



IOFI CODE OF PRACTICE



International Organization
of the Flavor Industry

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Code of Practice
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1. LIMITATION OF RESPONSIBILITY

The International Organization of the Flavor Industry (IOFI) has established the IOFI Code of Practice in good faith using the most accurate information available. The IOFI Code of Practice is intended for use as a best practices resource document by the individual company members of IOFI-member associations. It is the responsibility of the individual company members of IOFI-member associations to determine how they may best use the information in the IOFI Code of Practice. IOFI and its members, officers and employees are not responsible for the accuracy of the contents of the Code of Practice, nor are they responsible for any effects of the application and use of the contents of the Code of Practice.

2. PREFACE

2.1 About IOFI

The International Organization of the Flavor Industry (IOFI) is an association of regional and national associations of the global flavour industry, consisting of the national associations of flavour manufacturers of Australia, Brazil, Canada, Colombia, Indonesia, Japan, Mexico, Singapore, South Africa and the United States, and the regional flavour association of Europe (EFFA) which consists of Austria, Belgium, Denmark, France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

2.2 Mission Statement

The International Organization of the Flavor Industry represents the interests of the global flavour industry and its partners by providing leadership in safety, scientific and regulatory matters.

2.3 Roles and Responsibility

The safe use of flavourings is the flavour industry's first priority, in order to prevent risk to the health of consumers, employees and the environment. Acting in partnership with its members, IOFI provides sound scientific information to the industry, its customers, and government agencies in order to promote the benefits and safe use of flavours. As the global flavour industry's representative, IOFI:

- 2.3.1 Promotes and supports a consistent global approach for the safety assessment of flavouring substances based on sound science.
- 2.3.2 Supports and promotes legislation and regulation that will enhance its ability to provide safe flavours worldwide.
- 2.3.3 Communicates with its members about current and emerging scientific and regulatory issues that have an impact on the safety assessment of flavours.

2.4 IOFI and the CODEX ALIMENTARIUS COMMISSION

- 2.4.1 The Codex Alimentarius Commission was established by the United Nations Food and Agriculture Organization (FAO) and World Health Organization (WHO) to develop international food standards, guidelines and recommendations to protect the health of consumers and to ensure fair practice in food trade pursuant to the World Trade Organization (WTO) treaties. The Commission has the responsibility for developing food standards that may be adopted by member countries. The standards are science-based and are elaborated taking into consideration expert advice by the highly

regarded Joint FAO/WHO Expert Committee on Food Additives (JECFA), the group responsible for performing safety assessments of food additives and flavouring substances for use by the Codex Alimentarius Commission in its work in developing global food standards.

- 2.4.2 IOFI serves as a non-governmental organization (NGO) and has been granted Observer status with the Codex Alimentarius Commission with a standing invitation to Codex meetings and meetings of its subsidiary bodies such as the Codex Committee on Food Additives (CCFA), the Codex Committee on Food Contaminants (CCFC), and the Codex Committee on Food Labelling (CCFL). See www.codexalimentarius.net for more information on the Codex Alimentarius Commission.
- 2.4.3 IOFI has been involved in the development of the Codex Guidelines for the Use of Flavourings (CAC/GL 66-2008; C of P Annex III). IOFI supports the Codex Guidelines and recognizes their value in providing principles for the safe use of components of flavourings evaluated by JECFA and determined to present no safety concern at estimated levels of intake.

2.5 IOFI and the Global Reference List

The IOFI secretariat will maintain on the IOFI-website (www.iofi.org) a Global Reference List, which will identify flavouring substances and natural flavouring complexes appropriate for the formulation of flavourings as described in Section 18.1 of this Code of Practice. The Global Reference List will be subject to regular updates.

2.6 Application of the Code of Practice

The Code of Practice consists of information describing best practices regarding the safety, composition, manufacture, description and labeling of flavourings. The application of the Code of Practice does not relieve individual manufacturers from the obligation to comply with all local, national, or international regulations that pertain to their operations. These regulations take precedence over this Code. In those countries where specific legislation and regulations applicable to flavourings are not in force, the Code of Practice should serve as a best practices resource.

2.7 Accessibility

IOFI makes the Code of Practice available to its members and other interested parties through its website.

3. DEFINITIONS

3.1 Introduction

Definitions and terminology used in the IOFI Code of Practice are in compliance with definitions and terminology as used in the current Codex Guidelines on the Use of Flavourings (CAC/GL 66-2008) (Annex III to this Code of Practice). Key definitions and Codex references are listed below, together with additional terms for which the Codex Guidelines do not offer specific guidance or for which additional guidance is necessary.

3.2 Flavour (CAC/GL 66-2008 item 2.1)

Flavour is the sum of those characteristics of any material taken in the mouth, perceived principally by the senses of taste and smell, and also the general pain and tactile receptors in the mouth, as received and interpreted by the brain. The perception of flavour is a property of flavourings.

3.3 Flavourings (CAC/GL 66-2008 item 2.2)

3.3.1 Flavourings are products that are added to food to impart, modify, or enhance the flavour of food (with the exception of flavour enhancers considered as food additives under the Codex Class Names and the International Numbering System for Food Additives - CAC/GL 36-1989). Flavourings do not include substances that have an exclusively sweet, sour, or salty taste (e.g. sugar, vinegar, and table salt). Flavourings may consist of flavouring substances, natural flavouring complexes, thermal process flavourings or smoke flavourings and mixtures of them and may contain non-flavouring food ingredients within the conditions as referred to in section 3.5 of the Codex Guidelines (Annex III). They are not intended to be consumed as such.

3.3.2 Flavouring Substances (CAC/GL 66-2008 item 2.2.1) are chemically defined substances either formed by chemical synthesis, or obtained from materials of plant or animal origin.

3.3.3 Natural flavouring substances (CAC/GL 66-2008 item 2.2.1.1) are flavouring substances obtained by physical processes that may result in unavoidable but unintentional changes in the chemical structure of the components of the flavouring (e.g. distillation and solvent extraction), or by enzymatic or microbiological processes, from material of plant or animal origin. Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, torrefaction (roasting) and fermentation). This means substances that have been identified / detected in a natural material of animal or vegetable origin.

- 3.3.4 **Synthetic flavouring substances** (CAC/GL 66-2008 item 2.2.1.2) are flavouring substances formed by chemical synthesis.
- 3.3.5 **Natural flavouring complexes** (CAC/GL 66-2008 item 2.2.2) are preparations that contain flavouring substances obtained by physical processes that may result in unavoidable but unintentional changes in the chemical structure of the flavouring (e.g. distillation and solvent extraction), or by enzymatic or microbiological processes, from material of plant or animal origin. Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, torrefaction (roasting) and fermentation). Natural flavouring complexes include the essential oil, essence, or extractive, protein hydrolysate, distillate, or any product of roasting, heating, or enzymolysis.
- 3.3.6 A **thermal process flavouring** (IOFI Guideline chapter 14.3) is a product prepared for its flavouring properties by heating raw materials that are foodstuffs or constituents of foodstuffs. This process is analogous to the traditional home cooking of ingredients of plant and animal origin.
- 3.3.7 **Smoke flavourings** (CAC/GL 66-2008 item 2.2.3) are complex mixtures of components of smoke obtained by subjecting untreated wood to pyrolysis in a limited and controlled amount of air, dry distillation, or superheated steam, then subjecting the wood smoke to an aqueous extraction system or to distillation, condensation, and separation for collection of the aqueous phase. The major flavouring principles of smoke flavourings are carboxylic acids, compounds with carbonyl groups and phenolic compounds.
- 3.3.8 **Non-flavouring food ingredients** (CAC/GL 66-2008 item 2.3) are food ingredients, such as food additives and foodstuffs that can be added to flavourings and are necessary for dissolving, dispersing, or diluting flavourings, or are necessary for the production, storage, handling and use of flavourings. Substances falling under this heading are listed in Annex I.
- 3.3.9 **Flavourings produced by enzymatic and microbiological processes** (IOFI Guideline Chapter 16.3) are concentrated preparations, with or without non-flavouring food ingredients, used to impart flavour. They are produced by submitting a substrate or substrates to the action of enzymes or micro-organisms.
- 3.3.10 **Compounded flavours (*)** in modern food manufacturing are often mixtures of as many as one hundred or more flavouring substances, some of them complex mixtures themselves, chosen to provide a particular taste sensation. Other flavour ingredients, such as solvents, emulsifiers and antioxidants are required to allow the compounded flavour to function properly in the food to which it is added.

3.4 Manufacturing

All operations involved in the production of flavourings and their ingredients including processing, compounding, packaging and labeling.

3.5 Batch

A specific quantity of material manufactured in a single operation.

3.6 Batch Number

A combination of numerals and/or letters used to identify material pertaining to a particular batch and serving to distinguish it from all other batches of like material.

3.7 Shelf Life

The shelf life of flavourings is defined as the period from the date of production during which the flavouring remains suitable for further use.

3.8 Environment

Environment: Water, air and soil and their inter-relationship as well as relationship between them and any living organisms.

3.9 Waste

Waste: Any unavoidable material, resulting from an industrial process, which must be disposed of.

*Chapter 4: Hallagan J.B. and Hall R.L. *Food and Chemical Toxicology*. 47, 267. 2009.

4. THE NEED AND TECHNOLOGICAL FUNCTION OF FLAVOURINGS IN FOOD

The flavour of food is the most important component to the taste of that food and plays an important role in its consumption and acceptance. In addition, the flavour, taste and aroma of food stimulate salivary flow and consequently aid digestion and metabolism.

Flavourings are essential ingredients in the preparation of food demanded by today's consumers. A pleasant and interesting diet that offers a variety of flavours will not only be more acceptable but will encourage a more healthy lifestyle. A nutritionally balanced diet is best achieved through consumption of a variety of foods that do not compromise on taste.

The historical role of flavourings in food manufacturing was reviewed by Hall and Merwin (1981*) who provided several basic definitions. "Flavor" was defined as "... the sum of those characteristics of any material taken in the mouth, perceived principally by the senses of taste and smell and also the general pain and tactile receptors in the mouth, as received and interpreted by the brain." A flavour was further defined as "a substance which may be a single chemical entity, or a blend of chemicals of natural or synthetic origin (i.e. flavouring substances) whose primary purpose is to provide all or part of the particular flavor effect to any food or other product taken in the mouth." (Hall and Merwin, 1981*).

