NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

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NOSB POLICY AND PROCEDURES MANUAL
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INTRODUCTION

This document is intended as a guide for all members of the National Organic Standards Board (NOSB). 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. As in every business, the Board's success depends heavily upon the ability to understand each other's respective role, and to develop the working relationship necessary within those roles.

This manual is designed to assist the Board in its responsibilities. New Board members are encouraged to review this manual in depth as well as to become familiar with the Organic Foods Production Act (OFPA), 7 CFR Part 205, and the NOSB New Member Guide. 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 and procedures will be incorporated into the NOSB Policy and Procedures Manual from time to time, as determined by the Board.

SECTION I

This section presents the NOSB's vision and mission statement as well as specifics on NOSB members' duties, and professional and ethical standards.

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 STATUTORY MISSION

"To assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of this title." (OFPA, Sec 2119 (a))

NOSB MISSION STATEMENT

To provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program (NOP), and the consensus of the organic community.

In carrying out the mission, key activities of the Board include:

- Assist in the development and maintenance of organic standards and regulations;
- Review petitioned materials for inclusion on the National List of Approved and Prohibited Substances (National List);
- Recommend changes to the National List;
- Communicate with the organic community, including conducting public meetings, soliciting and taking public comments;
- Communicate, support and coordinate with the NOP staff;
- Provide information and education on the NOP.

DUTIES OF THE BOARD AND OFFICERS

The Organic Foods Production Act of 1990 (OFPA) defines the following specific responsibilities for the Board starting at Sec 2119(k)

(1) IN GENERAL.—The Board shall provide recommendations to the Secretary regarding the implementation of this title.

(2) NATIONAL LIST.—The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 2118.

(3) TECHNICAL ADVISORY PANELS.—The Board shall convene technical advisory panels to provide scientific evaluation of the materials considered for inclusion in the National List. Such panels may include experts in agronomy, entomology, health sciences and other relevant disciplines.

(4) SPECIAL REVIEW OF BOTANICAL PESTICIDES.—The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticide should be included in the list of prohibited natural substances.

(5) PRODUCT RESIDUE TESTING.—The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.

(6) EMERGENCY SPRAY PROGRAMS.—The Board shall advise the Secretary concerning rules for exemptions from specific requirements of this title (except the provisions of section 2112) with respect to agricultural products produced on certified organic farms if such farms are subject to a Federal or State emergency pest or disease treatment program.

(Additional Duties included in OFPA but not limited to):

6518(n)PETITIONS. The Board shall establish procedures under which persons may petition the Board for the purpose of evaluating substances for inclusion on the National List.

6509(d)(2) STANDARDS. The National Organic Standards Board shall recommend to the Secretary standards in addition to those in paragraph (1) for the care of livestock to ensure that such livestock is organically produced.

To fulfill their responsibilities, Board members agree to adhere to three duties as described in this Manual:

- **Duty of Care**
- **Duty of Loyalty**
- **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:

- Be reasonably informed—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.

- Participate in decisions—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.

- Make decisions with the care of an ordinary prudent person in a similar position—The law does not expect Board members to act as super human. 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. A Board member's loyalty is to the organic community and the public at large. In dispatching their Duty of Loyalty, Board members must:

- Address conflicts of interest—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.

- Recognize corporate opportunity—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 the NOSB Policy and Procedures 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 members and task force members 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 NOSB 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 members and task force members shall keep confidential all information identified by petitioners as confidential business information.[1]
  - 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

  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:*
  >
  > *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 from 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 manufacture distributes or holds exclusive title to a formula for a material or product, process or practice.*

SECTION II

This section provides a description of the composition the NOSB. It also provides a list of expectations from members and presents guidelines for conducting business.

BOARD MEMBER JOB DESCRIPTIONS

The National Organic Standards Board (NOSB) fulfills three important roles

- 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.
- The Board must approve all materials which appear on the National List.
- The Board maintains the responsibility to protect and defend the integrity of organic standards.

