## NATIONAL ORGANIC STANDARDS BOARD

# **BOARD POLICY MANUAL**

Adopted October 19, 2002 Revised April 29, 2004

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### NOSB POLICY MANUAL

#### INTRODUCTION

This document is intended as a guide for all members of the National Organic Standards Board. Board members are entrusted with a strong responsibility to treat the business of the Board as fiduciaries for all members of the organic community and the public at large.

The Board's primary role is to advise, rather than administer and implement. In every business, success depends heavily upon the ability of Board and management to each understand their respective roles, and to develop the working relationship necessary within those roles.

This handbook is designed to assist the Board in its responsibilities. New Board members are encouraged to review this Manual in depth. Existing members are advised to periodically review the contents to refresh their understanding of the Board's role and their duties.

New policies and revisions to existing policies will be incorporated into the NOSB Policy Manual from time to time, as determined by the Board.

## **SECTION I**

#### **NOSB VISION STATEMENT:**

The NOSB's vision is an agricultural community rooted in organic principles and values that instills trust among consumers, producers, processors, retailers, and other stakeholders. Consistent and sustainable organic standards guard and advance the integrity of organic products and practices.

#### **NOSB MISSION STATEMENT:**

To achieve its vision, the NOSB provides effective and constructive advice, clarification, and guidance concerning the National Organic Program to the Secretary of Agriculture, seeking to represent a consensus of the organic community. In carrying out the mission, key activities of the Board are:

- Assisting in the development and maintenance of organic standards and regulations;
- Conducting public meetings and listening to public comments;
- Maintaining a National List of Allowed and Prohibited Materials;
- Communicating with, supporting, and coordinating with the NOP staff;
- Communicating with the organic community;
- Providing information and education on the National Organic Program.

#### **DUTIES OF THE BOARD AND OFFICERS**

According to the Organic Foods Production Act of 1990 (OFPA), the responsibilities of the Board are to: provide recommendations to USDA regarding implementation of OFPA; develop the National List of Allowed and Prohibited Materials; convene Technical Advisory Panels (TAPs) to provide scientific evaluation of materials; advise the USDA concerning the testing of organic products for residues of prohibited materials; and advise the USDA concerning the impact of emergency spray programs on certified organic farms.

Board members' duties in upholding their responsibilities are generally divided into three categories, categorized in this policy manual as the Duty of Care, the Duty of Loyalty, and the Duty of Obedience.

#### **Duty of Care**

The Duty of Care calls upon a member to participate in the decisions of the Board, and to be informed as to the data relevant to such decisions. In essence, the Duty of Care requires that a member:

- <u>Be reasonably informed</u>—It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources.
- <u>Participate in decisions</u>—Board members are bound by responsibility to be active participants in decision-making. Absence from a meeting is no protection from the responsibility for decisions made at the meeting.
- <u>Make decisions with the care of an ordinary prudent person in a similar position</u>— The law does not expect Board members to act as superheroes. It simply requires Board members to exercise judgment of an ordinary prudent person who may be faced with a similar issue.

#### **Duty of Loyalty**

The Duty of Loyalty requires Board members to exercise their power in the interest of the public, and not in their own interest or the interest of another entity or person. As a Board member, your loyalty is to the organic community and the public at large. Period. In dispatching their Duty of Loyalty, Board members must:

- <u>Address conflicts of interest</u>—Board members bring to the NOSB particular areas of expertise based upon their personal and business interests in organic production and marketing. Board members may have interests in conflict with those of the public interests. Board members must be conscious of the potential for such conflicts and act with candor and care in dealing with such situations. Board members must abide by the NOSB conflict of interest policy.
- <u>Recognize corporate opportunity</u>—Before a Board member votes upon an issue in which they have a direct financial interest, that Board member must disclose the transaction to the Board in sufficient detail and adequate time to enable the Board to act—or decline to act—in regard to such transaction.

#### **Duty of Obedience**

Board members are bound to obey the tenants of the laws and regulations governing organic production, processing, and marketing. To this effect, Board members must:

- Act within the requirements of the law—Board members must uphold all state and federal statutes, including the Federal Advisory Committee Act (FACA – 5 U.S.C. App. 2 et seq.).
- Follow the responsibilities of the Board as defined by the Organic Foods Production Act of 1990.
- Follow the requirements specified in this Board Policy Manual.

#### Maintaining Professional and Ethical Standards

As appointees of the Secretary, NOSB members must maintain high professional and ethical standards for the conduct of all activities within and outside of the NOSB. Areas of particular concern include professional conduct and conflict of interest.

#### **Professional Conduct**

Public service is a public trust, requiring ethical principles above private gain.

NOSB members shall put forth honest effort in the performance of their NOSB duties.

NOSB members shall make no commitments or promises of any kind purporting to bind the Government.

NOSB members shall act impartially and not give preferential treatment to any organization or individual.

NOSB members, committee and task force members, and contractors and agents of the NOSB shall not engage in a financial transaction using nonpublic information, not allow the improper use of nonpublic information to further his/her own private interest or that of another, whether through advice or recommendation, or allow the unauthorized disclosure of nonpublic information.

Nonpublic information is defined as information that the board member gains by reason of participation in the National Organic Standards Board and that he/she knows or reasonably should know has not been made available to the general public. This includes information that is "routinely exempt from disclosure in 5 U.S.C. 552 (Freedom of Information Act) or otherwise protected from disclosure by statute, Executive Order or regulation; is designated as confidential by the agency or program; or has not actually been disseminated to the general public and is not authorized to be made available to the public upon request."

NOSB members, committee and task force members, and contractors and agents of the NOSB shall keep confidential, all information identified by petitioners as confidential business information.

To the maximum extent possible, NOSB members should speak with one voice. Although there may be disagreements within NOSB committee or working group sessions, once NOSB members leave the session they have the responsibility to support the integrity of the process, whether or not they agree with the final outcome. While NOSB members retain the right to express minority opinions, the public airing of dissension could strain interpersonal relationships and create distrust and conflict among NOSB members. Such stresses could undermine the NOSB's ability to effectively carry out its role as a governmental advisory board.

NOSB members with diverse backgrounds are recruited to provide balance to the Board. While individual NOSB members represent the segments of the population from which they were selected, they also represent the greater good of the population as a whole.

#### **Conflict of Interest**

To ensure that business conducted by the NOSB is above reproach in all aspects of Board activity the NOSB has adopted a Conflict of Interest policy. The policy includes but is not limited to any NOSB member or party who owns, manufacturers or distributes a material for which the party has petitioned the NOSB for inclusion on the National List.

The NOSB recognizes that members have been specifically appointed to the Board to provide advice and counsel to the Secretary concerning policies related to the development of organic standards and the creation and amendment of the National List. NOSB members have been appointed because they have professional expertise which enables them to advise the Secretary. This professional expertise may, at times, present an inherent conflict of interest. To prevent overt advocacy for direct financial gain and the appearance of self-interest or the appearance of wrongful activity, the NOSB has adopted the following conflict of interest policy.

#### Be it resolved by the National Organic Standards Board:

That members of the Board shall refrain from taking any official Board action from which that Board member is or would derive direct financial gain. Board members shall disclose their interest to the Board and the public, when they or their affiliated business stand to gain from a vote, which they cast in the course of Board business. Under certain circumstances, the Board may determine whether it is appropriate for the member to vote.