Hallagan and Hall (2009**) provide descriptions of a series of definitions related to flavour manufacturing including an explanation of how individual flavouring substances and other functional ingredients are combined to create a flavouring or a "compounded flavour." Compounded flavours in modern food manufacturing are often mixtures of as many as one hundred or more flavouring substances, some of them complex mixtures themselves, chosen to provide a particular taste sensation. Other flavour ingredients, such as solvents, emulsifiers and antioxidants are required to allow the compounded flavour to function properly in the food to which it is added. Flavour ingredients that impart or modify flavour (i.e., provide a taste sensation) are referred to as "flavouring substances" and include individual substances referred to as single chemically-defined flavouring substances, and natural materials such as extracts, essential oils, and oleoresins that are also referred to as natural flavouring complexes. (ref. Codex Guidelines for the Use of Flavourings" (CAC/GL 66-2008, Code of Practice Annex III)

Cultural and regional preferences, together with the local availability of foods and associated taste, result in different appreciations of flavourings by different populations. Considering the wide variety of foods that are

consumed and the complexity of the flavours of these foods, a large number of flavouring ingredients are used globally.

Individual flavouring substances that occur naturally in food, together with the flavours generated through cooking and other sorts of preparation of food for human consumption account for the majority of flavourings found in the daily intake of food. Even in industrialized countries, added flavouring materials represent only a minority of the flavouring materials that we consume.

Flavouring substances are among the most rigidly evaluated and tested food ingredients and as such can be regarded safe under their conditions of intended use. Many flavouring substances are self-limiting in their use and as such the consumer is able to detect the presence of flavouring substances by personal appreciation, but would also deny appreciation at the moment of over-application of flavourings. Effective and informative flavour labeling provisions ensure compliance with applicable laws and as such inform consumer needs and expectations.

The following technological functions of flavours can be identified:

1. The addition of flavourings can be necessary to compensate for the loss of flavour during the processing and storage of foods such as pasteurized foods.
2. Flavourings can be used to assist to compensate for reductions in undesirable food ingredients such as fat, sugar, and salt.
3. Flavourings may be used to compensate for natural seasonal or geographical variations in crops. The use of flavourings can compensate for supply limitations by helping to standardize the flavour of food.
4. Flavourings are used to create recognition such as when a food's characteristic flavour is adapted to preferred local tastes.
5. Flavourings can be critical ingredients because some food and beverage products would simply not be acceptable without the addition of flavourings such as soft drinks, edible ices, confectioneries, and milk desserts.
6. Many food products require a specific flavour note to characterize them among other similar products of the same food category such as citrus soft drinks, mint candy, and panettone cake.
7. Flavourings provide novelty and innovation through combinations of flavourings that provide interest and variety such as mango/passion fruit ice cream, and chicken tikka.

8. The production of foods based on bland, nutritionally valuable ingredients for underfed populations may be made more acceptable through the use of flavourings. In addition, palatable foods can now be made more widely available to larger parts of the population.

* Hall R.L. and Merwin E.J. The role of flavors in food processing. *Food Technology*. 35, 46. 1981.

**Hallagan J.B. and Hall R.L. Under the conditions of intended use ó New developments in the FEMA GRAS program and the safety assessment of flavor ingredients. *Food and Chemical Toxicology*. 47, 267. 2009.

5. COMPOSITION OF FLAVOURINGS

5.1 Introduction

Annex I contains information on IOFI acknowledged lists of flavouring substances and non-flavouring food ingredients.

5.2 Flavourings

IOFI considers as acceptable materials that meet one or more of the following requirements:

- 5.2.1 Flavourings accepted by the authoritative body the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as acceptable flavouring materials that pose no safety concerns at current levels of intake. **Note:** JECFA makes ongoing safety evaluations of flavouring materials.
- 5.2.2 Materials that have been evaluated and found, using the same or similar methodology as used by JECFA, to present no safety concern under conditions of intended use by authoritative bodies such as the European Food Safety Authority (EFSA) or the Japanese Food Safety Commission (FSC).
- 5.2.3 Materials that are deemed to be Generally Recognized As Safe (GRAS) or approved food additives by the US Food and Drug Administration (FDA) including GRAS determinations published by the independent Expert Panel of the Flavor and Extract Manufacturers Association of the United States (FEMA).

5.3 Non Flavouring Food Ingredients

The following explains groups of substances that may be essential for the manufacture of flavourings:

- 5.3.1 *Solvents and carriers* (Annex I, 18.3) are used to maintain uniformity and dilute concentrated flavourings in order to facilitate their incorporation and dispersion in food products. Some carriers may also be used for encapsulating flavourings with a view to protect them against evaporation and alterations during storage.
- 5.3.2 *Antioxidants* (Annex I, 18.4) are indispensable for the protection of certain essential oils, especially terpene-containing essential oils, as well as other flavouring substances. To obtain best protection it is common practice to add authorized antioxidants to most raw materials at the time of their manufacture.
- 5.3.3 *Sequestrants* (Annex I, 18.5) prevent the catalytic action of certain metal ions and protect the flavouring against oxidation.

- 5.3.4 *Preservatives* (Annex I, 18.6) are necessary to prevent microbial growth in certain flavourings.
- 5.3.5 *Emulsifiers* (Annex I, 18.7) and *weighting agents* (Annex I, 19.8) facilitate the homogenization of flavourings, or the incorporation of flavourings in food products.
- 5.3.6 *Acids, bases and salts* (Annex I, 18.9) are used to adjust the pH of certain flavourings.
- 5.3.7 *Anticaking agents* (Annex I, 18.10) may be necessary to keep powdered flavourings free flowing.
- 5.3.8 *Extraction solvents* are used for some manufacturing of natural extracts. Only limited amounts of solvent residues that are technically unavoidable are acceptable in food due to carry-over, unless the solvent is also a permitted carrier. A list of extraction solvents and their permitted residue levels can be found in Annex II.

6. FLAVOURINGS AND INTELLECTUAL PROPERTY

6.1 Intellectual Property Protection

- 6.1.1 Respecting the integrity and ownership of intellectual property, especially proprietary formulae, is a key commitment of the flavour industry in general and IOFI members in particular.
- 6.1.2 The intellectual property of flavour formulae belongs to the individual companies that create the flavours and is the most significant collective asset of the global flavour industry.
- 6.1.3 The process of creating flavour formulae is very expensive and time-consuming and requires significant elements of expertise, innovation and creativity. Each flavour formula is proprietary: it is a trade secret invention and a work of art and, as such, deserves intellectual property protection.
- 6.1.4 IOFI recognizes the importance, to the flavour industry and its customers, of the protection of intellectual property.
- 6.1.5 Trade secret laws in virtually all countries protect any formula, pattern, device, or compilation of information that provides a business advantage to the owner. A trade secret, also known as confidential business information, is an item of confidential information concerning the commercial practices or proprietary knowledge of a business, which requires the maintenance of strict confidentiality toward third parties and even within the creating company itself, where only a limited number of employees have access to the complete formulae.
- 6.1.6 Intellectual property law is largely civil in nature; therefore it is up to the owner of the intellectual property to protect it, and to seek remedies if it is misappropriated. Trade secrets or copyright protection of flavour formulae thus preserve the value of the flavour formula for the customer for whom it was created.
- 6.1.7 Illegal misappropriation of trade secret formulae unfairly misappropriates highly valuable flavour formulae without bearing the original creation effort and development costs. Unless duplication of third party flavour formulae is necessary (e.g. inability of original supplier to supply) and permitted, IOFI members shall refrain from illegal duplication of third party flavours. This will contribute to ensure the recognition of the intellectual property of flavour formulae.
- 6.1.8 IOFI members are committed to take all the actions necessary to promote and encourage the protection, respect and defense of flavour formulae intellectual

property and to discourage the infringement of flavour manufacturers' intellectual property rights.

- 6.1.9 IOFI and its members support legislative, regulatory or other appropriate actions taken to reinforce, expand and protect the intellectual property of flavour formulae against third party infringement or misappropriation.

6.2 Requests for Flavour Formula Disclosure

- 6.2.1 Many industrialized nations have laws and regulations covering the safe use and labeling of flavouring substances. Except for a few specialized areas, such as pharmaceutical products, none of these laws or regulations requires the disclosure of complete flavour formulae to authorities or customers. However, there may be situations where disclosing certain parts of a flavouring formula to a customer or to a government official may be required.

- 6.2.2 Because of the large number of individual flavouring substances used to create flavours, and the demonstrated safety of these substances, regulators do not require that consumer products bear labeling identifying each individual flavouring substance. Regulators around the world have generally adopted the "class naming" approach to identifying flavours in consumer products. IOFI supports class naming and agrees that classes such as "natural" and "synthetic" may be an effective way of informing the consumer.

- 6.2.3 Companies wish to protect the confidentiality of their formulae, both from third parties and often within the creating company itself, where only a limited number of employees have access to the complete formula. Therefore, the modern flavour manufacturer operates in an environment of competing pressures: an internal priority on protection of confidential formulae versus external requests and demands from end users, consumers and government officials for disclosure. This section of the Code of Practice provides guidance on balancing these competing pressures.

- 6.2.4 Evaluating requests for disclosure

The first step in responding to a request for some type of mandatory disclosure is to establish the authority behind the request. Who is requesting the disclosure and what position do they hold with the requesting organization? This is a sensitive analysis that may require input from senior management or the company's local representative in a particular country, or others with special expertise or understanding.

After establishing that the requester is an authority in a position that is entitled to receive confidential business information, then it should be confirmed that there is a legitimate and perhaps legally justified reason to make a disclosure.

6.2.5 Understanding reasons for disclosure

There can be many legitimate reasons for disclosing flavouring formula information. The goal in this situation is to confirm precisely the rationale for the request and its appropriateness. Answer the question, “Is this request truly justified?” Examples of legal justification for disclosure include allergen labeling requirements or special product approval such as pharmaceuticals. **Note:** Even with special product approvals, there should always be a mechanism in place so that it is not necessary to disclose the entire formula, or, if disclosure is required, that it is done in a protected manner.

6.2.6 Verifying the source of the request

If the requester cites a statute or regulation that is unfamiliar, request a copy of the relevant provisions so that it can be shared with colleagues, legal counsel, or association contacts and be added to the company’s regulatory database. View arbitrary requests that are not supported by documentation, such as “the Ministry of Health requires the formula,” with skepticism. If the Ministry of Health or other requesting body has such a requirement, then it should be codified somewhere and the requestor should be able to provide it by fax or email. The IOFI Secretariat is also available for consultation if necessary.

