



IOFI



Code of Practice

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Code of Practice of the International Organization of the Flavor Industry

IOFI has adopted the following 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 (CoP) in good faith using the most accurate information available. The IOFI Code of Practice is intended for use as a voluntary best practices resource document by the entire IOFI membership. It is the responsibility of the IOFI ordinary company members as well as of individual company members affiliated to 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 content of the Code of Practice, nor are they responsible for any effects of the application and use or misuse of the content of the Code of Practice.

2 PREFACE

2.1 About IOFI

The International Organization of the Flavor Industry (IOFI) is an umbrella association composed of ordinary association members, ordinary company members and corresponding member associations. See list of members under: www.iofi.org/members.

2.2 Mission Statement

The International Organization of the Flavor Industry advances the global trade of safe, responsibly produced flavorings that respect the environment and enrich the lives of consumers.

2.3 Strategic Objectives & Core Values

As the global flavor industry's representative, IOFI:

- 2.3.1 Uses and promotes highly reliable, state-of-the-art science to assure the safe use of flavoring materials.
- 2.3.2 Facilitates a harmonized approach to flavoring regulations that supports a global industry.
- 2.3.3 Builds understanding and trust in flavorings and the flavor industry through collaboration with member associations and other stakeholders.
- 2.3.4 Recognizes the impact of resource efficiency, biodiversity protection, circular economy, human health and environmental issues which are prerequisites for any responsible and sustainable business.

2.4 IOFI and the CODEX ALIMENTARIUS COMMISSION

- 2.4.1 The Codex Alimentarius Commission (CAC) was established by the United Nation's 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 CAC has the responsibility for developing food standards that may be adopted by member countries. The science-based standards take into consideration the

expert advice provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the group responsible for performing safety assessments of food additives and flavoring substances for supporting CAC 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 CAC 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 Contaminants in Food (CCCF), and the Codex Committee on Food Labeling (CCFL). See <http://www.fao.org/fao-who-codexalimentarius/en/> 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). IOFI supports the *Codex Guidelines* and recognizes their value in providing principles for the safe use of components of flavorings evaluated by JECFA and determined to present no safety concern at estimated levels of intake.

2.5 The IOFI Global Reference List

The IOFI Secretariat maintains a Global Reference List (GRL) that is publicly available under www.iofi.org.

The GRL is sub-divided in two parts: Part 1 contains a list of chemically defined substances (CDS, see also 3.3.1.1 the definition of “flavoring substances”) and Part 2 contains a list of natural complex substances (NCS).

The GRL is subject to regular updates.

2.5.1 Chemically defined substances (CDS)

Generally, materials that have been included in the Part 1 of the IOFI GRL have been reviewed and determined to be safe for flavor use in food by the European Food Safety Authority (EFSA)¹, the Council of Europe (CoE), the U.S. Food and Drug Administration (FDA), the Expert Panel of the Flavor and Extract Manufacturers Association of the United States (FEMA Expert Panel), the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or the Japanese Food Safety Commission (FSC).

¹ The Scientific Committee on Food (SCF), established in 1974, was the main committee providing the European Commission with scientific advice on food safety (including flavorings). Its responsibilities have been transferred to the European Food Safety Authority (EFSA) in 2003.

While the inclusion of a flavoring substance in the Part 1 of the IOFI GRL supports the conclusion that it can be safely added to food, it does not in and of itself confer regulatory authority to use in any specific regulatory jurisdiction. Regulatory authority for the market of intended sale must be separately determined.

2.5.2 Natural Complex Substances (NCS)

Materials of plant or animal origin (i.e., source materials) may be used to produce flavorings. The constituents derived from these source materials (e.g., essential oils, essences, extractives, etc.) are referred to as natural complex substances.

On Part 2 of the IOFI GRL, source materials and/or natural complex substances that have undergone a safety evaluation by the FEMA Expert Panel or have been recognized as safe by the US FDA and/or the Council of Europe are provided.

While the FEMA Expert Panel has evaluated the safety of numerous natural complex substances (i.e., products derived from specific source materials), the US FDA and the Council of Europe have considered only the source materials.

The safety recognition by US FDA and/or Council of Europe is based on the widely accepted assumption that substances naturally occurring in food that have a long history of use can be considered as safe. This principle has been enshrined in the EU Flavouring Regulation (EC) No 1334/2008 and appears to be applied by multiple national regulators around the world.

Natural flavoring complexes (as defined under CAC/GL 66-2008, 2.2.2) are preparations that contain flavouring substances obtained by physical processes (e.g., distillation and solvent extraction) that may result in unavoidable but unintentional changes in the chemical structure of the flavouring, 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).

Some jurisdictions have more precise descriptions of the acceptable processes (e.g., EU Flavouring Regulation (EC) No 1334/2008).

Typically, many of the constituents contained within natural complex substances are chemically defined substances that are also listed within Part 1 of the GRL. Due to the way they are produced, natural complex substances may also contain constituents that are naturally occurring in the source materials, e.g., intrinsic fruit water, as well as food/food ingredients used during the manufacturing process.

