

**NATIONAL ORGANIC STANDARD BOARD WORKING DRAFT 5:
“COMPATIBILITY WITH ORGANIC PRODUCTION AND HANDLING”
ORIGINALLY ADOPTED BY NOSB OCTOBER 24, 2003
REVISED BY POLICY DEVELOPMENT COMMITTEE APRIL 2, 2004
ADOPTED BY NOSB APRIL 29, 2004
13 YES, 0 NO, 1 ABSENT**

Deleted: JANUARY

ISSUE:

The NOSB has been asked to assist the National Organic Program by obtaining public input and issuing a recommendation on the following question: What are the factors (reasons, issues, parameters, strictures, limitations) and constraints that the National Organic Standards Board should use to determine a substance's compatibility with a system of sustainable agriculture and its consistency with organic farming and handling?

RECOMMENDATION:

NOSB Guidance Document on Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming and Handling

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- a) Does the substance promote plant and animal health by enhancing soil physical, chemical, or biological properties?
- b) Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- c) Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
- d) Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- e) Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- f) Does the substance allow for an increase in the long-term viability of organic farm operations?
- g) Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- h) If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- i) Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- j) Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- k) Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- l) Does use of the substance have a positive impact on biodiversity?

Summary of Comments

Six sets of comments were submitted in response to the NOSB's call for comments on working draft 4. The comments are summarized below, beginning with general comments, followed by detailed comments.

General Comments – All commenters expressed overall support for the draft, with minor changes. The following general comments were typical:

“I see that many changes have been made in response to public comments and I applaud your efforts in this regard.”

“The criteria established in this draft provide a firm basis for evaluating substances to determine if they are compatible with a system of sustainable agriculture and consistent with organic production and handling.”

Comments on Specific Items:

Introduction – No comments, no changes.

Items a) – d) – No comments, no changes.

e) – One commenter believes that organic consumer expectations must be considered in the criteria but that such expectations currently lack consistency, which makes consideration difficult. “As such, we encourage the NOSB to consider materials with an awareness of the potential for significant or widespread erosion of consumer confidence in, and support of, the organic label.”

No change was requested, and no change has been made.

f) – No comments, no changes.

g) – All commenters strongly endorsed inclusion of item g), with one stressing that “it takes into consideration social equitability issues.”

h) – No comments, no changes.

i) – One commenter stated, “this criterion would be more meaningful if phrased “Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?”” As NOSB is aware, a substance may be used in many ways and the specific way it is used affects the decision to approve or restrict its use.”

The words “use of the” have been inserted in item i) as suggested.

j) – No comments, no changes.

k) – Strong support by all commenters. No changes.

l) – Strong support by all commenters. No changes.

m) – All commenters supported deletion of item (m), “Does the substance facilitate the development of new organic products?”

On commenter objected its inclusion, saying, “The NOSB gave no explanation or justification for this addition. This question is not necessary and the intent is not clear in this case. The petitioners are already asked to provide a petition justification statement that in most cases will provide ample reasoning as to why this specific substance is perceived by the applicant as *necessary* for a requested use. The ability to facilitate product development in itself is not a measure of sustainability or compatibility with organic agriculture, and inclusion of this criterion may be used as justification in itself. In many cases new product development is based on economic factors.”

Another commenter said, “As stated in my earlier comments, I have concerns about the practical application of criteria that are not easily quantifiable. In my opinion, Criterion m) is an example of this problem and urge that it be deleted.”

A third said, “Item m) would be extremely difficult to quantify. For example what factors would be used to determine if the use of a petitioned substance would facilitate the development of new organic products? How much “development” would be needed to determine if a substance would make an adequate contribution? We find that Item m) has nothing to do with compatibility with a system of sustainable agriculture and consistency with organic production and handling.”

Item m) has been deleted.

ADDENDUM I
NOSB WORKING DRAFT:
COMPATIBILITY WITH ORGANIC PRODUCTION AND HANDLING
ADOPTED OCTOBER 24, 2003

ISSUE:

The NOSB has been asked to assist the National Organic Program by obtaining public input and issuing a recommendation on the following question: What are the factors, (reasons, issues, parameters, strictures, limitations), and constraints that the National Organic Standards Board should use to determine a substance’s compatibility with a system of sustainable agriculture and its consistency with organic farming and handling?

BACKGROUND:

1. Overview

The Organic Foods Production Act of 1990, Sections 6517 and 6518, charges the National Organic Standards Board with the review of substances for placement on the National List of Allowed and Prohibited Materials. Both the Act and the National Organic Program Final Rule, 7 CFR Part 205, establish criteria for the evaluation of substances petitioned to be added to or removed from the National List. Among other factors, the statute and the regulation require that substances be evaluated to determine if they are “compatible with a system of sustainable agriculture” and “consistent with organic farming and handling.”

When reviewing petitioned substances, the NOSB evaluates substances against all applicable statutory and regulatory criteria, including “compatible with a system of sustainable agriculture” and “consistent with organic farming and handling.” While the NOSB routinely makes “compatibility” and “consistency” determinations, the Board has not established a guidance document to help ensure that such determinations are made in a consistent, transparent, and equitable manner.

2. USDA Statutes and Regulations Governing This Issue

The excerpts shown in **Addendum G** from OFPA and the Final Rule contain language establishing

“compatibility” and “consistency” as criteria to be used in the materials review process. Addendum G also contains Final Rule definitions of “handle”, “handling operation”, and “organic production”

The term "**sustainable agriculture**" was defined by Congress in the 1990 Farm Bill. [Food, Agriculture, Conservation, and Trade Act of 1990 (FACTA), Public Law 101-624, Title XVI, Subtitle A, Section 1603]. According to the 1990 Farm Bill, "the term sustainable agriculture means an integrated system of plant and animal production practices having a site-specific application that will, over the long term:

- satisfy human food and fiber needs
- enhance environmental quality and the natural resource base upon which the agricultural economy depends
- make the most efficient use of nonrenewable resources and on-farm resources and integrate, where appropriate, natural biological cycles and controls
- sustain the economic viability of farm operations
- enhance the quality of life for farmers and society as a whole."

Addendum A: “Senate and House Reports on OFPA” provides further statutory background, including the following excerpts:

“The Committee does not intend to allow the use of many synthetic substances. This legislation has been carefully written to prevent widespread exceptions or “loopholes” in the organic standards which would circumvent the intent of this legislation. The few synthetic substances that are widely recognized as safe and traditionally used in organic production are explicitly cited in the bill as potential items to be included on the National List if the Board and the Secretary approve of their use.

The Board and the Secretary may consider allowing the use of synthetic active ingredients in the following categories only: pheromones; copper and sulfur compounds; soaps; horticultural oils; toxins derived from bacteria; treated seed; fish emulsions; vitamins and minerals; livestock parasiticides and medicines; and production aids such as machinery cleansers.”

“The Senate bill provides further that the National List may include exemptions for substances otherwise prohibited but which the National Organic Standards Board and the Secretary determine are harmless to human health and the environment, are necessary because of the unavailability of wholly natural substitute products, and are determined to be consistent with organic farming practices.”