6.2.7 Considering disclosure options

While the industry has legitimate reasons to protect its intellectual property, there are several approaches to consider when responding to requests for disclosure. They include:

- Providing a basis for not disclosing formulae because of reliable safety assessments
- Entering into nondisclosure agreements with requesting parties
- Exploring limited disclosure options
- Providing certificates of composition
- Identifying chemical family or class data as an alternative to full disclosure
- Using of “does not contain” statements to comply with disclosure requests

The following sections explain each of these alternatives.

6.3 Disclosure Options

6.3.1 Safety Assurance of Flavouring Ingredients

Occasionally, questions about the safety of a product prompt requests for disclosure of flavouring ingredients. There are globally recognized scientific

expert groups that conduct ongoing safety evaluation of flavouring substances. The Expert Panel of the Flavor and Extract Manufacturers Association of the United States (FEXPAN) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) conduct ongoing evaluations and publish their findings regarding the safe use of individual substances in foods and beverages. One strategy for addressing formula disclosure requests related to safety is to assure customers that all of the ingredients used in the formula have been approved by respected authorities such as Joint FAO/WHO Expert Committee on Food Additives (JECFA), the FEMA Expert Panel (FEXPAN), the European Food Safety Authority (EFSA) and the Japanese Food Safety Commission (FSC).

6.3.2 Nondisclosure Agreements

An important component of a limited disclosure of a flavour formula is an agreement not to further disclose the information, or a nondisclosure agreement (NDA). The precise contents of a nondisclosure agreement should be established by the company holding the trade secret formula and may vary in different situations. The agreement should be a signed pledge by a specific individual(s) in the receiving organization (governmental or private) not to disclose the confidential information being provided. By signing an NDA, the individual, and the company receiving the confidential information become legally bound to keep the information secret. Disclosures that are inconsistent with the terms of the NDA are a breach and should be dealt with through appropriate local legal remedies.

6.3.3 Types of Limited Disclosure

There are two general types of limited disclosure: quantitative and qualitative. Quantitative disclosures relate to the *quantity, amount* or *concentration* of contents in a flavouring formula. Qualitative disclosures concern non-quantitative information about the contents of a flavouring formula; such disclosures mean revealing the *identity of certain ingredients* in the formula. Often qualitative disclosures may satisfy requests for formula disclosure, especially if accompanied by information demonstrating the safety of the flavouring substances in the formula.

6.3.4 Certificates of Composition

A certificate or declaration of composition is another way to substantiate the safety of a compounded flavour without revealing the individual flavouring ingredients. Such certificates or declarations usually contain the following elements:

- A certification that the flavouring formula meets the legal requirements in the country where the flavouring will be used.

- A declaration of some, but not all, of the individual ingredients used.
- The function of the ingredients listed, (i.e., flavour, carrier, anticaking agent).
- Percent range for each of the ingredients listed, (i.e. 21-26%).
- “Does not contain” statements - these statements can be used to respond to concerns about a particular ingredient, such as alcohol or genetically modified organisms, without disclosing the formula.

6.3.5 Chemical Family and Class

Another approach to satisfying a request for disclosure is to provide a breakdown of the formula by chemical family or chemical class. Examples of chemical families include: acids; alcohols; aldehydes; ketones; etc. For example, a limited disclosure by chemical family could indicate:

- *“These flavour ingredients include aromatic compounds including those identical to those found in essential oils, and extracts, sulfur compounds, organic acids, ketones, aldehydes and products like these.”*

A limited disclosure might include a description of the chemical families contained in the formula as well as a percentage range for each particular family. This is an example of providing some additional information while still protecting the complete formula.

A limited disclosure using chemical classes could be offered in the same manner as a chemical family disclosure with the use of class names, such as: aliphatic saturated acids; aromatic ketones; and other esters. Once again, if additional information is requested, one could consider providing a percent range for each particular chemical class together with safety data on the class such as published JECFA and FEXPAN group summaries.

6.3.6 Use of “Does Not Contain” Statements

The use of “does not contain” statements can be an effective way of eliminating customer or regulatory authority concerns without disclosing formula contents. Examples of commonly used “does not contain” statements include:

- *“This product does not contain any ingredient of animal origin.”*
- *“This product does not contain alcohol, and alcohol has not been used in the manufacturing process.”*

6.4 Government Requirements for Disclosure

There are an increasing number of government requirements for limited disclosure or labeling of individual flavouring ingredients. Perhaps the most obvious example is the requirement to disclose on the label when certain allergenic foods are present. Such requirements are a source of legitimate questions about a flavour formula. The following sections address typical requests for disclosure, and strategies that both respond appropriately to government regulators and protect the intellectual property of the industry.

6.4.1 Allergen Disclosures

Certain ingredients when present in a flavouring formula must be disclosed on bulk and consumer product labels because they have been shown to cause an allergic reaction in a certain portion of the population. At the publication of this edition of the Code of Practice there is not a harmonized list of food allergens. The Codex Alimentarius, the European Commission, the U.S. Food and Drug Administration and many other authorities require the disclosure on the label when certain allergenic ingredients are present. Although many of the lists have common ingredients there are also distinctions among them. It is important to maintain an up-to-date list of allergens that require labeling in a particular jurisdiction. IOFI regularly publishes guidance on allergen labeling requirements for flavours. Labeling for allergens is an example where disclosure of specific ingredients in an otherwise trade secret protected flavouring formula would be legally justified.

6.4.2 Oral Care Products

In Europe, the 7th Amendment to the Cosmetics Directive requires the identification on the label when any one of 26 so-called fragrance allergens is present in a cosmetic product above certain concentrations. Due to the way some oral care products are regulated in Europe, it is possible that the Cosmetics Directive requires that the manufacturer of the oral care product disclose the presence of these ingredients when used in a flavouring formula in one of these oral care products.

6.4.3 Pharmaceuticals

In many countries, products regulated as prescription or over the counter drugs require the disclosure of inactive ingredients such as flavours to drug registration authorities. The authorities charged with reviewing these products sometimes are required to ask for flavour formula disclosures. Once again, if not already known, it is important to request a copy of the statute or regulation that requires or authorizes the disclosure. In addition, you may want to

consider the use of a nondisclosure agreement to limit the way the information can be used.

6.4.4 Workplace safety

It is increasingly common for consumer product manufacturers to request formula information related to the flavours that they use to manufacture their products so that they may comply with relevant regulations or requests from regulators requiring the disclosure of possible workplace hazards. Increasingly, regulators make requests directly to flavour manufacturers for formula disclosure on possible workplace safety hazards. Workplace exposure limits such as permissible exposure limits (PELs) for flavouring substances may lead consumer product manufacturers to request formula disclosure for these substances. In the absence of regulations requiring disclosure of flavouring substances, flavour manufacturers may choose to employ one or more of the disclosure options described previously in this section such as the use of "does not contain" statements, limited qualitative disclosure, or the limited disclosure of some members of specific structural classes that may be of interest (e.g. aldehydes, ketones, etc.).

6.4.5 Illegal Drug Precursors

Under an agreement of the United Nations, the U.S. and several other countries, including Canada, Brazil and Argentina, regulate the industrial use of chemicals that are precursors for illegal drugs. One example of these chemicals is benzaldehyde. The regulations require registration, reporting and recordkeeping depending on how the substance is used in a flavour. Compliance with these regulations sometimes requires flavour manufacturers to provide limited formula information to customers or regulatory authorities.

6.4.6 Tobacco Products

Relevant local regulations or agreements may require disclosure of ingredients added to tobacco products. This is a special product category and the best way to protect the information may be to execute a non-disclosure agreement with the party receiving the information.

6.5 Conclusion

The examples above represent some of the legal justifications for disclosure. They are meant to demonstrate that there are legal reasons why customers may need to sometimes ask about certain contents of an otherwise confidential trade secret flavouring formula.

In addition to legal requirements to disclose certain ingredients, occasionally individual product manufacturers will prohibit or restrict certain ingredients. This is rare but it could be a source of questions about your formula.

Helping to protect the intellectual property of the flavour industry is an important goal for IOFI. Although there are some circumstances where disclosures are warranted, there are often measures that can be taken to focus a formula inquiry and minimize or avoid disclosure, thus responding appropriately to requests while protecting valuable trade secrets.

7. BASIC STANDARDS OF GOOD MANUFACTURING PRACTICE

7.1 Background

Flavouring substances and flavourings are food ingredients and shall be treated as such. Flavourings should be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice-General Principles of Food Hygiene (CAC/RP 1-1969 Rev.4 - 2003).

7.2 Flavour Manufacturing Employers

7.2.1 Employers are obligated to comply with all applicable workplace safety regulations and are encouraged to explore and address aspects of flavour manufacturing that may not be covered by workplace safety regulations.

7.3 Employees

7.3.1 Employees responsible for the manufacturing of flavourings shall be adequately qualified and trained to perform the duties required and shall be instructed likewise.

7.3.2 All employees active in the departments of the manufacture and packaging of flavourings shall be adequately dressed and free from communicable diseases.

7.4 Premises and sanitation

7.4.1 All manufacturing areas shall be clean, orderly and well ventilated. Instructions shall be issued indicating the areas to be cleaned, cleaning frequency, cleaning procedures and personnel responsible for cleaning operations. Appropriate cleaning equipment and cleaning materials shall be available.

7.4.2 Consumption of food and/or drinks, smoking and other unhygienic practices shall not be allowed in manufacturing areas.

7.4.3 Sufficient clean and well-ventilated sanitary facilities, including facilities for hand washing and changing of clothes shall be available near the working areas for the use of manufacturing personnel.

7.4.4 Instructions on access to and behavior in manufacturing areas shall be visually mounted at entrance areas.

7.4.5 Access to all manufacturing areas shall be restricted to authorized persons.

7.5 Ingredients and raw materials

- 7.5.1 Ingredients and raw materials used in the manufacture of flavourings should comply with appropriate national law and shall be examined as to their fitness for intended use by appropriately qualified personnel.
- 7.5.2 Ingredients and raw materials shall be stored under conditions that will maintain their fitness for use.
- 7.5.3 Ingredients and raw materials deemed to be unfit for use shall be identified as such and stored away from materials that are fit for use.

