

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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ORGANIZATION



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Agenda Item 11

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

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DISCUSSION PAPER ON FLAVOURING AGENTS

Comments

The following comments have been received from: Argentina, Brazil, Canada, Chile, Cuba, European Community, USA, ICBA and IOFI

ARGENTINA:

1 - Regarding the item **Definition of flavourings** (paragraph 22), we believe it is important to work on the establishment of clear, univocal definitions of the words flavour, flavourings, flavouring agents and natural flavouring complexes. Argentina considers it is relevant to look at the word “flavour”, which is very much used in these papers and is often translated into Spanish both as “*sabor*” (which refers to the sense of taste) and as “*aroma*” (which refers to the sense of smell), while in its original language the word is used to describe a global perception of all the senses involved when eating a food. We believe the best option is to use the word “flavour” in all languages in order to avoid misunderstanding.

2 - It is worth stressing the importance of the evaluation of the toxicological safety of flavouring substances irrespective of their nature. We suggest starting with those which will be consumed by the child population (in candy, beverages, etc.).

BRAZIL:

1. We agree with recommendations in paragraphs 20 and 23
2. We agree that CCFAC should endorse one of the options described in paragraph 16 and we support the options 4 or 5.

CANADA:

Canada does not consider flavours to be food additives and does not view flavours as a priority area for new or future work. Canada is not aware of and has not encountered the difficulties regarding flavours elaborated in Paragraph 15 of this paper (i.e. trade problems re non-tariff barrier to the free movement of foods, national authorities being “hampered” by the lack of readily-available international standards, etc.). Nonetheless, Canada agrees with the desirability of establishing some type of standard for flavouring substances in order to have uniformity in regulating these amongst its trading partners. We also agree that the degree of involvement of future work in this area should be minimized, given the time and resource limitations and other working group initiatives to which CCFAC members are already subjected. Canada favours Option 4 and believes that it should be considered for further discussion.

CHILE:

In relation to this subject, we consider option 5 which reads: 'begin new work on revising the Preamble to the GSFA to establish safe conditions of use for flavouring substances and natural flavouring complexes in foods with a reference to the evaluations completed by JECFA' as the most appropriate; moreover, Chile supports the recommendations of paragraphs 20 and 22 given in this document.

CUBA:

The definitions are accurate and should be maintained. **Our country is in agreement with the discussion paper.**

EUROPEAN COMMUNITY:

The European Community (EC) appreciates the opportunity to comment on the discussion paper on possible options to integrate flavouring agents into the Codex system. The EC would like to make the following comments:

The EC thanks the drafting group for the clarity and completeness of the document. The explanations of the background, the previous discussions at CCFAC and the evolution of the JECFA approach to the safety evaluations of flavours are highly appreciated. The document is a good basis for opening the discussions on the possible options to integrate flavouring agents into the Codex system.

The EC would like to inform the CCFAC that in the European Community an extensive evaluation programme of flavouring substances is ongoing. To this end, about 2600 flavouring substances used in the Community have been entered in a register. The European Food Safety Authority was requested to evaluate the registered substances. By and large, the Authority is here for following the procedure applied by JECFA. The evaluations done by JECFA are also taken into account.

Should work start on the integration of flavouring substances in the Codex system, the EC would be pleased to offer to the Committee the evaluations carried out by the European Food Safety Authority (EFSA), in particular in relation to issues such as estimation of intake and substances with genotoxic potential.

The EC supports the recommendation that a working group should be established with a mandate to develop a proposal for definitions of flavourings in general and subcategories thereof. This work should be done before any work on integration of flavouring agents into the Codex can take place.

The European Community favours the fourth option but is of the opinion that the ongoing work on General Standards on Food Additives should receive the highest priority and should be finalised before any other extensive work is taken up by CCFAC.

USA:

The discussion paper describes five options for bringing into the Codex system the nearly 1500 chemically-defined flavoring substances evaluated during the last ten years by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). These are flavoring substances for which a conclusion of "no safety concern" for use in foods has been reached, and for which specifications of identity and purity have been established. The JECFA continues to evaluate more chemically-defined flavoring substances, while developing procedures for evaluating the safety of "natural flavouring complexes" (naturally derived flavoring agents that are mixtures of many individual flavoring substances). As noted in the discussion paper (para. 15), the elaboration of a Codex standard, or guideline, that establishes uniform and safe conditions of use of flavoring agents would promote fair trade and protect the health of consumers.