That members of the Board shall refrain promoting for consideration any material, process or practice for which the member is or would derive direct financial gain arising out of such Board action. The act of promoting such material, process or practice shall include private discussion with members of the Board advocating the value of the material, public discussion, and/or written advocacy.

A "direct financial gain" is defined as monetary consideration, contractual benefit or the expectation of future monetary gain to a Board member including but not limited to financial gain from a party who manufacturers, distributes or holds exclusive title to a formula for a material or product, process or practice.

## **SECTION II**

#### **BOARD MEMBER JOB DESCRIPTIONS**

The National Organic Standards Board fulfills three important roles. First, the Board serves as the primary linkage to the organic community. In that regard, the Board must advise the NOP on the implementation of OFPA. Second, the Board must approve all materials which appear on the National List. Finally, the Board maintains the responsibility to protect and defend the integrity of the organic sector.

#### Composition of the Board

The Board shall be composed of 15 members, of which:

- 1) four shall be individuals who own or operate organic farming operations;
- 2) two shall be individuals who own or operate organic handling operations;
- 3) one shall be an individual who owns or operates a retail establishment with significant trade in organic products;
- 4) three shall be individuals with expertise in environmental protection and resource conservation;
- 5) three shall be individuals who represent public interest or consumer groups;
- 6) one shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry; and
- 7) one shall be an individual who is a certifying agent.

Board members must maintain the following standards:

<u>Participate in meetings</u> – Members must make a commitment to attend meetings of the Board.

<u>Serve on committees, as assigned</u> – Each member must be willing to serve on committees as assigned by the Chair, and to participate in the work of those committees.

<u>Be informed about the decisions to be made</u> – Board members are expected to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board.

<u>Fully disclose any conflict of interest positions</u> – Members having any commercial or immediate family interest that poses a potential or perceived conflict of interest must disclose that conflict to the Board, and abide by any decision of the Board in dealing with the situation.

#### **CONDUCTING BUSINESS**

<u>Quorum</u> – A majority of the members of the Board shall constitute a quorum for the purpose of conducting business. A majority of the members of a Committee, including the Executive Committee, shall constitute a quorum for the purpose of conducting business.

<u>Decisive votes</u> – Two-thirds of the votes cast at a meeting of the board at which a quorum is present shall be decisive of any motion. All abstentions will be recorded as such; however, they will be tallied with the majority vote. All Board members who are absent and/or who recuse themselves due to conflicts of interest shall be recorded as such; their votes are not counted towards the total number of votes cast.

## **SECTION III**

#### **OFFICER RESPONSIBILITIES**

Three principal officers, the Chair, Vice Chair, and Secretary, guide the Board.

#### <u>Chair</u>

The Chair is responsible to assure the integrity of the Board process, including effectiveness of meetings and the board's adherence to its own rules. The Chair shall: schedule meetings of the Board and the Executive Committee; draft meeting agendas in consultation with committee chairs and NOP staff; convene and preside at meetings; review committee work plans; and review meeting minutes for accuracy.

#### Vice Chair

The Vice Chair shall act in the absence of the Chair. The Vice Chair shall also be responsible for maintenance and upkeep of the policy manual.

#### **Secretary**

The Secretary is responsible for the integrity of all legal and governing documents of the Board. It is the Secretary's responsibility to: record and maintain the official board proceedings; circulate draft minutes for approval of the Board; ensure that minutes of board actions are available to members of the public; and transfer custody of the minutes of the board to the Secretary's successor. The Secretary may delegate tasks to others, including USDA staff, but retains responsibility for the official record.

#### **ELECTION OF OFFICERS**

Officers shall be elected for terms of one year by majority vote at the annual fall meeting of the Board. Candidates may be self nominated or nominated by another member of the Board. Should an officer resign or fail to serve the full term, the Executive Committee shall appoint an interim officer. The interim officer shall serve in the capacity until the next regularly scheduled meeting of the Board, during which an election will be held to fill the remainder of the term.

#### **EXECUTIVE COMMITTEE**

The Executive Committee of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the chairs of the Certification, Accreditation, and Compliance, Crops, Handling, Livestock, Materials, and Policy Development Committees. The Executive Committee, with participation of the NOP, shall meet monthly, as needed, or as called by the Chair, and shall conduct business on behalf of the board, except that the Executive Committee shall not take action on any recommendation to the Secretary, including the status of materials on the National List.

## **SECTION IV**

#### **BOARD COMMITTEES**

Committees play an important role in administering the board's responsibilities. Committees exist to provide greater depth and clarity in the Board's responsibility to make informed decisions. Except for the Executive Committee, no committees are authorized to act in place of the Board. They are empowered to analyze information and bring draft recommendations to the Board for action.

Committee Chairs are appointed by the Board Chair. The Livestock Committee, the Crops Committee, and the Handling Committee will each have co-chairs. One co-chair will guide all committee discussion, and will oversee the committee's work plan. The other co-chair will be responsible for the committee's consideration of materials, and will serve as the liaison to the Materials Committee.

Committee recommendations are finalized by the NOSB according to the following process: 1) committee drafts the recommendation; 2) draft recommendation is posted for public comment; 3) public comments are considered by committee when making recommendation to the Board; and 4) Board takes action on the recommendation. All draft recommendations must be submitted to the NOP at least sixty (60) days prior to the next upcoming NOSB meeting, in order to be considered at that meeting.

Board actions may include adoption of the recommendation as presented by the committee; amending and then adopting the recommendation; rejecting the recommendation; or referring the recommendation back to committee for further development.

#### **Certification, Accreditation, and Compliance Committee**

The Certification, Accreditation, and Compliance Committee shall make draft recommendations for consideration by the Board concerning the applicability, certification, accreditation, and compliance sections of OFPA and the Final Rule and how those sections are implemented by the NOP, accredited certifying agents, and State Organic Programs.

#### **Crops Committee**

The Crops Committee shall make draft recommendations for consideration by the Board concerning the crop production section of OFPA and the Final Rule. The Crops Committee shall also review petitions, technical advisory panel reports, and public comments concerning materials used for crop production which have been requested for addition to or removal from the National List.

#### **Livestock Committee**

The Livestock Committee shall make draft recommendations for consideration by the Board concerning the livestock and livestock feed sections of OFPA and the Final Rule. The Livestock Committee shall also review petitions, technical advisory panel reports, and public comments concerning materials used for livestock production which have been requested for addition to or removal from the National List.

#### **Materials Committee**

The Materials Committee shall make draft recommendations for consideration by the Board concerning the National List section of the Final Rule. The Materials Committee shall work in conjunction with the NOP, NOSB Committees, and TAP Contractors in managing the Materials Review Process. In addition to a chair appointed by the Board Chair, the Materials Committee shall include in its membership one of the co-chairs from each of the Livestock, Crops, and Handling committees. Other members may be appointed as needed.

#### **Handling Committee**

The Handling Committee shall make draft recommendations for consideration by the Board concerning the handling and labeling sections of OFPA and the Final Rule. The Handling Committee shall also review petitions, technical advisory panel reports, and public comments concerning materials used for processing and handling which have been requested for addition to or removal from the National List.