7.6 Manufacturing operations

- 7.6.1 All manufacturing operations and quality control operations on intermediates and final products shall be supervised by qualified personnel.
- 7.6.2 Appropriate cleaning instructions shall be issued for all equipment in use, and the personnel responsible for executing these instructions and verifying the cleanliness of equipment shall be designated.
- 7.6.3 All manufacturing equipment shall be designed and maintained to make it suitable for its intended use.
- 7.6.4 All manufacturing equipment shall be installed in the production premises in positions facilitating cleaning and maintenance, and minimizing contamination during its use.
- 7.6.5 Weighing and measuring equipment used in production and quality control shall be calibrated and checked for accuracy at suitable intervals by appropriate methods.
- 7.6.6 All vessels and containers holding raw materials, intermediates or finished products shall bear suitable means of identifying their contents.
- 7.6.7 Records shall be maintained of each batch of material manufactured.
- 7.6.8 Each batch of manufactured material shall be examined as to its fitness for use by appropriately qualified personnel.
- 7.6.9 All batch manufacturing records shall be retained for at least one year in such a way that proper tracking and tracing systems are in place.

7.7 Packaging

- 7.7.1 In selecting, handling and control of all packaging materials, proper attention shall be given to their condition, cleanliness and suitability for the product they contain.
- 7.7.2 All packages and containers of finished products shall be identified by labels mentioning the name, code and batch number of the product, its weight or volume, and any special storage and handling instructions as well as any directions for use, warnings and precautions which may be required.
- 7.7.3 All packaging material should comply with appropriate national law.

8. LABELING

8.1 Introduction

The labeling of flavourings shall comply with national and local regulations of the Country of Origin and in the case of flavours to be exported flavour manufacturers shall make their best efforts to assure that their labeling also complies with the labeling regulations of the Country of Destination with the understanding that failure to do so may result in the denial of entry. Where applicable, the labeling of flavours shall also conform to the following:

- 8.1.1 Where the term labeling is used, it shall include the transmission of information on relevant trade documents such as in Material Safety Data Sheets or Product Specifications Data Sheets.
- 8.1.2 The name and address of the flavour manufacturer or the distributor, as well as the name or the product code and the quantity shall be shown on the label.
- 8.1.3 Labeling of flavours should comply with local regulations. Also it should permit food manufacturers to comply with the legal requirements for their products. Particular attention should be paid to the classification of non-flavour ingredients in flavourings as these may be subject to different regulatory requirements in different countries, especially in how such materials must be labeled on food products.

8.2 More Guidance on Labeling

- 8.2.1 Additional guidance on labeling can be found in the Codex Alimentarius General Standards for the labeling of Food Additives When Sold As Such (Codex STAN 107-1981).

9. CLAIMS MADE IN THE LABELING, PRESENTATION OR ADVERTISING OF FLAVOURINGS

9.1 Introduction

Flavour manufacturers shall not make misleading statements when promoting their products.

- 9.1.1 Specifically, flavour manufacturers shall abstain from making any claim by way of statement or representation with a view to promoting the sale of a flavouring which implies or suggests that it possesses particular characteristics relating to its nature, properties, composition, quantity, durability, origin or provenance, method of manufacture or production which is untrue or misleading or which, when such a claim relates to a measurable or objective characteristic, cannot be substantiated.
- 9.1.2 The flavour industry enjoys greater than 100 years of success in working through our associations to fund a strong scientific program to support the safety of our industry's products. Any claims that attempt to malign competitive products or differentiate products based on safety should be discouraged as this practice would suggest that our products are not, in fact, safe.
- 9.1.3 Any claim indicating the absence or the low concentration of substances that are of toxicological concern, or contaminants already subject to quantitative limits or otherwise proscribed in this Code or in relevant governmental regulations, is not covered by the present recommendation.

10. QUALITY ASSURANCE AND MANAGEMENT

10.1 Quality Assurance

- 10.1.1 Quality Assurance procedures should define in sufficient detail sampling, including the quantities, tests to be performed, sample retention, and the schedule for release of the results to relevant audiences requiring such services.
- 10.1.2 The Quality Assurance department should maintain adequate records regarding the specification and test results of each batch on file in paper copy or electronic data for a suitable amount of time to comply with local regulation.
- 10.1.3 The Quality Assurance organization and procedures should enable management or outside monitoring agencies to check regularly whether all instructions and procedures for any stage of manufacturing and quality control are being followed strictly.

10.2 Quality Management

- 10.2.1 Companies should compile a flow diagram for the production process that monitors, ensures and documents the production of safe ingredients and flavourings under consideration of general hygiene rules and, if needed, special requirements on all steps. The process should prevent or minimise any hazards.
- 10.2.2 Flavour companies are requested to identify the food safety-relevant critical points in the process operations and also establish, conduct, comply with and monitor safety measures based on HACCP principles in accordance with the annex of CAC/RCP 1-1969 (Rev.4 ó 2003).

11. QUALITY CONTROL AND STORAGE

11.1 Quality Control

11.1.1 A Quality Control department directed by a qualified person should monitor and control predefined properties of all ingredients and finished products. This department should operate according to defined procedures, with the responsibility and authority to approve or reject the evaluated materials. During the period between the arrival from the supplier or from the production centre and its use in flavour compounding or shipment to the customer, all ingredients and finished products should be stored under conditions compatible with their physical and chemical properties.

11.1.2 The laboratory facilities for Quality Control purposes should be staffed and equipped commensurate with the requirements of effective quality control.

11.1.3 QC samples should be uniquely labeled, with reference to the date and batch number for all ingredients and finished products. Records should be kept permitting identification of the batch, the production history or origin, and defining dates for the various control steps, including release by the Quality Assurance department.

11.2 Storage

11.2.1 Samples for external reference of a product in commerce should be stored under suitable conditions for future reference for at least one year after manufacture or as long as shelf life defines.

11.2.2 All ingredients to be used in flavour compounding and finished products should be properly sampled, tested for compliance with organoleptic and analytical specifications and released by the Quality Control department via defined procedures.

11.2.3 Ingredients and finished products that have been rejected for any reason should be designated accordingly, quarantined physically and treated in accordance with the nature of the rejection.

12. STATEMENT ON SHELF LIFE AND RE-TESTING

12.1 Shelf Life

12.1.1 The shelf life of flavourings is defined as the period from the date of production during which the flavouring remains suitable for further use. This shelf life will be indicated by an appropriate label description that indicates minimum durability under appropriate storage conditions.

12.2 Re-Testing

- 12.2.1 The flavour industry has a common practice of re-testing flavourings at regular intervals.
- 12.2.2 Instead of allocating one single extended shelf life, the intention of re-testing is to ensure that the quality is checked at designated intervals and that the optimum quality is maintained during storage and subsequent transportation to the customer, and at the customer's warehouse prior to final use. Typically this practice consists of managing a QA/QC program based on regular sensory, physical, chemical and, if appropriate, microbiological analyses for determining continued conformance with the product specifications.
- 12.2.3 Frequency of the evaluations is based on recommendations of material suppliers, historical data on the product stability, and product experience or company practice.
- 12.2.4 Test procedures and frequency of testing may vary from company to company. Frequency of testing shall be based on the anticipated shelf life of the flavourings and shall be indicated by label descriptions such as "best before [date]" "re-analyze by [date]" "re-test by [date]" "expiry [date]" or any other appropriate wording.
- 12.2.5 Within the shelf life period, the quality of the flavouring is guaranteed to be in compliance with sensory, physical, chemical and, if appropriate, microbiological specifications. However, unused product can be re-analyzed before or at the specified date to establish that the product is still in compliance with the product specifications.
- 12.2.6 Descriptions such as "best before" "re-analyze by" "re-test by" or "expiry date" indicate a point in time at which the product should be re-analyzed against the product specifications before it can be further used in flavour formulation and/or food production. When the product is found in compliance the product will receive a new "best before [date]" "re-analyze by [date]" "re-test by [date]" or "expiry [date]" description. Test data and results reflecting the re-qualification shall be documented within a revalidation report issued by the QA/QC Department.

13. GUIDELINES ON THE IOFI INTERPRETATION OF THE TERM “NATURAL”

13.1 Introduction

The purpose of these Guidelines is to provide guidance on the IOFI interpretation of the term “natural” as used in the IOFI terminology (Chapter 3-Definitions) and the Codex Alimentarius Guidelines for the Use of Flavourings (CAC/GL 66-2008 ó Annex III). The application of the Code of Practice, including its Annexes does not relieve individual manufacturers from the obligation to comply with all national or international regulations that pertain to their operations. These regulations, including official guidelines and rulings and officially condoned practices, will take precedence over these Guidelines. In those countries where corresponding specific legislation are not in force, the Code of Practice should serve as a best practices resource.

13.2 Raw Materials

Raw materials, which are used as a source for natural flavourings, are materials of animal, vegetable or microbiological origin. Sources for natural flavouring complexes and natural flavouring substances are the essential oils, oleoresins, extractives, distillates, or products of roasting, heating or enzymatic transformations of spices, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs and other animal products, dairy products, or fermentation products thereof.

13.3 Isolation Techniques

All physical processes may be used for the isolation of natural flavouring complexes or natural flavouring substances. pH adjustment may be used for the isolation of acidic and basic materials.

13.4 Biochemical Processes for Natural Flavouring Complexes, Concentrates and Natural Flavouring Substances

13.4.1 Organisms and Enzymes

Biological entities capable of self-replication or resulting from biological reproduction such as bacteria, yeast, fungi, plants and animals, in whole or in part, and enzymes derived thereof, are permitted for producing natural flavourings.

13.4.2 Substrates

If the substrates used to produce natural flavourings by biochemical processes are natural, as defined in the other sections of this document, then the end products isolated from such processes are considered natural flavourings.

13.4.3 Co-factors, Nutrients, Vitamins, Hormones and pH-adjusting Agents

Materials added to the substrate necessary for the growth and function of the organism(s) such as co-factors, minerals, nutrients, vitamins, hormones, pH adjusting agents and electromagnetic radiation are not restricted in origin, but they may not exceed the levels required for the purpose of maintaining the growth and function of the organism(s) or parts thereof.

13.4.4 Carrier System

The carrier system may be aqueous or non-aqueous. Natural substrates can be used as carriers. Non-natural carriers can only be used if they do not react irreversibly and do not serve as a substrate. Carriers may remain in the final mixture provided they are permitted as carrier solvents for natural flavourings.