National legislations stipulating specific provisions for undesirable substances (e.g., biologically active principles) contained in source materials and natural complex substances must be observed.

Natural flavoring complexes fulfilling the aforementioned prerequisites are safe and therefore acceptable for use in and on foods, even though they may not be listed in Part 2 of the Global Reference List.

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 flavorings. The application of the Code of Practice does not relieve individual manufacturers or users of flavorings 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 flavorings are not in force, the Code of Practice may serve as a best practices resource.

Additionally, this Code of Practice is published and provided to IOFI members in order to support fair and robust competition in the global marketplace. IOFI is an international trade association and its members work together to accomplish common goals that are appropriate under antitrust laws around the globe. However, it is contrary to antitrust laws for IOFI members to use the association to accomplish objectives that would benefit single members or select groups of members by diminishing competition. Therefore, the IOFI Code of Practice must not be used by members or groups of members to diminish competition or stifle innovation in contravention of antitrust laws.

3 DEFINITIONS AND TERMINOLOGY

3.1 Introduction

Definitions and terminology used in the IOFI Code of Practice are, where applicable, in compliance with definitions and terminology as used in the current *Codex Guidelines for the Use of Flavourings* (CAC/GL 66-2008). 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 Flavor (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 Flavorings

3.3.1 **Flavorings** (CAC/GL 66-2008 item 2.2) are products that are added to food to impart, modify², 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. They are not intended to be consumed as such.

3.3.1.1 **Flavoring Substances** (CAC/GL 66-2008 item 2.2.1) *are chemically defined substances (CDS) either formed by chemical synthesis, or obtained from materials of plant or animal origin. (See also section 2.5.1)*

² Nowadays the demand for foods and beverages with lower sugar, fat or salt content increases. However, often taste challenges come along with better-for-you products. There are flavoring ingredients with characteristics that can help improve the consumer's experience of these 'lite' products, for example by decreasing bitterness, masking off-notes and restoring mouthfeel. They are called Flavorings with Modifying Properties (FMPs) and they help to make healthier products taste great. They form an integral part of the ingredient group known as flavorings.

3.3.1.1.1 Natural flavoring 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.*

3.3.1.1.2 Synthetic flavoring substances (CAC/GL 66-2008 item 2.2.1.2) *are flavouring substances formed by chemical synthesis.*

3.3.1.2 Natural flavoring complexes³ (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.*

3.3.1.3 Thermal process flavorings (see also Chapter 14 of the CoP) *are prepared for its flavoring 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.*

3.3.1.4 Smoke flavorings (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.*

3.3.2 Non-flavoring food ingredients (CAC/GL 66-2008 item 2.3) (see also Chapter 5.3 of the CoP) *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*

³ Commonly known as “Natural Complex Substances” by the industry – see e.g., under section 2.5.

flavourings.

3.3.3 Flavorings produced by enzymatic and microbiological processes (see also Chapter 16 of the CoP) are concentrated preparations, with or without non-flavoring food ingredients, used to impart flavor. They are produced by submitting a substrate or substrates to the action of enzymes or microorganisms.

3.3.4 **Compounded flavoring⁴** is a term often used to describe mixtures of flavoring ingredients, some of them complex mixtures themselves, that are combined to provide a particular taste sensation (See also Article 5.1(c) of CODEX STAN 107-1981, rev. 2016). Other non-flavoring food ingredients, such as solvents, emulsifiers and antioxidants are required to allow the compounded flavoring to function properly in the food to which it is added.

The term “compounded flavorings” is consistent with the term “flavorings” as defined under the Codex Guidelines. However, “compounded flavorings” is often used to emphasize the complex mixture nature of flavorings over a single flavoring substance and to protect the intellectual property.

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

4 THE ROLE AND FUNCTION OF FLAVORINGS IN FOOD

The flavor of food is the most important attribute to the taste of that food and plays an important role in its consumption and acceptance. In one form or another, flavorings have been used since ancient times and are added to foods to impart or modify their flavor (aroma and taste).

Flavoring substances are among the most thoroughly evaluated food ingredients and as such, those that have been subject to a safety evaluation may be regarded safe under their conditions of intended use. Many flavoring substances are self-limiting in their use in food, adding larger amounts of the same flavoring substance does not further improve the flavor of a final food product. The levels of flavoring substances should be kept to the minimum needed to achieve the desired flavor effect.

Flavorings are critical ingredients in foods because:

1. Consumer preferences for foods, and the recognition of them as the foods that they expect, are largely based on the perception of taste.
2. The addition of flavorings can be necessary to compensate for the loss of flavor during the processing and storage of foods such as pasteurized foods.
3. Flavorings can help balance the taste profiles of processed foods. This is increasingly important as the demand for foods with less sugar, salt and fat increases.
4. Flavorings help maintain desired flavor profiles and balance natural seasonal or geographical variations in crops. The use of flavorings can compensate for supply limitations by helping to obtain the desired flavor profile that consumers will recognize.

