codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8 **CX/FAC 03/10**
February 2003

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES AND CONTAMINANTS
Thirty-fifth Session
Arusha, United Republic of Tanzania, 17 - 21 March 2003

COMMENTS SUBMITTED ON THE DISCUSSION PAPER ON PROCESSING AIDS AND CARRIERS (CX/FAC 02/9) IN RESPONSE TO CL 2002/10-FAC

The following comments have been received from USA, Canada, European Community:

USA:

The Discussion Paper highlights four key issues:
- Whether the definitions of processing aids and food additives should be amended.
- Defining carriers and including food additive carriers in the GSFA.
- Whether processing aids should be covered under Codex commodity standards.
- Options for considering processing aids in the context of the GSFA including what should be done with the Inventory of Processing Aids (IPA).

The discussion paper also provides several recommendations (CX/FAC 02/9, para. 82-87). The United States provides the following comments on those recommendations.

Definitions of Food Additive and Processing Aid

The United States supports the recommendation to retain the current definition of food additive as provided in the Codex Procedural Manual.

The United States does not support the suggestion to amend the Codex definition of processing aid by adding the phrase "*which have no technological effect in the final product*." The current definition recognizes that the use of processing aids "*may result in the non-intentional but unavoidable presence of residues or derivatives in the final product*." The amendment is intended, however, to account for the possibility that the quantities of non-intentional but unavoidable residues or derivatives of a processing aid in the final product may be sufficient to exhibit a functional effect. As noted in the Discussion Paper (CX/FAC 02/9, para. 18), the Codex General Standard for the Labelling of Prepackaged Food (section 4.2.3) requires labelling of direct food additives and any additives carried over into food in a quantity sufficient to perform a functional effect in that food. The United States concludes that (1) the current definition makes it clear that a processing aid fulfills its functional effect "*during treatment or processing*" of the food – not in the final food and (2) the possibility of a quantity of processing aid sufficient to exhibit a functional effect in the final food is fully addressed by the Codex standard on labelling. The United States reiterates its comment, provided in response to CL 2001/13-FAC, that the

definition of processing aid requires no change and that it is clear that processing aids are a subset of food additives.

Definition of Carrier and Inclusion of Carriers in the GSFA

The United States supports the proposed definition [with minor editing for clarity –strikeout and bold font] for a carrier as "*a substance that is intended to serve as a vehicle for the introduction of or facilitate the delivery of another food additive* ***into the final food****, or to stabilise another food additive, or to otherwise enhance the other food additive's intended functional effect in the final food*." In light of the comment in the Discussion Paper (CX/FAC 02/9, para. 24), regarding possible misinterpretation of the word "*stabilise*", the United States would like to suggest that the word "*stabilise*" be deleted and replaced with "*maintain the integrity of*."

The United States agrees that the term "carrier" should embrace three sub-classes: solid carrier, carrier solvent, and encapsulating agent.

The United States supports the proposal to include the above definition of carrier and the three sub-classes in the *Table of Functional Classes, definitions and technological functions for food additives* of the Codex Alimentarius (Volume 1A, Section 5.3).

The United States does not support the proposal to include a category for "food additive preparations" in the Food Category System of the GSFA. The Preamble to the GSFA establishes that the "food category system is based on product descriptors of foodstuffs as marketed…" Thus, the GSFA Food Category System is intended to include provisions for the use of food additives in finished foods, not in other food additives (or food additive preparations). Additives used in other additives (e.g., an antioxidant in a color or an encapsulating agent for a flavouring agent) or additives comprising food additive preparations should have individual provisions in the GSFA and be used in accordance with these provisions as they relate to the finished food. Therefore, the United States believes it unnecessary to establish a new food category in the GSFA for "food additive preparations."

The Discussion Paper (CX/FAC 02/9) proposes to include a "category for 'vitamin preparations' and other minor ingredients and permitting the use of carriers in these categories." Paragraph 32 of the Discussion Paper clarifies this statement. The proposal would establish food categories for minor ingredients such as "vitamin preparations (sold as such or used as ingredients in food)," which may need to use carriers. The Food Category System contains the category "13.6 Food supplements." This category includes vitamin and mineral supplements in tablet or liquid form, i.e., vitamin preparations sold as such. As appropriate, carriers included in such preparations may be listed in Tables 1 and 2 of the GSFA in food category 13.6 with their maximum use levels or in Table 3. As noted above, with regard to food additive preparations, the GSFA lists provisions for additives in finished foods. Therefore, it is inappropriate to establish categories for vitamin preparations used as ingredients and for other minor ingredients that may contain carriers. Each component of a preparation should have and be used in accordance with provisions for its use in the finished food.

