drinks that offer consumers greater variations in taste and experience. To achieve this cheaply and efficiently on a large scale, foods are flavoured with substances extracted from their original food source or made in laboratories from chemicals. Whilst outwardly diets seem to become more varied, flavourings enable a reduction in the number and amounts of ingredients that provide flavour in their basic form, thereby contributing to the narrowing of the nutritive and non-nutritive compounds consumers are exposed to. Consumers of cheap and convenient foods and drinks that are available all year round and have similar and consistent tastes may not be aware of the loss of basic food quality that accompanies an increasingly processed food supply.

The prevalence of foods that are artificially flavoured brings together a number of issues related to food safety, food choice and overall dietary composition at a time when diet-related chronic diseases are a major worldwide concern.

1.1 What are flavourings?

In this report we use the term ‘flavouring’ as an umbrella term to cover the components or ingredients of a flavour or overall flavour effect.

Flavourings are defined in a number of ways. In a recent textbook on the chemistry of flavours and fragrances they are described as:

“derived (directly or indirectly) from plant or animal sources or chemically synthesised from petrochemicals to develop products intended to flavour food and beverages” (Berger, 2007).

The British Essence Manufacturers’ Association, a trade association of the British flavour industry, defines flavourings as:

“concentrated preparations with or without solvents or carriers used exclusively to impart flavour”.

The terminology and understanding of flavourings is also defined by how they are regulated, and in the European Union the new EU regulation on flavourings (Regulation EC 1334/2008) defines flavourings as:

“products not intended to be consumed as such, which are added to food in order to impart or modify odour and/or taste”.

The EU Flavour Information System (FLAVIS) has been set up to compile information on flavourings across the EU and is administered by the Danish National Food Institute. The FLAVIS database lists flavourings by chemically defined groups and aims to classify flavourings with FL numbers which define their chemical category and use in food. The database has been used to compile a list of flavourings for evaluation by EFSA.

1.2 Current EU regulations relevant to flavourings

Details of all the legislation relevant to flavourings can be found in Appendix 2.

Regulation EC 1334/2008 is one of four regulations making up the Food Improvement Agents Package (FIAP) which came into force on 20 January 2009, with most of the measures applied from 20 January 2010.

The FIAP regulations are as follows:

- Regulation EC 1331/2008 establishes a common authorisation procedure for food additives, flavourings and enzymes for use within the European Union.
- Regulation EC 1332/2008 regulates food enzymes.

- Regulation EC 1333/2008 regulates 26 classes of food additives (sweeteners, colours, preservatives, antioxidants, carriers, acids, acidity regulators, anti-caking agents, anti-foaming agents, bulking agents, emulsifiers, emulsifying salts, firming agents, flavour enhancers, foaming agents, gelling agents, glazing agents, humectants, modified starches, packaging gases, propellants, raising agents, sequestrants, stabilisers, thickeners and flour treatment agents). All these compounds have E numbers.
- Regulation EC 1334/2008 is the specific regulation for flavourings.

Smoke flavourings are subject to a separate regulatory regime. Smoke flavourings are created to mimic the taste of foods that have been smoked over wood. Regulation EC 2065/2003 on smoke flavourings used or intended for use in or on foods lays down a procedure for the safety assessment and approval of smoke flavourings.

The specific regulation EC 1334/2008 for flavourings applies to:

- Flavourings
- Food ingredients with flavouring properties
- Food containing flavourings and/or food ingredients with flavouring properties
- Source materials for flavourings and/or source materials for food ingredients with flavouring properties.

It does **not** apply to:

- Substances with an exclusively sweet, sour or salty taste
- Raw foods
- Non-compound foods and mixtures such as fresh, dried or frozen spices and/or herbs, tea mixtures or mixtures for infusion, unless they have been used as food ingredients.

1.3 Categories of flavourings

The new EC regulation establishes the following categories of flavourings:

- Flavouring substances
- Natural flavouring substances
- Flavouring preparations
- Thermal process flavourings
- Smoke flavourings
- Flavour precursors
- Other flavourings.

The categories depend on the source materials used to produce the flavouring (for example, whether it is made from a chemical substance or from vegetable, animal or microbiological materials), and the process used for producing it. These categories are explained in detail in section 4.3 and in Table 4.

The regulation also sets out definitions for use of the term 'natural' for flavourings, which are explained on page 54. No regulatory definition of 'natural' exists for any other category of food additive. The terms 'artificial' and 'nature identical', commonly used for flavourings prior to the new regulation, are not defined and may no longer be used by the flavour and food industries.

It has been estimated that there are about 2,500 flavouring substances in use (EFSA, 2010a). An individual processed food or drink product may contain several different categories of flavouring, and dozens of flavourings may be used in combination to produce the exact flavour desired by the food manufacturer. For example, a popular strawberry flavouring may contain approximately 30 flavouring substances plus a flavouring preparation.

Carriers, solvents and encapsulation agents

Flavour carriers such as sugar, starch or dextrin are used to ensure flavour components are evenly distributed in foods.

The extraction of flavourings often requires the use of solvents which may leave a residue in the food or drink when the flavour is added. Solvents such as methanol, hexane or propan-2-ol are typically used to extract flavours used in soft drinks for example, and maximum limits on solvent extracts used in the preparation of natural flavourings from natural flavouring materials are specified in Directive 2009/32/EC. Additional amendments were made in Directive 2010/59/EU on maximum amounts of methanol and propan-2-ol solvent extracts permissible in foods and drinks. Limits on the amount of propan-2-ol were prompted by concerns that teenagers who were high consumers of soft drinks could exceed acceptable daily intakes and permissible amounts were lowered to take into account the very high intakes by some UK teenage consumers in particular (EFSA, 2005).

Microencapsulation technology is also used to coat flavour compounds, in order to preserve them and increase shelf-life, or to control the release of flavours into the mouth. A review of encapsulation substances and processes can be found in Madene et al (2006). The material used to encapsulate the flavouring must be included in the Union list of approved food additives required by Regulation EC 1333/2008 (Annex III, part 4), but it would not be included in the ingredients information panel of a finished food or drink product. This means that consumers may not know if a substance they would choose to avoid is used as a flavour encapsulator in a food or drink. For example, gelatin, lecithin or whey protein used as emulsifiers in encapsulator walls could come from animal sources (Madene et al, 2006). Their use to encapsulate flavours would be deemed misleading – and the manufacturer liable for prosecution – only in foods and drinks specifically labelled as suitable for vegetarians or vegans.

If the encapsulating substance is an allergen, however, the flavour company must inform the food manufacturer, and the substance must be listed as an allergen on the label.

1.4 Why are flavourings used in foods and drinks?

Flavourings are used in foods and drinks:

- to add or change their flavour
- to enhance production, or
- to contribute to their marketing and promotion.

Many of the uses described below are those that are typically given by flavour companies as a rationale for the use of flavourings in foods, and are in keeping with strong trends such as 'healthy' food production and combating commodity volatility. However, most flavourings are used in foods which are by their nature not generally part of a healthy diet (for example, alcoholic drinks, soft drinks, confectionery and ice creams), and it should be borne in mind that the use of flavourings in many foods is often driven by profit motives in a globalised processed food industry rather than by a desire to enhance human health through good food.

Adding or changing flavours of foods and drinks

Flavouring tasteless base materials

The base materials of some manufactured foods have little or no taste of their own (Schlegel, 1976). For example, jelly, crisps, most confectionery and some drinks can be substantially altered by the addition of flavourings. Flavourings are also used to differentiate products consisting of similar base materials. For example, there are dozens of mint-flavoured chewing gums on the market, all of which are made to taste slightly different.

Masking flavours lost or created in food processing and food storage

Flavours can mask unpleasant aromas and tastes that arise as a result of food processing and storage (Schlegel, 1976). Some food manufacturing processes can result in a loss of flavour, one response to which can be to add flavour back later via flavourings (EUFIC, 2003; IOFI, 2009).

Masking 'off' tastes in functional foods and drinks

The addition of functional ingredients such as vitamins or minerals can create unpleasant 'off notes' in a product and/or affect the 'mouthfeel' (Raithatha, 2008). Flavourings can be used to mask this effect.

Standardising the taste of processed foods and drink

Consumers may have expectations of how a processed food or drink will taste. However, natural seasonality and crop variation will result in a variety of tastes over time for the same recipe. Rather than explaining and respecting this, flavourings are often used to standardise the taste of a finished product and ensure it meets the consumer's more limited expectations (Dudai and Berlinger, 2008; EUFIC, 2003). Another reason for this standardisation is the variability in processing foods across different countries or factories – one company may

sub-contract manufacture of the same processed food or drink to many factories. Again, using flavouring can mask any variation between different processes or locations.

Meeting cultural taste preferences

Consumers in different countries and cultures have different taste expectations – for example, in one country an orange flavour would be expected to be very sweet, but in another very bitter. Use of flavourings allows manufacturers to tweak the flavour profile to meet local preferences.

Masking reductions in fat, sugar or salt

Flavourings, and associated technologies such as flavour enhancement, can support the reformulation of products to make them less unhealthy. They can be used to mask the taste impairment caused by reducing fat, salt or sugar levels, or to mimic their taste, or to mask off-notes from substitutes (such as artificial sweeteners). The use of flavourings in this way is increasingly significant as the Food Standards Agency (FSA) has set targets for the reduction of salt, saturated fat, and calories in certain food categories (FSA 2006; FSA, 2008; Leatherhead Food Research, 2009). Between 2003 and 2008 there was a 300% increase in new product lines that made low-sugar, no-sugar or reduced-sugar claims (Margetts, 2009).

Enhancing food or drink production

Reducing production costs

Flavourings made from ingredients that are not defined as natural are generally cheaper than natural ingredients or flavourings made from natural ingredients, and their price is less subject to variation (IOFI, 2009; Dowles, 2008; Schlegel, 1976). Flavourings can be potent and may be needed in very small quantities (parts per million or billion) compared with the volume of real ingredients. For example, the flavourings in a can of Coca-Cola are estimated to cost less than half a pence (Khatchadourian, 2009). Hence the use of flavourings can often be a means of increasing the profitability of a processed food compared with the profit levels if real ingredients were to be used (Givaudan, 2010).

Managing commodity price increases

Companies often change the formulation of food and drink products to reflect the cost of commodities on world markets and to reduce reliance on expensive real ingredients at any given time. For example, to reduce the exposure to cocoa prices, some of the cocoa butter in foods might be replaced with vegetable fat, and the flavour and texture rebuilt with additive ingredients. It is in the interest of flavour companies to assist manufacturers in predicting which commodity prices may rise, and to provide solutions to meet their requirements in advance.

Making new food sources palatable

There are presently concerns over how to feed the growing world population without increasing pressure on the earth's resources. Flavourings have been proposed as part of the solution by enabling the exploitation of food sources that do not have pleasant or familiar flavours (Schlegel, 1976; IOFI, 2009).

Marketing and promoting foods and drinks

Promoting foods and drinks that are perceived to enhance health and well-being

Foods and drinks perceived to be 'healthy' and products with added nutritional benefits are seen to offer a huge market opportunity for food and drink manufacturers, and many are seizing it. Manufacturers understand that, even if they believe it is good for them, consumers will not buy a product more than once if the taste is not acceptable. This means that flavourings play a crucial role in promoting 'value-added' foods, although ironically a healthy diet is defined as one that is made up predominantly of foods in their natural state, rather than processed equivalents.

Creating 'authentic' foods for special diets

Flavourings are used to create 'authentic' but safe products for people with allergies and intolerances. For example, nuts may be replaced with nutty-tasting flavourings derived from non-allergenic materials (Porzio, 2009; Gajendran, 2008; Ferguson, 2009; Knott, 2009; Pringle and Gilroy, 2009; Perfumer & Flavorist, 2009). Whether this is a sensible option for people with allergies, who may have better health by avoiding processed foods and eating foods they can tolerate without risk of contamination, is rarely discussed.

Encouraging purchase through flavour nostalgia

Humans can retain a preference for certain flavours experienced during childhood or happy times throughout their lives. Manufacturers are aware that foods containing flavourings that taste authentic and trigger positive thoughts are likely to be purchased repeatedly, as this quote from a food processing technology website demonstrates:

"A vanilla ice cream very often awakens childhood memories, for example, it causes pleasant feelings, and taste experiences from other countries remind us of our holidays, which are usually a time of joy and relaxation. If the flavours we taste in our everyday diet resemble those experiences as closely as possible then it is likely that they are added to the shopping cart again." (Food Processing Technology, 2011)

Engaging consumers with new products and trends

Flavourists constantly seek out new tastes and trends, and flavour magazines hail the new 'in' flavours each season, many of which reflect travel to exotic locations and food programmes on TV. Flavour companies have 'emerging trends teams' to forecast the next big flavours, often taking inspiration from chefs and restaurateurs. New flavours can extend the range and sales of an established

food product or brand. By expanding product ranges, companies can maintain a competitive advantage. At the same time, consumers may begin to expect the constant titillation of new recipes, which if created via flavours will result in them becoming less familiar with the flavour of real food.

Promoting foods for weight management

Satiety is a relatively new area of flavour research (Ruijschop et al, 2009; Euromonitor International, 2008; Partos, 2005). It is suggested that certain flavours can trigger feelings of fullness and discourage the consumer from over-eating, with new technologies determining the precise timing and manner of flavour release into the mouth (Ruijschop et al, 2009). As there is no firm evidence that flavourings in foods are related to body weight maintenance, use of flavours in this way is solely a marketing technique. Fullness is most likely to be achieved by eating foods naturally high in fibre such as wholegrain cereals, fruits and vegetables.

Marketing foods with a 'healthy halo'

The term 'superfoods' has been used in recent years to describe foods with a high antioxidant content, although this term has no scientific meaning or credibility. Some products are flavoured with cranberry and pomegranate and, although they do not contain any of the fruits' active compounds, their marketing is based on a 'healthy halo' of association with a food perceived to be healthy (Halliday, 2009a).

The report *Advances in Flavor and Aroma Technologies*, aimed at flavourists and product developers, outlines more than 40 new developments from company, academic, and government research laboratories around the world. The report is marketed using statements that highlight how flavourings can make industrial products seem authentic and appealing to consumers, such as:

"The appealing aroma and flavor of freshly baked products can be lost in a day. It is important to harness flavors and aromas and incorporate them into products to make them appear fresh, wholesome and attractive to consumers for as long as possible." (Food Technology Intelligence, 2011).

It could be argued therefore that flavourings are used primarily to mask inferior foods and lead the consumer to think they are fresher and more attractive than they in fact are.

2 THE USE OF FLAVOURINGS IN THE UK

2.1 Where can flavourings be used in the UK food supply?

Flavourings are used widely throughout the UK processed food and drink supply (Leatherhead Food International, 2008). Where and how they can be used are determined by many separate pieces of legislation including the general food safety laws, regulations setting out the general rules and principles of food law applicable across the EU (EC 178/2002), and legislation that provides standards of composition for certain food categories (UK Food Labelling Regulations, 1996). Flavourings-specific regulation (EC 1334/2008) and regulations for solvents used in foodstuffs (Directive 2009/32/EU) are also key. A general principle of food law is that no food can be placed on the market if it is unsafe (Regulation EC 178/2002).