5 INGREDIENTS FOR FLAVORINGS

5.1 Introduction

The present chapter describes the types of ingredients (as defined under Chapter 3 of the CoP) that may be used in food flavorings.

5.2 Flavoring Ingredients

Based on the *Codex Guidelines for the Use of Flavourings* (CAC/GL 66-2008, section 3. *General Principles for the Use of Flavourings*), the following flavoring ingredients may be used in the manufacture of flavorings:

5.2.1 Flavoring ingredients that are listed on the IOFI GRL (see Chapter 2.5 and Annex I / Chapter 18.1 of the CoP).

5.2.2 Natural flavoring complexes fulfilling the prerequisites as indicated under Chapter 2.5.2, which are safe and therefore acceptable for use in and on foods, even though they may not be listed in Part 2 of the Global Reference List.

5.2.3 Thermal process flavorings produced in compliance with the guidelines specified in Chapter 14 of the Code of Practice and/or – if applicable – produced and approved in accordance with national regulations.

5.2.4 Smoke flavorings produced in compliance with the guidelines specified in Chapter 15 of the Code of Practice and/or – if applicable – produced and approved in accordance with national regulations and/or as evaluated by one of the bodies mentioned in Chapter 2.5.

5.3 Non-Flavoring Food Ingredients (as defined under Chapter 3)

Based on the *Codex Guidelines for the Use of Flavourings* (CAC/GL 66-2008, section 3. *General Principles for the Use of Flavourings*), the following groups of non-flavoring food ingredients may be used in the manufacture of flavorings:

5.3.1 *Carriers* (including *carrier solvents*, listed under Annex I, Chapter 18.2.1) are used to maintain uniformity and dilute concentrated flavorings in order to facilitate their incorporation and dispersion in food products. Some carriers may also be used for encapsulating flavorings with a view to protect them against evaporation

and alterations during storage.

- 5.3.2 *Antioxidants* (listed under Annex I, Chapter 18.2.2) are indispensable for the protection of certain essential oils, especially terpene-containing essential oils, as well as other flavoring 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* (listed under Annex I, Chapter 18.2.3) prevent the catalytic action of certain metal ions and protect the flavoring against oxidation.
- 5.3.4 *Preservatives* (listed under Annex I, Chapter 18.2.4) are necessary to prevent microbial growth in certain flavorings.
- 5.3.5 *Emulsifiers* (listed under Annex I, Chapter 18.2.5) *and weighting agents* (Annex I, 18.2.6) facilitate the homogenization of flavorings, or the incorporation of flavorings in food products.
- 5.3.6 *Acids, bases and salts* (listed under Annex I, Chapter 18.2.7) are used to adjust the pH of certain flavorings.
- 5.3.7 *Anticaking agents* (listed under Annex I, Chapter 18.2.8) may be necessary to keep powdered flavorings free-flowing.
- 5.3.8 *Extraction solvents* (listed under Annex II, Chapter 19) are used for the manufacturing of certain 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.
- 5.3.9 Any appropriate food (e.g., sugars, fats, oils or food ingredient) may be used to dilute a flavoring and to facilitate its incorporation and dispersion in a food product.

6 FLAVORINGS 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 flavor industry in general and IOFI members in particular.

6.1.2 The intellectual property of flavoring formulae belongs to the individual companies that create the flavorings and is often the most significant asset of these companies.

6.1.3 The process of creating flavoring formulae is very expensive and time-consuming and requires significant elements of expertise, innovation and creativity. Each flavoring formula is proprietary: it is a trade secret and a work of art and, as such, deserves intellectual property protection.

6.1.4 IOFI recognizes the importance of the protection of intellectual property to individual flavor manufacturers and their customers who often protect their finished product formulae, including the flavor used in the product, as trade secrets. Therefore, IOFI also recognizes the importance of trade secret protections to the global flavor manufacturing industry as a whole.

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 protection of flavoring formulae thus preserve the value of the flavoring formula for the trade secret owner.

6.1.7 Illegal misappropriation of trade secret formulae unfairly misappropriates highly valuable flavoring formulae without bearing the original creation effort and development costs. Unless duplication of third-party flavoring formulae is necessary (e.g., inability of original supplier to supply) and permitted, IOFI members shall refrain from illegal duplication of third-party flavorings. This will contribute to ensure the recognition of the intellectual property of flavoring

formulae.

6.1.8 IOFI members are committed to take all the actions necessary to promote and encourage the protection, respect and defense of flavoring formulae intellectual property and to discourage the infringement of flavoring 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 flavoring formulae against third party infringement or misappropriation.

6.2 Requests for Flavoring Formula Disclosure

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

6.2.2 Because of the large number of individual flavoring substances used to create flavorings, and the demonstrated safety of these substances, regulators do not require that consumer products bear labeling identifying each individual flavoring substance. Regulators around the world have generally adopted the "class naming" approach to identifying flavorings in consumer products.

