codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4 **CX/FL 06/34/6**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING

Thirty-fourth Session
Ottawa, Canada, 1 – 5 May 2006

GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETTING OF ORGANICALLY PRODUCED FOODS;

CONSIDERATION OF THE PROCESS FOR EVALUATING SUBSTANCES IN ANNEX 2

PROBLEM STATEMENT

At the 33rd session of the Codex Committee on Food Labeling (CCFL), the Delegation of the United States agreed to coordinate an electronic drafting group for the purpose of continuing work to:

1. Develop a defensible and transparent process for evaluating substances considered for inclusion in Annex 2 of the Guidelines for the Production, Processing, Labeling, and Marketing of Organically Produced Foods (CAC/GL 32-1999, Rev.1 - 2001).

2. Develop a process that will ensure substances meet the general criteria in section 5 and principles of organic production as per the Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods; and

3. Ensure that the process will meet the requirements of Codex for establishing provisions for food additives.

During the 32nd session of the CCFL Working Group on Organically Produced Food, in Ottawa, Canada, the Working Group was tasked with recommending whether Annex 2 should be amended with specific substances and be progressed to the next step of the Codex process. As a result of the Working Group's deliberations, many substances that were being considered for inclusion on Annex 2 remained in square brackets and at the center of controversial debate. Some delegations noted the lack of transparency in the evaluation process and advocated for a transparent and standardized evaluation process. They argued that such a process would ensure an orderly and factual assessment of a substance and engender confidence in the conclusions reached in comparing the substance against the criteria in Section 5 of the CAC/GL 32. It was the consensus of the Working Group that the procedures arising from the electronic drafting group should be applied to existing substances remaining in square brackets at Steps 3 and 6, and any new requests for substance evaluation.

In late 2004, the United States Codex office invited all CCFL members interested in participating in the drafting group to provide contact information by December 31, 2004. The invitation was accepted by 16 member countries and three non-government organizations. In February 2005, the United States circulated a draft document that proposed a process by which to evaluate substances in Annex 2 of the CAC/GL 32. Comments were received from 3 member countries and 1 non-government organization.

The lack of comments was viewed by the United States as indicating a disinterest in moving forward on the development of a substance review process. In addition, there was not consensus among the comments. One member country noted that the proposed process was too paper intensive. Another noted that the process needs more transparency but that an extended discussion should occur on the objectives of the process. Yet another comment indicated that substance evaluation panels should be developed.

Given the lack of comments and the absence of consensus, the United States recommended to the 33rd Session of the CCFL that the drafting group discontinue its work. However, the recommendation to discontinue the work engendered an extended informal discussion between member countries and international organizations, during the 33rd Session of the CCFL. As a result of the discussions, several delegations supported a proposal to convene a physical working group prior to the next session of the CCFL in order to address all outstanding issues concerning organically produced foods in order to facilitate the revision of the *Guidelines*. The Committee therefore agreed in principle to continue work in this area and the Delegation of the United States agreed to prepare revised terms of reference for further work in an electronic working group.

In November of 2005, the United States Codex office invited all CCFL members interested in participating in the electronic drafting group to provide contact information and initial comments by January 2, 2006. The invitation was accepted by 14 member countries and 1 non-government organization. The United States acknowledges each member of the drafting group.

They are:

Delegation	**Name**	**E-mail Address**
Australia	Jenny Barnes	jenny.barnes@daff.gov.au
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United Kingdom	Joelle Appleby	joelle.appleby@foodstandards.gsi.gov.uk
IDF	Cary Frye	cfrye@idfa.org

Comments were received from 6 member countries.

In general, there was no consensus regarding the acceptance of the proposed process for evaluating substances in relation to CAC/GL 32-1999, Rev.1 - 2001. However, several comments did express that the proposed process was a good starting point for a discussion on a standardized decision process. One member country recommended that supplementary criteria should be further elaborated to provide additional guidance so as to prevent subjective decisions being made regarding the evaluation criteria.

On the other hand, some comments suggested that the proposed process was too detailed, resource intensive, impractical, and inefficient. One member country proposed that the decision process should be simple and questioned whether continuing a long debate in CCFL on the details of a procedure for evaluation would be the right approach for CCFL.