Flavourings may be used in all food and drink products except infant formula and follow-on formula* (Commission Directive 2006/141/EC).

2.2 What quantity of flavourings is used in foods and drinks in the UK?

- It is not possible to know with certainty what flavourings are being used in which packaged products on sale in the UK, and at what levels. There is currently no national or EU product recipe register for foods and drinks.
- There is no requirement for food and drink labelling to specify exactly which flavourings a product contains and in what amounts (EC 1334/2008, EC 2000/13).
- No testing programme is in place to monitor foods for their flavourings content.
- Dietary surveys are not conducted in a manner which allows an estimate of the intake of flavourings by different population groups to be made.

Food manufacturers may not know the exact ingredients of the flavourings they buy from flavouring companies, as business-to-business labelling requirements do not demand that level of specificity. Flavouring companies protect their exact recipe formulations, because disclosing them is considered to be detrimental to their commercial interests. Monitoring authorities tracing product contents may ask a flavouring company for a breakdown of a formulation, but this would not be released into the public domain.

* Flavourings may be used in complementary foods or milks other than infant formulae or follow-on formulae for infants (0-12 months) and young children (12-36 months).

The European Food Safety Authority (EFSA) currently gathers some information from industry about the amount of different flavourings or solvents used in particular food categories for risk assessment and approval purposes. For example, EFSA was asked to review regulation around the use of propan-5-ol as a solvent to carry flavours in soft drinks in 2005 (EFSA, 2005) and manufacturers gave information about the current levels of usage from which average intakes could be estimated to compare against acceptable daily intake values.

Generally speaking, however, EFSA has recognised that assessments of dietary exposure to chemicals are hampered by the limited data available on food consumption and limited data on chemical concentration in foods (EFSA, 2010b). Recent and current studies have aimed to develop and refine methods for estimating flavouring consumption levels. For example, Crispim et al (2010) used a stepwise approach to compare methods of assessing dietary intake of four flavourings – raspberry ketone, glycyrrhizinic acid, coumarin and caffeine – starting with the most conservative and moving to more refined methods using less aggregated data (see the next page for details on the methods). Although the collection of data from individuals for every hazardous substance is generally considered impractical and not cost-effective, the researchers concluded that such a refined method is useful for flavourings and should be explored further (Crispim et al, 2010).

A large EU-funded project called FACET (Flavourings, Additives and Food Contact Materials Exposure Task) is also underway. FACET aims to devise a more reliable method for assessing dietary exposure to flavourings. It is due to report in 2013.

The aims of FACET are:

- to provide detailed information on occurrence, concentration levels in foods and consumer exposure for about 40 flavouring substances chosen to represent the different typologies of flavours
- to provide a tool allowing efficient exposure assessment on other flavourings
- to reorganise food consumption data in order to make them available with a food categorisation system suitable for assessing potential exposure to flavourings
- to provide the capacity to take into account 'high consumption, special groups of consumers and different age groups', and
- to significantly reduce the uncertainty surrounding assessment of exposure to flavouring substances.

How can we measure exposure to flavourings?

Some of the current techniques for estimating dietary exposure to flavourings have limitations due to necessary assumptions about the distribution of flavours in the market and level of consumption of flavoured foods in the population.

The **Maximised survey-derived daily intake (MSDI)** method is used to estimate the intake of a particular flavouring and to compare it with thresholds of toxicological concern.

This is also known as the per capita method, or per capita x 10 method, and crudely compares the annual production of flavourings and divides it by number of consumer days.

$$\text{Intake} = \frac{\text{Annual production of the flavouring (kg x } 10^9 \text{ } \mu\text{g/kg)}}{\text{Population x 365 days}}$$

The **Single portion exposure technique (SPET)** looks at normal use and typical intakes by consumers, assuming daily consumption of one portion of a food over a long period.

$$\text{Intake (mg/kg)} = \text{maximum standard portion size (mg)} \times \text{normal use level of the flavouring (mg/kg)}$$

The **Theoretical added maximum daily intake (mTAMDI)** method is used by the European Food Safety Authority (EFSA) and is calculated on the basis of standard portions and normal use levels for flavourable foods and drinks, pulling out some particular 'exceptional' food groups that might offer higher exposure.

$$\text{Intake (mg/kg)} = (\text{normal use levels in beverages} \times 324) + (\text{normal use levels in foods} \times 133) + (\text{normal use levels in some exceptional food groups} \times 27) + (\text{normal use levels in some exceptional food groups} \times 20) + (\text{normal use in some exceptional food groups} \times 2)$$

For many substances, dietary exposure assessed with mTAMDI is up to 100,000 times that calculated using the MSDI method. These discrepancies create a significant uncertainty in the safety evaluation process. If FACET successfully achieves its aims, it will allow much greater transparency and more accurate assessment of the flavourings used in the EU.

Source: Raffo et al (2008).

Market research information on the quantity of flavourings used in the UK

The information in the public domain about quantities of flavourings in foods and drinks is almost exclusively market research data. The most comprehensive assessments of flavourings usage and consumption in the UK are found in market reports by Euromonitor International, which estimates intakes of a range of flavourings, including natural flavouring substances, flavouring preparations and smoke flavourings but excluding flavour precursors, thermal process flavourings and other flavourings. The Euromonitor data may underestimate total flavourings used because they are derived from estimations of content via sample recipes provided by industry and trade interviews.

In 2010 the estimated total volume of flavourings used in foods and drinks for human use in the UK was about 33,000 tonnes, with 28.6% of flavourings used in foods, 44.8% in alcoholic drinks and 26.6% in other beverages. Table 1 provides information about the estimated tonnage of flavourings used in the different food and drink product categories and the market percentage by volume for each.

The estimates do not take into account the concentration of flavourings in different products across the categories and there is some double-counting of food categories noted by those who compile the statistics, so these are at best estimates. Estimating average per capita intakes of flavourings from these data is not practicable, not least because intakes would be highly skewed to those who consume higher amounts of food and drink and those who consume foods and drinks which have higher than average levels of flavourings (see section 2.3).

TABLE 1: Estimated flavourings usage in foods and drinks in the UK, 2010

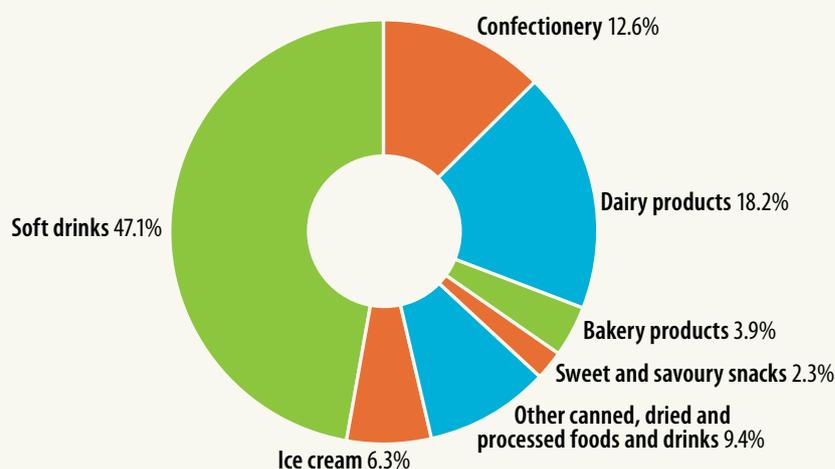
	Volume In tonnes	Market percentage By volume
Packaged food categories		
Dairy products	3,331.8	10.1%
Confectionery	2,297.9	6.9%
Pasta, noodles, soup and other dried, canned and preserved processed foods	1,245.8	3.8%
Ice cream	1,156.9	3.5%
Bakery products	713.7	2.2%
Sweet and savoury snacks	414.6	1.3%
Sauces, dressings and condiments	224.6	0.7%
Meal replacement products	41.3	0.1%
Spreads	29.7	<0.1%
Total food	9,456.3	28.6%
Beverage categories		
Alcoholic drinks	14,823.6	44.8%
Soft drinks	8,650.9	26.1%
Hot drinks	173.3	0.5%
Total beverages	23,647.8	71.4%
Total for food and beverages	33,104.1	100%

Note: These figures do not include use of flavourings in catered foods and in foods sold loose.

Adapted from: Euromonitor International (2012).

FIGURE 2: Flavourings usage in foods and non-alcoholic drinks in the UK, 2010, by market sector

For details and source of information, see Table 1.



2.3 Who are the highest consumers of flavourings?

There is a lack of information about the actual use of flavourings within food and drink, insufficient detail in dietary surveys, and no physiological monitoring of flavouring intake. A lack of assessment of the effects of varying levels of intake of flavourings on potentially vulnerable groups such as children or older people, means that little is known about which consumers may have high intakes – and whether this is a potential concern.

Risk assessments of flavourings have relied heavily on production figures extrapolated to population averages, rather than on estimates of consumption. While risk assessment methods based on global population intake estimates build in margins of error to allow for differences in intakes around the mean, some heavy consumers of highly flavoured foods and drinks may have higher intakes than those used in calculations. It is also important to consider the impact of chronic exposure to flavourings on those who consume large amounts frequently, particularly if these consumers are more vulnerable – for example, children or the chronically ill. Estimating gross intakes also ignores the possible 'synergistic' effects of multiple flavourings compounds, and heavy consumers of highly flavoured food and drinks are likely to receive a cocktail of flavourings ingredients.

Intake of flavourings correlates with consumption of processed and pre-prepared foods. Consumers with higher intakes of soft drinks, alcoholic drinks, dairy products and ice cream, and confectionery are likely to be particularly high consumers of flavourings. Other food categories that provide significant amounts of flavourings include bakery products, as well as other processed and canned foods.

Estimates of relative intakes of some of these foods by age and gender can be taken from dietary survey data and are shown in Table 2. These data relate to mean intakes however, and therefore intakes by some individuals are likely to be considerably higher.

TABLE 2: Mean consumption of foods and drinks that are high in flavourings in the UK, by age group per day

Food/drink g/day	Children 1½-3 years	Children 4-10 years	Children 11-18 years	Adults 19-64 years	Adults 65+ years
Confectionery	23	34	42	33	29
Biscuits, buns, cakes, pastries and fruit pies	31	50	60	56	61
Yoghurt / fromage frais and other dairy desserts	54	54	55	73	74
Ice cream	21	28	33	29	30
Soft drinks	463	479	663	559	335
Alcoholic beverages	-	-	711	920	611

Data are based on mean intakes by consumers of those foods or drinks.

Source: Rolling National Diet and Nutrition Survey (2008/9 and 2009/10 data combined), (Department of Health, 2011).

Eating outside the home

More than one in six meals is now eaten outside the home. Due to an absence of labelling requirements and no information in the public domain about the level of flavouring used by the food service sector, it is not possible to comment on its contribution to flavourings in the overall per-capita diet. However, given the increasing number of meal occasions outside the home, there is at the very least a need for information on flavour use, to gauge the contribution to overall flavouring consumption, and to allow consumers to make informed food choices.

2.4 Use of flavourings in high-fat, high-sugar and high-salt foods

Processed foods and drinks that are high in fat, saturated fat, sugar or salt (HFSS) are generally discouraged when looking at ways of making our diets healthier. Guidance on healthy and sustainable diets across the EU recommends that these foods are limited (Westland and Crawley, 2012). Most processed foods and drinks contain some flavouring as shown in Table 1, and many of these foods and drinks also tend to be high in fat, salt and/or sugar. The widespread use of flavourings to encourage consumers to eat and drink more HFSS foodstuffs is therefore counter-productive to efforts to alleviate chronic diseases caused by poor diet.

Soft drinks and confectionery are often composed of relatively cheap, tasteless base materials that derive their taste from cheap and simple fats, or salty or sweet flavours. The products themselves vary very little in terms of their basic ingredients. For example, soft drinks are offered in a multitude of varieties, and yet usually contain the same basic ingredients – sugar or sweetener, water, colouring, preservative and flavourings.

Processed foods that are HFSS and foods with added flavourings are disproportionately represented in the diets of many young people in the UK. There are many reasons for this, including:

- their easy availability from retail outlets near schools and from other settings where children and young people may socialise or meet
- the relative cheapness of such foods in terms of price per calorie in comparison to unprocessed alternatives
- marketing spend on processed foods being much higher than investment in government-approved or sponsored healthy eating campaigns, and
- the use of bright and attractive packaging and marketing of these products as well as endorsement by celebrities, leading to peer pressure and the glamorisation of HFSS foods and specific brands of these foods.

In his book *Fast Food Nation*, Eric Schlosser highlighted the use of flavourings by fast food chains and how these can have a lifelong impact on food choice:

“The flavours of childhood foods seem to leave an indelible mark, and adults often return to them, without always knowing why. These ‘comfort foods’ become a source of pleasure and reassurance, a fact that fast-food chains work hard to promote.” (Schlosser, 2002).

Very few studies have looked specifically at the impact of convenience foods on the diets of children. However, one notable study conducted by Alexy et al (2008), which analysed the impact of convenience foods in the diets of German children, concluded that diets high in convenience foods were higher in fat than diets of similar energy content with fewer convenience foods. Flavourings and/or flavour enhancers were found in about half of the convenience food products consumed.

The authors commented that frequent consumption of a low variety of foods with standardised flavouring is likely to result in a taste standardisation and a loss of the specific taste of 'mothers' cuisine'. As they grow up, children may choose foods with a similar taste with low nutritional value as a result.

2.5 Estimating the amount of flavourings added to individual foods and drinks

Estimating the amount of flavourings used in individual foods and drinks is problematic for a number of reasons:

- Food manufacturers are not required to label individual foods and drinks with information about the quantity of flavouring they contain.
- There are no standard levels of usage of flavourings in similar products.
- Usage of flavourings will vary depending on the carriers used.
- Flavourings may be added in manufacturing processes, but some may 'fall away' during production. For example, a powdered crisp flavouring might be added during production at a certain level, but some of this will fall off on the production line.

However, it is likely that flavourings are present in relatively small amounts in most processed foods and drinks, and that the range of content may be very variable.

Consumer concerns

A Europe-wide survey of 27,000 consumers on their perception of food-related risks published in 2010 (EFSA, 2010c) found that 19% of consumers cite chemicals, pesticides and other substances in foods as major concerns in their perception of food-related risks. Concern over chemicals in food was higher than concern about bacterial contamination of foods, and diet-related issues. Despite this, many consumers are unaware that foods they commonly buy and eat contain ingredients such as flavourings from chemical source materials.