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 flavoring manufacturer operates in an environment of competing pressures: an internal priority on protection of confidential formulae to maintain legal rights to trade secret protection 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 formula 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 certain legitimate reasons for disclosing flavoring formula information. The goal in this situation is to confirm the rationale for the request and its appropriateness. Examples of legal justification for disclosure include allergen labeling requirements or special product approval such as pharmaceuticals. Even with special product approvals, individual companies may pursue mechanisms to avoid complete formula disclosure. Where disclosure is required by law, disclosure may be limited to satisfy the legal disclosure or else protected in a manner such that disclosure is confidential to the regulator only or disclosure is protected under an appropriate confidentiality agreement negotiated by competent legal counsel.

6.2.6 Verifying the source of the request

If the basis of the formula disclosure request is a statute or regulation, 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 individual flavor companies, and by extension the global flavor industry, have legitimate reasons to protect their 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 "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 Flavoring Ingredients

Occasionally, questions about the safety of a product prompt requests for disclosure of flavoring ingredients. There are globally recognized scientific expert groups that conduct ongoing safety evaluation of flavoring 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 provide assurance 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 flavoring 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) having authority to legally bind the organization agreeing that the organization shall not under the terms of the NDA 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 or as specifically set forth in the NDA. In all cases, the consideration, negotiation and execution of any NDA or any other agreement affecting a company's rights related to its trade secrets should be done in consultation with competent legal counsel.

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 ingredients in a flavoring formula. Companies may be able to limit the scope of the disclosure, for example, by providing quantitative ranges of certain ingredients or groups of ingredients rather than exact percentages of each

ingredient or proprietary ingredients. Qualitative disclosures concern non-quantitative information about the contents of a flavoring 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 flavoring 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 flavoring without revealing the individual flavoring ingredients. Such certificates or declarations usually contain the following elements:

- A certification that the flavoring formula meets the legal requirements in the country where the flavoring will be used.
- A declaration of some, but not all, of the individual ingredients used.
- The function of the ingredients listed, (e.g., flavoring, carrier, anticaking agent).
- Percent range for each of the ingredients listed, (i.e., 21-26%).

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;

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.

6.4 Regulatory Requirements for Disclosure

There are an increasing number of government requirements for limited disclosure or labeling of individual flavoring 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 flavoring formula. The following sections address typical requests for disclosure, and strategies that both respond appropriately to regulators and protect the intellectual property of the industry.

6.4.1 Allergen Disclosures

Certain ingredients when present in a flavoring 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 and therefore their label disclosure is required by law. At the publication of this edition of the Code of Practice there is not a globally 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 flavorings. Labeling for allergens is an example where disclosure of specific ingredients in an otherwise trade secret protected flavoring formula would be legally justified.

6.4.2 Oral Care Products

In the European Union, Cosmetic Regulation (EC) N° 1223/2009 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 Regulation requires that the manufacturer of the oral care product disclose the presence of these ingredients when used in a flavoring formula in one of these oral care products.

6.4.3 Pharmaceuticals

In many countries, products regulated as either prescription or “over the counter” drugs require the disclosure of inactive ingredients such as flavorings to drug registration and regulatory authorities. The authorities charged with reviewing these products sometimes are required to ask for flavoring 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 flavorings 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. Workplace exposure limits such as “permissible exposure limits” (PELs) for flavoring substances may lead consumer product manufacturers to request formula disclosure for these substances. In the absence of regulations requiring disclosure of flavoring substances, flavoring 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.). See also Chapter 7.8 on GHS and IOFI/IFRA Labeling Manual.

6.4.5 Illegal Drug Precursors

Under an agreement of the United Nations, many countries 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 flavoring. Compliance with these regulations sometimes requires flavoring manufacturers to provide limited formula information to customers or regulatory authorities.

6.5 Conclusion

The examples directly above represent some of the legal frameworks under which flavor formula disclosure may be justified. 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 flavoring formula. However, it is important to carefully consider the legal basis of any disclosure request, as in many circumstances, disclosure can still be appropriately limited.

Helping to protect the intellectual property of the flavor industry is an important goal for IOFI. Although there are some circumstances where disclosures are warranted, measures can often 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

Flavoring substances and flavorings are food ingredients and shall be treated as such. Flavorings should be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice-General Principles of Food Hygiene (CXC 1-1969 Rev.4 - 2003).

7.2 Flavor 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 flavoring manufacturing that may not be explicitly covered by workplace safety regulations but which may further foster a safe workplace for employees.

7.3 Employees

7.3.1 Employees responsible for the manufacturing of flavorings 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 flavorings shall be adequately and appropriately dressed, comply with all personal hygiene requirements and avoid working if exhibiting symptoms of illness or disease that create risk of spreading illness to colleagues or contaminating the food supply.

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 Sufficiently 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 flavorings 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.

7.5.4 Ingredients and raw materials which are found to have a reasonable probability to cause serious adverse health consequences (i.e., pathogen contamination, presence of toxic contaminants) should be handled in accordance with local laws and regulations regarding either regulatory reporting, recall and/or disposal.

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.

