

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 8

CX/FA 07/39/12-Add. 1
March 2007

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES

Thirty-ninth Session

Beijing, China, 24-28 April 2007

COMMENTS ON THE PROPOSED DRAFT GUIDELINES FOR THE USE OF FLAVOURINGS

(Comments at Step 3)

The following comments have been received from the following Codex Members and observers:
Brazil, Canada, ICBA and IOFI

Brazil

- a) The substance benzopyrene, a biologically active substance that is usually present in smoke flavouring, should be included in item 4.
- b) Methods of analysis have not been discussed within CCFAC in the last years. Therefore, we are not sure whether this issue should be included in the document. Furthermore, as mentioned in the CX/FA 07/39/12, the CCMAS should be consulted on methods of analysis. In case these methods are to be kept in the document, we suggest their inclusion in the table containing the biologically active substances (Annex A) to which they refer, in order to facilitate the identification of each specific method.
- c) We would like to request the inclusion of the following references in Annex B:
 - i. Brazilian's Pharmacopeias; and
 - ii. Resolução RDC nº. 2, published in January 15th 2007 – Technical Regulation on Flavouring Agents. This legislation, which was agreed at Mercosul, contains a list of permitted botanic species of regional origin.

Canada

With respect to section 2.2.1 Flavouring substances, appearing under Section 2.0 Definitions, please note that in the Codex Standard for the Labelling of Pre-packaged Foods, STAN 1-1985, amended in 2005, under Section 4.2.3.4, "The expression "flavours" may be qualified by "natural", "nature identical", "artificial" or a combination of these words as appropriate". In order to harmonize terms of this Standard with the Proposed Guidelines, Canada suggests the inclusion of the term "nature identical" as a sub-class of synthetic flavours as follows:

2.2.1.2 Synthetic flavouring substances, including "nature identical" substances, are flavouring substances formed by chemical synthesis.

- Conversely, if the addition of this term to the Guidelines is not accepted, then, in the interest of harmonization, we suggest it should also be deleted from the above-named standard.
- In Section 4.0, Biologically active substances the sentence "Annex A contains a list of biologically active substances that should not be added directly to food, with the exception of quinine and quassine" should be expanded to ...with the exception of quinine, quassine, caffeine and oil of rue.

ICBA

ICBA, being a member of the e-working group, generally agrees with the proposed format and the recommendations, except that we would like to express the following comments and suggestions on Appendix I:

2.0 DEFINITIONS**2.2 Flavorings**

ICBA supports the proposed definition and the inclusion of the concept of flavour modification in the definition. Flavour or taste modifiers are becoming more common when manufacturers are seeking innovative ways to produce foods with less salt, fat, and sugar. In addition, flavorings that modify taste characteristics, such as bitterness or “beaniness,” will provide the means to introduce foods with enhanced health profiles with a better taste. While we do not wish to propose that a definition be included in the Guideline, we have drafted the following to explain flavour or taste modifiers:

Flavour modifiers are flavouring substances or preparations that may enhance, suppress, or otherwise change a food's flavour in the area of sweetness, bitterness, saltiness, sourness, or other taste characteristics and are used at levels comparable to those of other flavourings. They act through specific taste receptors or ion-channels modifying the taste characteristics of other flavourings, additives, or food ingredients.

2.2.2.1 Natural flavouring substances and 2.2.2 Natural flavouring complexes

We have a concern that the proposed definitions for natural flavorings do not follow the prevailing industry practice for obtaining natural flavorings. The wording “obtained by physical processes that do not intentionally modify the chemical identity of the components of the flavouring” could be interpreted to restrict the use of processes that result in any chemical change. These terms are difficult to define and could lead to inconsistent interpretations. If taken literally, the definition would prohibit the use of some traditional processes. For example, rectification and steam distillation, and even extraction, can modify the chemical nature of the components of the flavouring. Many processes, including home food preparation processes, lead to chemical modifications and these modifications are often intentional. Essential oils and extracts obtained from these processes must have continuity and constancy of organoleptic quality, i.e., intentional modifications will occur that are of chemical nature and that are repeated during each distillation or extraction process. These methods have been traditionally used to make essential oils and extracts and could be construed as being not acceptable under the definition. Examples of processes commonly used in the manufacture of natural flavorings or complexes that could be called into question if this language is maintained include liquid compounding, distillation and extraction:

Liquid Compounding

Liquid compounding involves the mixing of various flavours and intermediates, and can result in chemical changes. For instance, when natural aldehydes are mixed with propylene glycol or other alcohols, with a food acid present, acetals possibly important to a flavour are produced. Similarly, a small amount of a natural carboxylic acid added to natural ethanol will form an acidic alcoholic “flavour” containing a small amount of the (intentionally formed) corresponding ethyl ester.