3. Current Situation/Practices

When reviewing petitioned substances, the NOSB currently evaluates substances against all applicable statutory and regulatory criteria, including “compatible with a system of sustainable agriculture” and “consistent with organic farming and handling.” While the NOSB routinely makes “compatibility” and “consistency” determinations, and the Board has addressed the issue in 1995 and again in 2001, the Board has not established a guidance document to help ensure that such determinations are made in a consistent and equitable manner.

On October 17, 2001, the NOSB adopted “**Principles of Organic Production and Handling**” (**Addendum B**). The NOSB Principles are provided to TAP reviewers, and are referenced by NOSB members in the materials review process. Among other things, the Principles state:

“1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted

systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.”

“1.4 Organic handling practices are based on the following principles:

1.4.1 Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage;

1.4.5 Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions.”

“1.5 Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.”

The following excerpts are presented for historical reference:

In 1994, NOP Staff prepared a report for NOSB review entitled, **“Prologue: Moving Towards Sustainability” (Addendum C)**. In the report, the NOP staff stated:

“The following principles are the foundation of organic management methods:

1. Protect the environment, minimize pollution, promote health and optimize biological productivity.

6. Maintain the integrity and nutritional value of organic food and processed products through each step of the process from planting to consumption. Organically grown food and processed products must be processed, manufactured, and handled to preserve their healthful qualities and maintain the principles of the organic management system. Ingredients, additives and processing aids used in organic processed products must be consistent with the overall principles of organic production.

7. Develop and adopt new technologies with consideration for their long range social and ecological impact. New practices, materials and technologies must be evaluated according to established criteria for organic production. It is assumed that organic production systems will progress toward sustainability over time through technical innovation and social evolution.”

On November 1, 1995, the NOSB adopted **“Final Recommendation Number 26, NOSB Materials Review Criteria” (Addendum D)**. In the recommendation, the NOSB stated:

*“These criteria are offered in acknowledgment that adequate available scientific data may not be available to address the other six OFPA criteria. **It is important to emphasize that none of these criteria can be considered in isolation; any one may expand or diminish in importance in relation to the clarity (or ambiguity) of determinations about the others.** However, no material may be consistent with organic agriculture and appear on the National List in the absence of a strong factual showing in scientific criteria.”*

2. Synthetic materials that are not analogues of non-synthetic materials should be reviewed according to the following:

a) Similarity to other synthetic materials already allowed for organic production: Does a new material have a similar function, mode of action, and ecological profile to materials previously placed on the Allowed Synthetics list?

b) Environmentally superior alternative : Does the material reduce or eliminate the need for a more environmentally destructive nonsynthetic or allowed synthetic alternative? This is different from simply considering whether alternatives exist, as is required by the 6th OFPA criterion.

c) Historic precedent: If the material has been accepted for use in organic systems in the past, is there a continuing basis for this acceptance? While historic precedence is not sufficient cause to allow a material that fails on the other key criteria, it would

counterbalance some level of philosophical or opinion based opposition to accepting a material.

d) Consumer perception: *What is the consumer and public interest community perception of the material? This is an important question when the material's profile regarding the other criteria is ambiguous. This question could be analyzed quantitatively by conducting a survey of consumer and environmental groups about a material if the evaluators were divided about its status. Another possible judgment may in some cases be that greater public benefit would result from working to change consumer perceptions and provide more information about the use and function of the material in question, and allowed synthetics in general, in organic production systems.*

3. Establishment of Need: *It should be assumed that at least one organic producer or handler would claim to need to use any synthetic material being considered for inclusion on the National List. The following are guidelines for evaluating the validity of a claimed need for a material.*

a) Agronomic Need: *The need for a material as substantiated by a diversity of producers, i.e. of more than one crop in more than one region, who are unable to achieve the necessary results through cultural practices, biological methods, or use of materials which are more fully compatible with organic principles.*

b) Economic Need: *While allowance of a material cannot be justified on economic need alone, the economic impact on producers (including farm workers), handlers and consumers of allowing or prohibiting a given material should be factored into the decision. This is an assessment for which valid projections are often lacking, and for which the feasibility of more compatible alternatives becomes a subjective judgment."*

Addendum E contains excerpts from the **Office of Management and Budget, Circular No. A-119, February 10, 1998, revised. "Memorandum for Heads of Executive Departments and Agencies: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities."**

Revised OMB Circular A-119 establishes policies on Federal use and development of voluntary consensus standards and on conformity assessment activities. Circular A-119 directs all Executive Branch agencies to utilize voluntary consensus standards and to consider international standards when establishing regulations.

Circular A-119 states, *"in the interests of promoting trade and implementing the provisions of international treaty agreements, your agency should consider international standards in procurement and regulatory applications."*

The United States is a signatory to the **"Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (GL 32 – 1999, Rev. 1 – 2001)" (Addendum F)**. The Codex Guidelines contain a statement of principles of organic production very similar to the NOSB Principles. Among other things, the Codex principles state:

"6. The primary goal of organic agriculture is to optimize the health and productivity of interdependent communities of soil life, plants, animals and people."

"7. An organic production system is designed to:

g) 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;"

Section 5 of Codex contains "Criteria for the Development of Lists of Substances." The Codex criteria are shorter, but consistent with the criteria in OFPA and the Final Rule. Excerpts from Codex state:

”Any proposals for the inclusion in Annex 2 of new substances must meet the following general criteria:

i) they are consistent with principles of organic production as outlined in these Guidelines;”

“5.1 The following criteria should be applied in the evaluation process:

c) if they are used as additives or processing aids in the preparation or preservation of the food :

- the consumer will not be deceived concerning the nature, substance and quality of the food.”

4. Conclusion

When the NOSB evaluates a substance’s “compatibility with a system of sustainable agriculture” and “consistency with organic farming and handling,” ecological, social, and economic impacts; nutritional value; consumer perceptions; and international considerations all should be taken into account.

OPTIONS:

The Policy Development Committee submits three options for consideration by the Board to provide guidance on the evaluation of substances petitioned for use in organic production and/or handling. The first two options address the considerations reflected in the statute, regulations, and guidance documents referenced above, while the third option contains interpretive points implied by the statute and regulation which establish criteria for compatibility and consistency determinations.

Option 1:

Option 1 contains one draft statement to provide guidance on the evaluation of substances petitioned for use in organic production and/or handling.