7.8 GHS & IOFI/IFRA Labeling Manual

- 7.8.1 The Globally Harmonized System (GHS) defines and classifies the hazards of chemical products and communicates health and safety information on labels and safety data sheets.
- 7.8.2 IOFI Members are encouraged to follow the IOFI/IFRA Labeling Manual. The Labeling Manual provides guidance to the global membership in order to ensure a consistent hazard classification and labeling for flavor and fragrance ingredients.

8 LABELING

8.1 Introduction

The labeling for bulk shipment of flavorings from a flavor manufacturer to a customer (focusing on B2B⁵ scenarios in this Chapter) shall comply with national and local regulations of the Country of Origin and in the case of flavorings to be exported, flavoring 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 flavorings 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 Safety Data Sheets (SDS) or Product Specifications Data Sheets.

8.1.2 The name and address of the flavoring 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 flavorings should comply with local regulations. Flavor labels on bulk packaging sold and shipped to downstream customer companies must include accurate and sufficient labeling information such that the downstream customer company can comply with the legal requirements for the labeling of their products. Particular attention should be paid to the labeling of non-flavoring food ingredients in flavorings 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).

⁵ Business-to-Business

9 CLAIMS MADE IN THE LABELING, PRESENTATION OR ADVERTISING OF FLAVORINGS

9.1 Introduction

Flavoring manufacturers shall not make false or misleading statements when promoting or labeling their products.

9.1.1 Specifically, flavoring manufacturers shall abstain from making any claim by way of statement or representation with a view to promoting the sale of a flavoring 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 For many decades the flavor industry has successfully worked through 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.

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 Quality assurance 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 flavorings and flavoring ingredients under consideration of general hygiene rules and, if needed, special requirements on all steps. The process should prevent or minimize any hazards.

10.2.2 Flavour companies are requested to identify the food quality-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 CXS 1-1969 (Rev.4 – 2003). Companies must also otherwise comply with all local and/or regional laws and regulations pertaining to food safety.

11 QUALITY CONTROL AND SAMPLE 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 center and its use in flavor 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 of Samples and Rejected Products

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 flavor 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 SHELF LIFE AND RE-TESTING

12.1 Shelf Life

12.1.1 The shelf life of flavorings is defined as the period from the date of production during which the flavoring 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 Flavor manufacturers may engage in the common practice of re-testing flavorings 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 flavorings 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 flavoring should be in compliance with sensory, physical, chemical and, if appropriate, microbiological specifications established by the manufacturer. 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 flavor 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(s).

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 it relates to describing the character of a flavoring (see Chapter 3 Definitions and Terminology of the CoP). 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 governmental informal policies and rulings and officially condoned practices, will take precedence over these Guidelines. In those countries where corresponding specific regulations are not in force, the Code of Practice may serve as a best practices resource.

The sections below provide a general overview of the relevant factors when considering whether a flavor could be considered natural. Again, companies must consider the local or regional regulatory rules regarding the determination and labeling of natural flavor.

13.2 Source Materials

Source materials used as the starting material for natural flavorings, should be materials of animal, plant or microbiological origin. Sources for natural flavoring complexes and natural flavoring 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 Physical Production Processes

Physical processes may be used for the production of natural flavoring complexes or natural flavoring substances. pH adjustment may be used for the isolation of acidic and basic materials.

13.4 Biochemical Processes for Natural Flavoring Complexes and Natural Flavoring 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 flavorings.

13.4.2 Substrates

If the substrates used to produce natural flavorings 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 flavorings.

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 flavorings.

13.5 Other Processes for Natural Flavoring Complexes and Natural Flavoring Substances

Processing methods are generally considered to support the production of natural flavorings where they constitute typical or customary food processing or in-home preparation, or occur in nature. See examples in Table 1.

List of examples of food preparation processes which are generally considered to support the production of natural flavoring (non-exhaustive; subject to update):

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 of natural flavor.

13.7 Classification of Salts

Salts of natural flavoring substances with the following cations NH_4^+ , Na^+ , K^+ , Ca^{2+} and Fe^{3+} , or the anions Cl^- , SO_4^{2-} and CO_3^{2-} are classified as natural flavoring substances.

14 IOFI GUIDELINES FOR THE PRODUCTION OF THERMAL PROCESS FLAVORINGS

14.1 Introduction

The Codex Alimentarius Guidelines (CAC/GL 66-2008) states that flavorings may consist of flavoring substances, natural flavoring complexes, smoke flavorings or thermal process flavorings. The purpose of this section is to provide guidance on the production and use of thermal process flavorings 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 flavorings, will always take precedence over these Guidelines.

14.2 Scope

14.2.1 These Guidelines deal with thermal process flavorings only. They do not apply to foods, natural flavoring complexes, chemically defined flavoring substances or mixtures of flavoring substances.

14.2.2 These Guidelines define those raw materials and process conditions which are similar to the cooking of food and used to produce thermal process flavorings.

14.3 Definition

A thermal process flavoring is a product prepared for its flavoring 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 thermal process flavorings.