13.5 Other Processes for Natural Flavouring Complexes and Natural Flavouring Substances

Processing conditions are permissible if they are used in food processing or in-home preparation, or occur in nature. See examples in Table 1.

Table 1. Examples of food preparation processes

Absorption	Filtration
Adsorption	Grinding
Crystallization	Heating
Cutting	Mixing
Distillation	Osmoses
Drying (spray drying, freeze drying etc.)	Precipitation
Emulsification	Roasting
Encapsulation	Squeezing
Extraction	Sublimation
Extrusion	Ultrasonic treatment

13.6 Additional Provisions

The use of singlet oxygen or ozone is not allowed during processing.

13.7 Classification of Salts

Salts of natural flavouring substances with the following cations NH_4^+ , Na^+ , K^+ , Ca^{++} and Fe^{+++} or the anions Cl^- , SO_4^{--} and CO_3^{--} are classified as natural flavouring substances.

14. IOFI GUIDELINES FOR THE PRODUCTION OF THERMAL PROCESS FLAVOURINGS

14.1 Introduction

The Codex Alimentarius Guidelines (CAC/GL 66-2008) states that flavourings may consist of flavouring substances, natural flavouring complexes, smoke flavourings or thermal process flavourings. The purpose of this section is to provide guidance on the production and use of thermal process flavourings in countries that have no regulatory provisions covering this type of product. National regulations, if in existence and even if they do not use a special term to define thermal process flavourings, will always take precedence over these Guidelines.

14.2 Scope

14.2.1 These Guidelines deal with thermal process flavourings only. They do not apply to foods, flavouring extracts, chemically defined flavouring substances or mixtures of flavouring substances and flavour enhancers.

14.2.2 These Guidelines define those raw materials and process conditions which are similar to the cooking of food and which are process flavourings that are admissible without further evaluation.

14.3 Definition

A thermal process flavouring is a product prepared for its flavouring properties by heating raw materials that are foodstuffs or constituents of foodstuffs. This process is analogous to the traditional home cooking of ingredients of plant and animal origin.

14.4 Basic Standards of Good Manufacturing Practice

14.4.1 The requirements laid down in Chapter 7 of the IOFI Code of Practice are also applicable to process flavourings.

14.4.2 Process flavourings shall be prepared in accordance with the Codex Alimentarius General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4-2003)

14.5 Raw Materials that are Subject to Thermal Processing

Raw materials for process flavourings shall consist of one or more of the following:

14.5.1 Protein nitrogen sources:

- Foods containing protein nitrogen (meat, poultry, eggs, dairy products, fish, seafood, cereals, vegetable products, fruits, yeasts) and their extracts
- Hydrolysis products of the above, autolyzed yeasts, peptides, amino acids and/or their salts.

14.5.2 Reducing Sugars

- Examples: Maltose Syrup, glucose, fructose, galactose

14.5.3 Fat or fatty acid sources:

- Foods containing fats and oils
- Edible fats and oil from animal, marine or vegetable origin
- Hydrogenated, transesterified and/or fractionated fats and oils
- Hydrolysis products of the above.

14.5.4 Other raw materials listed in Table 1 below

14.6 Ingredients that may be Added After Thermal Processing

14.6.1 Flavourings as defined in the Codex Guidelines for the use of flavourings CAC/GL 66-2008 and flavour enhancers as defined by CAC/GL 36-1989.

14.6.2 Suitable non-flavouring food ingredients as listed in Annex I.

14.7 Preparation of Process Flavourings

Process flavourings are prepared by processing together raw materials listed under 14.5 as follows:

14.7.1 The product temperature during processing shall not exceed 180°C.

14.7.2 The processing time shall not exceed ¼ hour at 180°C, with correspondingly longer times at lower temperatures, i.e., a doubling of the heating time for each decrease of temperature by 10°C.

14.7.3 The pH during processing shall not exceed 8.

14.7.4 Flavourings, (14.6.1) and non-flavouring food ingredients (14.6.2) shall only be added after processing is completed, unless otherwise specified.

TABLE 1
Materials Used in Processing

- Foodstuffs, herbs, spices, their extracts and flavouring substances identified therein.
- Water
- Thiamine and its hydrochloric acid salt
- Ascorbic acid
- Citric acid
- Lactic acid
- Fumaric acid
- Malic acid
- Succinic acid
- Tartaric acid
- The sodium, potassium, calcium, magnesium and ammonium salts of the above acids
- Guanylic acid and inosinic acid and its sodium, potassium and calcium salts
- Inositol
- Sodium, potassium- and ammonium sulfides, hydrosulfides and polysulfides
- Lecithin
- Acids, bases and salts as pH, regulators:
 - Acetic acid, hydrochloric acid, phosphoric acid, sulfuric acid
 - Sodium, potassium, calcium and ammonium hydroxide
- The salts of the above acids and bases
- Polymethylsiloxane as antifoaming agent (not participating in the process).

15. IOFI GUIDELINES FOR THE PREPARATION OF SMOKE FLAVOURINGS

15.1 Introduction

The Codex Alimentarius Guidelines (CAC/GL 66-2008) states that flavourings may consist of flavouring substances, natural flavouring complexes, smoke flavourings or thermal process flavourings. The purpose of this section is to provide guidance on the production and use of smoke flavourings in countries that have no regulatory provisions covering this type of product. National regulations, if in existence and even if they do not use a special term to define smoke flavourings, will always take precedence over these Guidelines.

15.2 Scope

These guidelines deal with flavourings used for the purpose of imparting a smoke-type flavour to foodstuffs. These guidelines do not apply to foods, flavourings extracted from smoked foodstuffs or to flavourings obtained by compounding chemically defined flavouring substances. National regulations, if in existence, will always take precedence over these Guidelines. This includes the existence of specific definitions, rulings and officially condoned practices.

15.3 Definition

Smoke flavourings are complex mixtures of components of smoke obtained by subjecting untreated wood to pyrolysis in a limited and controlled amount of air, dry distillation, or superheated steam, then subjecting the wood smoke to an aqueous extraction system or to distillation, condensation, and separation for collection of the aqueous phase. The major flavouring principles of smoke flavourings are carboxylic acids, compounds with carbonyl groups and phenolic compounds.

15.4 Basic Standards of Good Manufacturing Practice

15.4.1 The requirements laid down in Chapter 7 of the IOFI Code of Practice are also applicable to smoke flavourings.

15.4.2 Smoke flavourings shall be prepared in accordance with the Codex Alimentarius General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4-2003)

15.5 Production of Smoke Flavourings

15.5.1 Raw materials

Untreated wood, bark and twigs of the following non-exhaustive list of species are used for the generation of smoke.

<i>Acer negundo</i> L.	Maple tree
<i>Betula pendula</i> Roth. (with ssp. <i>B. alba</i> L. and <i>B. verrucosa</i> Ehrh.)	White birch
<i>Betula pubescens</i> Ehrh. birch	European
<i>Carpinus betulus</i> L.	Hornbeam
<i>Carya ovata</i> (Mill.) Hickory (<i>C. alba</i> (L.) Nutt.)	Koch
<i>Castanea sativa</i> Mill. tree	Chestnut
<i>Eucalyptus</i> sp.	Eucalyptus
<i>Fagus grandifolia</i> Ehrh.	Beech
<i>Fagus silvatica</i> L.	Beech
<i>Fraxinus excelsior</i> L. ash	Common
<i>Juglans regia</i> L.	Walnut tree
<i>Malus pumila</i> Mill.	Apple
<i>Prosopis juliflora</i> DC., wood <i>P. velutina</i>	Mesquite
<i>Prunus avium</i> L.	Cherry tree
<i>Quercus alba</i> L.	White oak
<i>Quercus ilex</i> L.	Holm oak
<i>Quercus robur</i> L. red oak (<i>Q. pedunculata</i> Ehrh.)	Common
<i>Rhamnus frangula</i> L. Buckthorn	Alder
<i>Robinia pseudoacacia</i> locust	Black
<i>Ulmus fulva</i> Michx.	Sweet elm
<i>Ulmus rubra</i> Mühlenb.	Elm

Herbs and spices may also be added as well as twigs of Juniper (*Juniper communis*) and twigs, needles and cones of Pines.

15.5.2 Non flavouring food ingredients

Substances listed as non flavouring food ingredients in the Annex I.

15.6 Production Conditions

Smoke flavourings are prepared as follows:

15.6.1 By subjecting various untreated hardwoods to

- controlled burning, or
- dry distillation, or
- treatment with superheated steam and condensation
- and capturing of those fractions which have the desired flavour potential.

15.6.2 Then by applying further isolation techniques to the fractions obtained under 15.6.1 in order to retain only the flavour-important fractions or components.

15.6.3 The temperature during dry distillation is between 200°C and 600°C, and the treatment with superheated steam is between 300°C and 600°C

15.6.4 The solvents used for extraction and their residues are listed in Annex II.

16. IOFI GUIDELINES FOR ENZYMATIC AND MICROBIOLOGICAL PROCESSES FOR THE PRODUCTION OF FLAVOURINGS

16.1 Introduction

The purpose of these Guidelines is to assure the food industry and the ultimate consumer of food of the quality, safety and compliance with legislation of flavourings produced by enzymatic and microbiological processes. National regulations, if in existence, will always take precedence over these Guidelines. This includes the existence of specific definitions, rulings and officially condoned practices.

16.2 Scope

These Guidelines deal with enzymatic and microbiological processes used for the production of flavourings. These Guidelines do not apply to single chemically defined substances produced by these methods, provided that they comply with existing purity requirements (e.g. as reported in JECFA specifications) and are devoid of detectable residual enzymatic or microbiological activity.

16.3 Definition

Flavourings produced by enzymatic and microbiological processes are concentrated preparations, with or without non-flavouring food ingredients, used to impart flavour. They are produced by submitting a substrate or substrates to the action of enzymes or micro-organisms.

16.4 Basic Standards of Good Manufacturing Practice

16.4.1 The requirements laid down in Chapter 7 of the IOFI Code of Practice are also applicable to flavourings produced by enzymatic or microbiological processes.