NOSB Guidance Document on Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming and Handling

In order to be determined compatible with a system of sustainable agriculture and consistent with organic farming and handling, a substance, its use, and manufacture must be consistent with the NOSB Principles of Organic Production and Handling. As a general principle, non-synthetic substances are preferred over synthetic substances.¹ The substance, its use, and manufacture must complement sustainable cultural, biological, and mechanical production and handling practices which foster the cycling of resources, promote ecological balance, and conserve biodiversity while minimizing the use of synthetic inputs.² Use of the substance must maintain the integrity³ and nutritional value⁴ of organic products, and minimize environmental degradation⁵ and consumption of non-renewable resources.⁶ The substance must not be produced using excluded methods (genetic engineering), irradiation, or sewage sludge.⁷ The substance, its use, and manufacture must sustain the economic viability of farm operations and enhance the quality of life for farmers and society as a whole.⁸ In order to facilitate trade, approval of the substance must be compatible with domestic and international organic market expectations and regulations.⁹

Pros: Option 1 addresses the ecological, social, and economic impacts; nutritional value; consumer perceptions; and international considerations cited in applicable statutes, regulation, and guidance

¹ Supported by § 6504(1); § 6517(c)(1)

² § 205.2 definition of “organic production”

³ § 6504(1); § 205.105; § 205.272(b)(2); § 205.307(a)(3)

⁴ § 205.600(b)(3)

⁵ § 205.200; § 205.203(a), (c), and (d)

⁶ NOSB Principles 1.2.6; 1.4.5

⁷ § 205.105

⁸ Food, Agriculture, Conservation, and Trade Act of 1990 (FACTA), Public Law 101-624, Title XVI, Subtitle A, Section 1603 definition of “sustainable agriculture”

⁹ § 6505(b) discussion of “at least equivalent” for imported products; Revised OMB Circular A-119; Codex Guidelines

documents. By combining farming and handling criteria into one statement, Option 1 assures that the same criteria will be used for the evaluation of substances petitioned for use in farming and handling.

Cons: The convenience and consistency of option 1 may also be seen as a deficiency – that is, substances used in agricultural production should not be evaluated by the same criteria as substances used in handling. While the evaluation factors contained in Option 1 are rooted in statute and regulation, some cannot be easily linked to measurable indicators. The lack of measurable criteria means that the guidance document is open to variable interpretation, which could lead to a lack of equity, transparency, and consistent outcomes.

Option 2:

In Option 2, the Policy Development Committee submits separate draft statements for the evaluation of substances petitioned for use in production versus substances petitioned for use in handling.

A. NOSB Guidance Document on Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming

In order to be determined compatible with a system of sustainable agriculture and consistent with organic farming, a substance, its use, and manufacture must be consistent with the NOSB Principles of Organic Production and the 1990 Farm Bill definition of “sustainable agriculture”. Sustainable agriculture describes farming systems that are capable of maintaining their productivity and usefulness to society indefinitely while enhancing environmental quality and the natural resource base upon which consumers and the agricultural economy depend. Sustainable production systems integrate natural on-farm resources and minimize the use of non-renewable resources. In order to be compatible, a substance must not be produced using excluded methods (genetic engineering), irradiation, or sewage sludge. The substance, its use, and manufacture must sustain the economic viability of farm operations and enhance the quality of life for farmers and society as a whole. In order to facilitate trade, approval of the substance must be compatible with domestic and international organic market expectations and regulations.

B. NOSB Guidance Document on Consistency with Organic Handling

In order to be determined to be consistent with organic handling, a substance, its use, and manufacture must be consistent with the NOSB Principles of Organic Handling. As a general principle, non-synthetic substances are preferred over synthetic substances. Use of the substance must maintain the integrity and nutritional value of organic products, and minimize environmental degradation and consumption of non-renewable resources. The substance must not be produced using excluded methods (genetic engineering), irradiation, or sewage sludge. The substance, its use, and manufacture must sustain the economic viability of farming and handling operations and enhance the quality of life for farmers and society as a whole. In order to facilitate trade, approval of the substance must be compatible with domestic and international organic market expectations and regulations.

Pros: Taken together, Options 2A and 2B address the ecological, social, and economic impacts; nutritional value; consumer perceptions; and international considerations cited in applicable statutes, regulation, and guidance documents. By separating farming and handling criteria, Option 2 provides specified guidance for the evaluation of substances petitioned for use in farming vs substances petitioned for use in handling.

Cons: If Option 2 is adopted, NOSB committees and the Board as a whole will have to make sure that they are working with the applicable guidance document each time that a substance is reviewed. This could also complicate the work of the National Organic Program staff and TAP reviewers. While the evaluation factors contained in Options 2A and 2B are rooted in statute and regulation, some cannot be easily linked to

measurable indicators. The lack of measurable criteria means that the guidance document is open to variable interpretation, which could lead to a lack of equity, transparency, and consistent outcomes.

Option 3:

In Option 3, the Policy Development Committee presents an entirely different approach from the first 2 options. While Options 1 and 2 rely on statutory and regulatory justifications, Option 3 contains bullet points of measurable criteria implied, but not explicitly stated, in the statutory requirement that a substance be “compatible with a system of sustainable agriculture” and “consistent with organic farming and handling.”

NOSB Guidance Document on Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming and Handling

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered, when applicable:

- m) Does the substance promote plant and animal health by enhancing soil physical, chemical, or biological properties?
- n) Does the substance encourage and enhance preventative management?
- o) Does the substance promote the use of renewable resources and recycling, and reduce dependency on external inputs?
- p) Does the substance have a positive influence on the health, natural behavior, and welfare of animals?
- q) Does the substance satisfy consumer expectations regarding the authenticity and integrity of organic products?
- r) Does the substance promote the economic viability of organic farm operations?
- s) Is the substance mined, manufactured, or produced through reliance on child labor or any violations of International Labor Organization (ILO) conventions?
- t) Is use of the substance consistent with other listed uses of the substance?
- u) Is the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- v) What are the experiences in foreign markets with use of the substance?
- w) Is the substance compatible with the Precautionary Principle? i.e. when a substance, its use, and manufacture raise concerns, precautionary measures should be taken when scientific data is not fully established. The proponent of a substance should bear the burden of proof to demonstrate compatibility.

Pros: Option 3 presents criteria which capture the essence of the definitions of sustainable agriculture and organic production and handling. By combining farming and handling criteria into one statement, Option 3 assures that the same criteria will be used for the evaluation of substances petitioned for use in farming and handling.

Cons: While Option 3 contains tangible criteria, it may not reflect all concepts and perceptions related to the terms sustainable agriculture and organic production and handling.

RECOMMENDATION:

On October 24, 2003, Option 3 was unanimously approved by NOSB as a working draft, to be posted for public comment.

ADDENDUM I A: SENATE AND HOUSE REPORTS ON OFPA

101 ST CONGRESS 2nd Session SENATE REPORT 101-357
FOOD, AGRICULTURE, CONSERVATION, AND TRADE ACT OF 1990

REPORT OF THE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY, UNITED STATES SENATE

TO ACCOMPANY S. 2830 together with ADDITIONAL AND MINORITY VIEWS
JULY 6, 1990 Ordered to be printed

Filed under authority of the order of the Senate of June 26 (legislative day, June 11), 1990

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TITLE XVI—ORGANIC CERTIFICATION PROGRAM

The National List

Most consumers believe that absolutely no synthetic substances are used in organic production. For the most part, they are correct and this is the basic tenet of this legislation. But there are a few limited exceptions to the no-synthetic rule and the National List is designed to handle these exceptions.

Organic farmers have used some synthetic substances for several good reasons. For example, some organic farmers use certain synthetic analogues to natural substances when those substances are difficult to obtain. Insect pheromones a often-used biological control substance in organic farming, are very difficult to collect in nature and are therefore synthetically produced. The Committee does not specifically disallow the use of pheromones in organic farming simply because they are synthetically produced when pheromones are effective and ecologically benign.