14.4.2 Thermal process flavorings 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 May Be Subject to Thermal Processing

Raw materials for thermal process flavorings 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, 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 Flavorings as defined in CAC/GL 66-2008 and flavor enhancers as defined by CAC/GL 36-1989.
- 14.6.2 Suitable non-flavoring food ingredients as defined by CAC/GL 66-2008. Please see also the non-flavoring food ingredients listed in Annex I / Chapter 18.

14.7 Manufacturing of Thermal Process Flavorings

Thermal process flavorings are manufactured 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 Additional flavorings (see Chapter 14.6.1) and non-flavoring food ingredients (see

Chapter 14.6.2) shall only be added after processing is completed.

List of other raw materials that may be subject to thermal processing

Foodstuffs, herbs, spices, their extracts and flavoring 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:
<ul style="list-style-type: none"> • Acetic acid, hydrochloric acid, phosphoric acid, sulfuric acid
<ul style="list-style-type: none"> • 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 PRODUCTION OF SMOKE FLAVORINGS

15.1 Introduction

The Codex Alimentarius Guidelines (CAC/GL 66-2008) states that flavorings may consist of flavoring substances, natural flavoring complexes, smoke flavorings or thermal process flavorings. The purpose of this section is to provide guidance on the production and use of smoke flavorings 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 flavorings, will always take precedence over these Guidelines.

15.2 Scope

These guidelines deal with flavorings used for the purpose of imparting a smoke-type flavor to foodstuffs. These guidelines do not apply to foods, flavorings extracted from smoked foodstuffs or to flavorings obtained by compounding chemically defined flavoring 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 flavorings 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 flavoring principles of smoke flavorings 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 flavorings.

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

15.5 Manufacturing of Smoke Flavorings

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.

Latin name	English name
<i>Acer negundo</i> L.	Maple tree
<i>Betula pendula</i> Roth. (syn. <i>B. verrucosa</i> Ehrh.)	Silver birch or European white birch
<i>Betula pubescens</i> Ehrh. (syn. <i>B. alba</i> L.)	Downy birch or white birch
<i>Carpinus betulus</i> L.	Hornbeam
<i>Carya ovata</i> (Mill.) K.Koch	Shagbark hickory
<i>Carya alba</i> (L.) Nutt. ex Elliott	Mockernut hickory
<i>Castanea sativa</i> Mill.	Chestnut tree
<i>Eucalyptus</i> spp.	Eucalyptus
<i>Fagus grandifolia</i> Ehrh.	American beech
<i>Fagus sylvatica</i> L.	European beech
<i>Fraxinus excelsior</i> L.	Common ash
<i>Juglans regia</i> L.	Walnut tree
<i>Malus pumila</i> Mill.	Apple
<i>Prosopis juliflora</i> (Sw.) DC. & <i>P. velutena</i> Wooton	Mesquite wood
<i>Prunus avium</i> L.	Cherry tree
<i>Quercus alba</i> L.	White oak
<i>Quercus ilex</i> L.	Holm oak or Evergreen oak
<i>Quercus robur</i> L (syn. <i>Q. pedunculata</i> Hoffm.)	Common oak or European oak
<i>Frangula alnus</i> Mill. (syn. <i>Rhamnus frangula</i> L.)	Alder buckthorn
<i>Robinia pseudoacacia</i> L.	Black locust
<i>Ulmus rubra</i> Muhl. (syn. <i>Ulmus fulva</i> Michx.)	Slippery elm

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

15.5.2 Non-flavoring food ingredients

Suitable non-flavoring food ingredients as defined by CAC/GL 66-2008. Please see also the non-flavoring food ingredients listed in Annex I / Chapter 18.

15.6 Production Conditions

Smoke flavorings are prepared as follows:

- 15.6.1 By subjecting various untreated hardwoods (see Chapter 15.5.1) to
- controlled burning, or
 - dry distillation, or
 - treatment with superheated steam and condensation, and
 - capturing of those fractions which have the desired flavor potential.
- 15.6.2 Then by applying further isolation techniques to the fractions obtained under 15.6.1 in order to retain only the flavor-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 Chapter 19, Annex II of this Code.

16 IOFI GUIDELINES FOR ENZYMATIC AND MICROBIOLOGICAL PROCESSES FOR THE PRODUCTION OF FLAVORINGS

16.1 Scope

These Guidelines deal with enzymatic and microbiological processes used for the production of flavorings. These Guidelines do not apply to flavoring substances (as defined under Chapter 3) that are produced by these methods, provided that they are safe for the intended use as flavoring (see Chapter 5) and comply with existing purity requirements (e.g., as reported in JECFA specifications) and are devoid of detectable residual enzymatic or microbiological activity. National and regional regulations always take precedence over these Guidelines. This includes the existence of specific definitions, rulings and officially accepted practices.

16.2 Definition

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

16.3 Basic Standards of Good Manufacturing Practice

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

16.3.2 Flavorings 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)

16.4 Manufacturing of Flavorings by Enzymatic or Microbiological Processes (see also Chapter 13.4)

Flavorings 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:

16.4.1 Substrates

These include source materials (both food source and non-food source materials) and isolated constituents of source materials (both food and non-food).