Recommended Option

The United States recommends Option 4 (para. 16 of the discussion paper) as the best way to meet the needs of Codex Alimentarius. Option 4 calls for new work to elaborate an independent guideline that establishes conditions of safe use for flavoring agents using principles similar to those contained in the preamble of the General Standard for Food Additives (GSFA). Option 4 also provides for a reference to the evaluations completed by JECFA, as opposed to the creation of a separate positive list.

The United States believes that the creation of an independent guideline for the use of flavoring agents is the most viable option because this approach would produce a stand-alone document that could be developed independent of, and therefore not rely directly on, the elaboration of the GSFA. Also, referencing the list of flavoring agents evaluated by JECFA would eliminate the potential for introducing inconsistencies with the JECFA list, the need for CCFAC to periodically update a separate positive list, and any potential confusion that may result from having duplicate lists. The United States believes that this option would allow for the greatest flexibility as JECFA continues its evaluations.

Definitions for Flavoring Agents

The United States believes that CCFAC should request the Codex Secretariat to publish the definitions for "natural flavours and natural flavouring substances," "natural flavourings," and "nature identical flavouring substances" that were previously adopted by the Commission (ALINORM 72/35, para. 294). Additionally, the United States notes that the discussion paper indicates that the Commission has adopted two definitions for the term "natural flavours and natural flavouring substances." We suggest that CCFAC request that the Codex Secretariat publish the broader definition found in "General Recommendations for Natural Flavourings" (CAC/GL 29-1987), and in paragraph 8b of the discussion paper.

ICBA:

The International Council of Beverages Associations (ICBA) is a nongovernmental organization that represents the interests of the worldwide nonalcoholic beverage industry. The members of ICBA operate in more than 200 countries and produce, distribute, and sell a variety of water-based beverages, including carbonated soft drinks and noncarbonated beverages such as juice-drinks, bottled waters, and ready-to-drink coffees and teas. ICBA is pleased to provide the following comments in response to CX/FAC 05/37/15.

Need for a Codex Standard for Flavouring Substances (para 15)

ICBA supports integration of flavouring substances into the Codex system. There are varying national regulations and there is a need for international harmonization in this area to ensure consumer safety and facilitate trade.

Options (paras 16-19)

ICBA supports Option 4 as the most expedient way forward (to elaborate a Codex Guideline for the use of Flavouring Substances and Natural Flavouring Complexes with a reference to the evaluations completed by JECFA). The Committee lacks resources to develop a general standard. Further, we believe that the use of flavouring substances is sufficiently different from food additives that including them in the General Standard for Food Additives (GSFA) would not be appropriate. In many countries, flavouring agents are regulated differently from food additives since they often are natural oils or naturally occurring substances that are used at low levels in foods. The proposed Option 4 would reduce the workload by referencing to the evaluations completed by JECFA. Since the JECFA evaluations are ongoing, flavours currently in use, permitted by a country, or evaluated by another expert group, should continue to be permitted until the JECFA evaluation for that particular flavouring agent is complete.

Definitions (paras 20, 22 and 23)

ICBA supports requesting the Codex Secretariat to publish the definitions for natural flavours and natural flavouring substances, nature-identical flavouring substances and artificial flavouring substances as adopted by the 9th CAC. ICBA also supports establishing a working group with a mandate to develop a proposal for a definition of flavourings in general.

IOFI:

Introduction:

The International Organization of the Flavor Industry (IOFI) is the representative of the global flavour industry and appreciates the opportunity to comment on the "Discussion paper on Flavouring Agents" (CX/FAC 05/37/15).

Flavourings provide choice

The flavour industry produces flavourings by blending variable numbers of raw materials of natural or synthetic origin. There are several thousands of chemically defined substances available of which a large portion are of natural origin or have been identified in foods; in addition several hundreds of natural flavourings of more complex composition are found in the market place. All these substances are used by our industry to provide an almost limitless number of blends that are ultimately used by the food industry to provide and enhance taste in foods and beverages. These blends are developed according to the requirements of our customers, the food industry, which takes care that the flavour of a food product meets consumers' expectations.

Safety of flavourings

The safety of flavoured food is intricately linked with the safe use of flavourings. Therefore it is essential that the safety of flavourings and safe conditions of use are established in parallel.