The Committee does not intend to allow the use of many synthetic substances. This legislation has been carefully written to prevent widespread exceptions or “loopholes” in the organic standards which would circumvent the intent of this legislation. The few synthetic substances that are widely recognized as safe and traditionally used in organic production are explicitly cited in the bill as potential items to be included on the National List if the Board and the Secretary approve of their use.

The Board and the Secretary may consider allowing the use of synthetic active ingredients in the following categories only: pheromones; copper and sulfur compounds; soaps; horticultural oils; toxins derived from bacteria; treated seed; fish emulsions; vitamins and minerals; livestock parasiticide and medicines; and production aids such as machinery cleansers.

Organic farmers also use substances in which the active ingredient is known to be natural but which also contain inert ingredients that are undisclosed as a matter of trade secret law under the Federal Insecticide Fungicide Rodenticide Act. The Committee suspects that many of these inert ingredients are synthetic. For example, adjuvants would fall into this category.

Until such time as FIFRA is altered to require the full disclosure of inert ingredients, organic farmers should be allowed to continue using compounded substances if the active ingredient is natural and if use of the substance is recommended by the National Organic Standards Board and approved by the Secretary for inclusion on the National List. However, in order for the National Organic Standards Board to evaluate whether certain compounds should be listed, the Board will need some information about the inert

ingredients in question. The Committee directs the Board to seek the advice of the Administrator of the EPA, who has information on inert ingredients submitted as part of registration, as to whether such inert material would be appropriate for organic production. EPA's response will not limit its regulatory responsibility for such material.

Almost all state and private organization standards also provide for certain exceptions from the no-synthetic rule, some more explicitly than others.

In deciding upon an acceptable list of materials for the Organic Standards Board and the Secretary to consider the Committee surveyed State and private regulations to ensure that the above categories, while more restrictive than most of the current standards, will indeed protect the integrity of the organic product while at the same time provide the producer a reasonable amount of flexibility on production materials. The Committee understands that just because a substance is natural does not mean that it is safe and appropriate for organic production. The National List may also include natural substances otherwise allowed under this title but which are determined to be harmful to human health or the environment and inconsistent with organic farming. Certain botanical pesticides may be considered by the Organic Standards Board and the Secretary to be inappropriate for organic production because their use poses significant harm to human health or the environment. Whatever natural items appear on the National List shall be prohibited from use in organic production.

Finally, the National List is designed to cover ingredients used in processing. The bill allows that up to five percent of processed food labeled "organically produced" may contain non-synthetic ingredients which are not organically produced if those ingredients are included on the National List. The five percent figure was arrived at after consulting with various organic food processors as the amount of flexibility necessary in processed food. The Committee intends that the guideline for processed food ingredients on the National List be that some ingredients are difficult or impossible to obtain. An example might be certain spices that are unavailable at this time from an organic farm. It may also include items that are not technically organically produced such as yeast.

Several steps must be taken before an item appears on the National List in any of the above categories.

First the Organic Standards Board must review the substances in question based upon criteria cited in the bill and with the aid of the Board's technical panels. The Board may decide what substances require review. As well, individuals may petition the Board to evaluate substances for inclusion on the National List. The Board then constructs a Proposed National List which is submitted to the Secretary as a recommendation for composition of the Final National List.

The Secretary may not include exemptions for synthetic substances other than those exemptions recommended by the National Organic Standards Board. The Proposed National List represents the universe of synthetic materials from which the Secretary may choose. Before establishing the final National List the Secretary shall publish the Proposed National List in the Federal Register and seek Public comment. The same procedures are to be followed for any amendments to the National List.

101st Congress 2nd Session House of Representatives Report 101-916
Food, Agriculture, Conservation and Trade Act of 1990 Conference Report to Accompany S2830

OCTOBER 22, 1990. Ordered to be printed

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TITLE XXI—ORGANIC CERTIFICATION

(9) Contents of National List

The Senate bill provides that the National List may include prohibitions on natural substances which otherwise would be allowed under this title but which the National Organic Standards Board and the Secretary determine to be harmful to human health or the environment and inconsistent with organic farming. The Senate bill provides further that the National List may include exemptions for substances otherwise prohibited but which the National Organic Standards Board and the Secretary determine are harmless to human health and the environment, are necessary because of the unavailability of wholly natural substitute products, and are determined to be consistent with organic farming practices. Such exemptions, however must meet one of the following three criteria:

- (1) the substance is used in production and contains a synthetic active ingredient in the following categories: copper and sulfur compounds; toxins derived from bacteria; pheromones, detergents; horticultural oils; treated seed; fish emulsions; vitamins and minerals, livestock parasiticides and medicines; and production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers;
- (2) the substance contains synthetic inert ingredients; or
- (3) the substance is used in processing and is non-synthetic but not organically produced.

(Section 1625)

The House amendment contains a similar provision with three differences:

- (1) there is no allowance for production aids on the National List
- (2) there is no allowance for products with synthetic inert ingredients on the National List; and
- (3) the Secretary is required to consult with the Secretary of Health and Human Services and the Administrator of EPA regarding the contents of the National List. (Section 1495Q)

The Conference substitute adopts the House provision with an amendment that adds production aids to the category of synthetic active ingredients and the category of synthetic inert ingredients not of toxicological concern to the Administrator of EPA as possible exemptions on the National List. The Managers note that in the future it may be necessary to further develop a list of categories for processed food exemptions and therefore encourage the Secretary, working with the National Organic Standards Board, to recommend such a list to the Congress as soon as practicable in order to facilitate implementation of the national standards by October 1, 1993.

ADDENDUM I B: NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

Adopted October 17, 2001

- 1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.
- 1.2 An organic production system is designed to:
 - 1.2.1 Optimize soil biological activity;
 - 1.2.2 Maintain long-term fertility;
 - 1.2.3 Minimize soil erosion;

- 1.2.4 Maintain or enhance the genetic and biological diversity of the production system and its surroundings;
- 1.2.5 Utilize production methods and breeds or varieties that are well adapted to the region;
- 1.2.6 Recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;
- 1.2.7 Minimize pollution of soil, water, and air; and
- 1.2.8 Become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.
- 1.3 The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by:
 - 1.3.1 Providing good quality organically grown feed;
 - 1.3.2 Maintaining appropriate stocking rates;
 - 1.3.3 Designing husbandry systems adapted to the species' needs;
 - 1.3.4 Promoting animal health and welfare while minimizing stress; and
 - 1.3.5 Avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics.
- 1.4 Organic handling practices are based on the following principles:
 - 1.4.1 Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage;
 - 1.4.2 Organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in finished products which contain less than 100% organic ingredients;
 - 1.4.3 Organic products and packaging materials used for organic products do not come in contact with prohibited materials;
 - 1.4.4 Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and
 - 1.4.5 Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions.
- 1.5 Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.
- 1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.
- 1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.
- 1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.
- 1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.
- 1.10 Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.
- 1.11 Genetic engineering (recombinant dna technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically

engineered/modified organisms (geo/gmo's) and products produced by or through the use of genetic engineering are prohibited.