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.

16.4.2 Enzymes

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

16.4.2.2 Other enzymes

16.4.3 Micro-organisms

16.4.3.1 Micro-organisms that are traditionally used in the preparation of certain food products and/or that are (resulting from their traditional use) traditionally present in certain food products (where they contribute to their characteristics, taste and nutritional value, e.g., mold in blue cheeses or other cheeses, yeast in beer, micro-organisms in other fermented drinks, bacteria in yoghurts and other dairy products...).

16.4.3.2 Other micro-organisms

16.4.4 Non-flavoring food ingredients

16.4.4.1 Suitable non-flavoring food ingredients as defined by CAC/GL 66-2008. Please see also the non-flavoring food ingredients listed in Annex I / Chapter 18.

16.4.5 Production Conditions

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

16.4.5.2 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.

16.4.5.3 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-flavoring 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.

16.4.5.4 Enzymes (16.5.2) shall be separated from the flavoring, or inactivated, once the process is terminated. In the case of chemically defined flavoring substances, enzymes will be typically removed/separated as a result of a distillation step which takes place for the purification of the flavoring substance; also in case of natural flavoring complexes, further purification and heating processes take place which will either remove or at least denature the enzymes.

16.4.5.5 Micro-organisms (16.5.2) shall be separated from the flavoring or inactivated or destroyed once the process is terminated.

16.4.5.6 Micro-organisms shall not be used under conditions where they lead to products containing toxins or antibiotics. It is the responsibility of the manufacturer/producer to analyze the final flavoring and confirm the absence of any (myco-)toxins or antibiotic residues.

16.4.5.7 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.

16.5 General Requirements

The safety in use of flavorings 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)

16.6 Labeling

In the absence of specific national regulations, the labeling of flavorings 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) and all other conditions for natural flavorings are fulfilled (see Chapter 13).

17 GUIDELINES FOR OCCUPATIONAL SAFETY AND HEALTH AND ENVIRONMENTAL PROTECTION

17.1 Field of Application

17.1.1 These Guidelines shall apply to the manufacture and handling of all flavorings and raw materials used for their production, including storage, production and plant design, in the flavor 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

The protection of health in the workplace and the protection of the environment are of primary concern to the flavor industry. These Guidelines express a desire by the flavor industry to prioritize occupational safety and the environment by advancing measures which may be additional to those required to comply with national or international regulations.

17.3 Definitions

17.3.1 Manufacturing: All operations involved in the production of a flavor 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 Occupational Safety and Health

17.4.1 All personnel involved in the manufacture and handling of flavorings and raw materials used for their production shall have appropriate training and notice of and access to personal protective equipment where necessary to be protected

from recognized health hazards (e.g., skin irritants, respiratory toxins, irritants and sensitizers, etc.), physical hazards (e.g., noise, radiation, vibration) and chemical and detrimental health effects of gases, vapors or dusts, etc., in accordance with all relevant regulations. Employers have a legal duty to provide safe workplaces for their employees.

- 17.4.2 Companies shall make their best efforts to eliminate or minimize exposure to health and physical hazards by taking those precautions which are necessary under the prevailing regulations.
- 17.4.3 Priority should be given to reducing exposures to chemicals in the workplace emphasizing engineering controls, processes that minimize the potential for exposure, local ventilation, substitution of less hazardous chemicals when possible, and other means to reduce exposures.
- 17.4.4 If necessary, in addition to exposure control measures, appropriate personal protective equipment should be worn when appropriate 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 inappropriate handling of classified physical or health hazards in the workplace. Adequate and appropriate workplace training as well as providing all required documentation including SDS for each material handled in the flavor manufacturing workplace should be provided and updated as necessary.
- 17.4.6 Companies should periodically audit their workplaces that have potential health and physical hazards. If necessary, exposure-monitoring surveys should be carried out.
- 17.4.7 In all cases, recommendations on safe storage and handling should be provided to both employees and the employees of downstream customers who will handle products.

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 that could pose a risk to health of personnel or the general public, or that could adversely affect the environment.
- 17.5.4 Companies should create awareness of environmental protection among all personnel handling materials through documented training 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.
- 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 FLAVORING AND NON-FLAVORING FOOD INGREDIENTS

18.1 List of Flavoring Ingredients – Global Reference List of Flavorings (GRL)

The GRL can be consulted and downloaded under www.iofi.org.

For further explanations, please refer to Chapter 2.5 and Chapter 5.3.

Note on Isomers

1. In flavor manufacturing, during the isolation of naturals and/or chemical synthesis, pure stereoisomers, geometric isomers or positional isomers can be obtained, as well as mixtures of isomers of variable compositions.
2. Authoritative bodies involved in the safety assessment of flavoring substances may have reviewed the safety of the 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.
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 cannot 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.

18.2 Lists of Non-flavoring Food Ingredients

For definitions and further explanations regarding the various types of non-flavoring food ingredients listed under this chapter, please refer to Chapter 5.3.

Note:

1. The following lists of non-flavoring ingredients are non-exhaustive, and they shall not be the only source of information for the IOFI members in this regard.