NEXT STEPS

The objectives of this memorandum are: 1) to serve as a supplemental document to the March 13th, 2006 memorandum that was circulated to electronic drafting group participants, 2) to provide interested parties with a list of participants to date, 3) to present for continued discussion a revised draft document (based on comments of both drafting groups) outlining potential evaluation procedures and questions, 4) to provide a proposed time frame for the discussion, and 5) to provide U.S. contact information. Comments should be directed to: mark.bradley@usda.gov.

The revised draft evaluation process will be discussed during the Working Group Session at the 34th Session of CCFL. However, because of the nature and scope of this topic, we recognize that this topic may require an extended discussion period in order to obtain consensus.

CONTEXT

CAC/GL 32 sets forth six objectives. They are:

> To protect consumers against deception and fraud in the market place and unsubstantiated product claims;
>
> To protect producers of organic produce against misrepresentation of other agricultural produce as being organic;
>
> To ensure that all stages of production, preparation, storage, transport, and marketing are subject to inspection and comply with these guidelines;
>
> To harmonize provisions for the production, certification, identification, and labeling have organically grown produce;
>
> To provide international guidelines for organic food control systems in order to facilitate recognition of national systems as equivalent for the purposes of imports; and
>
> To maintain and enhance organic agricultural systems in each country so as to contribute to local and global preservation.

BACKGROUND

CAC/GL 32 sets forth the general criteria for determining whether or not a substance is compatible with organic production and handling. To be considered for inclusion on the Annex 2 lists, a substance must meet the following general criteria:

a) They are consistent with principles of organic production. CAC/GL 32 further states that "An organic production system is designed to:

> Enhance biological diversity within the whole system;
>
> Increase soil biological activity;
>
> Maintain long-term soil fertility;
>
> Recycle wastes of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;
>
> Rely on renewable resources in locally organized agricultural systems;
>
> Promote the healthy use of soil, water, and air as well as minimize all forms of pollution thereto that may result from agricultural practices;

Handle agricultural products with emphasis on careful processing methods in order to maintain the organic integrity and vital qualities of the product at all stages;

Become established on any existing farm through a period of conversion, the appropriate length of which is determined by site-specific factors such as the history of the land, and type of crops and livestock to be produced."

b) Use of the substance is necessary/essential for its intended use;

c) Use of the substance does not result in, or contribute to, harmful effects on the environment;

d) They have the lowest negative impact on human or animal health and quality of life; and

e) Approved alternatives are not available in sufficient quantity and/or quality.

CAC/GL 32 states that "the above criteria are intended to be evaluated as a whole in order to protect the integrity of organic production."

In addition to these general criteria, CAC/GL 32 sets forth specific evaluation criteria depending on the end use of the substance under review. For substances used for fertilization or soil conditioning purposes, the additional criteria require the substance to be essential for obtaining or maintaining the fertility of the soil or to fulfill specific nutrition requirements of crops, or specific soil conditioning and rotation purposes which cannot be satisfied by the practices included in Annex 1, or other products included in Table 2 of Annex 2. Further, the additional criteria for substances used for fertilization or soil conditioning purposes require the substance's ingredients to be of plant, animal, microbial, or mineral origin and have undergone only physical (e.g., mechanical, thermal), enzymatic, and microbial processes. Finally, the additional criteria require that the substance and its use do not have harmful impact on soil organisms and/or the physical characteristics of the soil.

The Guidelines also set out additional criteria for substances when they are used for the purpose of plant disease or pest and weed control. When used for these purposes, the substances should be essential for the control of a harmful organism or a particular disease for which other biological, physical, or plant breeding alternatives and/or effective management practices are not available. The substances should also be of plant, animal, microbial, or mineral origin and may undergo only physical (e.g., mechanical, thermal), enzymatic, and microbial (e.g., composting, digestion) processes. Notwithstanding these additional requirements, when used for the purpose of plant disease or pest and weed control, the Working Group may consider for addition to the Annex 2 lists chemically synthesized substances when such substances are used under exceptional circumstances such as in pheromone traps and dispensers, and when natural substances are not available in sufficient quantities. For these chemically synthesized substances to be considered they must also be used in a manner that does not directly or indirectly result in the presence of residues of the substance on edible plant parts.

Further, the Guidelines set out additional criteria for substances when used as additives or processing aids in the preparation or preservation of the food. When used for these purposes, the substances may be considered only when they are found in nature and have only undergone mechanical/physical (e.g., extraction, precipitation), biological/enzymatic or microbial (e.g., fermentation) processes. Notwithstanding these additional requirements, when substances are not available in sufficient quantities from the processes described above, the Working Group may consider for addition to the Annex 2 lists chemically synthesized substances when such substances are used under exceptional circumstances, provided that they are essential to prepare a food product and that the consumer will not be deceived concerning the nature, substance, and quality of the food.