- 1.12 Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

ADDENDUM I C: NOP Staff Report "Prologue: Moving Towards Sustainability"

Prepared by NOP Staff for NOSB review (1994, USDA-AMS, Grace Gershuny)
(excerpted, more narrative provided in original document)

"Intangible considerations such as personal satisfaction, social responsibility and respect for cultural traditions are inherent to the concept of sustainability. Although beyond the purview of government regulation, they are implicit in organic production systems. In order for an agricultural system to endure, it must be embedded within a social and economic system which equitably rewards all participants, and protects the capability of future generations to feed themselves."

Principles:

Organic production systems seek to provide food, fiber, and herbal products of the highest quality in sufficient quantities. The following principles are the foundation of organic management methods:

1. Protect the environment, minimize pollution, promote health and optimize biological productivity.
2. Replenish and maintain long-term soil fertility by providing optimal conditions for soil biological activity.
3. Maintain diversity within the farming system and its surroundings, and protect and develop plant and wildlife habitat.
4. Recycle materials and resources to the greatest extent possible within the farm and its surrounding community as part of a regionally organized agriculture system.
5. Provide attentive care that meets both health and behavioral requirements of farm animals.
6. Maintain the integrity and nutritional value of organic food and processed products through each step of the process from planting to consumption.

"Organically grown food and processed products must be processed, manufactured, and handled to preserve their healthful qualities and maintain the principles of the organic management system. Ingredients, additives and processing aids used in organic processed products must be consistent with the overall principles of organic production. Consumers should be provided with the assurance that products bearing organic labels are certified organic by independent verification from seed through sale."

7. Develop and adopt new technologies with consideration for their long range social and ecological impact.

"New practices, materials and technologies must be evaluated according to established criteria for organic production. It is assumed that organic production systems will progress toward sustainability over time through technical innovation and social evolution."

ADDENDUM I D: NATIONAL ORGANIC STANDARDS BOARD FINAL RECOMMENDATION

ADDENDUM NUMBER 26

NOSB MATERIALS REVIEW CRITERIA

Date adopted: November 1, 1995

Location: Austin, Texas

Objective: Develop review criteria or principles for proposed synthetic farm input materials that more clearly define and elaborate on the seventh OFPA criterion for evaluation: "compatibility with a system of

sustainable agriculture.” These criteria must refer back to the foundation principles of organic production stated in “Prologue: Moving Towards Sustainability,” and will be used to guide the NOSB and the Secretary in making decisions about whether to add a material to the National List of Allowed Synthetics. These criteria are offered in acknowledgment that adequate available scientific data may not be available to address the other six OFPA criteria. **It is important to emphasize that none of these criteria can be considered in isolation; any one may expand or diminish in importance in relation to the clarity (or ambiguity) of determinations about the others.** However, no material may be consistent with organic agriculture and appear on the National List in the absence of a strong factual showing in scientific criteria.

The Preamble to the National List (July 1995) language referencing Standards and Farm Plan requirements also applies; specifically, that the use of any allowed synthetic materials demands that the producer be making a good faith effort to find or develop alternatives that are more compatible with organic principles. Phase-out requirements are best considered in this context since the length of time for which the use of a material may be necessary will vary according to site-specific constraints which are best left to the judgement of the producer and the certifier.

1. Impact on Ecological Balances:

Organic agriculture is distinguished from conventional agriculture by its emphasis on nutrient recycling and maintaining ecological balances for soil and crop management. Therefore, the introduction of synthetically derived organisms whose interactions in the ecosystem are unpredictable should not be allowed without clear evidence that they meet all the OFPA review criteria. The risks of ecological disruption posed by such an introduction should be given stronger consideration than the short-term utility of a particular biological tool. For example, the possibility of inducing resistance in target species to biological control agents that are unselectively introduced via plant genetic manipulation, thereby seemingly eliminating the future effectiveness of the selectively applied biological control, could override any possible short-term benefits of introducing pest-resistant crops.

Any material used for the purpose of providing crop nutrient requirements should similarly be evaluated in light of its possible disruption of soil nutrient cycles. Any material that detracts from the soil’s capacity to recycle organic matter should be evaluated for its suitability in an organic system. A material that could potentially disrupt this capacity may be permitted, or at least not prohibited, with appropriate restrictions concerning acceptable applications.

2. Synthetic materials that are not analogues of non-synthetic materials should be reviewed according to the following:

- a) **Similarity to other synthetic materials already allowed for organic production:** Does a new material have a similar function, mode of action, and ecological profile to materials previously placed on the Allowed Synthetics list?
- b) **Environmentally superior alternative :** Does the material reduce or eliminate the need for a more environmentally destructive nonsynthetic or allowed synthetic alternative? This is different from simply considering whether alternatives exist, as is required by the 6th OFPA criterion. Example: PBO [piperonyl butoxide, a synergist used in pesticides].
- c) **Historic precedent:** If the material has been accepted for use in organic systems in the past, is there a continuing basis for this acceptance? While historic precedence is not sufficient cause to allow a material that fails on the other key criteria, it would counterbalance some level of philosophical or opinion based opposition to accepting a material.
- d) **Consumer perception:** What is the consumer and public interest community perception of the material? This is an important question when the material’s profile regarding the other criteria is ambiguous. This question could be analyzed quantitatively by conducting a survey of consumer and environmental groups about a material if the evaluators were divided about its status. Another

possible judgment may in some cases be that greater public benefit would result from working to change consumer perceptions and provide more information about the use and function of the material in question, and allowed synthetics in general, in organic production systems.

3. Establishment of Need: It should be assumed that at least one organic producer or handler would claim to need to use any synthetic material being considered for inclusion on the National List. The following are guidelines for evaluating the validity of a claimed need for a material.

a) Agronomic Need: The need for a material as substantiated by a diversity of producers, i.e. of more than one crop in more than one region, who are unable to achieve the necessary results through cultural practices, biological methods, or use of materials which are more fully compatible with organic principles (this coincides with the sixth OFPA criterion). Additionally, “necessary results” should also be evaluated in context of organic principles (for example, eradication of a pest specie is not a necessary or even desirable result in an organic production system.) Successful commercial (as opposed to home use or hobby) production of the same crop under similar ecological constraints without use of the material in question would represent a serious counterbalance to allowing it. Constraints such as market acceptability, labor availability and scale of production would have to be considered in the realm of economic need.

b) Economic Need: While allowance of a material cannot be justified on economic need alone, the economic impact on producers (including farm workers), handlers and consumers of allowing or prohibiting a given material should be factored into the decision. This is an assessment for which valid projections are often lacking, and for which the feasibility of more compatible alternatives becomes a subjective judgment. For example, the high cost of labor to achieve the same level of weed control provided by an herbicide could not be a valid argument for allowing an herbicide that otherwise fails the agronomic need test.

It becomes trickier with arguments such as the one made by California growers that Chilean nitrate is needed in order to maintain cold season vegetable production, and, additionally, year-round employment. In this instance, the agronomic need may be clear, but it is predicated on accepting the assumption that there is a pressing economic need for organic production of this particular crop under these circumstances. Here is where factors such as historical use in organic production, impact on consumers (availability and price of fresh broccoli in the winter), and the other OFPA criteria have to be weighed.