3 WHO PRODUCES AND SUPPLIES FLAVOURINGS?

3.1 Flavourings companies

Most companies that supply flavourings to the food and drink industry also supply fragrances for use in non-comestible products like perfumes, cosmetics, toiletries and household cleaning products. Both flavourings and fragrances are often referred to as 'aroma chemicals', with many of the same raw materials and similar production processes. The top 10 flavouring companies in the world controlled more than 90% of the flavour and fragrance market in the financial year ending 2009 (Leffingwell and Associates, 2010). Approximately 400 companies make and sell flavourings worldwide. With recent mergers and acquisitions, it is clear that the larger companies are controlling a greater percentage of the market each year. Market leader Givaudan acquired Quest International, ranked in fifth place, in 2007, giving it an almost 20% share of the market. In the same year the third largest company, Firmenich, acquired the 12th largest, Danisco Flavors, making it the second largest. The industry is increasingly globalised, and 9 of the top 10 companies operate on all continents. (T Hasegawa operates only in Asia and North America.)

The top 10 companies have significant research and development programmes covering a wide variety of activity, including the development of specialist technologies for creating and testing flavours, adding flavourings to products, understanding how humans experience flavour, and growing or harvesting plants in ways that result in the development of desired flavours. Some, such as Givaudan and IFF, have their own botanical gardens with thousands of fruit and aromatic plant varieties that are used as reference materials by flavourists (Halliday, 2009b). The biggest firms are vertically integrated with their own plantations or long-term agreements with producers of essential raw materials for their most important product lines, such as citrus and vanilla. In addition, a number of companies only supply flavouring chemicals and components to the flavour companies or directly to manufacturers and do not do any blending or flavour composition (for example, SAFC, Treatt, and DSM Food Specialities).

According to Leatherhead Food Research (2011), the global market for flavourings was worth approximately \$7.35 billion in 2010. Givaudan, Firmenich and IFF have been the top three companies in the sector every year since 2000, controlling in excess of 55% of the market between them (Euromonitor International, 2008), although there have been shifts within their ranking. Table 3 shows the ranking of the top 10 companies in 2007 according to the estimated percentage share of the flavourings market they controlled (Euromonitor International, 2008).

TABLE 3: Top 10 global companies, by share of the flavourings market, 2007

Company name and location of head office	Estimated percentage share of global flavourings market by value
1 Givaudan – Geneva, Switzerland	26%
2 Firmenich – Geneva, Switzerland	16%
3 IFF – New York, USA	13%
4 Symrise – Holzminden, Germany	10%
5 Sensient Flavors and Fragrances – Milwaukee, USA	10%
6 Takasago – Tokyo, Japan	5-10%
7 T Hasegawa – Tokyo, Japan	5%
8 Frutarom – Haifa, Israel	3%
9 Mane SA – Le Bar-sur-Loup, France	2%
10 Robertet SA – Grasse, France	2%

Source: Euromonitor International (2008).

A snapshot of the world's biggest flavour company

The world's biggest flavour company – Givaudan – typifies the complex, multi-dimensional and global nature of the top end of the flavourings business. Its headquarters are in Geneva, from where it oversees field offices on every continent, with more than 45 subsidiaries and almost 9,000 employees. Sales of flavours reached almost \$2.4 billion in 2010, when it controlled around a quarter of total world sales (Leffingwell and Associates, 2010). Givaudan produces flavourings for some of the biggest companies in the world, such as Coca-Cola, and keeps its lead through acquisitions and a multi-million pound annual research and development budget. The company runs annual 'taste treks' when expert staff visit a region of the world to look for new ideas and source materials for flavourings in local markets, farms or forest areas, sometimes staying for weeks. It is able to bring highly technical proprietary equipment into the field, such as a device that can measure the flavouring profile of fruit while it is still hanging from the tree. Givaudan is also investing in new flavourings production technology, including research into bio- and nanotechnology. It places high importance on collaboration with customers, tracking consumer needs and, more recently, sustainability reporting (Givaudan, 2010; Khatchadourian, 2009; Leffingwell and Associates, 2010).

Corporate social responsibility of flavourings companies

Consumers are increasingly aware of issues of social justice, animal cruelty and environmental sustainability, and retailers and food and drink manufacturers increasingly offer certified products that meet (their own or third-party) criteria on ethics and/or sustainability. Some of the largest companies are taking on board the need for more information through the food supply chain and in the last three years there has been a trend towards producing annual corporate and social responsibility (CSR) or sustainability reports that provide some information on environmental, labour and development issues relating to their operations and sourcing.* However, the glossy, positive reports are not independently audited and tend to focus on environmental performance with regard to issues such as waste management and internal resource consumption. In keeping with general food industry trends towards health and wellness there is also a tendency for companies to focus on the use of flavourings to develop healthier food products with less fat, salt and sugar and/or added vitamins and minerals. Natural flavouring collections have also been heavily promoted in recent years, as the new flavouring regulation (EC 1334/2008) provides definitions for use of the term 'natural'.

Flavourings companies, and food manufacturers that sell products with flavourings, can subject their products to voluntary labelling schemes such as:

- Organic labelling (incorporating wild harvest guidelines), led in the UK by the Soil Association
- Marine Stewardship Council labelling for the use of sustainable fish sources
- Fair trade certification
- Vegetarian and vegan labelling, and
- Halal and Kosher certification.

For more on the use of these certification schemes in relation to flavourings, see section 6.4.

Flavouring companies are subject to other areas of concern, such as the need to properly investigate whether they are involved in:

- biopiracy (exploitation of traditional knowledge and crops for commercial profit)
- land grabs or farming in developing countries by foreign companies who produce food or food ingredients for export, rather than crops for sale in local markets, and
- species extinction or endangerment, specifically in regard to plants used in the production of flavourings.

* As of December 2011 the top four companies produced annual CSR/sustainability reports. Takasago produced a slender report containing only environmental information.

These issues are not investigated in this review. However, we do recommend that companies should indicate in their CSR and sustainability reports that they will not take part in these activities, and outline whether they have a public monitoring system to ensure this.

3.2 Development and production of flavourings

The development of flavourings for use in foodstuffs combines current knowledge about taste perception with technological advancements in flavour production and delivery. On the technology side, for example, research and development on flavour delivery has resulted in technologies that allow some flavourings to be released all at once in 'bursts' of taste, whilst others may emerge more slowly or in repeated bursts, and some may fizz. Some flavourings are mass produced cheaply, while others are specially produced for high value foodstuffs.

Methods for producing flavourings are under continuous development:

- New source materials may require new production/processing methods.
- A flavouring may exist only in a form that is unsuitable for use in a particular category of product – for example, an essential oil that cannot easily be incorporated into a beverage product.
- A natural source for a flavouring substance may not have been found, preventing the final product from being labelled as 'natural'.
- A cheaper, artificial source with no supply chain complications may be required.
- New production methods can increase the amount or quality of a flavouring compound that can be extracted from, or produced with, the source material.
- Some production methods may produce undesirable residues or by-products.
- Some production methods are costly, or rely on scarce raw materials (both chemical and natural).

Recipes for creating flavours

Flavourings are produced in different forms, most commonly as gels, liquids, pastes, powders or oils. The form depends on the type of source material, the technique used for the production of the flavouring, and the characteristics of the food or drink product it is intended to be used in. A flavour is composed of three 'notes': the top notes, which are tasted first, the middle notes, and the lingering base notes (Clay, 2011).

Flavourists use a variety of reference sources to create their recipes for flavouring mixtures. Standard recipes, such as those in *Flavours and Essences – A Handbook of Formulae* (Gazan, 1936), have been adapted for new techniques and tastes. Flavourings have been described as jigsaw puzzles – assemblies of seemingly unrelated pieces that together provide the overall flavour profile (Wright, 2008). Sample recipes for some flavourings are contained in books such as *Ziegler's Flavourings: Production, Composition, Applications, Regulations* (Ziegler, 2007).

The chapter on blended flavourings includes basic recipes for apple, banana, pear and pineapple flavours, all of which use exactly the same chemical components but in different quantities (Grab, 2007). It follows that each chemical can be used in many different flavourings.

For example, Oxford Chemicals' 2,4,5-trimethyloxazole (C₆H₉N₀) is a newly marketed flavouring substance found naturally in beef, cooked pork, cocoa and coffee. The artificial flavour is marketed as a 'fatty', 'boiled beef', 'wasabi', 'nutty', 'cauliflower' and 'brothy' flavour. It is sold in liquid form and recommended for use in beef, chocolate, cocoa, coffee, pork and other nut flavour creations where it is often combined with other ingredients to complete the flavour profile required (Perfumer & Flavorist, 2008).

Smoke flavourings are typically made by heating wood in an atmosphere with a limited supply of oxygen (pyrolysis). The vapours are condensed into a liquid and separated into different components, before being added to food or drink. Smoke flavourings are regulated separately from other flavourings as some of the compounds created in the production of smoke flavourings, such as volatile nitrosamines, give rise to different safety issues.

Flavour companies conduct considerable amounts of consumer research to keep abreast of flavour trends and preferences in different parts of the world, so that they can offer appropriate products. Flavourists often work closely with research chefs. The chefs develop real food recipes to produce 'gold standard' flavours, which the flavourists then strive to replicate using the flavourings in the company's portfolio (Halliday, 2008). Companies also collaborate closely with their customers to develop the specific flavour required for a particular product.

4 OVERVIEW OF REGULATIONS ON FLAVOURINGS

A list of all the EC regulations and legislation relevant to flavourings is given in Appendix 2.

4.1 The regulatory framework

As explained in section 1.2, the use of flavourings in the UK is governed by Regulation EC 1331/2008 on common authorisation procedure, and by the EU regulatory controls in Regulation EC 1334/2008 on Flavourings and Certain Food Ingredients with Flavouring Properties for Use in and on Foods.

Regulation EC 1334/2008 provides for a 'Community list' of approved flavourings and source materials (also known as the Union list, see section 4.2). It sets the conditions for their use, such as conditions on the presence of biologically active principles (BAPs), over which there are toxicity concerns. It also sets rules for labelling, such as when the term 'natural' can be used (see section 6) and what information should be provided in business-to-business and business-to-consumer contexts.

The regulation also sets out definitions for different categories of flavourings, according to their source materials and production processes, and makes procedural provisions for implementation and transition, including monitoring and reporting by Member States.

The regulation is intended to ensure the effective functioning of the internal market for food flavourings, and to protect consumer health and interests, such as by ensuring fair practices in the food industry. It also aims, where appropriate, to help protect the environment.

Regulation EC 1334/2008 over-rides all other flavourings-specific regulations in the 27 EU Member States, including the UK, although it has been drafted to ensure it is compatible with other governing frameworks relevant to the worldwide flavourings industry, namely:

- the Codex Alimentarius Commission (which sets international food standards)
- Codes used by the Food and Drug Administration of the United States, and
- general food law provisions as set down in Regulation EC 178/2002 which requires those involved in the production and sale of food to safeguard consumers, and not to mislead them as to the nature of the food they are consuming.

Smoke flavourings are subject to separate regulations and will have their own Union list (see section 4.2).

4.2 The Union list

Regulation EC 1334/2008 provides for the publication of a 'Community list' of flavourings and source materials that have been evaluated for their safety and are approved for use in the EU. Since the entry into force of the Lisbon Treaty on 1 December 2009, the correct term is the Union list. It is therefore referred to as the Union list in this review. The Union list actually has its origins in Regulation EC 2232/96, which forms part of the foundations upon which the Food Improvement Agents Package (FIAP) is built (see section 1.2). This earlier regulation required Member States to notify the European Commission of all the flavouring substances lawfully marketed in their territory, and for the European Commission to adopt a register of these flavourings. The Regulation also required the Commission to establish an evaluation programme, which it did via Commission Regulation EC 1565/2000.

Each entry in the Union list must include the identification of the flavouring or the source material approved and, where necessary, the conditions of use. The list may be amended as new flavourings are evaluated and approved in accordance with the common authorisation procedure set out in Regulation EC 1331/2008. Eventually, of those that require evaluation (see Table 5 on page 45), only flavourings that are positively approved and which are on the Union list will be able to be sold in the EU or used in foods and drinks to be sold in the EU. Flavourings that require evaluation and which are not listed will be prohibited.

However, at the time of publishing this review (March 2012), the Union list had not yet been published by the European Commission, despite an initial deadline of January 2011. The Union list is currently expected to be published in June 2012 (DG SANCO, personal communication, 2012). It appears that the publication of the list will go ahead even though EFSA has not been able to complete the evaluation of flavouring substances currently in use in the EU.

While the majority of flavourings have been evaluated under this programme, EFSA considers it does not have sufficient data on around 400 flavourings to inform a final opinion. These data were not necessarily requested of the industry at the beginning of the evaluation programme. EFSA has set a deadline of December 2013 for flavour companies to supply these data from 90-day studies and general toxicity studies. The 400 unevaluated flavourings have all been assessed and approved by the Joint WHO/UN Expert Committee on Food Additives (JECFA), which considers them safe for human consumption.

The status of these 400 flavourings in respect of the anticipated Union list, until such time as they can be evaluated, is unclear. When the list is published, the European Commission will make a proposal concerning them. As their use is widespread, temporary removal from food and drink products pending evaluation

would have a negative economic impact that the European Commission, and flavouring and food industries, would wish to avoid.

Which flavourings must be evaluated and approved?

Flavourings and source materials for which evaluation and approval are required are:

- flavouring preparations of vegetable, animal or microbiological origin other than food
- thermal process flavourings obtained partly or totally from materials other than food
- smoke flavourings
- flavour precursors obtained from material other than food
- other flavourings that are not flavouring substances or flavour precursors, and source materials of vegetable, animal, microbiological or mineral origin other than food.

Evaluation and approval are **not** required for:

- flavouring preparations obtained from food
- thermal process flavourings obtained from food
- flavour precursors obtained from food, or
- food ingredients with flavouring properties.

Further explanation is given in Table 5 on page 45. The process for evaluation and approval is described in detail in section 5.

Timing of the new regulations

EC Regulation 1334/2008 entered into force in January 2009, but did not enter into application in all EU Member States until 20 January 2011 (EC 1334/2008 Article 30). The new definitions of flavourings and the new labelling rules, including the use of the word 'natural', have applied since that date.

The entry into application is not linked to the date of entry into force or date of application for the Union lists of flavouring substances or smoke flavourings. These dates will be determined in respective future measures.

Regulation 1334/2008 allows a window of 18 months from the application of the Union list, during which foods and drinks containing flavourings that are not on the list may still be sold (as long as the foods concerned comply with basic food safety requirements), in order to allow for the sale of products with long sell-by dates (see Article 30/Article 10). This means that, if the Union list is adopted in September 2012 three months after its planned publication, then by March 2014 there should be no flavourings on the market that are not on the list. As noted on page 37, however, the Commission will make a proposal in respect of the 400 flavourings for which full data are still required to inform EFSA's evaluation.