Distillation and Extraction

Both distillation and solvent extraction can and do lead to chemical transformations – intentional or not. An example is the changes in volatile flavour chemicals during the transformation of wine into brandy via distillation. Doubtless, some of these transformations are intentional. The distillation process is, after all, carefully controlled and guarded as a “trade secret” by that industry.

Similar to liquid compounding is the use of ethanol (or other solvents) during extraction to produce absolutes, concretes, oleoresins, etc. In the presence of acid (naturally occurring in plant materials or added intentionally to attain proper solution formation), alcohols can be transformed into minor amounts of ethyl ethers, and carboxylic acids into ethyl esters.

The use of some traditional permitted processes such as heating, frequently used in the home, would no longer be permitted in the industry if the phrase “intentional chemical modification” is used.

We believe that the definition should permit the use of physical, microbiological, or enzymatic processes (distillation, solvent extraction, heating, fermentation, etc.) while excluding certain processes such as the use of singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation. The process should be the factor that determines if a flavor is natural or not, assuming one starts with a natural material. A chemical modification should not change the natural status of the flavor because that is what occurs in nature and in food preparation process, in the home and in industry.

We suggest the elimination of that part of the sentence that reads, “that do not intentionally modify the chemical identity of the components of the flavoring” and adding language that would exclude the use of certain physical processes that would lead to significant chemical modifications. We also **suggest deleting the word “traditional”** because of the ambiguity of the word that has different meanings in different parts of the world. Further, the requirement to use “traditional food-preparation processes” would severely limit or prohibit the use of new technological advances, such as the use of new microwave-assisted flavour extraction processes. Some processing methods that commonly have been used to manufacture natural flavourings might not be considered traditional food processing methods in the most strict interpretation. For example, pH adjustment is a traditional process used routinely by the flavour industry to produce natural flavor components by fermentation, enzymatic transformation, or in “down stream” processing of materials. Would this be considered a “traditional food preparation process”? Such pH adjustments leading to consumable food and beverage items happen all the time in nature and the home. For example, the pH changes and the resultant enzymatic and non-enzymatic changes occurring in muscle postmortem; the changes occurring during the marinating of meat, fish, or vegetables upon pH adjustments with vinegar (acetic acid) or citrus juices (citric acid); the “dutching” of cocoa using alkali. There are many more examples of pH adjustment/control occurring both in the home and as part of “traditional” food manufacture that have always been considered “natural” but might not be considered natural based on the proposed definition.

Another example is extrusion cooking that is used by the flavour industry. Its parallel is its use in the production of snack and cereal foods, and breakfast cereals which should certainly be considered as “natural” food items but would extrusion cooking be considered a traditional food processing method under the draft definition? Further, the manipulation of pressure (which includes the use of vacuum) is widely employed in the flavor industry. Vacuum is used in distillations/concentrations. Pressure is used to raise the temperature of “wet” systems above the normal boiling point of water to accelerate processes and/or control sensory characteristics. Vacuum may be one of the few operations that is not done in the home, but certainly the use of “pressure cookers” and “old fashioned” home canning are examples of the use of pressure to produce “natural” foods. Common current practice dictates that the use of vacuum or pressure be allowed, combined with any other approved processes. But would it be considered a traditional food processing method?

We propose the following revised definitions of natural flavoring substances and complexes:

2.2.1.1 Natural flavoring substances are flavouring substances obtained by physical processes (e.g., distillation and solvent extraction) – *which do not involve the use of singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation* ~~that do not intentionally modify the chemical identity of the components of the flavouring~~ – or by enzymatic or microbiological processes, from material of plant and animal origin. Such material may be unprocessed, or processed for human consumption by ~~traditional~~ food preparation processes (e.g., drying, torrefaction (roasting) and fermentation).

2.2.2 Natural flavouring complexes are preparations that contain flavouring substances obtained by physical processes (e.g. distillation and solvent extraction) – *which do not involve the use of singlet oxygen, ozone, inorganic catalysts, metal catalysts, organometallic reagents and/or UV radiation* ~~that do not intentionally modify the chemical identity of the components 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). Natural flavouring complexes include the essential oil, essence, or extractive, protein hydrolysate, distillate, or any product of roasting, heating, or enzymolysis.