Addendum I E: Office of Management and Budget, CIRCULAR NO. A-119, February 10, 1998, Revised. MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities – selected excerpts

“Revised OMB Circular A-119 establishes policies on Federal use and development of voluntary consensus standards and on conformity assessment activities. Pub. L. 104-113, the “National Technology Transfer and Advancement Act of 1995,” codified existing policies in A-119, established reporting requirements, and authorized the National Institute of Standards and Technology to coordinate conformity assessment activities of the agencies. OMB is issuing this revision of the Circular in order to make the terminology of the Circular consistent with the National Technology Transfer and Advancement Act of 1995, to issue guidance to the agencies on making their reports to OMB, to direct the Secretary of Commerce to issue policy guidance for conformity assessment, and to make changes for clarity.”

”This Circular applies to all agencies and agency employees who use standards and participate in voluntary consensus standards activities, domestic and international, except for activities carried out pursuant to treaties. “Agency” means any executive department, independent commission, board, bureau, office, agency,

Government-owned or controlled corporation or other establishment of the Federal Government. It also includes any regulatory commission or board, except for independent regulatory commissions insofar as they are subject to separate statutory requirements regarding the use of voluntary consensus standards. It does not include the legislative or judicial branches of the Federal Government.”

“In the interests of promoting trade and implementing the provisions of international treaty agreements, your agency should consider international standards in procurement and regulatory applications.”

“Authority for this Circular is based on 31 U.S.C. 1111, which gives OMB broad authority to establish policies for the improved management of the Executive Branch. This Circular is intended to implement Section 12(d) of P.L. 104-113 and to establish policies that will improve the internal management of the Executive Branch. This Circular is not intended to create delay in the administrative process, provide new grounds for judicial review, or create new rights or benefits, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, or its officers or employees.”

ADDENDUM I F: CODEX GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS (GL 32 – 1999, Rev. 1 – 2001) – selected excerpts

FOREWORD

6. “Organic” is a labelling term that denotes products that have been produced in accordance with organic production standards and certified by a duly constituted certification body or authority. Organic agriculture is based on minimizing the use of external inputs, avoiding the use of synthetic fertilizers and pesticides. Organic agriculture practices cannot ensure that products are completely free of residues, due to general environmental pollution. However, methods are used to minimize pollution of air, soil and water. Organic food handlers, processors and retailers adhere to standards to maintain the integrity of organic agriculture products. The primary goal of organic agriculture is to optimize the health and productivity of interdependent communities of soil life, plants, animals and people.

7. Organic agriculture is holistic production management systems which promotes and enhances agroecosystem health, including biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. This is accomplished by using, where possible, cultural, biological and mechanical methods, as opposed to using synthetic materials, to fulfil any specific function within the system. An organic production system is designed to:

- a) enhance biological diversity within the whole system;
- b) increase soil biological activity;
- c) maintain long-term soil fertility;
- d) recycle wastes of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;
- e) rely on renewable resources in locally organized agricultural systems;
- f) promote the healthy use of soil, water and air as well as minimize all forms of pollution thereto that may result from agricultural practices;
- g) 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;
- h) 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.

SECTION 5. REQUIREMENTS FOR INCLUSION OF SUBSTANCES IN ANNEX 2 AND CRITERIA FOR THE DEVELOPMENT OF LISTS OF SUBSTANCES BY COUNTRIES (At Step 8 of the Procedure)

5.1 At least the following criteria should be used for the purposes of amending the permitted substance lists referred to in Section 4. In using these criteria to evaluate new substances for use in organic production, countries should take into account all applicable statutory and regulatory provisions and make them available to other countries upon request.

Any proposals for the inclusion in Annex 2 of new substances must meet the following general criteria:

- i) they are consistent with principles of organic production as outlined in these Guidelines;
- ii) use of the substance is necessary/essential for its intended use;
- iii) manufacture, use and disposal of the substance does not result in, or contribute to, harmful effects on the environment;
- iv) they have the lowest negative impact on human or animal health and quality of life; and
- v) approved alternatives are not available in sufficient quantity and/or quality.

The above criteria are intended to be evaluated as a whole in order to protect the integrity of organic production. In addition, the following criteria should be applied in the evaluation process:

(a) if they are used for fertilization, soil conditioning purposes --

- they are essential for obtaining or maintaining the fertility of the soil or to fulfil 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; and
- the ingredients will be of plant, animal, microbial, or mineral origin and may undergo the following processes: physical (e.g., mechanical, thermal), enzymatic, microbial (e.g., composting, fermentation); only when the above processes have been exhausted, chemical processes may be considered and only for the extraction of carriers and binders; and
- their use does not have a harmful impact on the balance of the soil ecosystem or the physical characteristics of the soil, or water and air quality; and
- their use may be restricted to specific conditions, specific regions or specific commodities;

(b) if they are used for the purpose of plant disease or pest and weed control

- they 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, and
- their use should take into account the potential harmful impact on the environment, the ecology (in particular non-target organisms) and the health of consumers, livestock and bees; and
- substances should be plant, animal, microbial, or mineral origin and may undergo the following processes: physical (e.g. mechanical, thermal), enzymatic, microbial (e.g. composting, digestion);
- however, if they are products used, in exceptional circumstances, in traps and dispensers such as pheromones, which are chemically synthesized they will be considered for addition to lists if the products are not available in sufficient quantities in their natural form, provided that the conditions for their use do not directly or indirectly result in the presence of residues of the product in the edible parts;
- their use may be restricted to specific conditions, specific regions or specific commodities;

(c) if they are used as additives or processing aids in the preparation or preservation of the food :

- these substances are used only if it has been shown that, without having recourse to them, it is impossible to:

.. produce or preserve the food, in the case of additives, or

.. produce the food, in the case of processing aids in the absence of other available technology that satisfies these Guidelines;

- these substances are found in nature and may have undergone mechanical/physical processes (e.g. extraction, precipitation), biological/enzymatic processes and microbial processes (e.g. fermentation),
- or, if these substances mentioned above are not available from such methods and technologies in sufficient quantities, then those substances that have been chemically synthesized may be considered for inclusion in exceptional circumstances;
- their use maintains the authenticity of the product;
- the consumer will not be deceived concerning the nature, substance and quality of the food;
- the additives and processing aids do not detract from the overall quality of the product.

In the evaluation process of substances for inclusion on lists all stakeholders should have the opportunity to be involved.

ADDENDUM I G: Citations from OFPA and 7 CFR Part 205

§ 6517 National List.

(c) Guidelines for Prohibitions or Exemptions.

- (1) **Exemptions for Prohibited Substances.** The National List may provide for the use of substances in an organic farming or handling operation that are otherwise prohibited under this chapter only if
- (A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that use of such substances (iii) is consistent with organic farming and handling
- (2) **Prohibition on the use of Specific Natural Substances.** The National List may prohibit the use of specific natural substances in an organic farming or handling operation that are otherwise allowed under this chapter only if
- (A) the Secretary determines, in consultation with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency, that use of such substances (ii) is inconsistent with organic farming or handling, and the purposes of this chapter;

§ 6518 National Organic Standards Board.