Flavouring substances that are on the Union list will not be re-assessed for safety unless new information about risks comes to light. However, flavourings may be taken off the market at any time under safeguard measures if new scientific evidence of risk becomes available at any time. Smoke flavourings on an approved Union list will be re-assessed for maintenance on the list after 10 years.

All new flavouring substances or smoke flavourings that are intended to come onto the market after the first Union lists are published will have to be evaluated by EFSA, which will duly publish opinions to inform their inclusion on the Union list. EFSA has published guidelines on the data it requires to carry out evaluations (EFSA, 2010b). Flavourings companies may submit data on new flavourings to EFSA before the publication of the Union list, but the regulation states that there is no timescale for EFSA to complete an evaluation as flavourings already on the market that have not yet been evaluated must take priority.

4.3 Categories of flavourings

In the past there has been considerable variation in the naming and categorisation of flavourings between EU Member States. Driven by the European Commission's wish to harmonise the internal market of the EU, EC Regulation 1334/2008 categorises and defines flavourings. The categories of flavourings are:

- flavouring substances
- natural flavouring substances
- flavouring preparations
- thermal process flavourings
- smoke flavourings
- flavour precursors
- other flavourings.

Table 4 sets out the definitions for these flavouring categories, along with examples of flavourings in each category.

The regulation specifies the types of source materials which can be used to produce flavourings in each category, and the processes that may be used to produce them, whether chemical or physical, microbiological or enzymatic.

The word 'natural' can only be used to describe a flavouring if the flavouring component comprises only 'natural flavouring substances' and/or 'flavouring preparations', and even then there are specific requirements as to the use of the term which are explained on page 54. The term 'natural flavouring' can never be used for thermal process flavourings, smoke flavourings, flavour precursors or food ingredients with flavouring properties.

TABLE 4: Categories of flavourings

This table gives the definitions of different categories of flavourings, as used in the EC regulations on flavourings (EC Regulation 1334/2008).

Category	Definition	Examples
Flavouring substance	Defined chemical substances (ie. their make-up has a single, defined, chemical formula) obtained by chemical synthesis or isolated using chemical processes.	<ul style="list-style-type: none"> Vanillin (C₈H₈O₃/152.15): Can be obtained by chemical extraction from the waste liquid of the wood pulp industry or synthesised from guaiacol (a petrochemical product). Rhodinyl formate (C₁₁H₂₀O₂/184.26): Can be obtained by treating rhodinol (extracted from geranium essential oil) with formic acid to produce a rose-like odour and a bittersweet, cherry-like taste. Benzaldehyde (C₇H₆O/106.12): Can be obtained from the oxidation of toluene to produce an oil with the flavour of almond. Ethyl butyrate (C₆H₁₂O₂/116.16): This is an ester, a type of chemical compound that can be formed by reacting an oxoacid with a hydroxyl compound such as an alcohol or a phenol. It has a fruity odour with pineapple undertones.
Natural flavouring substance See section 6 on use of the term 'natural'.	Defined chemical substances obtained by physical, enzymatic or microbiological processes from vegetable, animal or microbiological materials used either raw or after processing. ¹	<ul style="list-style-type: none"> Vanillin (C₈H₈O₃/152.15): A chemical substance identical to the one above, but which is not derived through chemical synthesis or isolation but through fermentation of an allowable source material. The source material must be vegetable, animal or microbiological in origin, but will not necessarily be from the vanilla plant, as vanillin occurs widely in nature. Citric acid (C₆H₈O₇/192.12): Obtained by various means including yeast fermentation using molasses and types of <i>Aspergillus niger</i>. Both benzaldehyde and ethyl butyrate can be produced in natural form.
Flavouring preparation May be labelled 'natural' depending on how it is used. See section 6 on use of the term 'natural' and on labelling criteria.	A product, other than a flavouring substance, obtained from food or material of vegetable, animal or microbiological origin using physical, enzymatic or microbiological processes. Materials may be raw or processed. ¹	<ul style="list-style-type: none"> Vanilla extract: from vanilla beans. Cedar leaf oil: from cedar tree leaves and branches. Cinnamon bark extract. Cinnamon bark oil.
Thermal process flavouring	A product obtained after heat treatment from a mixture of ingredients not necessarily having flavouring properties themselves, of which at least one contains nitrogen (amino) and another is a reducing sugar. The ingredients for the production of thermal process flavourings may be food and/or source materials other than food (of animal, vegetable or microbiological origin). The Maillard Reaction is one of those that produces a thermal process flavour.	<ul style="list-style-type: none"> Gravy granules contain ingredients whose flavour is released when they are heated with boiling water. Packet, dried soups also contain such ingredients – so that the consumer gets a 'hit' of odour and flavour when hot water is added. A ready meal meat dish can use thermal process flavouring to give a grilled meat taste without needing to grill the meat. Reducing sugars include dextrose/glucose and xylose. Nitrogen sources include amino acids and their salts, peptides and proteins from foods.
Smoke flavouring	A product added to foods to give a smoked flavour, as an alternative to traditional smoking. The products can be obtained by fractionation (separation) and purification of condensed smoke yielding primary smoke condensates, primary tar fractions and/or derived smoke flavourings.	<ul style="list-style-type: none"> Scansmoke SEF 7525 is a primary smoke extract made from hardwood type smoke and is one of only three smoke flavours for which there are no safety concerns for proposed uses and use levels.

Category	Definition	Examples
Flavour precursor	<p>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 food or other source materials.</p> <p>Precursors are a very wide variety of substances that are added to foods and drinks and which produce flavour when they are processed, not simply with the addition of heat. This can be through pressure change, enzymes, PH alteration or exposure to light.</p>	<ul style="list-style-type: none"> Flavour precursors include: carbohydrates, oligopeptides and amino acids. They are used in ready meals, powdered beverage mixes and sauce mixes.
Other flavouring	<p>A flavouring added or intended to be added to food in order to impart odour and/or taste and which is not one of the previous categories.</p>	<ul style="list-style-type: none"> Rum ether: A compound that is synthesised, with no natural form, in a liquid state with a burnt/smoky odour for use in caramel, bacon, vanilla, and brandy drinks. Gas chromatography has identified 22 separate components of rum ether in various concentrations (Burdock, 2010). An example could be flavouring that is obtained by heating oil or fat to an extremely high temperature for a very short period of time, resulting in a grill-like flavour. So, for example, vegetables could be made to taste 'grilled' even if heated in a microwave. This process could be similar to thermal process flavouring, but is categorised as 'other flavouring' if it does not have the legally defined constituents of a thermal process flavouring. Crucial to the definition is that the oil is not added for the oil content but for the purpose of flavour.
<p>Food ingredient with flavouring properties</p> <p>Not technically a category of flavouring, but covered by EC Regulation 1334/2008</p>	<p>A food ingredient which is not a flavouring but which may be added to food for the main purpose of adding flavour to it or modifying its flavour and which contributes significantly to the presence in food of certain naturally occurring undesirable substances (also called BAPs – biologically active principles).</p>	<p>Crucially, this category only includes ingredients that add 'undesirable' substances (BAPs) to food. The undesirable substances are detailed in the Appendices of EC Regulation 1334/2008. BAPs are chemical substances that occur naturally in a number of natural flavouring source materials but which, in some cases, cannot be deliberately added to food and in other cases can only be added in controlled doses to particular food categories, so that final foodstuffs sold to the consumer do not exceed set limits.</p> <p>Examples include:</p> <ul style="list-style-type: none"> Quassin (from the quassia tree) which cannot be added as such to food but which, if naturally present in flavourings or in food ingredients with flavouring properties, can be added to baked goods, generally to provide a bitter taste, as long as final amounts in those foods do not exceed set limits. Almond bitter oil from <i>prunus amagdalus</i>, which cannot be sold in unrectified form due to the presence of hydrocyanic acid which is a BAP. The tetraploid form of <i>acorus calamus l.</i>, which must not be used in the production of flavourings and food ingredients with flavouring properties due to the presence of <i>beta-asarone</i> (Appendices III and IV of EC Regulation 1334/2008). <p>The information on BAPs will be continually updated by regulators.</p>

1 Acceptable methods for processing foods beyond the raw are specified in Annex II of EC Regulation 1334/2008.

Sources:

Categories and definitions: EC Regulation (EC) No 1334/2008.

Examples: Burdock (2010), EFFA (2010), and the EFSA website www.efsa.europa.eu

4.4 Source materials

Source materials are crucial for determining the category into which flavourings fall. Individual flavourings are made from or derived from food, or materials of vegetable, animal, microbiological (bacteria, yeasts) or mineral origin other than food, or via chemical means. Vegetable, animal, microbiological and mineral source materials can be raw, or they can be processed using a range of means outlined in Annex II of EC Regulation 1334/2008.

Any flavouring that holds the label 'natural' must be derived from raw or processed food or materials of vegetable, animal or microbiological origin using specified physical, enzymatic and microbiological processes; chemical processes are not acceptable. Individual flavourings are then combined in mixtures to produce flavouring combinations that are used in foodstuffs.

Although information on source materials is collected as part of the risk assessment and approval procedures for flavourings, there is no up-to-date registry of all such information in the UK. The market is constantly evolving in terms of flavourings on offer (Burdock, 2010; Anthony, 2009; Ziegler, 2007), so it is not possible to be entirely specific about the source materials of all flavourings in the market. For example, one could not say exactly what types of strawberry flavourings are currently on sale across the UK market in terms of their full ingredients, or the sourcing or production of each.

There are several source books which give details of source materials used in flavourings. For example, *Fenaroli's Handbook of Flavor Ingredients* contains approximately 2,700 flavourings ingredients/source materials of all types and in all categories, as well as lists of food categories in which they are generally used, sources of origin, derivatives and composition. Although considered an industry 'bible', it does not cover all the source materials for flavourings on the market at a given moment. For example, its inclusion of 'botanicals' (flora sources) is still relatively new (Burdock, 2010).

Petrochemicals are the most common source materials for flavourings in the category 'flavouring substances' (Berger, 2007; Krammer, 2007). Petrochemicals can be processed to provide hundreds of different molecules that are of use in flavourings mixtures of all types.

Regulation EC 1334/2008 recognises that some source materials, including plants traditionally used as foods or food ingredients, contain naturally occurring substances that are considered undesirable due to toxicological concerns. Generally the presence of such undesirable substances originating from source materials is considered by EFSA in its evaluation of flavourings.

A small number of source materials listed in Annex IV of the regulation may be used in the production of flavourings or foods with flavouring properties only under certain conditions. For example, quassia may be used as a source material only for flavourings and foods with flavouring properties for use in bakery and

dairy products; white agaric mushroom, St John's wort, and wall germander may only be used as a source material for flavourings or foods with flavouring properties for use in alcoholic beverages.

4.5 Production methods

The category to which a flavouring belongs also depends on whether it is produced via physical, enzymatic, microbiological or chemical processes. A vast number of specific processes, some highly technologised, are encompassed within those four production categories (Ziegler, 2007). However, any flavouring labelled as 'natural' may be produced using physical, enzymatic or microbiological production methods, but not by any process involving chemical synthesis or isolation of molecules via chemical extraction. Flavouring substances that use chemical source materials may be subject to 'natural' processes (physical, enzymatic or microbiological) but they are not considered 'natural'.

- **Physical processes** include squeezing, slicing and steaming to release oils or juices from source materials.
- **Enzymatic processing** is used to increase the amount of oil or juices extracted from products, to separate skin from the flesh of fruit, or to speed up or increase the rate of transformation of a substance within a plant into a substance the flavourist desires. According to Menzel and Schreier (2007), around 400 enzymes are used in the production of various flavourings.
- An example of a **microbiological process** is the controlled fermentation of a source material.
- There are tens of thousands of **chemical processes** used to produce flavourings (Burdock, 2010). For example, vanillin can be extracted from vanilla; it can also be extracted from lignin, a by-product of the paper industry, using a chemical process, or synthesised from guaiacol (a petrochemical product). Synthesised vanillin is chemically identical to vanillin extracted using physical, enzymatic, and microbiological processes, but cannot be labelled as 'natural'.

Smoke flavourings are products that are added to foods including meat, fish, cheese, sauces, drinks and confectionery. The flavourings are an alternative to traditional smoking over actual wood or wood chips. Smoke flavourings are generally collected in a liquid (water or another solvent) as by-products of wood burning or charcoal making. This process can give rise to ingredients with toxic effects.

5 EVALUATION AND APPROVAL OF FLAVOURINGS

The EC's Food Improvement Agents Package of legislation (FIAP) provides for the publication of a Union list of authorised flavourings as described in section 4.2. This section describes the procedure for evaluating and approving flavourings for safe use within the EU.

5.1 Overview of the risk assessment process

The European Food Safety Authority (EFSA) has ultimate responsibility for the risk assessment of flavourings through its CEF Panel – the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids.

The European Commission's Standing Committee on the Food Chain and Animal Health decides whether to approve particular flavourings (or groups of flavourings) and include them in the Union list of flavourings approved for use. It makes its decisions based on EFSA's assessments.

It is within the power of EFSA to request information from government health and trade departments, and industry bodies, in order to fulfil their regulatory remit. Within the UK, the Food Standards Agency (FSA) is the main government body responsible for liaison with EU regulators on the issue of flavourings, via its Food Composition and Labelling Division. The Department of Health is responsible for nutritional and dietary work relating to flavourings, and the FSA for issues relating to food safety.

Which flavourings need to be evaluated?

Regulation EC 1334/2008 has divided flavourings into those which need evaluation and approval, for use in foods and drinks sold within the EU, and those that do not (see Table 5). Flavourings made from food do not need to be evaluated, while those made from sources other than food do. Evaluations are risk-based, and although substances arising from foods are not generally subject to separate toxicological evaluation, they are subject to broader conditions of UK food law around consumer protection.

TABLE 5: Categories of flavourings that need to be evaluated

For a description of the categories of flavourings, see Table 4.

Flavourings for which an evaluation and approval are required	Flavourings for which evaluation and approval are not required ²
<ul style="list-style-type: none"> • Flavouring preparations of vegetable, animal or microbiological origin other than food • Thermal process flavourings if obtained partly or totally from materials other than food and for which the conditions of production and maximum levels of use for certain substances are not observed¹ • Smoke flavourings • Flavour precursors obtained from materials other than food • Other flavourings that are not flavouring substances or flavour precursors, and source materials of vegetable, animal, microbiological or mineral origin other than food 	<ul style="list-style-type: none"> • Flavouring preparations obtained by appropriate physical, enzymatic, or microbiological processes from food, either in its raw state or after processing using a traditional food preparation process³ • Thermal process flavourings if obtained from food and if the conditions of production and maximum levels of use for certain substances are observed¹ • Flavour precursors obtained from food • Food ingredients with flavouring properties

1 The Conditions for the production of thermal process flavourings and maximum levels for certain substances in thermal process flavourings are set down in Annex V of EC Regulation 1334/2008. The conditions of production set down rules about the temperature, duration, and PH conditions during thermal processing. Maximum levels of use are set for two chemical substances used in thermal processing.

