

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.