#### **Policy Development Committee**

The Policy Development Committee shall work with the NOP to develop priorities for the Board. The Policy Development Committee shall make draft recommendations for consideration by the Board concerning Board operations, policies, procedures, and work plans.

#### **Task Forces**

As determined by the Board or Executive Committee, task forces shall be appointed to explore specific issues and present draft recommendations to the Board or to a committee. Task forces may include members of the public who do not serve on the Board. Each task force shall include at least one member of the NOSB. Minutes shall be taken of task force meetings. Each task force shall submit a final report to the Board. Each task force shall be disbanded when its work has concluded.

## **SECTION V**

#### **DUTIES OF COMMITTEE CHAIRS**

Committee chairs are obligated to schedule committee meetings as needed; draft committee meeting agendas in consultation with committee members and NOP staff; convene and preside at committee meetings; insure that minutes are taken of committee meetings; review committee meeting minutes for accuracy; and report the actions of the committee to the Board.

Committee chairs shall not act unilaterally, especially concerning issues which involve statutory responsibilities of the Board.

#### **NOSB POLICY ON COMMITTEE RECOMMENDATIONS**

All committee and task force draft recommendations must be submitted to the NOP at least sixty (60) days prior to the next upcoming NOSB meeting, in order to be considered at that meeting.

NOSB committees and task forces shall use the following format to present draft policy and/or material recommendations for consideration by the Board:

Introduction – The "introduction" shall summarize the issue.

**Background** – The "background" section shall explain the issue in sufficient detail and provide rationale for the proposed recommendation. It shall explain why the recommendation should be adopted, provide historical context, and describe the regulatory framework pertinent to the issue. For livestock and crop materials, the background section must include the committee's report of how the material was analyzed in the context of the specific criteria in Section 2119 of the OFPA (7 U.S.C. 6518(m)(1-7). For handling materials, the background section must include the committee's report of the criteria approved by the NOSB on February 10, 1999, incorporated in Section205.600(b) of the Final Rule.

**Recommendation** – This section shall contain the concise text of the committee or task force's recommended action.

**Committee vote** – The actual vote of the committee or task force shall be reported.

**Minority opinion** – If applicable, the opinion of committee or task force members who voted in opposition shall be summarized.

**Conclusion** – The recommendation of the committee or task force shall be summarized.

## **SECTION VI**

#### NATIONAL ORGANIC PROGRAM MATERIALS REVIEW PROCESS

The minimum timeframe for National List Material Review is 145 days. The following process is a description of the communications and expectations between NOP staff, Materials Committee, and TAP Contractors.

#### Day 1 through 14:

 The petition for request of a material to be added or deleted from the National List is received by NOP. The NOP staff reviews the petition to see if all of the requirements, as described by the petition process, are complete. If the petition has all the required information then a copy of the petition is sent to the NOSB Materials Committee Chair.

#### > <u>Day 14 through 21</u>:

 The Materials Chairperson sends a copy of the petition to the Vice- Chair of Materials along with a copy to the Chairperson of the designated NOSB committee (i.e., Crops, Livestock, or Processing). The Materials Chair, Vice-Chair, and designated NOSB committee chair will evaluate the petition to see if it will be forwarded for a TAP review. If so, they determine which contractor will be designated the work order. All contractors will review equal numbers of materials from all sectors. The TAP requests will be allotted on a rotation cycle. For example, equal numbers of crops, livestock, and processing materials will be forwarded to contractors up to the time their contract amount has been fulfilled.

#### > No later than 115 days prior to a NOSB Meeting:

- All TAP review requests that are sent to contractors 115 days prior to the next NOSB meeting will be guaranteed completed TAP reviews. Note: if there is a problem with completing the work then the contractor must notify the materials chair ASAP.
- Statement of Work: Please see your statement of work for specific tasks and responsibilities that fall under this time frame. This can be found under section #9 Scope of performance:

 Please note that in Phase I the contractor must notify NOP in writing of any substance(s) they feel are not appropriate for National List evaluation. Contractors must not directly correspond with the petitioner. All requests for additional information or clarification to a petition should be sent via email to NOP Staff. (see below for email addresses)

#### > <u>Ninety (90) days prior to the NOSB Meeting</u>:

 Copies of the completed TAP review must be received by NOP. One copy must be FedEx to:

USDA-AMS-TM-NOP 1400 Independence Avenue, S.W. Room 4008-So., Ag Stop 0268 Washington, D.C. 20250-0200 Attention: Mr. Robert Pooler or Ms. Toni Strother

- Also one copy must sent via e-mail to <u>bob.pooler@usda.gov</u> or <u>toni.strother2@usda.gov</u>
- The NOSB Committee will use this timeframe to review the TAP's and may call on contractors to clarify issues.
- TAP reviews are posted on the NOP website for review and public comment.

### **PROPOSED ADVISORY AND ASSISTANCE SERVICES**

#### STATEMENT OF WORK

Request for Proposals to Perform Technical Advisory Panel Evaluation of Substances Petitioned for Inclusion on or Removal from the National Organic Program's National List of Allowed and Prohibited Substances

#### AGENCY NEED

#### See Statement of Work 1.0 Background

#### **STATEMENT OF WORK**

#### 1. Background

The Organic Foods Production Act of 1990 (OFPA), as amended, requires the Secretary of Agriculture (Secretary) to establish a National List of Allowed and Prohibited Substances (National List). This list identifies the synthetic substances that may be used, and the nonsynthetic substances that cannot be used, by organic production and handling operations. The OFPA authorizes the National Organic Standards Board (NOSB) to develop and forward to the Secretary a recommended Proposed National List, and subsequent proposed amendments to it. The OFPA provides that persons may petition the NOSB to evaluate a substance for inclusion on or removal from the National List

The NOSB submitted a Proposed National List to the Secretary that was subsequently published on December 21, 2000, as part of the National Organic Program (NOP) final rule, 65 Fed. Reg. 80548-80684, (2000). Based on information supplied to the NOSB by trade associations, certification organizations and other organic industry sources, there are many substances currently used in organic production and handling that have not been evaluated by the NOSB for inclusion on the National List. Evaluations of these substances must be expedited to prevent the possible disruption of well-established and accepted production, handling, and processing systems.

Section 2119 of the OFPA (7 U.S.C. 6518 (k)(3)) provides that the NOSB shall convene technical advisory panels (TAP) to provide scientific evaluation of substances for inclusion on the National List. TAP evaluations assist the NOSB in evaluating substances being considered for addition to or removal from the National List. The NOP, on behalf of the NOSB, establishes contracts to conduct the TAP evaluations.

#### 2. Mission of USDA/AMS/NOP

The mission of NOP is to establish national standards governing the marketing of certain agricultural products as organically produced. The NOP is assisted by the NOSB, which provides policy advice in carrying out the program, including advising the Secretary on substances for inclusion on or removal from the National List.

The NOSB reviews information from various sources in evaluating substances for inclusion on or removal from the National List. Sources include TAP evaluations, the Environmental Protection Agency, the Food and Drug Administration, the National Institute of Environmental Health Studies, and public comment. The NOSB submits its recommendations, along with the results of the required evaluation and technical advisory panel evaluation for each substance, to the Secretary for consideration in accordance with the requirements of section 2118(d) of the OFPA (7 U.S.C. 6517(d)).