While the language of CAC/GL 32 provides significant criteria to guide the evaluation process, it is silent on the thresholds needed to meet the criteria. The Guidelines also establish a further degree of uncertainty by recognizing "that consumer perception on the organic production method may, in certain detailed but important provisions differ from region to region in the world." Adding to this uncertainty is a lack of detail

on the information required and the standard of proof used for making decisions on substances. Regarding the evaluation process, CAC/GL 32 provides only the following statement:

When a country proposes inclusion of a substance in Annex 2 it should submit the following information:
a) A detailed description of the product and the conditions of its envisaged use; and
b) Any information to demonstrate that the requirements under Section 5.1 are satisfied.

CAC/GL 32 does offer limited commentary on the scope and transparency of the evaluation process. It states that all stakeholders should be afforded the opportunity to be involved in the evaluation process. The Guidelines also recognize that the substance evaluation criteria are recommended to governments on a trial basis in order to achieve experience with organic production principles and rules at national level. Finally, the Guidelines state that "Member Countries may implement the Codex criteria or the criteria which they have developed on the basis of the experience they have made at national level." Therefore, the Guidelines establish a significant degree of flexibility at the Member State level while recognizing the long-term need for international harmonization of the requirements for organic products.

DISCUSSION

This discussion paper presents a draft procedure for a standardized evaluation of substances when the substances are considered by the Organic Working Group for inclusion in Annex 2 of CAC/GL 32. This draft procedure sets forth for discussion evaluation questions derived from the Guideline requirements. In general, these questions address a substance's potential for adverse impacts on human health or the environment and its essentiality in organic operations. The responses to these evaluation questions would be used by the Working Group in determining the compatibility of substances used for fertilization or soil conditioning, plant disease or pest and weed control, or as additives or processing aids in the preparation or preservation of the food with organic production and handling.

DRAFT PROCEDURES FOR CONSIDERATION OF SUBSTANCES IN RELATION TO EVALUATION CRITERIA IN CAC/GL 32 – SECTION 5

[SWEDEN: *Suggests introducing the sentence: "The evaluation process should be done in relation to the Criteria in CAC/GL 32 – Section 5" in the head line of the document***]**

1.0 Request for Inclusion

A country proposing inclusion of a substance in Annex 2 should submit its request to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, 00100, Rome, Italy. The request for inclusion of a substance should be presented within 120 days of the regulated scheduled meeting of the Working Group so as to establish the request for inclusion at Step 3 of the Codex process.

[SWEDEN: *Suggests the request be submitted to the Working Group with a copy to the Codex Secretariat. The Working Group should evaluate the request in relation to questions in Sections 3.0 and 4.0 of the proposal then send the request to the Codex Secretariat. The Codex Secretariat should propose the introduction at Step 3 of the Codex process.***]**

1.1 Request Elements

[SWEDEN: *Are the request elements mandatory? Is the intention that all 11 requests be fulfilled? The application forms used within the EU for fertilizers, soil conditioners and pesticides also ask for chemical names and dosage. These aspects should be added to point 1 and 2 of 1.1, respectively.***]**

[DENMARK: *Point 1 – Denmark suggests that more specification besides the common name is needed for example for food additives name from CCFAC and for pesticides name from CCPR. Point 2 – Denmark suggests that it is important that the technological purpose for the use and the process in which it is used is well described. Point 9 – Demark suggests that if the substance is to be used as an additive or processing aid in the preparation or preservation of the food, a copy of a Joint FAO/WHO Committee on Food*

*Additives (JECFA) toxicological monograph, (should be delivered), if available. If JECFA has evaluated and CCFAC has approved the food additive it should be enough.***]**

The requesting country must supply the following information:

1. The substance's chemical name and common name.
2. The intended use of the substance such as use for fertilization or soil conditioning purposes, plant disease or pest and weed control, or as additives or processing aids in the preparation or preservation of the food. The substance's rate and method of application must be described.
3. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.
4. A summary of any available previous reviews by public or private certification programs or other organizations of the substance.
7. Information regarding the substance under National regulatory authorities, including registration numbers, when applicable.
8. The Chemical Abstract Service (CAS) number, EU Registry number, INS number, or other product numbers of the substance.
9. If the substance is to be used as an additive or processing aid in the preparation or preservation of the food, a copy of a Joint FAO/WHO Committee on Food Additives (JECFA) toxicological monograph, if available.
10. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and (e) effects on soil organisms, crops, or livestock.
11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies.