2 The conditions of use of all foods (including flavourings) sold within the European Union must conform to the general principles and requirements of food law – in particular, that a food shall not be placed on the market if it is unsafe (EC Regulation 178/2002). However, such flavourings will not require specific evaluation and approval under EC Regulation 1334/2008.

3 Food is defined as any substance or product reasonably expected to be ingested by humans. However, it can also include ingredients not generally used for food, such as strawberry leaves or rosewood, if it can be demonstrated that they have previously been used to produce flavourings.

EFSA guidelines for risk assessment of flavourings

Until relatively recently, EFSA only had methodologies in place to assess the risk of smoke flavourings (EFSA, 2010d, 2010e) and flavouring substances (an ‘interim’ methodology) prior to inclusion in the Union lists. Work on establishing new EU methods for risk assessments of new flavouring substances and other flavourings was the subject of an EU-wide consultation that ended in December 2009, with the final results published in June 2010 (EFSA, 2010b; CEF, 2010). As a general principle wherever possible new flavouring substances are assigned to one of the existing Flavouring Group Evaluations (FGEs) on the basis of structural and metabolic similarities, and are assessed according to the FGE’s existing methodology. However, where flavouring substances cannot be assigned to an existing FGE the guidance provides a procedure for risk assessment on an individual basis. The guidance also covers flavourings other than flavouring substances for which an evaluation and an approval are required according to Article 9 (b) – (f) of the Regulation EC No 1334/2008.

At the time of publishing this review, EFSA is prioritising risk assessment of flavouring substances already in use in the EU. Once that exercise is complete it will assess new flavourings that industry would like to place on the market; these will have to meet the requirements of the updated risk assessment guidelines.

EFSA

EFSA – the European Food Safety Authority – was set up in January 2002 (Regulation EC 178/2002) to improve EU food safety, ensure a high level of consumer protection and maintain confidence in the EU food supply. In collaboration with national authorities and in consultation with stakeholders, EFSA provides independent scientific advice and communication on existing and emerging risks. In the European food safety system, risk assessment is carried out independently from risk management. As the risk assessor, EFSA produces scientific opinions and advice to provide a foundation for European policies and legislation and to support the European Commission, European Parliament and EU Member States in taking effective and timely risk management decisions. EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health.

DG SANCO

The Directorate General for Health and Consumers – DG SANCO – has responsibility for ensuring that food (and other consumer goods) sold in the EU are safe. It has a key risk management role, and aims to ensure that the internal market works to the benefit of consumers, and that the health of European consumers is protected.

5.2 Status of EFSA evaluations of flavouring substances

The huge task of reviewing approximately 2,700 flavouring substances has taken years longer than originally envisaged. At the time of publishing this report (March 2012), about 2,500 flavouring substances are theoretically eligible for inclusion on the Union list. However, industry needs to provide further information for 400 before the assessments can be completed.

Flavouring substances already removed from sale

The following individual substances were removed from the European register of flavourings during the evaluation programme as there were toxicological concerns about their use as flavourings. Foods and drinks containing these compounds should therefore not be on sale in the EU:

- 4-allyl-1,2-dimethoxybenzene
- 1-allyl-4-methoxybenzene
- N-(4-hydroxy-3-methoxybenzyl)-8-methylnon-6-enamide
- Propyl-4-hydroxybenzoate

- Pentane-2,4-dione
- Acetamide
- 2-butylbuta-1,3-diene
- 2-methylbuta-1,3-diene (known as isoprene).

5.3 Status of EFSA evaluations of smoke flavourings

EFSA completed its initial assessment of the 11 smoke flavourings used in foods and drinks in the EU in summer 2010 (EFSA, 2010d, 2010e) and has recently reviewed additional evidence on two smoke flavours, Fumokomp and Zesti Smoke Code 10 for which there were originally insufficient toxicological data from the required 90-day toxicity studies in animals (EFSA, 2011a, EFSA 2011b).

Table 6 summarises the findings of the risk assessment for smoke flavourings. There were safety concerns about eight of the 11 smoke flavourings, including one for which genotoxic (damage to DNA) potential could not be clearly ruled out. These flavourings remain on sale while the EC decides what to do about them. It is possible that they could be included on the Union list with a requirement to alter their proposed uses or use levels.

In a press statement from EFSA (EFSA, 2010d), Klaus-Dieter Jany, the chair of EFSA's expert Panel on flavourings (CEF Panel) said:

"The Panel based its conclusions on the limited data which are currently available as well as conservative – or cautious – intake estimates. The Panel expressed safety concerns for several smoke flavourings where intake levels could be relatively close to the levels which may cause negative health effects. However, this does not necessarily mean that people consuming these products will be at risk as, in order to be on the safe side, the consumption estimates deliberately over-estimate intake levels."

Risk assessments for smoke flavourings are valid for 10 years, at which point a new assessment must be conducted.

TABLE 6: Findings of evaluations of smoke flavourings

Smoke flavourings	Findings
AM 01	Safety concern for proposed uses and use levels (genotoxic potential cannot be ruled out).
Fumokomp	No safety concern for proposed uses and levels.
Scansmoke PB 1110	Safety concern for proposed uses and use levels.
Scansmoke R909	Safety concern for proposed uses and use levels.
Scansmoke SEF 7525	No safety concern for proposed uses and levels.
Smoke concentrate 809045	No safety concern for proposed uses and levels.
SmokeEz C-10	Safety concern for proposed uses and use levels.
SmokEz Enviro 23	Safety concern for proposed uses and use levels.
TRADISMOKE A MAX	Safety concern for proposed uses and use levels.
Unismoke	Safety concern for proposed uses and use levels.
Zesti Smoke Code 10	Safety concern for proposed uses and use levels. This was reviewed again in 2011 and still not passed.

5.4 Methodology for assessments of flavourings

According to Regulation EC 1334/2008, the aim of the risk assessment of flavourings is to determine that:

“They do not, on the basis of scientific evidence available, pose a safety risk to the health of the consumer.”

The research and data used to assess safety comes from the flavourings industry and from scientific expert committees and regulators.

For each compound, a risk assessment is conducted by EFSA whose scientists review all the evidence made available to them and commissioned by them, and they publish an opinion. The European Commission then has the following options:

- Accept the flavouring for inclusion on the Union list.
- Accept the flavouring but with altered conditions of use – for example, making a requirement to ban use in certain foodstuffs or to reduce the level of use in products.
- Request more data of various types – for example: where it is used; level of use; further experimental data; immunotoxicity or neurotoxicity information; allergenicity and intolerance reaction information; human volunteer studies; and predictive mechanistic studies.
- Take the flavouring off the market.

The EFSA risk assessment guidelines for flavourings now:

- require the assessment of all flavourings from each category via the use of a single set of guidelines overseen by EFSA
- introduce new guidelines for the assessment of dietary intake that are less reliant on information about the amount of production of flavourings (although they still rely on information from industry about levels of use in foodstuffs)
- introduce new guidelines for the assessment of genotoxicity (damage to DNA), and
- require laboratory toxicological studies from industry that are of a stricter standard and type.

5.5 Assessing dietary intake for risk assessment purposes

Under the risk assessment guidelines, EFSA estimates intake of flavourings, and then works to wide safety margins designed to ensure safety in use with acute, chronic and cumulative exposure, and 'extreme' diets. Research is being carried out to identify better ways of measuring dietary intakes of food chemicals including flavourings (see details on FACET in section 2.2). This recognises a need for information that will enable better consideration of the combined effect of dietary chemicals on health.

The new methodology also takes account of acute, chronic and cumulative exposure through dietary intakes, in both adults and children. (Separate assessments are to be made for children and infants because the intake of flavourings per kilogram of body weight is higher than that for adults, and so any effects will be more significant.)

- **Acute levels** – those at which a flavouring substance would produce immediate negative effects on the body – may be determined. Questions will be asked about whether or not such levels could possibly be reached under the conditions of use.
- **Cumulative effects** are those that would occur over the course of a day – through the consumption of a range of foodstuffs.
- **Chronic effects** are those that would accumulate over a period of months or years.

As indicated in section 2, the estimation of dietary intake of flavourings is a difficult issue. Previous methods for estimating intake have been based on formulas that rely on industry production figures for flavourings. If, for example, a flavouring was produced in relatively low tonnages, used in relatively few foodstuffs, at low levels, and had a low toxicity class, it was not likely to be considered a safety concern. The new risk assessment guidelines will focus more on the level of use in particular foodstuffs in sample diets.

5.6 Are there still concerns about the safety of flavourings?

Much remains unknown about the impact of flavouring components on human health and on the health of children in particular, and assessments of safety are only as good as the data given to EFSA for review. Flavourings are generally used in very small amounts in foods and drinks and many people feel that the risk associated with their use is therefore minimal. The toxicity of some compounds remains under review by experts, however, and it is likely that as new data appear, the use of some flavourings may be further restricted. It could be argued that, where there is any doubt over safety, the use of a compound in foods and drinks should be restricted until evidence of safety is presented, but this is not the approach currently adopted.

An example of a potentially toxic flavouring compound

Diacetyl (also known as Butanedione and 2,3-Butanedione) is a chemical which is used, singly or in combination with other chemicals, to produce artificial flavours. These are mainly dairy flavours (for example, butter, cheese, sour cream, egg, and yoghurt flavors), brown flavours (for example, caramel, butterscotch, brown sugar, maple and coffee flavors) and some fruit flavours including strawberry, raspberry and banana. It is also used in vanilla, tea, and other flavourings.

Diacetyl has been linked to the lung disease bronchiolitis obliterans, known as 'popcorn workers' lung' after a number of cases developed among workers in the US making butter-flavoured microwave popcorn, which uses diacetyl in relatively high concentrations. Workers in restaurants or commercial kitchens are also at potential risk, since diacetyl is used in some cooking oils and sprays. When heated for cooking, these ingredients can release toxic vapours. EFSA has declared that diacetyl is safe when ingested in amounts used in foodstuffs (EFSA, 2011c), but the impact when inhaled by those working with this flavouring has not been considered. California State Assembly Bill 514 was approved in 2007 to prohibit the use of food flavourings containing diacetyl in the workplace in California.

6 LABELLING OF FLAVOURINGS

6.1 Labelling regulations

Flavourings used in packaged and prepared food and drink products are subject to:

- flavourings-specific labelling rules
- general food labelling rules, and
- compositional and marketing requirements for certain foods or food ingredients.

Such rules are set down with the intention of ensuring that consumer health is protected, that the consumer is not misled as to the nature, substance or quality of a product, and that fair trade is protected. It is the responsibility of food manufacturers to ensure that products are labelled as required by legislation. Essential information that supports consumer choice must be given top priority in terms of placement and prominence. Previously the Food Standards Agency published guidance on clear food labelling, and this remains the case in Scotland and Northern Ireland, but in England and Wales this responsibility has moved to DEFRA and at the time of writing this report (March 2012) the guidance notes were being updated. Previous FSA guidance notes on food safety and food labelling can be accessed at: <http://webarchive.nationalarchives.gov.uk/20100817075455/http://www.food.gov.uk/foodindustry/guidancenotes/>

There are mandatory labelling requirements specifically relevant to flavourings, that cover:

- product naming requirements, including use of the words 'flavour' or 'flavoured', and 'smoked' or 'smoky' in product names, and the use of pictures on product labels
- how the flavourings should be listed in the ingredients list (see page 53)
- the use of the word 'natural' to describe flavourings (see page 54)
- notification about GM content (see page 58), and
- notification about allergen content (see page 58).

Product labels may also include information about flavourings that is not mandatory – for example, giving reference to particular certification schemes. Flavourings companies can pursue voluntary certification for their products by organisations that set down requirements for: organic; halal; kosher; fair trade; sustainable fisheries; vegetarians; and vegans. The requirements are set down by the relevant certification bodies, and are not set out within labelling regulations and directives. These are described in more detail in section 6.4.

Foods sold loose, or catered foods prepared or packed on site, are subject to much less stringent requirements in terms of food labelling. Such goods are not required to provide a list of ingredients, nor do they need to declare their flavouring content. The new Food Information Regulation (FIR) Regulation EU 1169/2011 does require labelling of allergenic ingredients for non-prepackaged foods however, and this requirement applies also to flavourings.

Information about the monitoring of labelling of flavourings is given in section 7.

Labelling of flavourings provided to food manufacturers

When a flavouring company provides a flavouring mixture to a food manufacturer, the flavouring company needs to label the product under rules set down in Regulation EC 1334/2008. Of particular relevance to this review are requirements for listing:

- information about BAPs (undesirable substances called biologically active principles)
- all of the categories of flavouring present, in descending order of weight
- an indication of the amount of each category present, and
- a list of other materials in the product, if relevant, along with percentage amounts and E numbers if applicable.

For example, a strawberry flavouring mix might include: ethyl butyrate at 1.0%, ethyl acetate at 2.0%, vanilla extract at 4.0%, lemon oil at 3.0%, and the solvent propylene glycol at 90%. The label provided to the food manufacturer would state: flavouring preparations 7.0%; flavouring substances 3.0%; and solvent – propylene glycol – 90.0%. If questioned, the food manufacturer would be able to state that they use X flavouring company's strawberry flavouring at 0.1% in their formula for 'Fred Bloggs Strawberry Flavour Iced Dessert' – although this information would not be included on the product label for consumers. The authorities could ask the flavouring company for a breakdown of its formulation if they so wished, but this would not go into the public domain or be provided to the food manufacturer (personal communication with a flavourist, 2010).

The percentage of the solvent may be need to be given, as there are laws on the amount of some solvents in finished products, so the food manufacturer has to know how much it is adding to its foodstuffs. Some solvents are regulated food additives, and some have E numbers to aid their identification. Some solvents are not subject to particular regulation – for example, water can be used as a solvent.

6.2 Consumer information for packaged foods and drinks

Compositional standards

Food standards, and to some extent food marketing regulations, set out specific requirements for the labelling and composition of some basic foods. The FSA states that these basic foods are: infant formulas and follow-on formulas; bottled waters; milk and milk products such as cheese or ice cream; bread and flours; fats and oils; meat products; cocoa and chocolate products; soluble coffee; fruit juice and nectars; honey; jams and marmalades; and sugars. DEFRA also enforces horticultural marketing standards for the labelling of fresh fruits, vegetables and nuts.

These foods are said to have 'reserved names' or 'reserved descriptions' because they must meet specific compositional standards. The specific standards exist for these foods because they are seen as at particular risk of 'adulteration', with lower-quality alternatives being misleadingly substituted.

Foods within these categories, with the exception of infant formula, may be processed to include the addition of flavourings. However, if they are altered in such a way, the naming and labelling of the product must fundamentally change so as not to mislead the consumer as to the nature of the product. For example, if chocolate contains flavourings that mimic the taste of cocoa, it cannot be called a chocolate bar but it could be called 'chocolate flavour bar' or 'chocolate bar with flavouring'.