The safety of flavourings needs to be established by an international scientific process that meets the safety assessment requirements of Codex. The flavour industry continues to support the safety evaluation started by JECFA in 1996 and hopes that JECFA will, during the forthcoming years, complete its work on chemically defined flavourings and start also to consider the safety of more complex natural flavourings.

The safe use of flavourings in foods requires the compliance of flavour suppliers and food manufacturers with Good Manufacturing Practices, basic guidelines for addition of flavours to foods, and general legislation about the labelling aspects of the food as consumed. As far as possible these guidelines need to be agreed at a global level and should be consistent with global use of flavourings. Some elements important for the safe use of flavourings were already discussed by Codex and are found in a number of Codex texts but they are not accessible as a single concise document and they do not cover all relevant issues.

Development of a guideline for the use of flavourings:

Although JECFA has started the evaluation of flavourings, an internationally recognised list does not exist yet; this and the lack of uniformity in the regulation of flavourings present significant non-tariff barriers to the free movement of foods. IOFI supports work by Codex to address this situation and is willing to participate actively in the discussion and work.

IOFI supports Option 4: to begin new work on the elaboration of a "Codex Guideline for the Use of Flavouring Substances and Natural Flavourings" that establishes the principles for the safe use for flavourings in foods. A working group shall be charged with the task to develop a draft guideline taking into account all the already adopted (and some of the historic) Codex texts that contain rules applicable to flavours.

In our view the discussion of the working group shall focus at least on the following issues:

1. Global positive list of safe flavourings

Flavour industry, food manufacturers, consumers, and regulatory authorities would benefit from an internationally recognised positive list of safe flavourings. Within the global marketplace such a list is currently lacking. Moreover, there is a lack of uniformity in the safety evaluation and regulation of flavourings among different countries and continents. The evaluation and regulation of the large number of flavourings that exhibits unique patterns of use (i.e. low level of use and self-limiting use) requires specialised expertise that is not currently available in many countries.

As mentioned above, JECFA has developed a formalised evaluation procedure that has been used to evaluate systematically, nearly 1500 flavourings so far. IOFI is of the opinion that JECFA has established a sound operational approach for the safety evaluation of flavourings and that this effort should be continued in the future. To date there are probably up to 3000 flavourings in use in the world and of potential importance for inclusion onto a global list. E.g. the EU has identified up to 800 additional substances that are currently reviewed by the European Food Safety Authority, and a recent survey of the Japanese flavour market has revealed another 700 materials.

Whether the list that is created as a result of JECFA's ongoing safety evaluation of flavours needs to be adopted as a separate Codex list or could simply be referred to by Codex is open for discussion.

2. *Definitions*

With regard to definitions IOFI supports the three definitions adopted by the 9th Session of CAC (1972) on natural flavours and natural flavouring substances, nature-identical and artificial flavouring substances, as well as the modifications adopted by CAC at its 16th Session (1985) on definitions for natural flavourings, natural flavours and natural flavouring substances and adjuncts.

3. *Conditions of use*

Only flavouring ingredients which have been evaluated by the JECFA and found to be safe can be considered for addition to food. CCFAC should recognize the JECFA flavour safety assessments and develop guidelines for their addition to food. The development and the adoption by Codex of a guideline for the safe use of flavouring substances would continue to recognize the unique nature of flavouring substances as requiring evaluation and approval procedures separate, but at least equal in the level of consumer protection provided, to those procedures used for the evaluation and approval of food additives.

4. *Labelling*

IOFI recommends that the proposed guideline makes reference to the current provisions for the labelling of flavourings as laid down in the Codex General Standard (CODEX STAN 107-1981) for the Labelling of Food Additives when sold as such and the General Standard (CODEX STAN 1-1985) for the Labelling of Prepackaged Foods when added to food.

5. *Food additives and hygiene*

Where still applicable the essential provisions as laid down within the "General requirements for the Use of Natural Flavourings" (CAC/GL 29-1987) should be incorporated and possibly updated.

Conclusion:

The development of a guideline on the safe use of flavourings would provide the most economic solution to integrate flavouring substances into the Codex system. The recognition of the JECFA safety assessments of flavourings would provide the basis for the safe use of flavourings and achieve the goal of a global list of safe flavourings to which, in the future, new materials could be expeditiously evaluated and added. The presence of such a list would not only create global consistency, but would also save resources for Codex members to dedicate to other more urgent priorities.

IOFI strongly recommends that the CCFAC create a workgroup for the preparation of a guideline on the safe use of flavourings. Our industry is willing to commit time and resources to support this important work.