2.0 Standard of Proof for Answering Evaluation Questions

[SWEDEN: *Instructions should be provided that explains how to evaluate the information in the dossier. In 1.1 very concrete requests are made. The requests should be related to general criteria in Section 5 and specific Criteria in 5.1 and 5.2. To make the evaluation process easier, we propose that the evidence should be based on the criteria. We need a better formulated standard proof.***]**

The standard of proof should be based on the preponderance of the evidence. This simply means that the greater weight of the evidence is not determined alone by the greater number of evidentiary submissions presenting data pro or con. Rather the greater weight of evidence is that which in the mind of the reviewers has the greater and more persuasive force, and which they believe more closely details the factual truth. The evidentiary submissions should be obtained from data sources that would be deemed trustworthy, reliable, and competent.

3.0 Evaluation Questions for Substances Used for Fertilization or Soil Conditioning or as Controls for Plant Diseases, Pests, and Weeds.

[JAPAN: *Why does the proposed procedure combine the evaluation questions for substances used for "Fertilization or Soil Conditioning" and "plant disease or pest and weed control"? If the purposes of using the substances are different, usage and prescription of the substances differ, and consequently we should evaluate different items, such as effects on the environment or users and residues in products. This is especially true for "fertilization or soil conditioning" and "control for plant disease." Therefore, clarification is needed in order to specify evaluation questions depending on the purposes for using substances and provide scientific data necessary for responding to the evaluation questions.***]**

[SWEDEN: *More clarification about the roles of JECFA and JMPR in the evaluation process is necessary. In our understanding more clarification about the relation between JECFA and the organic Working group is requested in relation to the Questions 7 and 11 (par. 4). JECFA already answered during the evaluation process to the questions about food safety. The task for the organic Working*

*group cannot be to take position on the toxicity of the substances or the effects on human health. Concerning the list of evaluation questions, Sweden proposes: to add "evaluation question #XX: "Is the substance a finite natural resource, or is its use depending on the use of such resources?" (following from the principles mentioned in "Background). Sweden also proposes to delete evaluation question #6, since it is already covered by evaluation question #7 and combine evaluation questions 4 and 9. The new evaluation question would be "Is there environmental contamination during the substance's manufacture, use, possible misuse, disposal or breakdown?"***]***

[CANADA: *Suggests that evaluation question #5 be combined with #8 as both are dealing with detrimental effects (on organisms and the environment); evaluation question #6 be combined with question #7 as both are dealing with detrimental interactions; and Evaluation question #9 be combined with question #10 as both deal with toxicity or persistence of breakdown products. In addition, Canada suggests evaluation question #12 follow question #3 and evaluation question #11 follow question #4.***]**

[NORWAY: *Suggests the addition of two new evaluation questions (#s 14 and 15)***]**

The following questions have been developed in order to address questions which arise through comparison of a substance with the general criteria set forth in CAC/GL 32.

Evaluation Question #1: Is the substance formulated or manufactured by a chemical process?

Data Required: In responding to this question, the documentation submitted by the country should describe the process used to manufacture or formulate the substance, including a discussion of the substance's feedstocks and/or precursors. For the purposes of this question, chemical processes are processes such as alkalization, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation, polymerization, etc., obtained through process units such as compressors, cracking towers, distillation columns, heat exchangers, mixers, reactors, pumps, etc.

Evaluation Question #2: Is the substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources?

Data Required: In responding to this question, the documentation submitted by the country should describe any chemical changes effected on any naturally occurring feedstock or precursor by the manufacturing or formulation process. For the purposes of this question, a chemical change is the addition or deletion of one atom to the substance's molecular structure. In identifying a chemical change, the documentation submitted by the country should note when a chemical change is one that could occur naturally over time such as the degradation by sunlight of hydrogen peroxide into water and nascent oxygen.

Evaluation Question #3: Is the substance created by naturally occurring biological processes?

Data Required: In responding to this question, the documentation submitted by the country should describe whether or not the substance is created by naturally occurring biological processes. For the purposes of this question, naturally occurring biological processes are processes such as aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

Evaluation Question #4: Is there a wholly natural product which could be substituted for the substance?

