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Agenda Item 5 b)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

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DISCUSSION PAPER ON A STRUCTURED APPROACH TO THE REVIEW OF THE GUIDELINES FOR PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS

(Prepared by United States of America)

Introduction

At the 37th Session of the Codex Committee on Food Labeling (CCFL), the United States presented a proposal in a Conference Room Document for a more structured approach to the review of the *Guidelines For The Production, Processing, Labelling And Marketing Of Organically Produced Food* (hereafter referred to as the *Guidelines*) consistent with Section 8, periodic review of the *Guidelines*. After some discussion, the Committee agreed that the United States would develop a discussion paper which would more clearly define the process for consideration of amendments and the need for establishment of support mechanisms to facilitate such a process for review by the Committee at its next Session.

II. Background

The Codex Alimentarius Commission adopted the *Guidelines* at its 23rd Session in 1999, with the exception of the provisions for livestock and livestock products that were adopted at its 24th Session in 2001.

The Codex Alimentarius Commission adopted the revised *Section 5. Requirements for Inclusion of Substances in Annex 2 and Criteria for the Development of Lists of Substances by Countries* at its 26th Session in 2003; the revised Tables 1 and 2 in *Annex 2: Permitted Substances for the Production of Organic Foods* at its 27th Session in 2004; and the revised Table 3. *Ingredients of Non Agricultural Origin Referred to in Section 3 of these Guidelines* at its 30th Session in 2007.

1) Committee Intent for a Periodic Review of the Guidelines

The guidance in section 5.3 and section 8.1 concerning the review of the *Guidelines* indicates the intent of the Committee at the time the *Guidelines* were established.

Section 5.3 of the *Guidelines* establishes the open nature of the lists, and notes that “the procedure for requesting amendments to the lists is set out under Section 8 of these Guidelines.”

Section 8.1 of the *Guidelines* states that “once a final document is agreed, the Codex Committee on Food Labelling shall conduct a review each 4 years of these *Guidelines* and review each two years (or as required) the lists included in Annex 2 in order to take into account the latest developments in this area.”

2) Organic Guidelines as an illustrative listing is not being followed

Annex 2 - Permitted Substances for the Production of Organic Foods is an illustrative list of the materials used in organic agriculture and was never intended to be used “as an inclusive or exclusive list, or a finite regulatory tool...”, as noted in Annex 2.

The examples provided in the illustrative lists were never meant to take the place of individual country lists of permitted organic substances as exemplified by the *Guidelines* “Foreword,” point 3: “Guidelines are a useful instrument in assisting countries to develop national regimes regulations regulating production, marketing, and labelling of organic foods.”

However, since the adoption of the *Guidelines*, countries have continuously submitted proposals for additions to the lists. This practice creates the need for frequent amendment of the list to include every possible substance, defeats the purpose of both indicative lists and the periodic review process, and diminishes the role of national regimes.

3) Original Review Process is Inadequate

The inclusion or removal of substances from the Codex organic permitted substance list (Annex 2) must occur through a fair, scientifically-based, and transparent approval process by individual countries based on the criteria established in Section 5.1 – Requirements for Inclusion of Substances to Annex 2 and Criteria for the Development of Lists of Substances by Countries.

Any proposal for amendment of the lists should be accompanied by a complete data package addressing the criteria in Section 5.1. However, proposals for new work often are not accompanied by necessary or complete data and have resulted in continuous and ongoing yearly review of proposals. Moreover, review of amendments to the *Guidelines* requires significant and specialized technical expertise and many Members are unable to provide such expertise on a yearly basis. In addition, proposals are not always submitted in sufficient time prior to the Committee’s plenary session and, in some cases, the proposals are made available as Conference Room Documents after delegates arrive at the meeting. In such instances, full and thorough review by the Committee is not possible during the plenary as, in general, only a few countries have organic experts on hand to advise them on such proposals.

Because of these types of difficulties, the review processes for the *Guidelines* needs to be reassessed, including the consideration of a need for a structured review process. A structured process and establishment of a support mechanism is needed to improve the efficiency of the reviewing such proposals and to limit the strain on the resources of the Committee.