Processing Aid Provisions in Commodity Standards

The United States supports the recommendation that commodity standards should contain only lists of the functional classes of processing aids (e.g., antifoaming agents), not the individual substances. The United States also agrees that these provisions should appear in a clearly delineated subsection under the food additives section of a commodity standard.

The United States agrees that the Codex Secretariat should inform all commodity committees of the requirements in the Procedural Manual that processing aids should appear as a subsection of the food additives section of a commodity standard.

The Discussion Paper proposes that CCFAC propose as new work the modification of the Procedural Manual concerning endorsements of processing aids in commodity standards (see the "Food Additives and Contaminants" section of the Procedural Manual's chapter on "Relations Between Commodity Committees and General Committees). The Paper proposes to place the term "*processing aids*" in brackets after the term "*food additive*," wherever it is used on "p 95 and 96". This "requirement" would

remain until a general standard covering processing aids is developed. The United States understands that this proposal refers to pages 84-85 of the current 12th edition of the Procedural Manual. The United States agrees in principle with this proposal, but notes that the first paragraph of the section on Food Additives and Contaminants advises that the section on additives in commodity standards should include "*the names of those additives…*". In light of the proposal, discussed above, to list only provisions for functional classes of processing aids, the United States believes that CCFAC may wish to consider including the first paragraph of the section in a proposal for new work. The amendment should clarify what specifically should be listed in the food additive (including processing aids) sections of commodity standards - names of the additives or additive functional classes.

Horizontal Approaches to Processing Aids

The Discussion Paper suggests that CCFAC consider expanding the GSFA to include processing aids. The United States supports this recommendation, in principle, while noting that any provisions for processing aids in an expanded GSFA (or in any parallel document) should include their uses for both standardized and non-standardized foods. Including provisions in the GSFA for processing aids listed only in the commodity standards would be of limited value for achieving Codex goals of developing standards that protect the health of the consumer health and ensure fair practices in international trade of foodstuffs.

The United States agrees that it will be appropriate for the use of certain processing aids to be limited by GMP for general use and that numerical limits for residues may be appropriate in other cases for specific food uses. The United States also agrees that it may be possible to establish a threshold level for residues that would serve as a basis for a GMP provision. To establish a threshold in terms of analytical concentration of a processing aid in food, however, provides a limited *a priori* basis for determining whether a residual amount of individual processing aids is safe. The United States believes that a threshold limit for residues, if one is to be elaborated, should be elaborated through considerations of consumer exposure and toxicological concern. Further, the threshold level itself should be expressed as a dietary concentration below which the CCFAC would consider risk to be negligible.

The United States supports the recommendation that CCFAC propose as new work the inclusion of provisions for the use of processing aids in the GSFA.

Advice from JECFA on the Safety of Processing Aids:

The United States agrees that the JECFA would be the appropriate body to ask to evaluate consumer exposure and toxicological data for processing aids and to formulate a model that CCFAC could use to establish its policy for a threshold level for residues expressed in terms of a daily dietary concentration. It should be recognized, however, that implementation of such a policy would require consideration of consumer exposure for individual substances. Establishment of a threshold would not, *a priori*, eliminate the need for referring individual processing aids to JECFA. As noted in the Discussion Paper (CX/FAC 02/9, para. 60), at present there appear to be only limited data in the Inventory on Processing Aids (IPA) on residues, interactions with food, and toxicology that would be needed for a JECFA evaluation. Lack of such data will certainly hinder the development of Codex provisions for processing aids.

The Discussion Paper notes that about half of the processing aids listed in New Zealand's update of the IPA presently have been assigned an ADI by JECFA. Some of these assessments are for direct food use. The United States agrees that it would be appropriate to ask the advice of JECFA on whether additional intake of such a substance through its use as a processing aid would be insignificant. If so, use as a processing aid would be of negligible safety concern. Further, if use of a processing aid leads to no residues in a finished food, there would be no need to seek the advice of JECFA.

What Should be Done With the IPA?

The United States believes that it is unnecessary to make a request to the CAC to "withdraw" the IPA as a Codex document. The IPA is not a Codex standard, guideline or code of practice. It has never been entered into the Codex standard elaboration process. In effect, the IPA is already a working document for the use of CCFAC.

The United States supports the recommendation to circulate for comment and further consideration by CCFAC New Zealand's updated IPA, along with the list of substances that have been proposed over a number of years for inclusion in the IPA, but on which CCFAC has never taken a decision.

The United States fully supports revising the title of the circulated IPA to make it clear that the IPA is NOT a positive list of Codex-adopted processing aid provisions. The United States also agrees that the circulation of the IPA be accompanied by a request for further information on those substances in the updated IPA and information for additions to the IPA. Information for each substance should include the relevant GSFA Food Categories, a description of the application, available information on residues in food, a citation(s) to any existing JECFA evaluations of the processing aid, and a statement as to whether the GSFA already lists the processing aid for applications of direct addition to food.