Data Required: In responding to this question, the documentation submitted by the country should describe whether or not a wholly natural product could be substituted for the substance under consideration. If the documentation submitted by the country asserts that there is not a wholly natural product, the documentation should indicate the nature and scope of the research used to reach this conclusion. The determination should utilize an itemized comparison of the effect, form, function, quality, and quantity of the wholly natural product with the substance being considered.

New Evaluation Question #5: Is the substance a finite natural resource, or is its use depending on the use of such resources?

Data Required: TBD

Evaluation Question #6: Is there environmental contamination or other adverse action created during the substance's manufacture, use, possible misuse, disposal, or breakdown?

Data Required: In responding to this question, the documentation submitted by the country should describe the occurrence and severity of known environmental contamination during the manufacture, use, misuse, or disposal of the substance. As a practical matter, the country requesting inclusion may submit this data may through reports or other documents prepared under any formal review and approval processes conducted under various authorities of the country.

Evaluation Question #7: Is there any harmful effect on human health by using the substance?

Data Required: In responding to this question, the documentation submitted by the country should describe the biological, chemical, and physical agents capable of causing adverse health effects, either present in the substance or arising from the degradation of the substance over time including the toxicity, mode of action, and persistence of the substance and its breakdown products.

Evaluation Question #8: Is the substance harmful to the environment?

Data Required: In responding to this question, the documentation submitted by the country should describe the biological, chemical, and physical agents capable of causing harmful environmental effects, either present in the substance or arising from the degradation of the substance over time including the toxicity, mode of action, and persistence of the substance and its breakdown products.

~~**[Evaluation Question #6: Is there potential for the substance to cause detrimental chemical interaction with other substances used in organic crop or livestock production?]**~~

~~**[Data Required:** In responding to this question, the documentation submitted by the country should describe the biological, chemical, and physical agents capable of causing adverse health and/or environmental effects, either present in the substance or arising from the degradation of the substance over time including the toxicity, mode of action, and persistence of the substance and its breakdown products.**]**~~

Evaluation Question #9: Are there adverse biological or chemical interactions in the ecosystem caused by using the substance?

Data Required: In responding to this question, the documentation submitted by the country should describe the biological, chemical, and physical agents capable of causing adverse health and/or environmental effects, either present in the substance or arising from the degradation of the substance over time including the toxicity, mode of action, and persistence of the substance and its breakdown products. In addition, the documentation submitted by the country should describe the substance's impacts, if any, on endangered species and the likelihood, if any, of measurable reductions in genetic, species or eco-system diversity through the use of the substance.

Evaluation Question #10: Are there detrimental physiological effects on soil organisms, crops, or livestock caused by using the substance?

Data Required: In responding to this question, the documentation submitted by the country should describe whether or not the substance affects the survival and function of soil organisms such as earthworms, mites, grubs, bacteria, nematodes, algae, and protozoa by creating unacceptable changes in soil temperature, water availability, pH levels, nutrient availability, or salt concentration. If the substance is to be used in crop production, the documentation submitted by the country should also describe whether or not the substance affects the physiology of the plant by creating unacceptable changes in plant pH, brix readings, or nutrient or water utilization. If the substance is to be used in livestock production, the documentation submitted by the country should also describe whether or not the substance affects the physiology of the animal by creating unacceptable changes in behavior, fertility, metabolism, or mortality.

~~**[Evaluation Question #9: Is there a toxic or other adverse action created by the substance or its breakdown products?]**~~

~~**[Data Required:** In responding to this question, the documentation submitted by the country should describe the biological, chemical, and physical agents capable of causing adverse health and/or environmental effects, either present in the substance or arising from the degradation of the substance over time including the toxicity, mode of action, and persistence of the substance and its breakdown products.**]**~~

Evaluation Question #11: Is there toxic or undesirable persistence or concentration of the substance or its breakdown products in the environment?

Data Required: In responding to this question, the documentation submitted by the country should describe the biological, chemical, and physical agents capable of causing adverse health and/or environmental effects, either present in the substance or arising from the degradation of the substance over time including the toxicity, mode of action, and persistence of the substance and its breakdown products.