Do countries agree that a more structured process would improve the efficiency of the review process?

Do countries agree that proposals for additions to the list need to be provided with sufficient time for appropriate review by countries in advance of the Committee meeting?

III. Elaboration of the Proposed Structured Review Process

This guidance presented in Sections 5.3 and 8.1 can be used as a starting point to consider the approach to a revised structured review process.

A. Review of Sections 1-8 of the Guidelines

Since demand has been small for amendments to Sections 1-8 of the *Guidelines*, it is proposed that the requirement for a periodic review of the main portion of the *Guidelines* is not needed. The normal approach for the revision of Codex texts generally can be followed; that is, a new work proposal for revisions of the main Guideline can be developed and brought forward when the Committee believes

Do countries agree that amendments to Sections 1-8 of the Guidelines can be accomplished through the normal process of a new work proposal?

significant changes have occurred in the processes used for the production, processing, labelling and marketing of organically produced food such that a revision to the main portion of the Guidelines is warranted..

B. Periodic Review of Annexes 1-3

A structured review process for Annexes 1-3, especially the permitted substances lists as outlined in Annex 2, would be beneficial and would support the original intent of the Committee. The following process is proposed.

- 1. Review Cycle:** A four-year review cycle is proposed in which proposals for review would be collected in years 1-3 and consideration of the proposals by CCFL would occur in year four (4).
- 2. Collection of Requests for Amendment of the *Guidelines*:** Proposals to amend Annexes 1 -3 may be submitted in any of years 1-3 to the Codex and/or CCFL Canadian Secretariats. For consideration, full data packages must be submitted in support of amendments according to the criteria in Section 5.1 of the *Guidelines*.

The Secretariat would provide these proposals to an **Electronic Organic Working Group (EOWG)** that would be created at each 3rd CCFL meeting. Additionally a Project Document would be prepared containing the amendments as proposed for CCFL's review/approval and submission to the Commission as proposed new work.

- 3. Establishment of an EOWG prior to Each Fourth Committee Session:** At the conclusion of year 3, the CCFL would establish an electronic EOWG to operate between the conclusion of year 3 CCFL Session and the following year 4 CCFL Session. (If no proposals for amendment are submitted, the EOWG would not be established.) The EOWG would review the proposed amendments and the associated data packages and make recommendations to the year 4 CCFL Session to either accept or deny each proposed amendment. During the one-year review process the EOWG may request additional supportive data to complete the review process. If a proposed amendment is denied, the EOWG must provide a justification for the denial.

When prioritizing proposed amendments to the permitted substances list in Annex II, the EOWG will give priority to substances that are significant to international trade. As such, the EOWG would consider the following criteria in addition to those in Section 5.1:

1. Is the substance registered for use in the Member Country;
2. Volume of use of the substances by individual country and volume of usage and relevance to the international community;
3. Availability of regional/national reviews and risk assessments, and coordination with other regional/national lists;

4. Commitment by the sponsor of the substance to provide supporting data for review (against 5.1 criteria).

CCFL, at the 4th Session of the cycle, would consider the recommendations of the EOWG, make decisions regarding the amendments, and submit the Committee's recommendations to the Codex Commission for adoption.

Proposed amendments that are not accepted would be returned to the original submitters of the proposals along with a justification for the denial including the need for additional data. The submitter would be able to make a decision as to whether they wish to resubmit (including addressing the need for additional data) a revised proposal for the next subsequent review cycle. There would be no provision for automatic resubmittal of the unaccepted proposals.

Do countries agree that the proposed cycle would allow for a more structured review of proposed additions to the list?

Do countries have suggestions for other cycles that would accomplish a more structured review and allow countries sufficient time to review proposals for additions to the list well in advance of the meeting and allow feedback to countries if their proposal does not contain sufficient information?

Do countries agree that establishment of the EOWG is a helpful support mechanism?

Do countries agree that additional criteria are needed for prioritization of the worked to be undertaken by the EOWG?