The United States supports the recommendation that the CCFAC use the updated IPA as a "worksheet" for developing the provisions for processing aids in the GSFA (or a parallel document). Should the CCFAC agree to circulating an updated IPA with a request for additional information, as noted above, the United States proposes that the CCFAC also agree to develop a companion Discussion Paper outlining the mechanism for incorporating the provisions for processing aids into the GSFA (or into a parallel document) for discussion at the 36th CCFAC.

CANADA:

General

At the request of the 33rd CCFAC, a drafting group led by New Zealand prepared a discussion paper on processing aids and carriers for consideration in relation to the GSFA. Canada participated in this drafting group and offered two sets of comments to New Zealand as a member of this drafting group. The second set of detailed comments offered by Canada did not reach New Zealand in time to be considered and incorporated and Canada would ask that these be re-considered and taken into account in any future revisions to this document.

Canadian Position

In Canada, a processing aid is considered to be a substance that is used in the production of a food but is not intended to have an effect in the final food and does not leave residues in the food (i.e. residues are negligible). The Codex definition is similar except that it states that a processing aid may or may not leave a residue in the final food and hence, under the Codex definition, processing aids are considered to be a sub-set of food additives.

The discussion paper considers a number of options for dealing with processing aids, including:

(1) revising the definition
(2) adding processing aids to the GSFA
(3) establishing a separate horizontal standard for processing aids
(4) updating the existing inventory of processing aids
(5) adding processing aids to commodity standards with either specific listings or the use of general listings by functional class

It is Canada's view that, on the issue of processing aids, the Committee's attention should focus only on processing aids that result in residues in the final food and, as such, these substances should be reviewed with the same rigour as any food additive, including an assessment by JECFA. While addition of these substances to the GSFA seems reasonable, Canada would be prepared to support other options that achieve the same result. However, any option that is chosen must ensure that the use of a processing aid does not

result in a barrier to trade, particularly when that processing aid does not result in residues in the final food and, therefore, poses no risk to the consumer.

In its last set of comments as a member of the Drafting Group, Canada indicated to New Zealand that the document was greatly improved with respect to organization, layout and coherence since Canada last made comments and that New Zealand is to be congratulated in attempting to put some order into what is potentially a chaotic subject and upon which Member States certainly have disparate views due to their own individual experiences and long histories of regulatory development.

While, as indicated above under the section entitled ***General***, Canada offered many detailed comments on specific aspects of the actual document considered at the 34th Session of CCFAC, all of the comments supported the position presented above. Again, Canada requests that its detailed comments, already provided to the Government of New Zealand, be taken into account in revising this document.

EUROPEAN COMMUNITY:

The European Community would like to congratulate New Zealand and the drafting group for the discussion paper on processing aids and carriers. The paper provides many considerations on how to clarify the status of processing aids and carriers within the Codex work.

The European Community would like to make the following remarks:

Definitions of food additive and processing aid

1. The European Community does not see a need to amend the current definition of a food additive. The definition describes well the intended use of food additives.

2. In the contrary, the European Community sees the need to amend the current definition of processing aids to add the requirement that the residues of processing aids **do not have any technological effect in the final food and that these residues do not present any health risk.**

3. By adding the criteria on technological effect clarifies the difference between the processing aid and food additive the latter having a technological function in the final food. The criterion on safety of food additives is included in the preamble of the GSFA. As processing aids are neither systematically evaluated for safety neither by JECFA nor subject to any general criteria, the definition of processing aids should contain this requirement.

Definition of carrier and inclusion of carriers in the GSFA

4. For carriers the European Community prefers more constrained definition than proposed in point 23. Carriers should not exert any technological effect themselves in the food where they are carried over.

5. The European Community agrees that a specific listing should be provided in the GSFA for food additives that may be used as carriers. The listing could also include the use of any other type of food additive needed for handling or use of another food additive.

6. However, the EC does not consider it necessary to establish a separate food category for other minor ingredients such as vitamin preparations. In the EC, these are considered as food and, therefore, the rules for use of food additives are applicable to these types of ingredients. In the GSFA, they could be contained in the food categories mentioned in section 13.0.

Processing aids in commodity standards

7. In the view of the European Community, the CCFAC should not begin the work to create a general standard for processing aids nor incorporate them into the GSFA simply because of **lack of time and resources**. CCFAC's priority must be to finalise the GSFA.

8. If the definition of processing aids is being amended as suggested in point 2 above, the European Community does not see that processing aids should cause barriers to trade.

9. However, the inventory of processing aids (IPA) is a useful general information that should be provided to those interested. Therefore, the EC suggests that the inventory is being updated, but no official status should be given to it.