~~**Evaluation Question #11: Is there any harmful effect on human health by using the substance?**~~

~~**Data Required:** In responding to this question, the documentation submitted by the country should describe the biological, chemical, and physical agents capable of causing adverse health effects, either present in the substance or arising from the degradation of the substance over time including the toxicity, mode of action, and persistence of the substance and its breakdown products.~~

~~**Evaluation Question #12: Is there a wholly natural product which could be substituted for the substance?**~~

~~**Data Required:** In responding to this question, the documentation submitted by the country should describe whether or not a wholly natural product could be substituted for the substance under consideration. If the documentation submitted by the country asserts that there is not a wholly natural product, the documentation should indicate the nature and scope of the research used to reach this conclusion. The~~

~~determination should utilize an itemized comparison of the effect, form, function, quality, and quantity of the wholly natural product with the substance being considered.~~

Evaluation Question #12: Are there other already allowed substances that could be substituted for the substance?

Data Required: In responding to this question, the documentation submitted by the country should describe whether or not an already allowed substance or substances could be substituted for the substance under consideration. If the documentation submitted by the country asserts that there is not an already allowed substance or substances that could be substituted, the documentation should indicate the nature and scope of the research used to reach this conclusion. The determination should utilize an itemized comparison of the effect, form, function, quality, and quantity of the already allowed substance or substances with the substance being considered.

Evaluation Question #13: Are there alternative practices that would make the use of the substance unnecessary?

Data Required: In responding to this question, the documentation submitted by the country should describe whether or not an alternative practice could be substituted for the substance under consideration. If the documentation submitted by the country asserts that there is not an alternative practice that could be substituted, the documentation should indicate the nature and scope of the research used to reach this conclusion. The determination should utilize an itemized comparison of the effect, form, function, quality, and quantity of the alternative practice with the substance being considered.

Evaluation Question #14: Are there specific conditions which require restricted use of the substances?

Data Required: Documentation submitted by the country should describe and document why this region is unique. It should also indicate if there are some criteria in CAC/GL 32 which support use of these substances.

Evaluation Question #15: How will use of this substance be assessed as a renewable resource in a local agricultural system?

Data Required: In responding to this question, the documentation submitted by the country should describe how this substance is regarded to be a renewable resource and it should also describe how this substance contribute to maintain a locally organized systems.

4.0 Evaluation Questions for Substances Used as Additives or Processing Aids in the Preparation or Preservation of Food.

[DENMARK: *In evaluation question 2 we do not understand the last sentence. Can we have examples from e.g. foodstuff? In evaluation question 8 we would like to know examples of food additives depleting the presence of essential nutrients and energy-yielding substances. Evaluation question 11 asks if the substance contain residues of heavy metal or other contaminants. This is a superfluous question as only additives approved by CCFAC can be used and JECFA/CCFAC specifies the purity etc of accepted additives.***]**

[NORWAY: *Suggests the addition of four new evaluation questions (#s 12 through 15)***]**

The following questions have been developed in order to address questions which arise through comparison of a substance with the general criteria set forth in CAC/GL 32.

Evaluation Question #1: Is the substance formulated or manufactured by a chemical process?

Data Required: In responding to this question, the documentation submitted by the country should describe the process used to manufacture or formulate the substance, including a discussion of the substance's feedstocks and/or precursors. For the purposes of this question, chemical processes are processes such as alkalization, calcification, thermal or catalytic cracking, esterification, hydrogenation, mixing of substances or elements, oxidation, polymerization, etc., obtained through process units such as compressors, cracking towers, distillation columns, heat exchangers, mixers, reactors, pumps, etc.

Evaluation Question #2: Is the substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources?

Data Required: In responding to this question, the documentation submitted by the country should describe any chemical changes effected on any naturally occurring feedstock or precursor by the manufacturing or formulation process. For the purposes of this question, a chemical change is the addition or deletion of one atom to the substance's molecular structure. In identifying a chemical change, the documentation submitted by the country should note when a chemical change is one that could occur naturally over time such as the degradation by sunlight of hydrogen peroxide into water and nascent oxygen.

Evaluation Question #3: Is the substance created by naturally occurring biological processes?

Data Required: In responding to this question, the documentation submitted by the country should describe whether or not the substance is created by naturally occurring biological processes. For the purposes of this question, naturally occurring biological processes are processes such as aerobic and anaerobic digestion, decomposition, fermentation, various metabolic processes, and photosynthesis.

Evaluation Question #4: Is there a natural source of the substance?