These proposed changes would better reflect the current industry practice, be consistent with permitted processes, and provide for future innovation.

4.0 BIOLOGICALLY ACTIVE SUBSTANCES

In general, we consider that Annex A requires further consideration. Further, we believe that there was an omission concerning caffeine. Surely the intention was not to state that caffeine should not be added to foods. Further, caffeine is also used as a functional ingredient in some products. If caffeine is added to the Annex A, it should be made clear that Annex A and the maximum levels are intended for flavorings. If the second sentence of the paragraph is maintained, it should be revised:

“Annex A contains a list of biologically active substances **used as flavorings** that should not be directly added to food, with the exception of quinine ~~and~~, quassine **and caffeine.**”

IOFI

IOFI is representing the global flavour industry and is pleased to provide comments at Step 3. As requested by the Secretariat of the Codex Committee on Food Additives, please find below our comments along the following points:

1. List of substances identified in annex A of the proposed draft guideline
2. Proposed Draft Codex Guideline for the Use of Flavourings (Appendix 1), relating to:
 - the overall structure and completeness of the guideline
 - the completeness and relevance of the definitions
 - the references to lists of aromatic raw materials suitable for the preparation of flavourings

1. List of substances identified in annex A of the proposed draft guideline:

IOFI is of the opinion that those substances which have flavour use either as such or as constituents of flavour complexes and which were never reviewed by JECFA need to be evaluated first. For those that were evaluated already, a re-evaluation is recommended to account for any new data which have become available since the latest evaluation.

Substances for which an ADI or recent evaluation is available, leading to the conclusion of “safe under current estimated conditions of intake”, should not be re-evaluated as a priority: e.g. quinine (Latest evaluation: 1993- ADI: acceptable, current use levels up to 100 mg/l as quinine base in soft drinks not of toxicological concern) and pulegone (JECFA 753, latest evaluation: 2000-Conclusion based on current intake: no safety concern).

The following priorities are suggested:

- Substances that were never evaluated by JECFA so far: quassine, santonin
- Substances that were evaluated already by JECFA: beta-asarone (Latest evaluation: 1981 – No ADI allocated), coumarin (Latest evaluation: 1981 – No ADI established), safrole and iso-safrole (Latest evaluation: 1981 – No ADI allocated), alpha and beta thujones (Latest evaluation: 1981 – No ADI allocated), estragole (Latest evaluation: 1981 – No ADI allocated), methyl eugenol (Latest evaluation: 1981- No ADI allocated).
- Substances which are less relevant to the flavour industry (berberine, agaric acid) or have no direct flavouring properties since these are unavoidable non-flavouring constituents of flavouring complexes (aloin, HCN, hypericine).

2. Proposed Draft Codex Guideline for the Use of Flavourings

Regarding the proposed draft Codex Guideline for the Use of Flavourings (Appendix I of CX/FA 07/39/12) IOFI would like to provide the following comments:

Overall structure and completeness of the guideline

Safety evaluations by JECFA

As stated in the introduction of CX/FA 07/39/12 a major objective of the guideline is that principles for the safe use of flavouring substances should be similar to the principles of food additives contained in Codex STAN 192 with a reference to the evaluation of flavouring substances completed by JECFA. IOFI is concerned that completion of the work for the evaluation of all flavouring substances in global use is not possible within a short timeframe. Therefore the guideline should have provisions and criteria to accommodate acceptable safety evaluations by other bodies, pending final evaluation by JECFA.

IOFI recommends bringing footnote 5 into the guideline text “This guideline does not imply that the use of flavouring components that have not yet been evaluated by JECFA are unsafe or otherwise unacceptable for use in food” and add the following:

“A flavouring substance which has not yet been evaluated by JECFA may be used temporarily in foods which enter international trade provided that it complies with at least two of the following criteria:

- Availability of a safety evaluation by a scientific body that applied criteria consistent with those as developed by JECFA
- The substance is of suitable purity for use in food
- The substance has a documented history of safe use”

Definitions for natural flavouring substances and complexes and smoke flavourings

IOFI would like to stress that the intent of the guideline is to provide “principles for the safe use and principles for the establishment of practices that do not mislead the consumer”.

IOFI would like to point out that the definitions related to the “natural flavouring substances and complexes” and “smoke flavourings” are primarily related to labelling aspects and intend to inform the consumer on the nature/origin of the substances. Definitions of specific categories of flavourings are therefore preferably introduced within the labelling section of the guideline. Therefore IOFI recommends that the definitions 2.2.1.1 (Natural flavouring substances), 2.2.1.2 (Synthetic flavouring substances), 2.2.2 (Natural flavouring complexes) and 2.2.3 (Smoke flavourings) are moved to 6.0 LABELLING.