The ingredients list

Flavourings will be referred to using the term 'flavourings' or a more specific description if appropriate – for example 'flavouring substance', 'flavouring preparation', 'thermal process flavouring' or 'food ingredient with flavouring properties'. A further description can be added, for example, 'X flavouring', or 'X flavouring substance'.

- The term 'smoke flavouring/s from X' (where X is the wood source used for production of the flavouring) will be used if the flavouring component contains smoke flavouring and gives a smoky flavour to the food.
- The use of the term 'natural' is restricted to certain categories of flavouring, as outlined in Regulation EC 1334/2008 (see the next page).
- Flavourings that do not require evaluation and approval are subject to the same labelling requirements as those flavourings that do require evaluation and approval.

Flavourings are generally used in mixtures to provide the overall flavour of a food and drink product, but the label does not need to specify each of the individual ingredients contained in a flavouring. For example, a simple strawberry flavouring can be produced by combining gamma-decalactone from a peach, ethyl butyrate from an apple, methyl cinnamate from a guava, and furaneol from a pineapple. The label of a product containing that strawberry flavouring could read 'natural flavourings' or 'flavourings' or 'natural flavouring substances'. Some

of those substances (gamma-decalactone, ethyl butyrate and methyl cinnamate) can also be produced through chemical synthesis; a flavouring composed of such substances would then be labelled with either 'flavourings' or 'flavouring substances' (Khatchadourian, 2009).

An example

More complex strawberry flavouring mixtures can be composed of dozens of different flavouring substances and preparations. A sample flavouring recipe may contain the following substances, but the product's ingredients list would simply include the term 'flavourings' (Schlosser, 2001).

-
- | | | |
|------------------------|-------------------------------|--------------------------|
| • amyl acetate | • 4-methylacetophenone | • methyl anthranilate |
| • amyl butyrate | • alpha-ionone | • methyl benzoate |
| • amyl valerate | • ethyl lactate | • methyl cinnamate |
| • anethol | • ethyl heptanoate | • metachloroquinone |
| • anisyl formate | • ethyl heptylate | • carbonate |
| • benzyl acetate | • ethyl methylphenylglycidate | • methyl naphthyl ketone |
| • benzyl isobutyrate | • ethyl nitrate | • methyl salicylate |
| • butyric acid | • ethyl propionate | • mint essential oil |
| • cinnamyl isobutyrate | • ethyl valerate | • neroli essential oil |
| • cinnamyl valerate | • heliotropin | • nerolin |
| • cognac essential oil | • hydroxyphenyl-2-butanone | • neryl isobutyrate |
| • diacetyl | (10% solution in alcohol) | • orris butter |
| • dipropyl ketone | • isobutyl anthranilate | • phenethyl alcohol |
| • ethyl acetate | • isobutyl butyrate | • rose |
| • ethyl amyl ketone | • lemon essential oil | • rum ether |
| • ethyl butyrate | • maltol | • solvent |
| • ethyl cinnamate | • gamma-undecalactone | • vanillin |
-

Use of the word 'natural' on labels

In accordance with Regulation EC 1334/2008, the word 'natural' may only be used to describe a flavouring if the flavouring component comprises only flavouring preparations and/or natural flavouring substances, both of which must be produced using physical, enzymatic or microbiological processes. The natural designation can only apply to substances that have been identified in nature, although the *actual* source found in nature need not be used; rather, the same substance produced via physical, enzymatic, or microbiological processes may be used. The regulation defines natural in the articles 3.2(a), (d) and (k) and there are some key guiding principles, for example:

"Flavouring substances or flavouring preparations should only be labelled as 'natural' if they comply with certain criteria which ensure that consumers are not misled."

The conditions placed on the use of the term 'natural' also include flavourings produced using genetic modification technology – for example, flavourings preparations extracted using genetically modified enzymes can be described as

'natural'. Labels do not need to specify the 'natural' status of a flavouring, but in practice they are likely to because it is seen as a desirable attribute for consumers.

For the purposes of labelling, the following key principles apply to the use of the term 'natural':

- 100% of the flavouring components must come from natural sources – that is, from vegetable, animal or microbiological sources.
- In most instances, the term 'natural' must be used only in reference to a food, food category, or vegetable/animal flavour source and the source of the flavouring should be listed.

How and when can the word 'natural' be used? – An example

In a case where only one source is mentioned – for example, 'natural mint flavouring' – at least 95% of the weight of the flavour must be derived from mint. The remaining 5% can be from other sources but they must also be natural. This is known as the 95/5% rule. A more specific name may also be used for the flavouring – for example, 'mint oil'.

In a case where less than 95% of the weight of the flavour is derived from one natural flavouring – for example, from natural apple flavouring – but the flavour of the apple is recognisable, this should be labelled as 'natural apple flavouring with other natural flavouring/s'. All of the other flavouring components must also be from natural sources.

If 100% of the flavouring component is natural flavouring but the taste would not reflect the source used*, the product is labelled with the phrase 'natural flavouring/s'. For example, a product that tastes of apple may be flavoured with all natural flavouring substances, but the mixture of substances may be derived from natural sources that are not apple.

* The decision about whether a taste reflects the source is somewhat subjective, and it must be taken by the food manufacturer, where best practice would be to define the taste with reference to consumer panel taste tests.

If the flavouring component contains only flavouring substances that can be found naturally present and which have been identified in nature, the term 'natural flavouring substances' may be used.

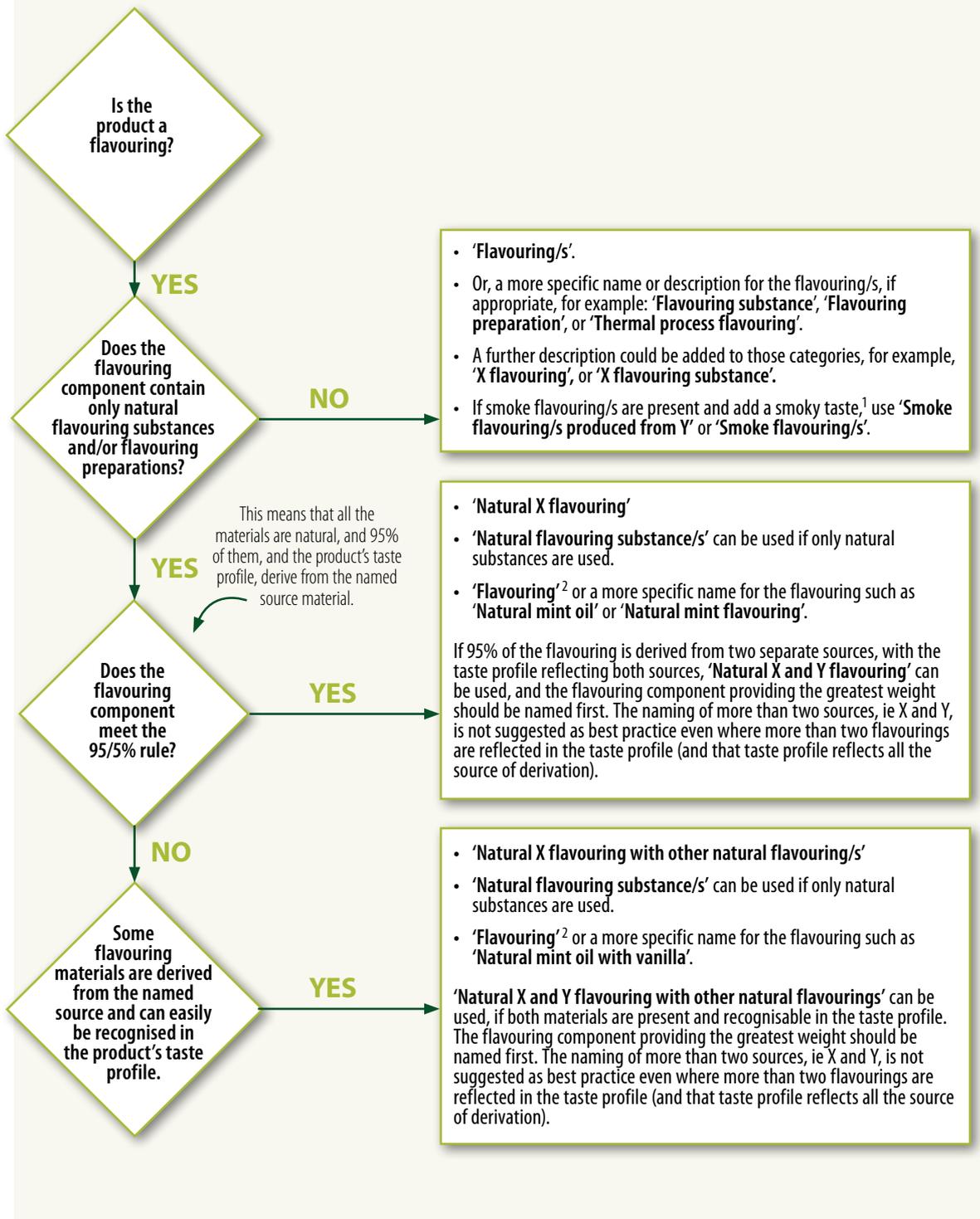
If the flavouring substance has been obtained by a permitted process but is not necessarily naturally present, then the term 'flavouring preparation' can be used.

The terms 'nature-identical' or 'identical to natural flavourings', and the term 'artificial', were previously used to describe flavouring substances but can no longer be used.

Figure 3 is a flow chart of how decisions might be made about how flavourings must be listed in the ingredients list.

FIGURE 3: Labelling of flavourings in ingredients lists

This flow chart illustrates how decisions about how flavourings must be labelled.

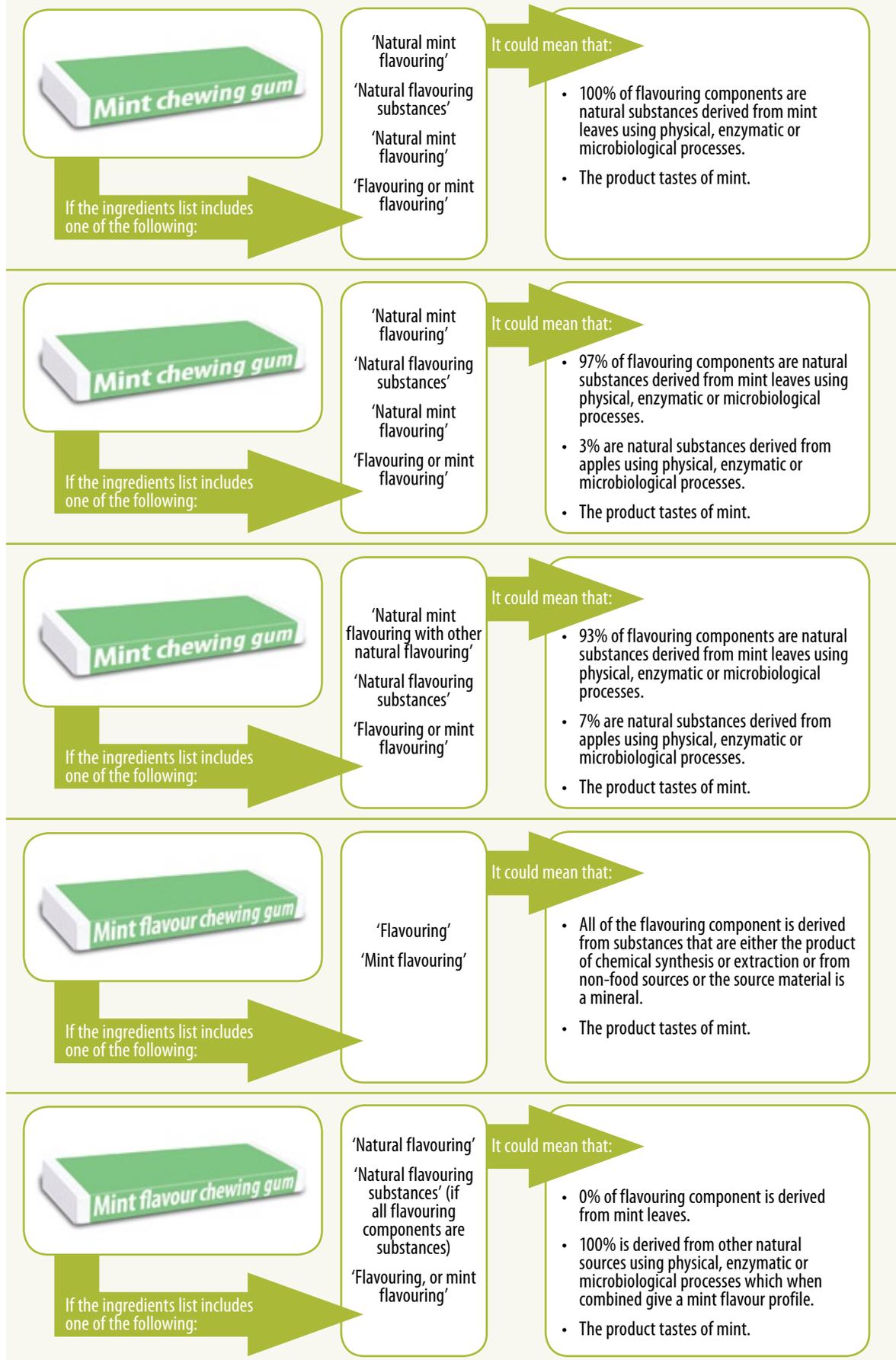


1 The determination of whether a smoke flavouring is being used in a product to contribute a smoky taste must be made by the food manufacturer (EFFA, 2010). Similarly, the determination of whether a flavour or taste profile reflects a particular named ingredient must be made by the food manufacturer. This may be done with the support of a flavourist or other experts.

2 'Flavouring' can be used to describe a natural flavouring. Natural status does not need to be specified.

Source: Adapted from EFFA (2010).

FIGURE 4: Examples of labelling of flavourings



6.3 Genetic modification and allergen labelling

New flavourings that consist of, contain, or are produced from, a genetically modified organism (GMO) require authorisation under EC Regulation 1829/2003 on genetically modified (GM) food and feed. If the flavouring is from a category that requires evaluation under EC Regulation 1334/2008, it will be evaluated under both regulations. Flavourings placed on the Union list and then produced from a different GM source approved under EC Regulation 1829, will not then require another evaluation under EC Regulation 1334/2008, but they will have been evaluated under relevant GM legislation which includes labelling provisions.

If a food or drink contains deliberately added GMOs, or ingredients produced from GMOs, this must be shown on the label. If foods are sold loose, the information must be displayed next to the food, to indicate that it contains GMOs. For example, an alcoholic spirit that contains caramel flavouring produced from genetically modified maize, could be labelled 'a spirit containing caramel produced from genetically modified maize' or it could include the declaration: 'caramel (produced from genetically modified maize)'. This information can appear on the ingredients list, or as a footnote to the ingredients, and should be in a font size at least as large as the font used in the ingredients list.