#### 3. Specific Task

The contractor(s) shall furnish technical advisory panel evaluations for crop production, livestock production, and processing substances submitted to the NOSB in response to petition notices, such as was published in the <u>Federal Register</u> on July 13, 2000, as well as other substances requiring evaluation as determined by the NOP.

For crop and livestock production substances, the contractor(s) shall use the criteria in Section 2119 of the OFPA (7 U.S.C. 6518 (m)(I-7)). The criteria are:

- The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems;
- The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence in the environment;
- The probability of environmental contamination during manufacture, use, misuse or disposal of the substance;
- Its effects on human health;
- The effects of the substance on biological and chemical interactions in the agroecosystem;
- The alternatives to using the substance; and,
- The compatibility of the substance with a system of sustainable agriculture.

For processing substances, the contractor(s) shall use the criteria approved at the February 10, 1999, NOSB meeting. The criteria are:

- That processing aid or adjuvant cannot be produced from a natural source and has no organic ingredients as substitutes;
- If manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA;
- The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations;
- Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law;
- It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances;
- Its use is compatible with the principles of organic handling; and,
- There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

#### 4. Minimum Skills and Experience Requirements

Contractor(s) shall utilize qualified individuals or organizations who have specialized knowledge of the petitioned substances. Contractor(s) must have demonstrable expertise in organic production and handling or scientific disciplines such as veterinary medicine, chemistry, food technology, microbiology or toxicology. Contractor(s) must be familiar with the requirement for technical advisory panels described in the Organic Foods Production Act of 1990.

#### 5. Place of Performance

Contractor(s) shall perform all task related activity within the United States of America at specific locations determined by contractor(s). During the contract period, the contractor(s) shall travel at contractor(s)'s expense to NOSB meetings for the purpose of disseminating substance review findings to the NOSB and general public.

#### 6. Government Furnished Equipment and Facility

None, except that the NOP shall provide Contractor(s), (on a non-routine basis), with substance review petitions, ancillary documents or other applicable information in possession of NOP.

#### 7. Compensation

The NOP may award multiple contracts for tasks outlined in this statement of work. Contractor(s) shall be compensated at a firm-fixed price rate not to exceed \$4,000.00 per substance reviewed. Total compensation shall not exceed \$100,000.00.

#### 8. Period of Performance

September 30, 2001 – September 30, 2002 (262 working days)(Holiday time off is at contractor(s)' discretion.)

#### 9. Scope of Performance

#### Phase I --- Data Gathering and Compilation (120 days)

Phase I is not to exceed 120 days for any one substance. During this phase the contractor(s) provider shall perform the following activities:

- Characterize [the] substance(s) and identify uses and applications;
- Determine whether [the] substance(s) are synthetic or non-synthetic (See 7.S.C. 6502 (21) for definition of synthetic);
- Determine [the] substance(s) chemical or biological composition and possible impact on human/animal health and the environment;
- Identify [the] substance(s) relevant toxicological studies, including ensuring substance does not contain residues of heavy metals or other environmental contaminants in excess of Food and Drug Administration Action Level or Environmental Protection Agency tolerances;
- Determine [the] substance(s) persistence in the environment;
- Determine [the] substance(s) effect on soil structure and ecology;
- Identify alternatives to the use of the substance(s);
- Determine [the] substance(s) historical use in organic production, processing and handling; and

 Determine [the] substance(s) status under OFPA and with other government agencies

Additionally, within 45 days of commencement of Phase I, the contractor(s) must notify the NOP in writing of any substance(s) not appropriate for National List evaluation. Other substances for evaluation may be substituted upon agreement between the NOP, the NOSB, and the contractor(s).

#### Phase II---Evaluation against Criteria (100 days)

Phase II is not to exceed 100 days for any one substance. The contractor(s) shall engage no less than three evaluators for each substance. No current member of the NOSB may serve as an evaluator. Evaluators may use data from all relevant sources. Evaluators shall make recommendations to the contractor(s) as to the substance's status as synthetic or non-synthetic and whether, in either case, the substances should be added to or removed from the National List.

#### Phase III---Recommendation (42 days)

Phase III is not to exceed 42 days for any one substance. Contractor(s) shall provide the NOP with a recommendation regarding each substance's suitability for inclusion on or removal from the National List. All data and analyses collected in Phase I and II will be forwarded to the NOP upon the completion of Phase III in accordance with the reporting requirements stated below.

#### **EVALUATION FACTORS FOR AWARD**

The NOP may award multiple contracts for tasks outlined in this statement of work. Contractor(s) selection will be based on evaluation of proposals in accordance with the responses received to the criteria outlined in Section 4.0, Minimum Skills and Experience Requirements and Section 9.0, Scope of Tasks. Award will be made to that offeror whose combination of technical experience and cost represents the best value to the Government and is most advantageous, cost, and other factors considered, and which is within the available NOP resources.

The NOP also reserves the right to reject any or all proposals received and/or request clarification or modification of proposals. The NOP reserves the right to determine a competitive range for negotiation based upon the technical and cost acceptability of proposals. In addition, the NOP reserves the right to award a contract without discussions.

Cost evaluation will include an analysis of the total cost and cost elements (if applicable) to perform the required work. The total costs supplied by the offeror shall constitute the total firm-fixed unit price for that service or deliverable.

Proposals that are unrealistic, in terms of technical commitment or unreasonably low or high in costs will be deemed reflective of an inherent lack of technical competence or as indicative of a failure to comprehend the complexity involved in the contract requirements. Such may be grounds for rejection of the proposal.

#### **OTHER EVALUATION FACTORS**

Technical proposals will be initially evaluated with respect to six (6) major factors for determination of the competitive range. Technical factors are listed in descending order of importance. The technical proposal is of greater importance than the cost proposal; when technical proposals are relatively equal in technical merit, cost will increase in importance.

#### **Technical Factors**

Factor 1	Overall Technical Approach; Proposed Methodology; Demonstrated Understanding of the Scope of Work and the Requirements
Factor 2	Previous Demonstrated Experience and Past Performance
Factor 3	Quality Control
Factor 4	Capability and Experience of Key Personnel
Factor 5	Project Management and Support Capability
Factor 6	Reasonableness of Cost

#### **REPORTING REQUIREMENTS**

Progress reports are due to the NOP each 60 days after the contract award date. A final report is due within 60 days of the end of the contract period. The contractor(s) shall forward five copies of the bi-monthly progress reports and the final report and all deliverables to the NOP in Washington DC. Documents should be addressed to: Richard H. Mathews, Program Manager, National Organic Program, USDA-AMS-TM-NOP, 1400 Independence Avenue, S.W., Room 4008-So., Ag Stop 0268, Washington, D.C. 20250-0200, Attention: Substance Evaluations.

The narrative in the progress reports should refer back to the stated objectives and timeline of the original contract proposal. Beneath each objective, the objective's current status should be reported. Any substantive diversion from a stated objective, or any deviation from the proposed timeline should be explained. Only the activities required under the contract should be reported. At a minimum, the progress reports should also include the following:

1. A short summary of the accomplishments for the reporting period;

- 2. Progress on completing individual project tasks;
- 3. The planned and actual schedules for task completion;
- 4. Projected accomplishments for the next reporting period: and,
- 5. Data on financial expenditures by task category.