Completeness and relevance of definitions

Definition of Flavour (2.1) and Flavourings (2.2)

IOFI recommends to delete the sentence “The perception of flavour is a property of flavourings”, since the perception of flavour is actually a property of the brain in response to appropriate stimuli.

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 the flavour is a property of flavourings.~~

IOFI supports the proposed definition for flavourings (2.2) and recommends the following modifications:

Flavourings are products that are added to food to impart or modify the flavour of food, rather than to enhance nutritional quality or to fulfil other technological effects. 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, ~~and natural flavouring complexes, or smoked flavourings~~ and may contain **food and non-flavouring food ingredients (Section 2.2.4)** that make flavourings compatible with the foods and beverages in which they are used. They are not intended to be consumed as such.

Flavouring substances versus Flavouring complexes

IOFI has no objections against the definition for flavouring substances (2.2.1), but for the sake of coherence a generic definition might be needed for flavouring complexes. From the description for flavouring complexes as presented under 2.2.2 complexes appears to be always “natural flavouring complexes”.

IOFI proposes the following definition for flavouring complexes:

2.2.2 Flavouring complexes are mixtures of substances either formed by chemical synthesis or obtained from materials of plant or animal origin.

Food ingredients

The guideline provides a definition for non-flavouring food ingredients (2.2.4). IOFI agrees that such a definition appropriately addresses the practice of using foodstuffs for dissolving, dispersing or diluting flavourings.

However, there is some concern that foodstuffs with a definite ‘flavour’ such as cheese may not be used in a strict interpretation of 3.5.

Therefore IOFI recommends the following re-wording of 3.5:

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

Natural flavouring substances and natural flavouring complexes:

IOFI strongly objects to the inclusion of the sentence “that do not intentionally modify the chemical identity of the components of the flavourings” in both the definition for natural flavouring substances (2.2.1.1) and natural flavouring complexes (2.2.2). A strict interpretation of this sentence would lead to dismissing substances that are extracted from food that is traditionally processed in such a way that it is fit for human consumption. These traditional processes knowingly induce chemical changes to food to reduce or avoid toxicity or elicit a specific taste to food. (e.g. frying meat, cooking potatoes, etc...).

IOFI proposes the following modification:

Natural flavouring substances are flavouring substances obtained by physical processes ~~that do not intentionally modify the chemical identity 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).

Natural flavouring complexes are preparations that contain flavouring substances obtained by physical processes ~~that do not intentionally modify the chemical identity 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.....

Biologically active substances

IOFI recommends replacing 4.0 BIOLOGICALLY ACTIVE SUBSTANCES by 4.0 SUBSTANCES OF POTENTIAL CONCERN and modify the text as follows:

~~Biologically active~~ Substances identified to be of potential toxicological concern can be present in flavourings or in food ingredients with flavouring properties (e.g. herbs and spices). Annex A contains a list of ~~biologically active~~ substances that should not be added directly to food, with the exception of quinine, quassine **and caffeine**. The presence of these ~~biologically active~~ substances in foods that are ready for consumption can occur from the use of certain natural flavourings or food ingredients with flavouring properties (herbs and spices). Their presence in food should not pose a risk to health and therefore should not exceed the maximum levels indicated in the Annex. Annex A also contains references to analytical methods for the determination of such ~~biologically active~~ substances.

References to lists of aromatic raw materials suitable for the preparation of flavourings

IOFI would like to point out that the proposed draft guideline under 8.0 refers to “Aromatic Raw Materials suitable for the preparation of Natural flavourings”. Therefore the purpose of any reference to these lists is to simply indicate support to the decision whether a flavouring substances qualifies for the status “natural”. It does not contain or imply a decision on safety as described in the footnote 7 “It should be understood that the references contain potential sources for natural flavours without reference to the safety or acceptability for human consumption of any specific source”.

Therefore IOFI questions the need to maintain such a list within a guideline that primarily aims at “providing principles for the safe use of the components of flavourings” (see 1.0 SCOPE).

Therefore IOFI recommends deleting the list as it would also be difficult updating the list as suggested by footnote 8 “This list is not exhaustive and will be up-dated from time to time”. It is unclear what criteria should be used for such an update. In the case the list is maintained, the objective and the process for maintaining the list should be better specified in the guideline.