Flavourings that are produced using GM technology – such as dairy flavourings produced with GM enzymes – do not have to be labelled as such because the enzymes are used as processing aids. Similarly flavourings produced from the products of animals fed on GM animal feed do not have to be labelled as such. Regulation EC 1829/2003 (and Regulation EC 1830/2003) also allows for a 0.9% level of "adventitious or technically unavoidable" GM material. The 0.9% level applies per ingredient, and not simply to the whole foodstuff. It only applies to authorised GMOs and not to unapproved GMOs.

The use of the voluntary labelling terms like 'GM free' and 'GMO free' on foodstuffs is discouraged by the FSA (Northamptonshire County Council, 2010), as there is no legal definition of these terms at EU level. The Soil Association's definition states that 'GM free' should be taken to mean not produced from GMOs, and free of any GM material or substances derived from GMOs, including GM contamination. This is distinguished from 'non GM' or 'non GMO' which allows for accidental, low levels of GM content due to contamination. The Soil Association has supported the use of the labelling terms 'non GM' or 'non GMO', if supported by thorough verification systems (Soil Association, 2008).

Allergen labelling and flavourings

Flavourings need to comply with allergen labelling provisions under the new Food Information Regulation EU 1169/2011, which says:

"It is important that information on the presence of food additives, processing aids and other substances or products with a scientifically proven allergenic or intolerance effect should be given to enable consumers, particularly those

suffering from a food allergy or intolerance, to make informed choices which are safe for them.”

The requirement to label allergens extends to non-prepackaged foods, although other labelling aspects of such foods, such as country of origin labelling and nutritional information, are left open for Member States to decide.

Allergenic ingredients

SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES

Regulation EU 1169/2011, Annex 2 defines these substances or products as follows:

- 1 Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof, except:
 - (a) wheat based glucose syrups including dextrose;
 - (b) wheat based maltodextrin;
 - (c) glucose syrups based on barley;
 - (d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;
- 2 Crustaceans and products thereof;
- 3 Eggs and products thereof;
- 4 Fish and products thereof, except:
 - (a) fish gelatine used as carrier for vitamin or carotenoid preparations;
 - (b) fish gelatine or Isinglass used as fining agent in beer and wine;
- 5 Peanuts and products thereof;
- 6 Soybeans and products thereof, except:
 - (a) fully refined soybean oil and fat and the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated;
 - (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;
 - (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;
 - (d) plant stanol ester produced from vegetable oil sterols from soybean sources;
- 7 Milk and products thereof (including lactose), except:
 - (a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;
 - (b) lactitol;
- 8 Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholettia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;
- 9 Celery and products thereof;
- 10 Mustard and products thereof;
- 11 Sesame seeds and products thereof;
- 12 Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;
- 13 Lupin and products thereof;
- 14 Molluscs and products thereof.

6.4 Certification schemes

Vegetarian and vegan labelling and certification

Vegetarians do not eat meat or fish or meat- or fish-derived products, and vegans eat no animal-derived products of any type. Where animal products are used as flavouring ingredients, they are subject to the labelling requirements of EC Regulation 1334/2008 and that relating to allergens in food, Regulation EU 1169/2011. The taste of a flavouring may not reflect its source and labelling requirements are not specific enough to be clear about whether a flavouring has come from an animal source in all instances.

An example

The following examples illustrate the difficulty consumers have in identifying whether products contain flavourings that are made using animal-derived products.

Civet absolute is a flavouring preparation made from the gland excretions of civet cats. This has a history of use (less so now) in chewing gum, baked goods, frozen dairy products, puddings, hard and soft confectionery, and alcoholic and non-alcoholic beverages (Burdock, 2010). Such products might appear to the consumer to be either vegetarian or vegan, when they are not. Civet absolute is unlikely to be identified on product labels, as it will not be used in sufficient quantities, and will not form the basis of the overall taste profile of a product. Civet cake or civet flavoured gum is not generally on sale named as such. Flavouring labelling regulations will apply but, for example, the ingredients list for mint chewing gum with some civet absolute could simply include the term 'flavourings' or 'natural flavourings' or 'mint flavouring with other natural flavouring'.

Another example is the flavouring substance *p*-creosol (C₈H₈O₂/108.14) which can be obtained from lean fish, boiled egg or smoked pork, to provide a phenol-type odour for use in baked goods, frozen dairy products, hard and soft confectionery, alcoholic and non-alcoholic beverages, and puddings (Burdock, 2010). Labelling regulations do not require either the direct identification of the substance, nor its possible animal origin.

As explained in section 1.3, animal-derived additives used as encapsulators for flavourings do not need to be listed separately in the ingredients unless they are allergenic.

In some cases such as eggs, milk, molluscs, crustaceans and fish, the requirements for allergen labelling provide for the identification of animal products. Previous

FSA guidance on the use of the terms 'vegetarian' and 'vegan' in food labelling can be found at <http://webarchive.nationalarchives.gov.uk/20100817075455/http://www.food.gov.uk/foodindustry/guidancenotes/>

Flavourings companies do sell products with vegetarian and vegan specifications, although neither the Vegetarian Society nor the Vegan Society has specifically certified any flavourings products. If a food or drink product is labelled as suitable for vegetarians or vegans, it must not contain any animal ingredients. However, there are some products which a vegetarian or vegan might consider suitable because no animal-derived products are given in the ingredients list, but the products may in fact contain animal ingredients. The flavouring used could potentially contain encapsulating material from a non-vegetarian/non-vegan source or a flavouring ingredient from a non-vegetarian/non-vegan source that does not require labelling for allergenicity purposes.

There is no requirement to label products as 'not suitable for vegetarians'. However, the Vegetarian Society in the UK has called for the government to require such 'negative' labelling (Vegetarian Society, personal communication, 2010) and many vegetarians and vegans may be unaware that flavourings could potentially contain encapsulating materials from animal sources.

Halal and kosher certification

Halal consumers are generally Muslims, and specific dietary restrictions apply, including to flavourings ingredients. Three key requirements are the avoidance of pork-based products, the specific types of slaughter of animals, and the avoidance of alcohol products or by-products. Vegetable products are generally halal (unless they are intoxicating materials). Restrictions apply to all food and drink, including flavourings, additives and processing aids such as enzymes. There are several organisations that certify foods as halal (permissible) and haram (not permissible).

The dietary requirements for kosher products are similar to halal guidelines. There are a number of certifying organisations for kosher products, including flavourings. The London Beth Din Kashrut Division (LBDKD) produces guidance on Jewish dietary laws, and publishes *The Really Jewish Food Guide* (LBDKD, 2010) that contains information about products and ingredients.

There is no official definition in law of the terms halal or kosher, either at UK or European level, and therefore no mandatory labelling of products as halal or kosher.

The market for halal and kosher products has been increasing with particular demand for halal-certified flavourings. For example, in 2008 the company SAFC announced an expansion of its halal products – with around 550 halal flavourings and fragrance raw materials on offer certified by the Islamic Food and Nutrition Council of America (www.ifanca.org) (SAFC, 2008).

Many companies give both kosher and halal certification to the same flavourings. The Raw Materials Bulletin of *Perfumer & Flavorist* magazine makes regular announcements of new flavourings, with information about halal or kosher certification – for example:

“SAFC’s 2-furyl methyl ketone is a natural flavor material that occurs in burley tobacco, chestnuts, cocoa, coffee, cooked beef, raisins, roasted almonds and peanuts, tamarind, tea, yogurt, and wheat bread. It possesses a caramel, musty, peanut, earthy, coffee, meaty and vegetable organoleptic profile. This yellow to gold liquid or solid is certified kosher and halal.” (Perfumer & Flavorist, 2008).

Organic certification and guidelines for wild harvesting

Organic certification is a form of voluntary labelling and certification for food and drink products, including ingredients such as flavourings. Such certification applies to a wide range of food products and ingredients, processed and not, animal-based or derived, agriculturally produced, and wild-gathered or harvested. There are a number of private organic standards and many certifying bodies, but there are also EU organic standards, labelling rules and an EU organic logo to which all products must conform as set out in Regulation EC 834/2007. This came into force across Member States in 2009. DEFRA is the official UK competent authority responsible for enforcing the regulation in the UK, and a number of ‘control bodies’ have been authorised by DEFRA, including Soil Association Certification Ltd.

Flavourings can be certified as organic if they are made from organic ingredients, provided they meet the processing standards in their own right. Products that contain organic flavourings can include the term ‘organic flavourings’ on the ingredients label. This is most likely to be the case if the finished product is labelled as organic, or if the flavour is closely identified with the character of the product, such as vanilla ice cream, for example. However, for food or drink products seeking organic certification, it is also acceptable under EC Regulation 834/2007 to use natural flavouring substances and natural flavouring preparations, as defined under EU Regulation 1334/2008. Finished products may be labelled as organic as long as 95% of the ingredients are of organic origin.

The Soil Association sets further requirements that are more restrictive with regard to composition and labelling before a flavouring can be called an organic flavouring:

- Flavourings made from genetically modified organisms (GMOs) are not allowed.
- Water, glycerol, vegetable oil and ethanol are the only carrier solvents allowed for liquid flavours.
- Water, glycerol, vegetable oil, ethanol and carbon dioxide are the only solvents allowed for extraction.
- Organic ingredients must be used if these are available.
- For each flavour, a GMO and natural flavouring declaration form must be submitted to the control body, and approved.

A food producer must use flavours made from organic ingredients if the name of the flavour is to be used in the name of the product. For example, if a flavouring is to be used in organic strawberry flavoured ice cream, an organic strawberry flavour must be used.

Relatively small quantities of flavourings are used in food and drink products, and products certified as organic can contain non-organic natural flavouring ingredients. The Soil Association is working for a progression towards the use of only organic flavourings.

Some industry commentators note the difficulties in ensuring and sustaining supplies of organic certified flavourings (Sansone and Palmer, 2008). This is partly due to the majority of production taking place in developing countries, where small farmers may shift in and out of producing source materials for flavourings. Organic certification cannot be achieved under such circumstances. Wildwood (2003) has drawn attention to the difficulties of certifying aroma chemicals as organic due to the complexity and diverse nature of the supply chain.

Wild harvesting guidelines (Soil Association, 2010) must also be followed if Soil Association certification is to be sought for products based on wild-gathered products. Many plants used in flavourings are wild-gathered – for example, seaweeds; herbs such as immortelle from the island of Corsica (Hellivan, 2009); and various nuts. The requirements for Soil Association certification include the production of a management plan for a crop that details how sustainability issues will be addressed, and the quality of the environment in which the crop grows. Some commentators claim that wild harvesting is very difficult to monitor, and therefore difficult to reliably certify as organic (Wildwood, 2003; Burfield 2003, 2004). These same commentators note the need for further evidence about the sustainability of harvesting wild plant and animal species for the aroma trade.

Marine Stewardship Council certification for sustainable fisheries

There is no official definition in law for sustainable fish, either at UK or European level, and therefore no mandatory labelling of products with such information.

The Marine Stewardship Council (MSC) works to encourage sustainable fishing practices, and has an eco-label for sustainable fish and seafood products that applies to wild-capture fish only. The eco-label cannot be applied to farmed fish. The MSC eco-label is the most widely used certification in the world for sustainable fish and seafood products.

If a manufacturer or producer were to use MSC-certified fish to produce flavourings, the flavouring produced would be eligible to be MSC-certified, and the producer would be entitled to put the MSC eco-label on the product (provided that the total product contained acceptable proportions of MSC-certified versus non-MSC-certified fish content). However, the MSC has not so far certified any (Marine Stewardship Council, personal communication, 2010).

If a company uses flavouring made from non-MS-C-certified fish in a product recipe, it needs to follow certain guidelines before it can use the MSC eco-label on the end product:

- Flavourings made of non-MS-C-certified input can only be used where flavourings made from certified fish are not commercially available.
- The maximum amount of fish flavouring that is allowed is 2% of the total fish content of the final product.

It is understood that some foods in the UK market have complied with the MSC standard by using flavouring that is not itself MSC-certified but which makes up less than 2% of the final product. Since suppliers can meet the certification standard without using certified flavourings, a market for certified flavourings has not yet developed.

If non-certified fish flavourings are used in a foodstuff, the product's name must not refer to the name of the non-certified species of fish.

Fair trade certification

Fair trade is a form of voluntary labelling and certification for food and drink products, including ingredients such as flavourings, and applies to products produced in developing countries and not to countries within the EU.

There are a number of certifying bodies and standards around labour, environment and development conditions, but the largest standard-setting body in the world is Fairtrade Labelling Organizations International. The UK wing of that confederation is represented by the Fairtrade Foundation. Certification applies to a wide range of products and ingredients, processed and unprocessed, agriculturally produced, and wild-gathered or harvested. The standard applies to animal-derived products such as honey, but not to meat products.

There is no information available about the extent of sales of fair trade flavourings, and they are relatively new additions to the offerings of some of the top 10 companies (see Table 3 for a list of companies). Flavourings for which fair trade certification is sought tend to be the most popular and iconic flavours which may be closely identified with the finished product, such as vanilla.

6.5 Will the new labelling requirements benefit the consumer?

Changes to the regulation of flavourings within the EU are designed to ensure better protection for the health of consumers, including ensuring that they are not misled as to the nature or quality of products, whilst also supporting free trade. Clear labelling is seen as a cornerstone of the regulation.

The terms 'nature-identical' and 'artificial' can no longer be used to describe to flavourings. Products will only be able to use the word 'natural' with regard to

flavouring preparations and substances if certain conditions are met about the source materials for the flavouring and the production processes used.

However, even after the changes to labelling have been made, there will still be limited information available to the consumer about the exact content of flavourings in the food and drinks they purchase. A single food product may contain dozens of flavourings, of different types, and yet the ingredients list might only include the word 'flavourings'. There is no E number equivalent system in place for flavourings that would allow the consumer to know exactly which flavourings are used in products, although a system could be devised using the Flavis numbering system. Where flavourings are labelled using the various 'natural' terms, no research has been conducted to date to ascertain how far consumers are aware of the distinctions.

Catered products, and foods sold loose, will still not have clear information, at point of sale, about flavourings content.

7 MONITORING OF FLAVOURINGS IN FOODS AND DRINKS

EC Regulation 1334/2008 requires Member States to set up systems to monitor consumption and use of flavourings in the Union list, and to monitor use of the substances listed in Annex III of the regulation. It also requires for a common methodology to be established, in consultation with EFSA, for Member States to gather information on flavourings consumption, use, and the restricted substances.

At the time of publishing this review, however, neither the systems nor the methodology had been developed. This is because the development of updated initial risk assessment procedures for all categories of flavourings has taken precedence over the development of on-going monitoring systems. In autumn 2010, the Food Standards Agency (FSA) began a consultation on the enforcement of Regulation 1334/2008 in the UK (FSA, 2010) that outlined procedures for monitoring the implementation of the regulation in the UK, but the results have not yet been published. FSA Scotland published a response summarising consultations in the UK and outlining the potential impact of the new regulation on businesses in the UK (Scottish Government, 2011) suggesting that the cost to the approximately 5,940 food manufacturers affected of responding to Regulation 1334/2008 would be in the region of £18 million.