16.4.2 Flavourings produced by enzymatic and microbiological processes shall be prepared in accordance with the Codex Alimentarius General Principles of Food Hygiene (CAC/RCP 1)1969, Rev.4-2003)

16.5 Production of Flavourings by Enzymatic or Microbiological Processes- See also 13.4

Flavourings produced by enzymatic or microbiological processes shall be prepared from or in the presence of one or more of the following and in accordance with the conditions cited hereafter:

16.5.1 Substrates

16.5.1.1 Source materials normally considered as foods.

16.5.1.2 Source materials not normally considered as foods

16.5.1.3 Isolated constituents of foods.

16.5.1.4 Isolated constituents of source materials not normally considered as foods

16.5.1.5 **Note:** Materials added to the substrate necessary for the growth and function of the organism(s) such as co-factors, minerals, nutrients, vitamins, hormones, pH adjusting agents and electromagnetic radiation are not restricted in origin, but they may not exceed the levels required for the purpose of maintaining the growth and function of the organism(s) or parts thereof.

16.5.2 Enzymes

16.5.2.1 Enzymes obtained from source materials which are normally considered as foods, traditionally accepted constituents of food, or normally used in the preparation of food.

16.5.2.2 Other enzymes

16.5.3 Micro-organisms

16.5.3.1 Micro-organisms that traditionally accepted constituents of food or that are traditionally used in the preparation of food.

16.5.3.2 Other micro-organisms

16.5.4 Non-flavouring food ingredients

16.5.4.1 Substances listed as non-flavouring food ingredients in Annex I of the IOFI Code of Practice.

16.5.5 Production Conditions

16.5.5.1 Enzymes (16.5.2) and micro-organisms (16.5.3) shall be used either as such or immobilised on a carrier. The carrier shall not release harmful substances.

16.5.5.2 Enzymes (16.5.2) and micro-organisms (16.5.3) shall be used as part of a fermentation medium, or in a more purified form.

- 16.5.5.3 The substrates (16.5.1) (see also 14.4) may be processed in the presence of enzymes (16.5.2) or micro-organisms (16.5.3). Non-flavouring food ingredients (16.5.4) may be present provided that they are added subsequent to enzymatic or microbiological processing, or provided that they are not modified in any way by such processing in accordance with the relevant requirements.
- 16.5.5.4 Enzymes (16.5.2) shall be separated from the flavouring, or inactivated, once the process is terminated.
- 16.5.5.5 Micro-organisms (16.5.2) shall be separated from the flavouring, or inactivated or destroyed once the process is terminated.
- 16.5.5.6 Micro-organisms shall not be used under conditions where they lead to products containing toxins or antibiotics.
- 16.5.5.7 Other materials: Materials such as co-factors, minerals, nutrients, feed stock, vitamins, hormones may be added only if they are necessary for the growth and function of the organism(s) or parts thereof, but their use may not exceed the levels required to maintain growth and function.

16.6 General Requirements

The safety in use of flavourings produced with the following materials and processes should be adequately established:

Materials or processes described above and specifically for the following:

- Substrates described under 16.5.1.2. and 16.5.1.4 and/or
- Enzymes described under 16.5.2.2 and/or
- Micro-organisms described under 16.5.3.2 and/or which may contain incompletely inactivated enzymes (see 16.5.5.4) and/or micro-organisms (see 16.5.5.5)

16.7 Labeling

In the absence of specific national regulations, the labeling of flavourings produced by enzymatic or microbiological processes can be considered as natural, provided the substrates from which they are derived are also natural (See 13.4.2).

17. GUIDELINES FOR HEALTH AND ENVIRONMENTAL PROTECTION

17.1 Field of Application

- 17.1.1 These Guidelines shall apply to the manufacture and handling of all flavourings and raw materials used for their production, including storage, production and plant design, in the flavour industry.
- 17.1.2 These Guidelines may require revision if future developments in the industry make it necessary.
- 17.1.3 The application of these Guidelines does not exempt individual manufacturers from the obligation to comply with all national or international regulations which are relevant to their operations.

17.2 Basic Principles

- 17.2.1 The protection of health in the workplace and the protection of the environment are of primary concern to the flavour industry. These Guidelines express a determination to protect human health and the environment from adverse effects by measures which may be additional to those required to comply with national or international regulations.
- 17.2.2 Risks to human health and the environment shall be minimized by taking all appropriate precautions and actions which are practicable, compatible with operational requirements and consistent with local conditions and national regulations. Measures taken should be appropriate to the degree of risk involved.
- 17.2.3 Free exchange of information on health and environmental subjects among individual companies should be encouraged.

17.3 Definitions

- 17.3.1 Manufacturing: All operations involved in the production of a flavour material including processing, compounding, packaging and labeling (see 7.6).
- 17.3.2 Environment: Water, air and soil and their inter-relationship as well as relationship between them and any living organisms.
- 17.3.3 Waste: Any unavoidable material, resulting from an industrial process, which must be disposed of.

17.4 Health Protection

- 17.4.1 All personnel involved in the manufacture and handling of flavourings and raw materials used for their production shall be protected from health hazards of a physical nature (e.g. noise, radiation, vibration) or chemical effects of gases, vapors or dusts in accordance with all relevant regulations.
- 17.4.2 Companies shall make their best efforts to eliminate or minimize exposure to health hazards by taking those precautions which are necessary in the light of experience, feasible according to the state of technology, and appropriate to the operating conditions.
- 17.4.3 Priority should be given to technical measures and improvements such as closed systems, the use of less hazardous materials, source venting and general ventilation.
- 17.4.4 If technical and organizational measures are not sufficiently effective, personal protective clothing and equipment should be worn such as respiratory protection (gas mask, breathing apparatus, etc.), eye and ear protection (safety glasses, face visor, ear plugs, etc.), hand and body protection (gloves, suit, apron, shoes, etc.).
- 17.4.5 Specific information and instructions on required protective measures should be provided to personnel in order to avoid health hazards in the workplace.
- 17.4.6 Companies should periodically audit any of their workplaces that have potential health hazards, with regard to health protection performance. If necessary, exposure-monitoring surveys should be carried out.
- 17.4.7 Where law requires no safety data sheets, recommendations on safe storage and handling should nevertheless be provided to customers.

17.5 Environmental Protection

- 17.5.1 The environment should be protected from adverse effects by appropriate organizational and technical measures. Companies should comply with all relevant regulations and avoid pollution that affects water, air, soil and public health.
- 17.5.2 Emissions that can have an adverse effect on the environment should be identified, assessed and, if feasible, reduced.
- 17.5.3 Provision should be made to avoid accidental discharges into the environment which could pose a risk to health of personnel or the general public, or could adversely effect the environment.

17.5.4 Companies should create awareness of environmental protection among all personnel handling materials and instruct them on emergency procedures in case of accidental discharge.

17.5.5 Recommendations should be provided to customers on storage and handling precautions in those cases where this is required to protect the environment.

17.6 Water Protection

17.6.1 Technical and administrative measures should be taken to make sure that discharged wastewater complies with the legal requirements relevant to the receiver (water stream, public or private sewer, or treatment plant).

17.6.2 Provision should be made to avoid discharging polluting materials into surface water drains.

17.7 Air protection

17.7.1 The emission of inorganic or organic materials into the atmosphere must be kept within the levels specified in national or local regulations, whichever are most stringent.

17.7.2 Technical and administrative measures should be taken to avoid the accidental discharge into the atmosphere of quantities of materials hazardous to health or to the environment.

17.8 Soil and Groundwater Protection

17.8.1 The soil shall be protected from adverse contamination by inorganic or organic materials.

17.8.2 Technical and organizational measures shall be taken to avoid contamination of groundwater arising from soil contamination.

17.9 Waste Disposal

17.9.1 Priority should be given to reducing the quantity of waste material produced. Efforts should be made to recycle waste where practical as feedstock, to use it for energy production or for other purposes.

17.9.2 Chemical wastes shall be disposed of according to national or international legal requirements. Only officially approved disposal sites shall be used.

17.9.3 The most appropriate disposal methods should be selected for each waste so as to ensure adequate protection of the public and the environment. Currently, incineration is to be preferred to landfill, wherever possible.

17.9.4 Appropriate waste management methods should be applied. Adequate records of all disposed wastes should be kept. Landfill disposal records should be maintained in accordance with relevant regulations.

18. ANNEX I: LISTS OF FLAVOURINGS AND NON-FLAVOURING FLAVOUR INGREDIENTS

18.1 Global Reference List of Flavourings – See also Chapter 5.

The inclusion of flavouring substances and natural flavouring complexes in the IOFI Global Reference List (GRL) is based on their evaluation in a robust safety evaluation process resulting in a determination that they are safe under the conditions of intended use. Generally, materials that have been included in the IOFI GRL have been reviewed and determined to be safe for flavour use by the European Food Safety Authority (EFSA), the Council of Europe (CoE), the Scientific Committee on Food (SCF), the U.S. Food and Drug Administration (FDA), the Expert Panel of the Flavor and Extract Manufacturers Association of the United States (FEMA), the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or the Japanese Food Safety Commission (FSC).

While, the inclusion of a flavouring substance or natural flavouring complex in the IOFI GRL supports the general recognition that it can be safely used in flavours, it does not in and of itself confer regulatory suitability in any specific regulatory jurisdiction. Regulatory authority for the market of intended sale must be separately determined.

18.2 Note on Isomers

18.2.1 In flavour manufacturing, during the isolation of naturals and/or chemical synthesis, pure stereo isomers, geometric isomers or positional isomers can be obtained, as well as mixtures of isomers of variable compositions.

18.2.2 Authoritative bodies involved in the safety assessment of flavouring substances may have reviewed the safety of either the individual stereo-, geometric or positional isomers, or mixtures thereof, as can be deduced from the name, the structural formula or the specifications of the evaluated substance.

18.2.3 In assessing whether a particular component or isomer has been positively evaluated, it is important to investigate whether the safety assessment related to the mixture, or to one of the individual components.

- If the assessment occurred on the mixture, it can be assumed that this assessment remains valid for the safety assessment of the individual components or isomers.
- In situations where the safety assessment only related to a specific component or isomer, it can not simply be assumed that this assessment is valid for the mixture or a different isomer of the related compound. In this case a specific safety assessment may be required to cover either the related isomer or the mixture of isomers.

18.3 LIST OF SOLVENTS AND CARRIERS FOR FLAVOURINGS

Any appropriate food (e.g. sugars, fats, oils or food ingredient) may be used to dilute a flavouring and to facilitate its incorporation and dispersion in a food product.