Any deliverables required under the contract should be submitted upon completion and addressed to: Richard H. Mathews, Program Manager, National Organic Program, USDA-AMS-TM-NOP, 1400 Independence Avenue, S.W., Room 4008-So., Ag Stop 0268, Washington, D.C. 20250-0200, Attention: Substance Evaluations.

#### **INFORMATION TO BE INCLUDED IN A PETITION**

## ITEM A

Please indicate within which of the following categories your substance is being petitioned for inclusion on or removal from the National List:

- 1. Synthetic substance's allowed for use in organic crop production;
- 2. Nonsynthetic substances prohibited for use in organic crop production;
- 3. Synthetic substances allowed for use in organic livestock production;
- 4. Nonsynthetic substances prohibited for use in organic livestock production; and
- 5. Nonagricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)."

### ITEM B

- 1. The substance's common name.
- 2. The manufacturer's name, address, and telephone number.
- 3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer, or disinfectant.
- 4. A list of the crop, livestock, or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.

- 5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.
- 6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.
- 7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.
- 8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance.
- 9. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.
- 10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.
- 11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.
- 12. A "Petition Justification Statement" which provides justification for one of the following actions requested in the petition:
  - When petitioning for the inclusion of a synthetic substance on the National List, the petition should state why the synthetic substance is necessary for the production or handling of an organic product. The petition should also describe the nonsynthetic substances or alternative cultural methods that could be used in place of the petitioned synthetic substance. Additionally, the petition should summarize the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support the use of it instead of the use of a nonsynthetic substance or alternative cultural methods.

- When petitioning for the removal of a synthetic substance from the National List the petition must state why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.
- When petitioning for the inclusion on the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should not be permitted in the production or handling of an organic product.
- When petitioning for the removal from the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should be permitted in the production or handling of an organic product.
- 13. A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:
  - (a) Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim.
  - (b) "Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy.
  - (c) Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."
  - (d) The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy. (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBIdeleted copy.

- (e) Each page with CBI-deletions should be marked "CBI-deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI- deleted."
- (f) If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBI-deleted.")
- (g) All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information usually cannot be claimed as confidential.

However, the National List substance evaluations will involve a public and open process. No confidential information will be available for public inspection.

The NOP Program Manager may request additional information from the petitioner following receipt of the petition.

# EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

#### Category 1. Adverse impacts on humans or the environment? Substance \_\_\_\_\_\_

1. Are there adverse effects on environment from manufacture, use, or disposal?	Question	Yes	No	N/A <sup>1</sup>	Documentation
environment from manufacture, use, or disposal? [\$205.600 b.2] 2. Is there environmental contamination during manufacture, use, misuse, or disposal? [\$6518 m.3] 3. Is the substance harmful to the environment? [\$6517c(1)(A)(i):6517(c)(2)(A)i] 4. Does the substance contain List 1, 2, or 3 inerts? [\$6517 c(1)(B)(ii); 205.601(m)2] 5. Is there potential for detrimental chemical interaction with other materials used? [\$6518 m.1] 6. Are there adverse biological and chemical interactions in agro-ecosystem? [\$6518 m.5] 7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [\$6518 m.5] 8. Is there a toxic or other adverse action of the material or its breakdown products? [\$6518 m.2] 9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[\$6518 m.2] 9. Is there any harmful effect on human health? [\$6517 c(2)(A)(); 6517 c(2)(A)]; §6518 m.4] 11. Is there an adverse effect on human health as defined by					(TAP; petition; regulatory agency; other)
use, or disposal?         [§205.600 b.2]         2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]         3. Is the substance harmful to the environment?         [§6517c(1)(A)(i):6517(c)(2)(A)i]         4. Does the substance contain List 1, 2, or 3 inerts?         [§6517 c (1)(B)(ii); 205.601(m)2]         5. Is there potential for detrimental chemical interaction with other materials used?         [§6518 m.1]         6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]         7. Are there detrimental physiological effects on soil organisms, crops, or livestock?         [§6518 m.2]         9. Is there undesirable persistence or concentration of the material or breakdown products?         [§6518 m.2]         9. Is there any harmful effect on human health?         [§6517 c(2)(A)(i); 6517 c(2)(A)]; §6518 m.4]	1. Are there adverse effects on				
[§205.600 b.2]	environment from manufacture,				
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]	use, or disposal?				
contamination during manufacture, use, misuse, or disposal? [\$6518 m.3]         3. Is the substance harmful to the environment? [\$6517 c1(1)A(0)(0;5517(c)(2)(A))]         4. Does the substance contain List 1, 2, or 3 inerts? [\$6517 c (1)(B)(ii); 205.601(m)2]         5. Is there potential for detrimental chemical interaction with other materials used? [\$6518 m.1]         6. Are there adverse biological and chemical interactions in agro-ecosystem? [\$6518 m.5]         7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [\$6518 m.5]         8. Is there a toxic or other adverse action of the material or its breakdown products? [\$6518 m.2]         9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[\$6518 m.2]         9. Is there an adverse effect on human health? [\$6517 c1(1)(4)(0); 6517 c2(2)(A)]; §6518 m.4]	[§205.600 b.2]				
manufacture, use, misuse, or disposal? [§6518 m.3]	2. Is there environmental				
disposal? [§6518 m.3]	contamination during				
3. Is the substance harmful to the environment?	manufacture, use, misuse, or				
the environment?       [§6517c(1)(A)(i);6517(c)(2)(A)i]         4. Does the substance contain	disposal? [§6518 m.3]				
[§6517c(1)(A)(i);6517(c)(2)(A)i]         4. Does the substance contain         List 1, 2, or 3 inerts?         [§657 c (1)(B)(ii);         205.601(m)2]         5. Is there potential for         detrimental chemical interaction         with other materials used?         [§6518 m.1]         6. Are there adverse biological         and chemical interactions in         agro-ecosystem? [§6518 m.5]         7. Are there detrimental         physiological effects on soil         organisms, crops, or livestock?         [§6518 m.2]         9. Is there a toxic or other         adverse action of the material or         its breakdown products?         [§6518 m.2]         9. Is there undesirable         persistence or concentration of         the material or breakdown         products in environment?[§6518         m.2]         10. Is there any harmful effect         on human health?         [§6517 c (1)(A)(i); 6517         c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on         human health as defined by	3. Is the substance harmful to				
4. Does the substance contain         List 1, 2, or 3 inerts?         [§6517 c (1)(B)(ii);         205.601(m)2]         5. Is there potential for         detrimental chemical interaction         with other materials used?         [§6518 m.1]         6. Are there adverse biological         and chemical interactions in         agro-ecosystem?         [§6518 m.5]         7. Are there detrimental         physiological effects on soil         organisms, crops, or livestock?         [§6518 m.5]         8. Is there a toxic or other         adverse action of the material or         its breakdown products?         [§6518 m.2]         9. Is there undesirable         persistence or concentration of         the material or breakdown         products in environment?[§6518         m.2]         10. Is there any harmful effect         on human health?         [§6517 c (1)(A)(i); 6517         c(2)(A)I: §6518 m.4]         11. Is there an adverse effect on         human health as defined by	the environment?				
List 1, 2, or 3 inerts?         [§6517 c (1)(B)(ii);         205.601(m)2]         5. Is there aptential for         detrimental chemical interaction         with other materials used?         [§6518 m.1]         6. Are there adverse biological         and chemical interactions in         agro-ecosystem?         physiological effects on soil         organisms, crops, or livestock?         [§6518 m.5]         8. Is there a toxic or other         adverse action of the material or         its breakdown products?         [§6518 m.2]         9. Is there undesirable         persistence or concentration of         the material or breakdown         products in environment?[§6518         m.2]         10. Is there any harmful effect         on human health?         [§6517 c (1)(A)(i); 6517         (2)(A)I: §6518 m.4]         11. Is there an adverse effect on         human health as defined by	[§6517c(1)(A)(i);6517(c)(2)(A)i]				
[§6517 c (1)(B)(ii);         205.601(m)2]         5. Is there potential for         detrimental chemical interaction         with other materials used?         [§6518 m.1]         6. Are there adverse biological         and chemical interactions in         agro-ecosystem? [§6518 m.5]         7. Are there detrimental         physiological effects on soil         organisms, crops, or livestock?         [§6518 m.5]         8. Is there a toxic or other         adverse action of the material or         its breakdown products?         [§6518 m.2]         9. Is there undesirable         persistence or concentration of         the material or breakdown         products in environment?[§6518         m.2]         10. Is there any harmful effect         on human health?         [§6517 c (1)(A)(i); 6517         c(2)(A)!; §6518 m.4]         11. Is there an adverse effect on         human health as defined by					
205.601(m)2]					
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]					
detrimental chemical interaction with other materials used?       [§6518 m.1]         6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]       [§6518 m.5]         7. Are there detrimental physiological effects on soil organisms, crops, or livestock?       [§6518 m.5]         8. Is there a toxic or other adverse action of the material or its breakdown products?       [§6518 m.2]         9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]       [§6517 c.2]         10. Is there any harmful effect on human health?       [§6517 c.2]         11. Is there an adverse effect on human health as defined by       [§6518 m.4]					
with other materials used?       [§6518 m.1]         6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]       7. Are there detrimental physiological effects on soil organisms, crops, or livestock?         [§6518 m.5]       8. Is there a toxic or other adverse action of the material or lits breakdown products?       9. Is there undesirable persistence or concentration of the material or breakdown products?         9. Is there any harmful effect on human health?       10. Is there any harmful effect on human health?         10. Is there any harmful effect on human health?       11. Is there an adverse effect on human health as defined by					
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agro-ecosystem? [§6518 m.5]					
7. Are there detrimental physiological effects on soil organisms, crops, or livestock?         [§6518 m.5]         8. Is there a toxic or other adverse action of the material or its breakdown products?         [§6518 m.2]         9. Is there undesirable persistence or concentration of the material or breakdown products in environment?[§6518 m.2]         10. Is there any harmful effect on human health?         [§6517 c (1)(A)(i); 6517 c(2)(A)]; §6518 m.4]         11. Is there an adverse effect on human health as defined by					
physiological effects on soil       organisms, crops, or livestock?         [§6518 m.5]       8. Is there a toxic or other         adverse action of the material or       its breakdown products?         [§6518 m.2]       9. Is there undesirable         persistence or concentration of       the material or breakdown         products in environment?[§6518       m.2]         10. Is there any harmful effect       on human health?         [§6517 c (1)(A)(i) ; 6517       c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on       human health as defined by					
organisms, crops, or livestock? [§6518 m.5]Image: Second					
[§6518 m.5]         8. Is there a toxic or other         adverse action of the material or         its breakdown products?         [§6518 m.2]         9. Is there undesirable         persistence or concentration of         the material or breakdown         products in environment?[§6518         m.2]         10. Is there any harmful effect         on human health?         [§6517 c (1)(A)(i) ; 6517         c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on         human health as defined by					
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adverse action of the material or its breakdown products?       Image: Constraint of the material or breakdown products in environment? [§6518 m.2]         9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]       Image: Constraint of the material or breakdown products in environment? [§6518 m.2]         10. Is there any harmful effect on human health?       Image: Constraint of the material or breakdown products in environment? [§6517 c (1)(A)(i) ; 6517 c (2)(A)]; §6518 m.4]         11. Is there an adverse effect on human health as defined by       Image: Constraint of the material or breakdown products of the material or breakdown products in environment? [§6518 m.4]					
its breakdown products?       [§6518 m.2]         9. Is there undesirable       persistence or concentration of         persistence or concentration of       the material or breakdown         products in environment?[§6518       m.2]         10. Is there any harmful effect       on human health?         [§6517 c (1)(A)(i) ; 6517       c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on       human health as defined by					
[§6518 m.2]       9. Is there undesirable         persistence or concentration of       9. Is there undesirable         persistence or concentration of       9. Is there any breakdown         products in environment?[§6518       9. Is there any harmful effect         m.2]       10. Is there any harmful effect         on human health?       11. Is there an adverse effect on         human health as defined by       11. Is there an adverse effect on					
9. Is there undesirable         persistence or concentration of         the material or breakdown         products in environment?[§6518         m.2]         10. Is there any harmful effect         on human health?         [§6517 c (1)(A)(i) ; 6517         c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on         human health as defined by					
persistence or concentration of         the material or breakdown         products in environment?[§6518         m.2]         10. Is there any harmful effect         on human health?         [§6517 c (1)(A)(i) ; 6517         c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on         human health as defined by					
the material or breakdown         products in environment?[§6518         m.2]         10. Is there any harmful effect         on human health?         [§6517 c (1)(A)(i) ; 6517         c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on         human health as defined by					
products in environment?[§6518         m.2]         10. Is there any harmful effect         on human health?         [§6517 c (1)(A)(i) ; 6517         c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on         human health as defined by					
m.2]     10. Is there any harmful effect       on human health?     [§6517 c (1)(A)(i) ; 6517       c(2)(A)I; §6518 m.4]     11. Is there an adverse effect on human health as defined by					
10. Is there any harmful effect         on human health?         [§6517 c (1)(A)(i) ; 6517         c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on         human health as defined by					
on human health?         [§6517 c (1)(A)(i) ; 6517         c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on human health as defined by	-				
[§6517 c (1)(A)(i) ; 6517         c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on         human health as defined by					
c(2)(A)I; §6518 m.4]         11. Is there an adverse effect on human health as defined by					
11. Is there an adverse effect on human health as defined by					
human health as defined by					
	applicable Federal regulations?				
[205.600 b.3]					
12. Is the substance GRAS					
when used according to FDA's					
good manufacturing practices?					

[§205.600 b.5]			
13. Does the substance contain			
residues of heavy metals or			
other contaminants in excess of			
FDA tolerances? [§205.600 b.5]			

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

#### Category 2. Is the Substance Essential for Organic Production? Substance \_\_\_\_\_

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is there a natural source of the substance? [§205.600 b.1]				
2. Is there an organic substitute? [§205.600 b.1]				
3. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]				
4. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]				
5. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				
6. Is there any alternative substances? [§6518 m.6]				
7. Is there another practice that would make the substance unnecessary? [§6518 m.6]				

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b)are N/A—not applicable.