One of the objectives of the FACET research programme is to develop a methodology for estimating exposure to flavourings and the restricted substances (see section 2.2). Once the Union list has been established, it is expected that work will focus on agreeing a common methodology for data gathering, which will take into account the results of FACET, EFSA's work on exposure methodology, and the experiences of Member States.

The purpose of the monitoring of flavourings will be:

- to determine whether foods and drinks contain only flavourings approved for use
- to determine whether flavourings in foods and drinks are meeting their conditions of use as established in their initial risk assessments
- to require notification from food manufacturers about changes to the production methods or source materials used for flavourings that are already on the Union list, for report to the European Commission
- to require notification from food manufacturers of other information relevant to the existing risk assessments for flavourings that are already on the Union list, for report to the European Commission
- to require notification from food manufacturers of levels of use of flavourings

in order to conduct on-going reviews of consumption and use, for report to the European Commission

- to monitor the level of BAPs (undesirable substances) in foodstuffs and their consumption levels, and
- to ensure that products are labelled and marketed in a way that is not misleading, and which complies with the regulations.

7.1 Who will carry out the monitoring?

The appropriate regulatory government departments across the UK will develop a final enforcement plan and will have overall responsibility for the conduct of the UK with regard to the appropriate EC regulation. However, in practice, responsibility for the vast majority of enforcement and monitoring will be with local authorities. This is likely to be through trading standards or environmental health departments. The enforcement and monitoring system will require the co-operation of food manufacturers, who are ultimately responsible for placing food on the market.

Anyone convicted of an offence under the regulation can be fined. The fine will not exceed level 5, the highest level of penalty on the standard scale as set down by the Criminal Justice and Public Order Act 1994, and related instruments. Also, foodstuffs will be condemned if found to be labelled incorrectly, to contain a flavouring not approved for use, or to contain a flavouring that does not meet its conditions or level of use. If food manufacturers fail to comply with requests to provide information, their products can, eventually, be removed from sale. Members of the public can make complaints about products to trading standards departments.

Currently in the UK, there is no on-going monitoring of foodstuffs to examine the levels of flavouring they contain. It is up to the food industry to ensure that a flavouring meets its conditions of use (with regard to levels of use in particular food and drink categories) and, theoretically, it would be the role of local authority trading standards departments to handle breaches of the law. However, trading standards departments have not, in practice, monitored the use of flavourings. There has been no requirement in place to analyse foods and drinks for their flavourings content, and the lack of specificity with regard to ingredient labelling limits the use of product labels for monitoring purposes.

The budgets allocated to the public sector analysts, who do this type of chemical analysis on behalf of local authorities, have been subject to significant cuts (Association of Public Analysts, 2011) and they are unlikely to have capacity to assess compliance to the regulations. The information about levels of flavourings in use is therefore heavily dependent on what industry reports that it is using and on transparency within the industry. The FSA has not issued information that directly addresses this aspect of monitoring. However, the requirements of generic food law still apply, and companies are not allowed to continue to use

flavourings if information becomes available which suggests that they are not safe for purpose.

Analysis of flavourings in foodstuffs has its complexities for a range of reasons. For example, a soft drink might be found to contain ethyl butyrate when it is analysed. This might be through the addition of orange oil (or another flavouring), or through the addition of orange juice. The analysis will not be able to discern where the ethyl butyrate came from in terms of source – it could be from the flavouring, the juice, or perhaps reactions in the tin. In effect, it will be difficult to be certain whether the flavouring component is meeting its conditions on levels of use.

7.2 Monitoring of labelling

In the UK, it is the Advertising Standards Authority (ASA) that regulates advertising of products across other media, through the application of the Advertising Codes, including sources such as the internet, TV, newspapers, magazines and direct marketing. The ASA works on a response-style system in that it does not directly seek out breaches of the law, but instead responds to complaints. The ASA can issue fines if adverts are found to be misleading, offensive or inappropriate, but in practice companies are usually told not to repeat the advertising. ASA rulings could affect the advertising of products containing flavourings, as such advertisements need to follow guidelines set down in Regulation EC 1334/2008 for the presentation of foodstuffs.

Monitoring of labelling – an example

The ASA archives contain only one case in which it was called to adjudicate in a case relating to flavourings. A member of the public complained that Pizza Hut's Cheesy Bites pizza did not have "beautiful toupees of garlic butter", as advertised on TV, but had been sprayed with garlic flavouring. A representative of the restaurant responded that a garlic butter spray was used "which included the ingredients vegetable oil, natural garlic flavouring, natural butter flavouring and beta-carotene" and "because the spray contained both naturally sourced garlic and butter flavouring, the term 'garlic butter' was a fair and reflective description of the topping". The ASA did not uphold the complaint (Advertising Standards Authority, 2007).

8 CONCLUSION

Flavourings are in many cases non-essential additives used in foods and drinks and they have become increasingly prevalent in the worldwide food supply as increasing volumes of food and drink are consumed having been purchased 'ready prepared'. They are produced by a small number of companies who dominate worldwide production and use and therefore it is important that the industry is scrutinised and held to account to ensure that these additives are used as safely and appropriately as possible.

The extraction of flavour compounds from foods and their addition to other foods to recreate complex flavours have been part of the globalisation and technologisation of the processed food industry over the last 50 years, and reflect a reduction in the number and amounts of integral food ingredients used to prepare dishes for commercial sale. The global market value of flavouring compounds was estimated to be \$7.35 billion in 2010, making up 45% of the flavour and fragrance industry along with fragrances (\$6.3 billion) and essential oils (\$2.4 billion) (Leatherhead Food Research, 2011). Flavourists work alongside an array of other specialised food technologists to develop processed products for supermarket shelves, and their toolkit consists of substances that are derived from plants or animals or are chemically synthesised from sources including petrochemicals. Flavour compounds are commonly used to make foods of limited nutritional value with attractive tastes, and add to the degradation of the nutritional value and quality of the food supply.

A new regulation is in place, but there are clearly gaps and delays in its implementation to date, and questions about consumer understanding of the categories of flavours in the foods they eat, and whether the new regulation contributes to transparency.

In 2011, deaths from chronic disease worldwide overtook deaths from infectious and communicable diseases, with poor diet highlighted as a major risk factor in the rise of obesity, coronary heart disease, diabetes, hypertension and other diseases (United Nations, 2011). Global calls for populations to consume more health-promoting diets rich in unprocessed foods are at odds with an increasingly technology-heavy food industry which uses artificial flavours to encourage consumption of foods that are predominantly not compatible with a healthy diet.

Heavily flavoured foods and drinks may habituate children to diets that are high in fat, sugar and salt and detrimental to health, and the safety and well being of children should be a priority in all EU planning and regulation review.

All those responsible for promoting better nutritional health should consider the role of additives such as flavourings in this big picture, and ensure that consumers are able to make clear choices about the foods and drinks they consume and that they can avoid chemicals if they wish to do so.

APPENDIX 1: METHODOLOGY FOR EFSA ASSESSMENT OF FLAVOURING SUBSTANCES

This Appendix outlines the overall procedure followed by the European Food Safety Authority (EFSA) for the risk assessment of new flavouring substances. An overview of the procedure is shown in Table 7 (CEF, 2010; EFSA 2010b).

Each flavouring substance will be assigned a Flavis (FI) identity number.

Companies must submit to EFSA the following information about the flavouring:

- the production process
- the chemical specification of the flavouring substance
- levels of use in foods, drinks and non-food items
- estimations of dietary intake, and
- details of relevant toxicological studies, including those giving information about genotoxicity.

EFSA can request more information about a flavouring substance in any of the areas of assessment, and can insist on further studies if necessary.

If EFSA considers that there are no indications of genotoxicity, it will decide whether to assign the flavouring to one of the flavouring groups, or whether to carry out an individual assessment. The majority of flavouring substances have been divided into groups that have chemical similarities. Many flavourings are evaluated as part of one of those groups using what is called a Flavouring Group Evaluation (FGE). Flavouring Group 19 (alpha, beta-unsaturated aldehydes and ketones, and precursors for these) are subject to more stringent testing for genotoxicity due to their particular chemical structure.

Both Flavouring Group Evaluations and individual evaluations use a 'stepwise approach' that looks at information about:

- intake
- metabolism, and
- toxic effects.

Of course, experimental data on all possible risks are not available about every flavouring substance in use. Such experimental data might be available for one flavouring substance in a flavouring group evaluation, and that data might be regarded as relevant to the assessment of other flavourings in the same group. Some assessments are made about toxicity using knowledge about the metabolism of particular types of chemicals inside the body.

TABLE 7: Procedure for EFSA risk assessment of flavouring substances

Steps	Information sources	Summary of required evidence
1 Description of the production process	Industry body or company	Production method and source materials.
2 Specification for the flavouring	Industry body or company	This includes the following information: chemical name and registration number; physical form; molecular weight; chemical structure and formula; stability and decomposition products; impurities and interaction with food components.
3 Level of use in foods, drinks and non-food items	Industry body (such as the European Flavour Association) or flavouring company submits information, and explains their methods for estimation.	Levels at which the substance is added to food and drink categories. Level at which the substance is thought to occur in other non-food sources, which may nonetheless be absorbed into the body, for example, through cosmetics or shampoo.
4 Estimation of dietary intake	As for step 3 above. EFSA recommends method for assessing intake.	The calculations are based on formulas that use level of use information along with estimates of consumption or exposure. The methods for estimating intake are set by EFSA. (See section 5.5.)
5 Genotoxicity assessment. If EFSA considers that there is evidence of genotoxicity (or a lack of certainty that genotoxicity is not a risk), the evaluation will not proceed beyond this point.	As for step 3 above.	The information may include experimental data relating to the specific flavouring, or to the flavouring group. The information does not always include experimental data about specific flavouring substances. Flavouring Group 19 (alpha, beta-unsaturated aldehydes and ketones, and precursors for these) are subject to more stringent testing for genotoxicity.
6 Assessment of flavouring – either to assign it to one of the flavouring groups, or to proceed to an individual assessment.	EFSA makes this decision based on the chemical specification, using information submitted by the company.	Information on the specification will be used to determine: <ul style="list-style-type: none"> • if the flavouring substance has structural and metabolic similarities with one of the chemically defined flavourings groups, or • if it should be assessed individually.
7 Flavouring Group Evaluation or individual evaluation	EFSA conducts these, using all available evidence. Some experimental data are required for all evaluations – including studies that examine the effects of intake on rats over 90-day periods. For group evaluations, the data may not be from the particular flavouring substance under consideration, but from a related one.	In both the group and individual assessment procedures, EFSA considers the available range of data about intake, metabolism and toxicity. In group evaluations, some predictions are made as to the risks associated with a particular flavouring substance by consideration of information (some of which must be experimental data from intake studies) about similar chemical substances. EFSA may request further experimental data for individual assessments, if information is not available from chemicals with similar structures. The extent of the data required will depend on estimates of consumption, and level of toxicity. If these are high, more data will be required.
8 Other information	To be supplied by the company wishing to gain flavouring approval.	Studies about: immunotoxicity and neurotoxicity; ethical, environmental and social information; feasibility of control; allergenicity; intolerance reactions; human volunteer studies; and predictive mechanistic studies.
9 Decision	EFSA reports on assessments. The EC makes a decision about regulatory status, with reference to CEF.	Possible outcomes: <ul style="list-style-type: none"> • Assess the flavouring as acceptable for inclusion on the Union list. • Alter the conditions of use – for example, a requirement to ban use in certain foodstuffs or to reduce the level of use in products. • Delay decision until completion of more information gathering. • Take the flavouring off the market.

Source: Adapted from European Food Safety Agency Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF, 2010).

APPENDIX 2: EC REGULATIONS AND LEGISLATION RELEVANT TO FLAVOURINGS

Framework legislation

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Agency (EFSA) and laying down procedures in matters of food safety. OJ L31/1.

Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production. OJ L184/61.

Commission Directive 91/71/EEC completing Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production. OJ L42/25.

Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods. OJ L354/34.

Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. OJ L354/1.

Legislation on flavouring substances

European Parliament and Council Regulation 2232/96/EC of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs. OJ L299/1.

Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation 2232/96/EC of the European Parliament and of the Council of 28 October 1996 (1999/217/EC). OJ L128/73.

Commission Decision 2000/489/EC of 18 July 2000 amending Decision 1999/217/EC adopting a register of flavouring substances used in or on foodstuffs. OJ L197/53.

Commission Decision 2002/113/EC of 23 January 2002 amending Commission Decision 1999/217/EC as regards the register of flavouring substances used in or on foodstuffs. OJ L49/1.

Commission Decision 2004/357/EC of 7 April 2004 amending Decision 1999/217/EC as regards the register of flavouring substances. OJ L113/28.

Commission Decision 2005/389/EC of 18 May 2005 amending Decision 1999/217/EC as regards the register of flavouring substances used in or on foodstuffs. OJ L128/73.

Commission Decision 2006/252/EC of 27 March 2006 amending Decision 1999/217/EC as regards the register of flavouring substances used in or on foodstuffs. OJ L91/48.

Commission Decision 2008/478/EC of 17 June 2008 amending Decision 1999/217/EC as regards the register of flavouring substances used in or on foodstuffs. OJ L163/42.

Commission Decision 2009/163/EC of 26 February 2009 amending Decision 1999/217/EC as regards the register of flavouring substances used in or on foodstuffs. OJ L55/41.

Commission Regulation 1565/2000/EC of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation 2232/96/EC of the European Parliament and of the Council. OJ L180/8.

Commission Regulation 622/2002/EC of 11 April 2002 establishing deadlines for the submission of information for the evaluation of chemically defined flavouring substances used in and on foodstuffs. OJ L95/10.

Legislation on smoke flavourings

Regulation (EC) 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods. OJ L309/1.

Commission Regulation (EC) No 627/2006 of 21 April 2006 implementing Regulation (EC) No 2065/2003 of the European Parliament and of the Council as regards quality criteria for validated analytical methods for sampling, identification and characterisation of primary smoke products. OJ L109/3.

Legislation on extraction solvents

Commission Directive 2009/32/EC of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. OJ L141/9.

Commission Directive 2010/59/EU amending the Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. OJ L225/10.

Legislation on allergen labelling of foods

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. OJ L304/18.

Legislation on GM foods

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268/1.

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. OJ L268/24.

Legislation on labelling

Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. OJ L109/29.

Legislation on infant formula and follow-on formula

Commission Directive 2006/141/EC of the 22 December 2006 on infant formula and follow on formulae and amending Directive 1999/21/EC. OJ L401/1.

Legislation on organic food

Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91. OJ L109/1.

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