- (m) **Evaluation.** In evaluating substances considered for inclusion in the proposed National List or proposed amendment to the National List, the Board shall consider
- (7) its compatibility with a system of sustainable agriculture.

§ 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

- (a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).
- (b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:
 - (2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

§ 205.2 Terms defined. Below are the definitions of “handle,” “handling operation,” and “organic production” taken directly from the Final Rule. As indicated, handling involves selling, processing, packaging, and storing activities.

Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

Handling operation. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

Organic production. A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

ADDENDUM II
NATIONAL ORGANIC STANDARD BOARD WORKING DRAFT:
COMPATIBILITY WITH ORGANIC PRODUCTION AND HANDLING
ADOPTED OCTOBER 24, 2003
REVISED JANUARY 13, 2004, BASED ON COMMENTS RECEIVED

ISSUE:

The NOSB has been asked to assist the National Organic Program by obtaining public input and issuing a recommendation on the following question: What are the factors (reasons, issues, parameters, strictures, limitations) and constraints that the National Organic Standards Board should use to determine a substance's compatibility with a system of sustainable agriculture and its consistency with organic farming and handling?

NOSB Guidance Document on Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming and Handling

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

- a) Does the substance promote plant and animal health by enhancing soil physical, chemical, or biological properties?
- b) Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- c) Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
- d) Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- e) Does the substance satisfy organic consumer expectations regarding the authenticity and integrity of organic products?
- f) Does the substance allow for an increase in the long-term viability of organic farm operations?
- g) If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?

- h) Is the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- i) Is the substance consistent with international organic regulations and guidelines, including Codex?
- j) Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- k) What is the impact of the substance on biodiversity? Is biodiversity improved through the use of the substance?
- l) Does the substance limit or facilitate the development of new organic products?
- m) Does use of the substance maintain and protect the integrity of organic products?

Summary of Comments

Six sets of comments were submitted in response to the NOSB's call for comments on the working draft. The comments are summarized below, beginning with general comments and following the order of the text above, ending with discussion of new items suggested by commenters.

General comments – Several commenters took the position that petitioners should not automatically be required to satisfy all of the items, but that each item serves as one indicator of compatibility during NOSB discussion of materials petitioned. In other words, there should not be a numerical summing of the items, but consideration of all the items as a whole would show the relative compatibility of a material with organic production and handling. None of the criteria should be considered an absolute requirement of a petition or TAP review.

One commenter pointed out that what is considered sustainable may change over time. As the state of the art and technology advances, so does the understanding of sustainability. What may be incompatible at one point in time may be later found to be compatible due to technological improvements that overcome problems considered unsustainable or to additional data that clarifies the long-run implications of a substance's use. On the other hand, those who consider a substance sustainable at one point may later decide that the same substance is unsustainable given new data regarding the impact of continued use. Innovation and acceptance of new technologies, and research that discovers previously unknown beneficial or adverse effects that result from the use of certain substances are reasons that can justify reconsideration of NOSB recommendations or NOP standards.

Another commenter mentioned that a well crafted standard must be 1) clearly written, 2) measurable, and 3) verifiable using methodology that is both practical and accessible. The NOSB's evaluation criteria, which function as standards for defining the types of materials allowed for use in organic systems, provide valuable guidance on which aspects of "compatibility" must be assessed. However, the lack of endpoints associated with each criterion will create difficulties when the criteria are used during the petition and evaluation processes.

In order for the criteria on "compatibility" to be adequately understood by petitioners and implemented by the NOSB, the commenter urges the NOSB to further develop the criteria by associating each with a qualitative and/or quantitative endpoint which will define acceptable, measurable ranges for materials being assessed.

The same commenter encourages the NOSB to develop decision making procedures for materials review. The NOSB Materials Committee has been using flowcharts to show the timing and flow of the decision making process from petition to TAP to NOSB to the Secretary, but the effort to clarify the NOSB's materials evaluation process will require detailed written procedures as well. The commenter suggests that this information be incorporated into the NOSB Policy Manual.

Another commenter acknowledged that OFPA 6518(m)(7) has historically been a challenge to quantify, yet “Compatibility with a system of sustainable agriculture” is a critical component when considering a material for inclusion on or prohibition from the National List. The commenter felt that the eleven factors identified in the recommendation will go a long way to quantify the Board’s reasons for their decisions. “Legally and for historical precedence this is beneficial.” The eleven factors must all be examined for applicability and compatibility but they must each be weighed and not considered as ultimate criteria for inclusion or exclusion. “As first hand witnesses throughout the development of this recommendation we believe the exercise was conducted fairly and thoroughly and that the NOSB has done a commendable job with this draft recommendation.”

Comments on Specific Sections:

Introduction – One commenter specifically mentioned support for the reference to the NOSB Principles in the Introduction, saying, “these should be the basis for all NOSB actions involving standards development and materials review.” The commenter felt that the term “when applicable” is unnecessary, and indicates that some criteria may be ignored without a clear reason for so doing. While some may not apply, they should all be considered by the NOSB and explicitly identified as “not applicable” with justification.

The phrase “when applicable” has been deleted.

a) – One commenter does not endorse or support items a, b, c, d, and k. The only reason given was “the difference between a benign result, a neglectful result, and a positively good result of the use of any material.” The commenter “does not feel comfortable mandating the demonstration of a positive result and feels that demonstrating the benign nature of a material is a better approach and is more consistent with OFPA and the NOP Rule.”

Items a, b, c, d, and k have not been deleted, but they have been changed to reflect other comments.

b) – A commenter felt that the intent of item b is not clear. The commenter reasoned that, “in general, sustainable and organic systems stress the use of preventive cultural or management practices that reduce the need for synthetic inputs for disease control, insect management, or soil fertility. Prophylactic materials use is often considered unsustainable. Certain preventative management practices are explicitly prohibited in organic production: subtherapeutic feeding of antibiotics, routine use of parasiticides, and administration of medications in the absence of illness. Integrated Pest Management techniques often rely on prophylactic use of pesticides in anticipation of problems that will require even greater amounts of biologically active substances if an organism is not controlled in a timely way. For example, fungicides may be applied prior to wet weather or on a calendar basis to inhibit spore germination.”

Item b has been changed to better reflect the sentiments expressed by the commenter and to clarify the intent of the Board, to read, “Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?”

c) – A commenter pointed out there are actually three sustainability factors addressed in item c: (a) a preference for renewable resource use over non-renewable resource use; (b) a preference for recycling over resource depletion and disposal; and (c) efficient resource use. Manufacture, use, and disposal, as well as employment of renewable resources and recycling, are included under criterion (3) in TAP reviews. Historically, TAP reviewers have generally agreed that non-renewable, energy-intensive, and fossil fuel-dependent materials were unsustainable. Alternative inputs have been taken into consideration in criterion (6) in the TAP reviews.

The commenter suggested that the NOSB consider the intent of the last clause of the factor. Asking if a petitioned external input 'reduces dependency on external inputs' presents a contradiction or paradox. In some cases, a petitioned substance may provide an advantage over existing permitted materials, but this issue can be addressed more directly when considering alternatives under criterion (6). If the intent is to increase efficiency of resource use and reduce the application of both biologically active substances and the total amount of materials released into the environment, a particular inert ingredient might increase the efficacy of a formulation and reduce the rate at which a synthetic active ingredient is applied and the amount of formulated product released into the environment. Certain inert ingredients, binders, and carriers can also improve farmer and worker safety by reducing exposure to harmful substances.

