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 integrity[3] and nutritional value[4] of organic products, and minimize environmental degradation[5] 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 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 faming 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

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

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 faming 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 faming 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:

a) Does the substance promote plant and animal health by enhancing soil physical, chemical, or biological properties?
b) Does the substance encourage and enhance preventative management?
c) Does the substance promote the use of renewable resources and recycling, and reduce dependency on external inputs?
d) Does the substance have a positive influence on the health, natural behavior, and welfare of animals?
e) Does the substance satisfy consumer expectations regarding the authenticity and integrity of organic products?
f) Does the substance promote the economic viability of organic farm operations?
g) Is the substance mined, manufactured, or produced through reliance on child labor or any violations of International Labor Organization (ILO) conventions?
h) Is use of the substance consistent with other listed uses of the substance?
i) Is the substance consistent with other substances historically allowed or disallowed in organic production and handling?
j) What are the experiences in foreign markets with use of the substance?
k) 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 faming 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 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, l990 0rdered 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 it's 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, l990. 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 I 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 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 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 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 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 CircularA-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 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 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.