IOFI acknowledges the use of the following solvents and supports for flavourings, but also recognizes that other suitable materials may be used. Ingredients with an INS (International Numbering System) code are ingredients present on the Codex Alimentarius Food Additives List (CAC/GL 36-1989, revision 2008).

Note: Listing in one section does not preclude the use of those in other categories.

Acetic acid	INS 260
Acetylated distarch adipate	INS 1422
Acetylated distarch phosphate	INS 1414
Agar agar	INS 406
Alginic acid	INS 400
Beeswax	INS 901
Benzyl alcohol	INS 1519
beta-Cyclodextrine	INS 459
Calcium carbonate	INS 170
Calcium silicate	INS 552
Calcium sulphate	INS 516
Candelilla wax	INS 902
Carboxymethyl cellulose, Na salt	INS 466
Carnauba wax	INS 903
Carrageenan	INS 407
Cellulose, microcrystalline	INS 460
Dextran	
Dextrin	
Diammonium phosphate	
Distarch phosphate	INS 1412
Edible fats	
Edible oils	
Elemi resin	
Ethyl alcohol	
Ethyl lactate	
Ethyl cellulose	INS 462
Ethyl hydroxyethyl cellulose	INS 467
Ethyl tartrate	
Gelatin	
Gellan gum	INS 418
Ghatti gum	

Glucose	
Glycerol	INS 422
Glyceryl diacetate	
Glyceryl diesters of aliphatic fatty acids C ₆ -C ₁₈	INS 471
Glyceryl monoesters of aliphatic fatty acids C ₆ -C ₁₈	INS 471
Glyceryl triacetate (Triacetin)	INS 1518
Glyceryl triesters of aliphatic fatty acids C ₆ -C ₁₈	
Glyceryl tripropanoate	
Guar gum	INS 412
Gum Arabic	INS 414
Hydrogenated vegetable oils	
Hydrolyzed vegetable protein	
Hydroxypropylmethyl cellulose	INS 464
Hydroxypropyl cellulose	INS 463
Hydroxypropyl distarch phosphate	INS 1442
Hydroxypropyl starch	INS 1440
iso-Propylalcohol	
Karaya gum	INS 416
Konjac gum	INS 425
Lactic acid	INS 270
Lactose	
Locust bean gum (Carob bean gum)	INS 410
Magnesium carbonate	INS 504 i
Magnesium salts of fatty acids	INS 470b
Maltodextrin	
Mannitol	INS 421
Methyl cellulose	INS 461
Medium chain triglyceride	
Modified Starches	
Acetylated distarch adipate	INS 1422
Acetylated oxidized starch	INS 1451
Acid-treated starch	INS 1401
Alkaline treated starch	INS 1402
Bleached starch	INS 1403
Dextrins, roasted starch	INS 1400
Distarch phosphate	INS 1412
Hydroxypropyl distarch phosphate	INS 1442
Acetylated distarch phosphate	INS 1414
Hydroxypropyl starch	INS 1440
Monostarch phosphate	INS 1410
Oxidized starch	INS 1404
Phosphated distarch phosphate	INS 1413
Starch acetate	INS 1420
Starch sodium octenyl succinate	INS 1450

Starches, enzyme treated	INS 1405
Mono-,di- and tri-Calcium orthophosphate	INS 341i, ii, iii
Na, K, NH ₄ and Ca alginate	INS 401-404
Pectins	INS 440
Processed eucheama seaweed	INS 407a
Propylene glycol	INS 1520
Propylene glycol alginate	INS 405
Sodium chloride (salt)	
Silicon dioxide	INS 551
Sodium aluminium diphosphate	INS 541
Sodium aluminium silicate	INS 554
Sodium, potassium and calcium salts of fatty acids	INS 470 i, ii
Sorbitol	INS 420 i
Sorbitol sirup	INS 420 ii
Starch	
Starch (sodium) octenyl succinate	INS 1450
Starch acetate	INS 1420
Sucro glycerides	INS 474
Sucrose	
Sucrose esters of fatty acids	INS 473
Sucrose oligoesters, type I and type II	INS 473a
Taragum	INS 417
Tragacanth	INS 413
Triethylcitrate	INS 1505
Water	
Whey powder	
Xanthan gum	INS 415
Xylitol	

18.4 LIST OF ANTIOXIDANTS FOR FLAVOURINGS

IOFI acknowledges the use of the following antioxidants for flavourings, but also recognizes that other suitable materials may be used.

Ascorbic acid	INS 300
Na and Ca salts of ascorbic acid	INS 301-302
Ascorbyl palmitate	INS 304
BHA (Butylated hydroxyanisole)	INS 320
BHT (Butylated hydroxytoluene)	INS 321
Dodecyl gallate	INS 312
Erythorbic acid	INS 315
Sodium, potassium, calcium erythorbate	INS 316, 317, 318
Octyl gallate	INS 311
Propyl gallate	INS 310
TBHQ (tert.-Butyl hydroquinone)	INS 319

Tocopherols - natural	INS 306
Tocopherols - synthetic	INS 307-309

18.5 LIST OF SEQUESTRANTS FOR FLAVOURINGS

IOFI acknowledges the use of the following sequestrants for flavourings, but also recognizes that other suitable materials may be used.

Citric acid multifunctional	INS 330
Ethylene diamino tetraacetic acid and its mono-di- and tri-sodium and calcium di-sodium salts	INS 385, 386
Tartaric acid	INS 334
Tetrasodium diphosphate	INS 450iii
Other phosphates ADD	INS 450, 451

18.6 LIST OF PRESERVATIVES FOR FLAVOURINGS

IOFI acknowledges the use of the following preserving agents for flavourings, but also recognizes that other suitable materials may be used.

Benzoic acid	INS 210
Na, K and Ca salts of benzoic acid	INS 211-213
Ethyl p-hydroxybenzoate	INS 214
Sodium ethyl p-hydroxybenzoate	INS 215
Methyl p-hydroxybenzoate	INS 218
Sodium propyl p-hydroxybenzoate	INS 217
Propyl p-hydroxybenzoate	INS 216
Propionic acid	INS 280,
Na and K salts of propionic acid	INS 281, 283
Sorbic acid	INS 200
Na, K and Ca salts of sorbic acid	INS 201-203
Sulphur dioxide	INS 220
Na, K, Ca sulphites, bisulphites, hydrogen sulphite and metabisulphites	INS 221-228
Sodium methyl p-hydroxybenzoate	INS 219

18.7 LIST OF EMULSIFIERS AND STABILIZERS FOR FLAVOURINGS

IOFI acknowledges the use of the following emulsifiers and stabilizers for flavourings, but also recognizes that other suitable materials may be used.

Agar-Agar	INS 406
Alginic acid	INS 400

Na, K, NH ₄ and Ca salts of alginic acid	INS 401-404
Carageenan	INS 407
Citric and fatty acid esters of glycerol	INS 472c
Diacetyl tartaric and fatty acid esters of glycerol	INS 472
Glyceryl diesters of aliphatic fatty acids C ₆ -C ₁₈	INS 471
Glyceryl monoesters of aliphatic fatty acids C ₆ -C ₁₈	INS 471
Guar gum	INS 412
Gum arabic	INS 414
Gum ghatti	INS 419
Gum tragacanth	INS 413
Lactates of mono and di-glycerides of fatty acids	INS 472b
Lecithin	INS 322
Locust bean gum (Carob bean gum)	INS 410
Methyldihydroabietate	
Modified Starches	
Acetylated distarch adipate	INS 1422
Acetylated oxidized starch	INS 1451
Acid-treated starch	INS 1401
Alkaline treated starch	INS 1402
Bleached starch	INS 1403
Dextrins, roasted starch	INS 1400
Distarch phosphate	INS 1412
Hydroxypropyl distarch phosphate	INS 1442
Acetylated distarch phosphate	INS 1414
Hydroxypropyl starch	INS 1440
Monostarch phosphate	INS 1410
Oxidized starch	INS 1404
Phosphated distarch phosphate	INS 1413
Starch acetate	INS 1420
Starch aluminium octenyl succinate	INS 1452
Starches, enzyme treated	INS 1405
Pectins	INS 440
Polyglycerol esters of fatty acids	INS 475
Polyoxyethylene (20) sorbitan monolaurate	INS 432
Polyoxyethylene (20) sorbitan monooleate	INS 433
Polyoxyethylene (40) sorbitan monopalmitate	INS 434
Polyoxyethylene (40) stearate	INS 431
Polyoxyethylene (60) sorbitan tristearate	INS 436
Polyoxyethylene (8) stearate	INS 430
Polyoxyethylene(80) sorbitan monostearate	INS 435
Processed euchema seaweed	INS 407a
Propylene glycol alginate	INS 405
Propylene glycol stearate	
Propyleneglycol esters of fatty acids	INS 477

Sodium citrate	
Sodium stearoyl-2-lactate	INS 481 i
Sorbitan monolaurate	INS 493
Sorbitan monooleate	INS 494
Sorbitan monopalmitate	INS 495
Sorbitan monostearate	INS 491
Sorbitan tristearate	INS 492
Stearyl tartrate	INS 483
Sucro glycerides	INS 474
Sucrose acetate isobutyrate	INS 444
Sucrose esters of fatty acids	INS 473
Xanthan gum	INS 415

18.8 LIST OF WEIGHTING AGENTS FOR FLAVOURINGS

IOFI acknowledges the use of the following weighting agents for flavourings, but recognizes that other suitable materials may be used.

Glycerolester of wood rosin (Estergum)	INS 445
Glyceryl tribenzoate	
Glycerylester of hydrogenated rosin	
Hydrogenated colophonium	
Methyldihydroabietate	
Methylester of hydrogenated rosin	
Propyleneglycol dibenzoate	
Sucrose acetate isobutyrate	INS 444

18.9 LIST OF ACIDS, BASES, SALTS FOR FLAVOURINGS

IOFI acknowledges the use of the following acids, bases, salts for flavourings, but also recognizes that other suitable materials may be used.