2. IOFI members must perform their own due diligence to confirm the regulatory authority of the listed ingredient for the intended use in flavorings and food within the appropriate jurisdiction.
3. The INS numbers indicated in the following lists refer to those identified in the *Codex Class Names and the International Numbering System (INS) for Food Additives* (CAC/GL 36-1989). If a certain INS number listed here is not in line with that used in CAC/GL 36-1989, one shall refer to the latter.

18.2.1 List of Carriers (including Carrier Solvents)

Substance	INS No.
Acetic acid	INS 260
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(i)
Dextran	-
Dextrin	-
Diammonium phosphate	INS 342(ii)
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	INS 428
Gellan gum	INS 418
Ghatti gum	INS 419
Glucose	-
Glycerol	INS 422
Glyceryl diacetate	-
Mono- and di- glycerides of fatty acids	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	-
Hydroxypropyl methyl cellulose	INS 464
Hydroxypropyl cellulose	INS 463
Hydroxypropyl distarch phosphate	INS 1442
Hydroxypropyl starch	INS 1440
iso-Propylalcohol	-
Karaya gum	INS 416
Konjac flour	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 470(iii)
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 341(i), (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, amorphous	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	-
Sucroglycerides	INS 474
Sucrose	-
Sucrose esters of fatty acids	INS 473
Sucrose oligoesters, type I and type II	INS 473a
Tara gum	INS 417
Tragacanth gum	INS 413
Triethyl citrate	INS 1505
Water	-
Whey powder	-
Xanthan gum	INS 415
Xylitol	INS 967

18.2.2 List of Antioxidants

Substance	INS No.
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 & synthetic)	INS 307-309

18.2.3 List of Sequestrants

Substance	INS No.
Citric acid multifunctional	INS 330
Calcium disodium ethylenediaminetetraacetate	INS 385
Disodium ethylenediaminetetraacetate	INS 386
Tartaric acid	INS 334
Tetrasodium diphosphate	INS 450(iii)
Other phosphates	INS 450, 451

18.2.4 List of Preservatives

Substance	INS No.
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

18.2.5 List of Emulsifiers and Stabilizers

Substance	INS No.
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 472e
Mono- and di- glycerides of fatty acids	INS 471
Guar gum	INS 412
Gum arabic	INS 414
Gum ghatti	INS 419
Tragacanth gum	INS 413
Lactic and fatty acid esters of glycerol	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 (20) sorbitan monopalmitate	INS 434
Polyoxyethylene (40) stearate	INS 431
Polyoxyethylene (20) sorbitan tristearate	INS 436
Polyoxyethylene (8) stearate	INS 430
Polyoxyethylene (20) sorbitan monostearate	INS 435
Processed eucheama seaweed	INS 407a
Propylene glycol alginate	INS 405
Propylene glycol stearate	-
Propyleneglycol esters of fatty acids	INS 477
Sodium citrate	INS 331
Sodium stearyl-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
Sucroglycerides	INS 474
Sucrose acetate isobutyrate	INS 444
Sucrose esters of fatty acids	INS 473
Xanthan gum	INS 415

18.2.6 List of Weighting Agents

Substance	INS No.
Glycerol ester of wood rosin (Ester gum)	INS 445(iii)
Glyceryl tribenzoate	-
Glyceryl ester of hydrogenated rosin	-
Hydrogenated colophonium	-
Methyldihydroabietate	-

Methylester of hydrogenated rosin	-
Propylene glycol dibenzoate	-
Sucrose acetate isobutyrate	INS 444

18.2.7 List of Acids, Bases, Salts

Substance	INS No.
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 356-357
Calcium carbonate	INS 170, 170(i), 170(ii)
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, NH ₄ 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	INS 296
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 335-337

18.2.8 List of Anticaking Agents

Substance	INS No.
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, 470(i), 470(iii)

19 ANNEX II: LIST OF EXTRACTION SOLVENTS USED FOR THE PRODUCTION OF NATURAL FLAVORINGS AND RESIDUE LIMITS (see also Chapter 5.3)

Note:

1. The following list is non-exhaustive, and it shall not be the only source of information for the IOFI members in this regard.
2. IOFI members must perform their own due diligence to confirm the regulatory authority of the listed substances for the intended use as extraction solvents for the production of natural flavorings and the corresponding residue limits within the appropriate jurisdiction.
3. The following list (including the residue limits) is subject to update by the IOFI Secretariat. For IOFI members, the updates are communicated via Information Letters whenever available. For non-members, please contact the IOFI Secretariat for the latest update.

Substance	Residue limit (ppm) ^{6 7}
Butane	1
Propane	1
Isobutane	1
Toluene	1
Cyclohexane	1
Hexane	1
Heptane	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
Supercritical carbon dioxide	GMP

⁶ This refers to the level of residue limits as in finished food.

⁷ Some of these substances exist in the environment as pollutant/contaminants, as a result, certain level of these substances may be detected in finished food even though they are not used for extracting the flavorings added to the finished food.