Data Required: In responding to this question, the documentation submitted by the country should describe whether or not there is a natural source of the substance under consideration. If the documentation submitted by the country asserts that there is not a natural source for the substance, the documentation should indicate the nature and scope of the research used to reach this conclusion. The determination should utilize an itemized comparison of the effect, form, function, quality, and quantity of the natural source with the substance being considered.

Evaluation Question #5: Is there an organic agricultural product that could be substituted for the substance?

Data Required: In responding to this question, the documentation submitted by the country should describe the availability of an organic agricultural product that could be substituted for the substance. If the documentation submitted by the country asserts that there is not an organic agricultural product that could be substituted for the substance, the documentation should indicate the nature and scope of the research used to reach this conclusion. The determination should utilize an itemized comparison of the effect, form, function, quality, and quantity of an organic agricultural product with the substance being considered.

Evaluation Question #6: Are there adverse effects on the environment from the substance's manufacture, use, or disposal?

Data Required: In responding to this question, the documentation submitted by the country should describe the occurrence and severity of known environmental contamination during the manufacture, use, misuse, or disposal of the substance.

Evaluation Question #7: Does the substance have an adverse effect on human health?

Data Required: In responding to this question, the documentation submitted by the country should describe the biological, chemical, and physical agents capable of causing adverse health and/or environmental effects, either present in the substance or arising from the degradation of the substance over time including the toxicity, mode of action, and persistence of the substance and its breakdown products.

Evaluation Question #8*:* Is the nutritional quality of the food maintained when the substance is used?

Data Required: In responding to this question, the documentation submitted by the country should indicate whether the use of the substance depletes the presence of essential nutrients and energy-yielding substances (e.g., proteins, carbohydrates, fats, vitamins, and minerals) commonly found in the food product for which the substance will be used.

Evaluation Question #9: Is the substance to be used primarily as a preservative?

Data Required: In responding to this question, the documentation submitted by the country should confirm whether or not the substance's primary use will be as a preservative.

Evaluation Question #10: Is the substance to be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)?

Data Required: In responding to this question, the documentation submitted by the country should independently confirm whether or not the substance's primary use, as described by the petition, is to recreate or improve flavors, colors, textures, or nutrition value lost during processing. When replacement or improvement of nutrients is required or allowed by regulation, the documentation submitted by the country should cite the appropriate regulations requiring or allowing replacement or improvement of nutritional value lost during processing.

Evaluation Question #11: Does the substance contain residues of heavy metals or other contaminants?

Data Required: In responding to this question, the documentation submitted by the country should indicate whether the substance contains residues of heavy metals or contaminants such as aflatoxin, aldrin and dieldrin, benzene hexachloride, cadmium, chlordane, chlordecone (kepone), dicofol (kelthane), DDT, DDE, TDE, dimethylnitrosamine (nitrosodimethylamine), ethylene dibromide (EDB), heptachlor and heptachlor epoxide, lead, lindane, mercury, methyl alcohol, mirex, N-Nitrosamines, paralytic shellfish toxin, and polychlorinated biphenyls (PCBs).

Evaluation Question #12: Are there alternative practices that would make the use of the substance unnecessary?

Data Required: In responding to this question, the documentation submitted by the country should describe whether or not an alternative practice could be substituted for the substance under consideration. If the documentation submitted by the country asserts that there is not an alternative practice that could be substituted, the documentation should indicate the nature and scope of the research used to reach this conclusion. The determination should utilize an itemized comparison of the effect, form, function, quality, and quantity of the alternative practice with the substance being considered.

Evaluation Question #13: Is there an exceptional circumstance which requires restricted use of the substances?

Data Required: Documentation submitted by the country should describe and document why this is such an exceptional circumstance. If there are some criteria in CAC/GL 32 which support use of this substances, these should also indicate.

Evaluation Question #14: Is the substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources?

Data Required: In responding to this question, the documentation submitted by the country should describe any chemical changes effected on any naturally occurring feedstock or precursor by the manufacturing or formulation process. For the purposes of this question, a chemical change is the addition or deletion of one atom to the substance's molecular structure. In identifying a chemical change, the documentation submitted by the country should note when a chemical change is one that could occur naturally over time such as the degradation by sunlight of hydrogen peroxide into water and nascent oxygen.

Evaluation Question #15: How will use of this substance be assessed as a renewable resource in a local agricultural system?

Data Required: In responding to this question, the documentation submitted by the country should describe how this substance is regarded to be a renewable resource and it should also describe how this substance contribute to maintain a locally organized systems.