IV. Recommendation to Modify Section 8

It is recommended that Section 8 of the *Guidelines* be amended as follows to incorporate language that would allow for a periodic structured review process in line with the original intent of the Committee:

- 8.1 In order to take into account the open nature of the lists as outlined in Section 5.3, governments, member governments and international organizations are encouraged to submit proposals for amendment of Annex 1 – 3 to be reviewed by an Electronic Organic Working Group (EOWG).
- 8.2 A four-year cycle of review would be established. Proposals may be submitted during years 1-3. Proposals should be directed to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Rome, Italy 00153. The Secretariat will provide collected proposals to an EOWG established at each 3rd CCFL Session. A Project Document containing proposals to be evaluated by the EOWG would be prepared for approval as new work.
- 8.3 The EOWG will evaluate all proposals providing a recommendation to the Committee. When prioritizing proposed amendments to the permitted substances list in Annex II, the EOWG will give priority to substances that are significant to international trade. As such, the EOWG will consider the following criteria in addition to those in Section 5.1:
 1. Is the substance registered for use in the Member Country;
 2. Volume of use of the substances by individual country and volume of usage and relevance to the international community;
 3. Availability of regional/national reviews and risk assessments and coordination with other regional/national lists;

4. Commitment by the sponsor of the substance to provide supporting data for review (against 5.1 criteria).

8.4. At each 4th meeting the Committee would agree to accept or deny the EOWG recommendation.

V. Initiation of the Process

If the Committee concurs with the above proposals, it is recommended that the amendments to the Guidelines be developed at the 38th Session of CCFL and recommended for adoption by the Commission at the 33rd Session. Following adoption, the process for submittal under the 4-year cycle could be initiated with the first EOWG established at the 41st Session of CCFL. Accordingly, the timeline for the 4-year review cycle would be as follows:

38th to 41st CCFL Session

Accept Proposals for amendments to Annexes 1-3

At the 41st CCFL Session

Establish EOWG; and

Prepare Project Document with proposals and submit to Commission for approval as new work

41st to 42nd CCFL Session

EOWG evaluates proposals; and

EOWG prepares recommendations to either accept or deny each proposal

At the 42nd CCFL Session

Consider EOWG recommendations on each proposal;

Accept or deny each proposal; and

Submit amendments to Commission for adoption, as appropriate

It is also recommended that the three existing proposals for amendments to the Guidelines as presented in Annex A be moved forward outside of the new procedure with a recommendation to expedite completion of this work so as not to interfere with the new process.

Annex A. Outstanding Amendments to the Guidelines before the CommitteeInclusion of Ethylene for Other Products in Annex 1

Several delegations, along with the United States, opposed the extension of ethylene to other fruits and uses as no new justification was presented against the criteria in section 5.1 of the *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* (Guidelines). Other delegations expressed the view that ethylene could be used for other purposes including ripening of tropical fruits, degreening of citrus fruit, sprouting inhibitor for onions and potatoes, and inducement of flowering in pineapples. After further discussion, the Committee agreed that more scientific justification was needed to further consider these other uses of ethylene. The Committee decided to return other possible uses of ethylene to Step 6 for comments and invited delegations to provide justification against criteria in Section 5.1 of the Guidelines for consideration at the next Session.

Proposed New Work for Inclusion of New Substances in the Guidelines

The Delegation of the European Commission proposed new work to include the following substances into Table 2 of Annex II of the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods: spinosad, potassium bicarbonate and copper octanoate. The Committee noted that more justification against the criteria in Section 5.1 of the Guidelines was needed and indicated that interested delegations could prepare a new proposal on the inclusion of these substances for the next Session of CCFL, taking into account the need for more justification.

Proposed New Work Relating to Fraud Concerning Organic Proposals

The Delegation of the European Community proposed new work on the need to develop guidance relating to the exchange of information between competent authorities when suspecting fraud concerning organic products. While some delegations noted the appropriateness of such work, it was noted that there was existing Codex guidance on the exchange of information on food control issues already existed as developed by the Codex Committee on Food Import and Export Inspection and Certification Systems and that the proposal should be dealt with by CCFICS. The Committee agreed that the Delegation of the European Community would prepare a Discussion Paper on issues relating to the exchange of information between competent authorities when suspecting fraud concerning organic products and the scope of possible new work, for consideration by CCFL at its next Session.