Item c has been re-worded into separate sub-points to better reflect the intent of the Board and to break the item down into quantifiable factors.

d) – One commenter stated, “Livestock concerns are not specifically addressed in the other factors and deserve specific mention.” The commenter suggested changing the reference from “animal” to “livestock” to avoid prohibiting materials that disrupt the behavior of pest animals (e.g., deer repellents) or confuse insects (e.g., pheromones).

The word “animal” has been changed to “livestock”.

e) – Several commenters endorsed the item, but felt that the NOSB should specify that it is concerned with the expectations of those who currently buy organic food, and not the entire marketplace. They commented that the question of compatibility is in many ways consumer-driven and is based on the acceptance in the marketplace of different techniques. Above all, with organic food production as a consumer-driven system, it is the consumer, not the producer or processor, who ultimately should guide the criteria for compatibility.

One commenter pointed out that use of the phrase “authenticity and integrity” is consistent with Codex Guidelines and IFOAM criteria, and means that the use of the substance should not be deceptive or misleading.

Another commenter felt that consumer expectations are very important. Furthermore, the organic food industry is vulnerable to consumer backlash so this factor must be carefully considered. “Unfortunately consumers are increasingly out of touch with food production reality making this factor both important and potentially dangerous.”

The word “organic” has been inserted to clarify the Board’s intent.

f) – One commenter stated that the inclusion of “economic viability” in item f is a “gigantic loophole whereby excuses can be made to allow for materials that do not fulfill the other ten criteria.” The commenter felt that this criterion could put many diligent organic farmers at a competitive disadvantage because they choose not to use an unsound material in their organic system, while a producer more motivated by greed than by ecological stewardship reaped unfair economic rewards.” The commenter urged deletion of item f.

Another commenter pointed out that one of the most critical factors to address in the consideration of economic viability is the difficulty in obtaining reliable data. “Economic viability needs to be examined in context and requires a more comprehensive level of study than is generally available in a TAP review. Specific factors to consider regarding economic viability would have to be spelled out clearly, so that petitions can provide accurate economic data and each TAP review evaluates this criterion in a consistent way each time. If the NOSB wants to include economic considerations as a factor in sustainability, they may want to consider the factor in a broader sense.”

In response to the comments cited above, and as suggested by several commenters, item f has been reworded to read, “Does the substance allow for an increase in the long-term viability of organic farm operations?”

g) – Several commenters opposed inclusion of item g. As one stated, “the consideration of working conditions is too specific to make generic materials decisions in most cases. While there may be a few substances that are produced or manufactured by a limited number of sources under working conditions that would violate this principle, such a question is really specific to a particular manufacturer and is really a brand name review issue.” The commenter suggested that this particular factor be deleted for the purposes of evaluating petitioned generic substances.

Another said, “since the goal of this document is to define criteria that can be tangibly quantified in order to justify NOSB decision it is our opinion that such factors not be included.”

Item g has been deleted. (Suggestions for tangible and applicable evaluation points are welcome. ed.)

h) – A commenter pointed out that the wording of item h seems to imply that the substance in question is already on the National List, and the petition is to modify or remove the annotation.

Item h has been re-phrased to clarify the intent of the Board, to read, “If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?”

i) – There was no opposition to item I, and no changes suggested. One commenter pointed out that while substances should not be automatically allowed simply because of historical use or prohibited because they are new, this factor needs to be taken into consideration and given an appropriate weight, with a justification for the change from the historical status.

j) – Several commenters did not like the phrasing of item j and suggested changes. As one stated, “the actual status of a given substance in various foreign markets is less important than the process of determining what is allowed and the basis for making that decision.” In the interest of greater clarity, specificity, and harmony with other national as well as international standards, commenters provided text which gives more specific guidance to petitioners, TAP reviewers, the NOSB, and the Secretary.

Item j has been changed to read, “Is the substance consistent with international organic regulations and guidelines, including Codex?”

k) – Several commenters supported inclusion of the concept of precaution, but urged that the item be re-written to better function as an evaluation point. One commenter sees the precautionary principle as an overarching principle related to compatibility and consistency with organic systems. As the commenter stated, “the principle is basic common sense: better safe than sorry, look before you leap.” The entire National List process can be considered to be an application of the precautionary principle, yet this principle is not specifically embodied in the other criteria or in procedural policies for decision-making.

The commenter supported inclusion of the concept in this section as a reminder to those participating in the review process, as well as those filing petitions. As pointed out, “synthetic substances are generally considered unsustainable by OFPA. The burden is on the petitioner—not on the NOSB, the NOP, or the public—to establish that a given synthetic substance is sustainable. In the case of a petition to prohibit a non-synthetic substance, the presumption is that a natural substance is sustainable and the petitioner must demonstrate that it is unsustainable.”

Another commenter strongly supports use of the Precautionary Principle (PP) in the materials evaluation process. But, because the commenter sees the PP as an overarching principle of decision making, the commenter disagrees with its inclusion as an evaluation criterion. The commenter stated, “it is a critically important concept that should be considered in relation to each relevant evaluation criterion.”

A third commenter reminded the Board that “writing a petition is set up for and needs to remain simple enough for non-scientifically trained parties to complete. In recent years there has been a disturbing trend to require information from the petitioner that could be ferreted out by the TAP process. Petitioning the National List needs to remain accessible by the lay user or producer.”

In order to address the concerns summarized above, item k has been re-phrased to read, “Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?”

l) – Two commenters urged inclusion of a criterion to address biodiversity, and they suggested tools by which biodiversity can be assessed. “Researchers have developed several indices that can help to compare and evaluate the impact of various specific management practices on intra-specific and inter-specific biodiversity.”¹⁰

A new item l has been inserted to address biodiversity.

m) – One commenter suggested that the following be included, “Will the use of the material not limit or halt the development of new organic products?”

A new item m has been inserted which reads, “Does the substance limit or facilitate the development of new organic products?”

n) – Another commenter urged inclusion of an item which addresses protection of organic integrity. As stated, “given that the application or use of a given prohibited substance used to produce or handle food will result in loss of organic status, substances that protect organic food from the loss of organic status can be viewed as compatible. In particular, one rationale behind allowing equipment cleansers in (7 USC 6517(c)(1)(B)(i)) was that they helped to prevent contaminated equipment from compromising the organic integrity of an organic product. The use of such products cannot be construed as permitting the intentional application of prohibited substances, but their allowance helps to prevent organic food from losing its status due by helping the operator avoid contamination. The Codex criteria also take into account the protection of organic integrity.”

A new item n is proposed, which reads, “Does use of the substance maintain and protect the integrity of organic products?”

¹⁰ Peter Kenmore, editor, *Biodiversity and the Ecosystem Approach in Agriculture, Forestry, and Fisheries*. (Rome, Food and Agriculture Organization, 2003). <http://www.fao.org/DOCREP/005/Y4586E/Y4586E00.HTM>