#### Category 3. Is the substance compatible with organic production practices?

Substance \_\_\_\_\_

Question	Yes	No	N/A <sup>1</sup>	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]				
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]				
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]				
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]				
5. Is the primary use as a preservative? [§205.600 b.4]				
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)?				
[205.600 b.4] 7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: a. copper and sulfur				
compounds; b. toxins derived from bacteria;				
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?				
d. livestock parasiticides and medicines?				
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?				

<sup>1</sup>If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

#### 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?
- I) Does use of the substance have a positive impact on biodiversity?

Adopted April 29, 2004 - 13 yes, 0 no, 1 absent

## NOSB RECOMMENDED DECISION FORM Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: Substance:						
A. Evaluation Criteria (Documentation attached; committee recommendation attached)						
1. Impact on humans and environment       Yes □ No □ (see B below)						
		ent		Yes 🗌 No 🗌 (		
2. Availability crite						
3. Compatibility &	3. Compatibility & consistency Yes 🗌 No 🗌 (see B below)					
		C. Proposed An	notation:			
B. Substance fails criteria	a?					
Criteria category:		Basis for annota	tion:			
Comments:		To meet criteria	above:	Criteria:		
		Other regulatory	criteria:	Citation:		
D. Final Board Action & V	/ote: Motion by	·	Seco	ond:		
<u>Vote</u> :	Agricultural	Nonagricul	ltural	Crops		
Yes:	Synthetic	Not synthe	etic	Livestock		
No:	Allowed <sup>1</sup>	Prohibited	2	Handling		
	Deferred4		Rejected <sup>3</sup>			
Abstain: 1—substance voted to be added as "allowed" on National List Annotation:						
2—substance to be added to "prohibited" paragraph of National List Describe why a prohibited substance:						
3—substance was rejected by vote for amending National List Describe why material was rejected:						
4-substance was recommended to be deferred Describe why deferred; if any follow-up is needed. If follow-up needed, who conducts follow- up						
E. Approved by NOSB Chair to transmit to NOP:						
Dave Carter, NOSB Chair Date						

F. NOP Action: Include in FR to amend National List:		
Richard H. Mathews, Program Manager	Date	

## NOSB COMMITTEE RECOMMENDATION FORM Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: Substance:							
Committee: Crops  Livestock  Handling							
A. Evaluation Criteria (Documentation attached; committee recommendation attached)							
<ol> <li>Impact on huma</li> <li>Availability crite</li> <li>Compatibility &amp;</li> </ol>	Criteria Satisfied? Yes No (see B below) Yes No (see B below) Yes No (see B below)						
		C. Proposed An	notation:				
B. Substance fails criteria	a?						
Criteria category:		Basis for annota	ation:				
Comments:		To meet criteria	above: Criteria:				
		Other regulatory	y criteria: Citation:				
D. Recommended Comm	nittee Action & Vot	te: Motion by: _					
		Seconded:					
<u>Vote</u> :	Agricultural	Nonagricu	Itural Crops				
Yes:	Synthetic	Not synthe	etic Livestock				
No:	Allowed <sup>1</sup>	Prohibited	<sup>2</sup> Handling				
	No restriction	Deferred4	Rejected <sup>3</sup>				
Abstain: 1—substance voted to be added as "allowed" on National List Annotation:							
2—substance to be added to "prohibited" paragraph of National List Describe why a prohibited substance:							
3—substance was rejected by vote for amending National List Describe why material was rejected:							
4-substance was recommended to be deferred Describe why deferred; if follow-up is needed. If follow-up needed, who will follow up							

E. Approved by Committee Chair to transmit to NOSB:		
Committee Chair	Date	

# PROCEDURES FOR THE MATERIALS REVIEW PROCESS FOR NOSB MEMBERS

- 1. Upon receipt of the TAP reviews each member should read the report prepared by the contractor, along with the submitted petition, additional information and recommendations of the contracted panel of experts.
- 2. Questions or clarification of the review may be answered by further review of the literature provided by the TAP contractor or by the Chair of the committee contacting the contractor directly. Questions regarding the process can be directed to the Chair of the Materials Committee.
- 3. The materials are either directed to the processing, crops or livestock committee(s) depending on the specified use(s) of the material as stated in the petition. NOSB members assigned to those committees shall conduct a thorough review of the material and vote on whether it is synthetic or nonsynthetic and if it should be allowed or prohibited for specific use as either a crop, livestock or processing material. Materials may be followed by an annotation which restricts their use. Recommended annotations applicable to the material must be voted on by committee.
- Committee draft recommendations will be submitted to the NOP at least thirty (30) days prior to the next NOSB meeting where the material will be considered.
- 5. The Chair of each committee will present the Board with the committee's written votes and recommendations during the Materials Review process at the NOSB meeting. The recommendation should come in the form of a motion which must be seconded by an NOSB member to move forward. The process will follow Robert's Rules of Order in which the Chair would open the motion for discussion. The Chair shall ask if any Board members have conflicts of interest. After discussion board members will vote on the motion.
- 6. NOP staff will record the votes of the each NOSB member and announce whether or not the motion passed.
- 7. If the motion fails the Board Chair asks for a new motion and the procedure is repeated until a final motion is passed by a 2/3 majority.

# SUBSTANCE PETITION PROCESS

## A NOTE FROM THE NATIONAL ORGANIC STANDARDS BOARD

The NOSB is aware of a number of substances presently used in organic production, handling and processing that have not been petitioned for inclusion on the National List of Approved and Prohibited Substances. As a result, the Board anticipates receiving a large number of materials petitions over the next 12 to 18 months. Since the accompanying Technical Advisory Panel reviews cannot be completed simultaneously, the NOSB has established the following draft criteria for prioritizing the order in which the substances are reviewed. These draft criteria are being made available to the public for feedback and informal comment to ensure a smooth and timely material review process.

#### **General Petition Guidelines**

Any petition to reconsider a material would automatically go to the bottom of the list unless the petition was for removal of the substance from the List.

Any petition to remove a material presently on the list would be examined and moved to the top of the list if the NOSB concluded that the issue raised serious health or regulatory concerns.

#### In prioritizing substance petitions the NOSB will consider the following criteria:

•	Versatility	Is the substance used in a wide range of products and/or by a number of users?
٩	Proportionality	Is the substance selected from livestock, crops and processing in relationship to the numbers of materials petitioned and awaiting action, with some emphasis on livestock medications to prevent animal suffering?
•	Acceptance	Is the substance acceptable in international trade?

### Background

The NOSB carefully considered the "essentiality" criterion for end users. In the course of its discussions, the Board became concerned that such a criterion is too subjective to be useful for prioritizing materials prior to a TAP review. It is the belief of the NOSB that "versatility" captures the critical aspects of "essentiality."