Acetic acid	INS 260
Acetic acid, Na, K and Ca salts	INS 261-263
Adipic acid	INS 355
Adipic acid, Na and K salts	INS 356-7
Calcium carbonate	INS 170,170i,170ii
Citric acid	INS 330
Citric acid, Na, K and Ca salts	INS 331-333
Fumaric acid	INS 297
Hydrochloric acid	INS 507
K and Na mono-and dibasic orthophosphates	INS 339-340
K, Ca and Mg chlorides	INS 508-511
K, Ca, NH ₄ and Mg hydroxides	INS 525-528
Lactic acid	INS 270

Lactic acid, Na, K and Ca salts	INS 325-327
Magnesium carbonate	INS 504
Malic acid	
Malic acid, Na, K and Ca salts	INS 350-352
Na, K, Ca, NH ₄ and Mg sulphates	INS 514-518
Phosphoric acid	INS 338
Potassium carbonate	INS 501
Sodium carbonate	INS 500
Sodium hydroxide	INS 524
Succinic acid	INS 363
Succinic acid, Na	INS 364
Succinic acid, K	
Sulphuric acid	INS 513
Tartaric acid	INS 334
Tartaric acid, Ca salt	INS 354
Tartaric acid, Na and K salts	INS 335-7

18.10 LIST OF ANTICAKING AGENTS FOR FLAVOURINGS

IOFI acknowledges the use of the following anticaking agents for flavourings, but also recognizes that other suitable materials may be used.

Aluminium silicate (Kaolin)	INS 559
Calcium aluminium silicate	INS 556
Calcium carbonate	INS 170
Calcium silicate	INS 552
Magnesium carbonate	INS 504
Magnesium silicate	INS 553
mono-, di- and tri-Calcium orthophosphate	INS 341
Potassium aluminium silicate	INS 555
Silicon dioxide, amorphous (silicic acid, colloidal)	INS 551
Sodium aluminium silicate	INS 554
Stearic acid, salts	INS 470,470i,470ii

19. ANNEX II: EXTRACTION SOLVENTS AND FLAVOURING SUBSTANCES REQUIRING ADDITIONAL ATTENTION

19.1 EXTRACTION SOLVENTS FOR NATURAL FLAVOURING COMPLEXES REQUIRING SPECIFIC ATTENTION

For the use of the following extraction solvents maximum concentrations, contributing to the finished food as consumed by extraction solvent residues present in flavourings, must comply with national and regional legislation.

IOFI acknowledges the use of the following solvents for extraction in the production of flavourings, but also recognizes that other suitable materials may be used.

In the absence of regulations the residue limits listed below are considered appropriate.

	ppm
Butane	1
Propane	1
Isobutane	1
Toluene	1
Cyclohexane	1
Hexane	1
Light petroleum	1
Methanol	10
Butan-1-ol	10
Acetone	2
Ethylmethylketone	2
Ethyl acetate	10
Diethyl ether	2
Dibutyl ether	2
Methyl tert.-butyl ether	2
Dichloromethane	2
Carbon dioxide	limit not specified

Note: Carrier solvents, some flavouring substances and some natural food materials may be used as extraction solvents.

19.2 FLAVOURINGS SUBSTANCES AND COMPONENTS OF NATURAL FLAVOURING COMPLEXES REQUIRING SPECIFIC ATTENTION

IOFI is aware that some substances are being evaluated by various regulatory bodies. Pending completion of the evaluations consistent with the Codex Guidelines on the Use of Flavourings CAC/GL 66-2008 (Annex III), IOFI recognizes that for these substances restrictions may apply under national/regional regulations.

20. ANNEX III – GUIDELINES OF THE CODEX ALIMENTARIUS COMMISSION FOR THE USE OF FLAVOURINGS

CAC/GL 66-2008

1.0 SCOPE

This guideline provides principles for the safe use of the components of flavourings evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and determined to present no safety concern at estimated levels of intake, or that have established JECFA acceptable daily intakes (ADIs), and for which corresponding specifications of identity and purity have been established and adopted by Codex.¹ In addition, the guideline provides principles for the establishment of practices that do not mislead the consumer.

2.0 DEFINITIONS

2.1 Flavour is the sum of those characteristics of any material taken in the mouth, perceived principally by the senses of taste and smell, and also the general pain and tactile receptors in the mouth, as received and interpreted by the brain. The perception of flavour is a property of flavourings.

2.2 Flavourings are products that are added to food to impart, modify, or enhance the flavour of food (with the exception of flavour enhancers considered as food additives under the Codex Class Names and the International Numbering System for Food Additives - CAC/GL 36-1989). Flavourings do not include substances that have an exclusively sweet, sour, or salty taste (e.g. sugar, vinegar, and table salt). Flavourings may consist of flavouring substances, natural flavouring complexes, thermal process flavourings or smoke flavourings and mixtures of them and may contain non-flavouring food ingredients (Section 2.3) within the conditions as referred to in 3.5. They are not intended to be consumed as such.

2.2.1 Flavouring substances are chemically defined substances either formed by chemical synthesis, or obtained from materials of plant or animal origin.

2.2.1.1 Natural flavouring substances are flavouring substances obtained by physical processes that may result in unavoidable but unintentional changes in the chemical structure of the components of the flavouring (e.g. distillation and solvent extraction), or by enzymatic or microbiological processes, from material of plant or animal origin. Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, torrefaction (roasting) and fermentation). This means substances that have been identified / detected in a natural material of animal or vegetable origin.

2.2.1.2 Synthetic flavouring substances are flavouring substances formed by chemical synthesis.

2.2.2 Natural flavouring complexes are preparations that contain flavouring substances obtained by physical processes that may result in unavoidable but unintentional changes in the chemical structure of the flavouring (e.g. distillation and solvent extraction), or by enzymatic or microbiological processes, from material of plant or animal origin. Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, torrefaction (roasting) and fermentation). Natural flavouring complexes include the essential oil, essence, or extractive, protein hydrolysate, distillate, or any product of roasting, heating, or enzymolysis.

2.2.3 Smoke flavourings are complex mixtures of components of smoke obtained by subjecting untreated wood to pyrolysis in a limited and controlled amount of air, dry distillation, or superheated steam, then subjecting the wood smoke to an aqueous extraction system or to distillation, condensation, and separation for collection of the aqueous phase. The major flavouring principles of smoke flavourings are carboxylic acids, compounds with carbonyl groups and phenolic compounds.²

2.3 Non-flavouring food ingredients are food ingredients, such as food additives and foodstuffs that can be added to flavourings and are necessary for dissolving, dispersing, or diluting flavourings, or are necessary for the production, storage, handling and use of flavourings.

3.0 GENERAL PRINCIPLES FOR THE USE OF FLAVOURINGS

3.1 The use of flavourings in food should not lead to unsafe levels of their intake.

3.2 Flavourings should be of a purity suitable for use in food. Unavoidable impurities should not be present in the final food at levels that would pose an unacceptable risk to health.

3.3 The use of flavourings is justified only where they impart or modify flavour to food, provided that such use does not mislead the consumer about the nature or quality of food.

3.4 Flavourings should be used under conditions of good manufacturing practice, which includes limiting the quantity used in food to the lowest level necessary to accomplish the desired flavouring effect.

3.5 Flavourings may contain non-flavouring food ingredients, including food additives and foodstuffs, necessary for their production, storage, handling, and use.

Such ingredients may also be used to facilitate the dilution, dissolution, or dispersion of flavourings in food. Non-flavouring food ingredients should be:

Limited to the lowest level required to ensure the safety and quality of the flavourings, and to facilitate their storage and ease of use;

Reduced to the lowest level reasonably possible when not intended to accomplish a technological function in the food itself; and,

used in accordance with the provisions of the Codex General Standard for Food Additives (GSFA; CODEX STAN 192) whenever they are intended to provide a technological function in the finished food.

4.0 FLAVOURING SUBSTANCES AND COMPONENTS OF NATURAL FLAVOURING COMPLEXES THAT MAY REQUIRE SOME RISK MANAGEMENT MEASURES

4.1 Some flavouring substances, and substances that may be components of natural flavouring complexes, or of food ingredients with flavouring properties (e.g. herbs and spices) may be identified by Codex members to be of potential health concern. Based on the evaluations by the JECFA, the Codex Alimentarius may consider proposals for specific risk management measures for certain flavouring substances or components of natural flavouring complexes to ensure consumer protection.

4.2 It may be appropriate in certain cases for Members to establish risk management measures to minimize specific risks. To avoid potential conflicts in risk management decisions between Codex and its members, any risk management measures selected by Members should complement existing Codex risk management guidance and take into account relevant JECFA evaluations.

4.3 When establishing risk management measures to reduce the risk to human health from such flavouring substances whether added as such or as components of natural flavouring complexes or as naturally occurring components of food, the following criteria should be considered.

An appropriate risk assessment of the flavouring substance, component of a natural flavouring complex or a naturally occurring component of food has been conducted.

The risk assessment has identified a specific human health risk associated with the presence of the substance in food as a result of its use as a flavouring substance, as a component of a natural flavouring complex or as a naturally occurring component of food.

Acceptable maximum levels for substances of concern in specific

foods have been established based on an assessment of dietary exposure using an appropriate method to ensure that the intake of the substance from all sources does not present a safety concern.

A reference to a validated analytical method for the determination of the substance in food should be available. Methods of analysis should comply with the Principles for the Establishment of Codex Methods of Analysis (CAC Procedure Manual.).

5.0 HYGIENE

5.1 It is recommended that flavourings covered by the provisions of these guidelines be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice ó General Principles of Food Hygiene (CAC/RCP 1-1969), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.ö

5.2 Flavourings should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

6.0 LABELLING

Labelling of flavourings should be in accordance with the requirements of the *Codex General Standard for the Labelling of Food Additives when sold as such* (CODEX STAN 107-1981). Labelling of foods containing added flavourings should be in accordance with the requirements of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985).

7.0 JECFA EVALUATIONS OF FLAVOURINGS AND THEIR SPECIFICATIONS

The flavourings for which JECFA has completed its safety evaluation are available from the WHO JECFA website, (<http://www.who.int/ipcs/publications/jecfa/en/index.html>) through the link *Database of evaluation summaries*, or by contacting the WHO JECFA Secretariat. Specifications for flavouring substances evaluated by JECFA are available, in an on-line searchable database at the FAO JECFA website (http://apps3.fao.org/jecfa/flav_agents/flavag-q.jsp), or by contacting the FAO JECFA Secretariat.

¹ This guideline does not imply that the uses of flavouring components that have not yet been evaluated by JECFA are unsafe or otherwise unacceptable for use in food.

² FAO JECFA Monographs 1 (Volume 3) 2005 FAO Rome.