### How To Comment:

This is an informal comment process sponsored by the NOSB. Please mark all comments "Petition Process." The comment period will close **November 4, 2000**. Comments may be submitted electronically and by mail or by fax as follows:

Electronically:	bob.pooler@usda.gov
By Mail:	National Organic Standards Board C/O Bob Pooler Agricultural Marketing Specialist USDA/AMS/TM/NOP Room4008-S, Ag Stop 0268 1400 Independence Avenue, S.W. Washington, D.C. 20250–0200
By Fax:	(202) 205-7808

# **SECTION VII**

### **MISCELLANEOUS POLICIES**

#### NOSB policy for presenters invited by committees

- 1. Need for presentation established within the appropriate committee by the committee chairperson.
- 2. NOSB Chairperson must receive notice 45 days prior to meeting. Exceptions are at the discretion of the NOSB Chairperson.
- 3. Presenter(s) must be invited by committee chair and/or NOSB chair and approved by the NOSB Chairperson.
- 4. Reason(s) for presentation, subject area and bio/resume of presenter(s) to be circulated via email to entire board at least 2 weeks prior to meeting.
- 5. Invited presenter(s) must provide objective information.
- 6. Presenter(s) cannot be a petitioner on the topic under discussion.
- 7. Presenter(s) must disclose any actual or perceived conflict of interest including information concerning who provided funding for the presentation.

Adopted June 7, 2001

### NOSB policy for surveys conducted on behalf of NOSB committees

- 1. All written surveys, including electronic surveys, that go out in the name of any NOSB Committee, must be approved by the NOSB Executive Committee before they are sent out; and
- 2. A written report summarizing the results of the survey must be submitted to the full board and the NOP as soon as possible after completion.

Adopted October 19, 2002

### NOSB policy for public comment at NOSB meetings

- 1. All persons wishing to comment at NOSB meetings during public comment periods must sign up in advance.
- 2. Persons will be called upon to speak in the order they signed up.

#### **National Organic Standards Board Policy Manual**

- 3. Unless otherwise indicated by the chair, each person will be given 5 minutes to speak.
- 4. Persons must give their names and affiliations for the record.
- 5. A person may submit a written proxy to the NOP or NOSB requesting that another person speak on his or her behalf.
- 6. No person will be allowed to speak during the public comment period for more than 10 minutes.

Adopted October 19, 2002

# 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 offfarm 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

## National Organic Standards Board Policy Manual

- 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.

# **DECISION MAKING PROCEDURES FOR THE NOP**

### 1. Define the Problem

- a. What is the problem?
- b. Identify where we are now.
  - i. State the present condition in no more than two sentences.
- c. Identify where we want to be.
  - i. State the future objective in no more than two sentences.

### 2. Analyze the Problem

- a. Why is there a problem?
- b. Is the evidence of the problem supported by credible and compelling facts or data?
  - i. What are the facts or data used to draw an affirmative conclusion?
- c. Who does this problem affect?
- d. What is the problem's effect?
- e. In what time frame must the problem be resolved?
- f. If the problem deserves immediate attention, what other priorities must be adjusted to accommodate this problem?
- g. If the problem deserves immediate attention, what are the consequences of a delay?

## 3. Develop Possible Solutions

- a. Propose ideas for possible solutions
- b. Evaluate ideas for possible solutions
  - i. List pros for each possible solution
    - ii. List cons for each possible solution
- c. Select a Solution
  - i. Is the recommended solution legal?
  - ii. Is the recommended solution practical?
  - iii. Is the recommended solution supported by credible and compelling facts or data?
    - 1. What are the facts or data used to draw an affirmative conclusion?
  - iv. How does the recommended solution solve the problem?
  - v. How does the recommended solution meet the time frame identified in 2(b)?
- d. Review recommended solution for unintended consequences.

## 4. Develop Action Plan

- a. Develop Action Steps
  - i. Identify action steps to bridge the gap between present condition and future objective using the recommended solution.
- b. Approve Action Plan
- c. Implement Action Plan

Final - 5/9/2003

### **National Organic Standards Board Policy Manual**

# FACA FACTS

- The Federal Advisory Committee Act (FACA) (5 U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.
- 2. Advisory committees must be chartered before they can meet or conduct any business. Charters must be renewed every two years or they will be terminated under the sunset provisions of Section 14 of the FACA, unless otherwise provided by law.
- 3. Advisory committee meetings are required to be open to the public, with limited exceptions as provided for in Section 552b of title 5, United States Code. Meetings not subject to FACA include NOSB briefing meetings initiated by USDA to exchange facts and information, such as member orientation, and NOSB committee meetings. Such meetings are not subject to FACA because they are not conducted for the purpose of providing the USDA with NOSB advice or recommendations.
- 4. Designated Federal Officials must approve all meetings and agendas, and attend meetings. The NOP program manager is the NOSB's Designated Federal Official.
- 5. Meeting notices and agendas must be published in the Federal Register to accommodate public participation. It is the goal of the NOP to:
  - a. Post a provisional agenda, on its web site, no later than 60 days before the meeting is scheduled to begin,
  - b. Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin, and
  - c. Publish notice of the meeting in the Federal Register no later than 30 days before the meeting is scheduled to begin.
- 6. Detailed minutes will be kept and must contain:
  - a. Date and location of the meeting,
  - b. A record of the persons present,

- c. A complete and accurate description of matters discussed and conclusions reached, and
- d. Any advice or recommendations provided by the committee.
- 7. Advisory committee documents must be available for public inspection and copying until the committee ceases to exist.
- 8. Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.
- 9. Additional information may be found at the FACA homepage http://policyworks.gov/org/main/mc

## DUTIES OF THE DESIGNATED FEDERAL OFFICER

The Designated Federal Officer assigned to the National Organic Standards Board and its committees, under the Federal Advisory Committee Act (U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10), is the National Organic Program's Program Manager. The Program Manager:

- 3. Must approve or call the meeting of the NOSB;
- 4. Must approve the agenda;
- 5. Must attend the meetings;
- 6. Shall adjourn the meetings when such adjournment is in the public interest; and
- 7. Chairs the meeting when directed by the Secretary of Agriculture or the Secretary's designee.

# PARLIAMENTARY PROCEDURE AT A GLANCE

TO DO THIS	YOU SAY THIS	May you interrupt speaker?	Must you be seconded?	Is the motion debatable?	Vote required
Adjourn the meeting	I move that we adjourn	no	yes	no	majority
Recess the meeting	I move that we recess until	no	yes	no	majority
Complain about noise, room temperature, etc.	Question of privilege	yes	no	no	no vote
Suspend further consideration of something	I move that the motion be laid on the table	no	yes	no	majority
End debate	I move the previous question	no	yes	no	2/3 vote
Postpone consideration of something	I move we post pone this matter until	no	yes	yes	majority
Have something studied further	I move to refer the motion to the committee	no	yes	yes	majority
Amend a motion	I move to amend	no	yes	yes	majority
Introduce business (a primary motion)	I move that	no	yes	yes	majority
Object to procedure or to a personal affront	Point of order	yes	no	no	chair decides
Request information	Point of information	yes	no	no	no vote
Ask for a vote by actual count to verify a voice vote	I call for a division	no	no	no	no vote
Object to the consideration of some undiplomatic matter	l object to the consideration of the question	yes	no	no	2/3 vote
Take up a matter previously tabled	I move to take from the table	no	yes	no	majority
Reconsider something already disposed of	I move to reconsider	yes	yes	yes	majority
Consider something vote out of its scheduled order	I move we suspend the rules and consider	no	yes	no	2/3 vote
Vote on a ruling by the chair	l appeal the decision of the chair	yes	yes	yes	majority