Composition of the Board 6518 (b)

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

(1) four shall be individuals who own or operate an organic farming operation;

(2) two shall be individuals who own or operate an organic handling operation;

(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 areas of environmental protection and resource conservation;

(5) three shall be individuals who represent public interest or consumer interest 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 as identified under section 2116 of OFPA. [§2119(b)]

Additionally, the position of Executive Director of the NOSB was added in 2005 to facilitate contact between NOP and NOSB

BOARD MEMBER STANDARDS

- Participate in meetings—Members must make a commitment to attend meetings of the Board.
- Serve on committees, as assigned—Each member must be willing to serve on committees as assigned by the Chair, and to participate in the work of those committees.
- Be informed about the decisions to be made—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.
- Fully disclose any conflict of interest positions—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

- Quorum—As specified in OFPA, a majority of the members of the Board shall constitute a quorum for the purpose of conducting business. [§2119(h)] A majority of the members of a Committee, including the Executive Committee, shall constitute a quorum for the purpose of conducting business.

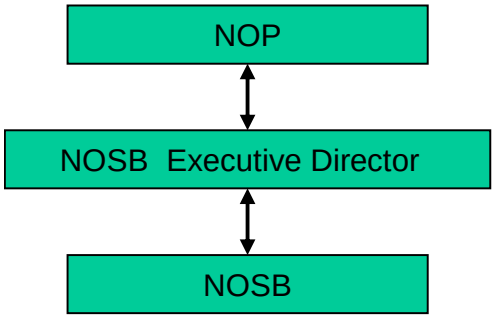
- Decisive votes—As specified in OFPA, two-thirds of the votes cast at a meeting of the board at which a quorum is present shall be decisive of any motion [§2119(i)]. Following Robert's Rules of Order, all abstentions will be recorded as such and will not be included as part of the total vote cast. Similarly, all Board members who recuse themselves due to conflicts of interest, or are absent, shall be recorded as such and their votes will not counted towards the total number of votes cast. Both abstentions and recusals will be considered in order to establish a quorum.

SECTION III

This section focuses on the responsibilities of the NOSB officers, as well as providing the procedures for electing officers, components of the Executive Committee and conducting meetings.

ROLE OF THE EXECUTIVE DIRECTOR

The Executive Director (ED) of the NOSB is the operational liaison to the National Organic Program. The ED is an employee of the U.S. Department of Agriculture and works with the NOP on behalf of the Board on a standing basis.



The most important functions of the ED are outlined below:

- Implement the policies, goals, objectives, strategic plans and recommendations set by the NOSB and NOP.
- Coordinate Board and committee meetings, and manage information reporting and communications between Board and NOP.
- Work as liaison with NOP staff, TAP contractors and other government agencies (e.g., EPA, FDA, AAFCO).
- Coordinate the recording and maintenance of records of all Board and committee meetings. This includes maintaining all board archives and records in a manner that provides for easy access to all public information in cooperation with the Board Secretary.

OFFICER RESPONSIBILITIES

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

Chair

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 and Procedures 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 Board minutes to the Secretary's successor.

The Secretary may delegate tasks to others, 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 standing 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.

MEETINGS

For any in-person meeting, three months' notice should be provided. To the extent possible, the date, time and location of the meeting shall be set by consensus of the Board through E-mail or telephone communication. All E-mail requests should allow 48 hours to respond. For public meetings all NOSB members shall remain at the meeting until the adjournment time (set by agenda) or if the Board Chair officially adjourns the meeting.

For full Board conference calls, three weeks' notice should be given to the members. This will reasonably allow for each to schedule the appropriate time to accommodate the call. The date and time of the call will be set by a consensus of the Board through E-mail or telephone discussion. All E-mail requests for meeting times should allow for 48 hours to respond.

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. For example, at the request of the Secretary seeking advice on a matter related to the NOP, the full Board may request that a committee conduct research and analysis or draft proposed recommendations to be considered by the full Board. Except for the Executive Committee, no committees are authorized to act in place of the Board. Committees are empowered to analyze information and bring draft recommendations to the Board for action.

Committee chairs are appointed by the Board Chair. The current standing committees are:

- Certification, Accreditation, and Compliance
- Crops
- Handling
- Livestock
- Materials
- Policy Development

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.
4. Board takes action on the recommendation.

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.

COMMITTEE MEETINGS

Committees may hold meetings via telephone conference calls. Two weeks' notice should be provided in scheduling such calls. The date and time set for the call is a product of committee dialog regarding the most conducive schedule. This dialog may occur on a previous conference call or through E-mail. All E-mail requests for meeting times should allow 48 hours to respond.

Emergency calls may be scheduled with less notice only after each member is contacted to reach a consensus on time and date of the meeting. If the members do not respond to E-mail requests, the chair or their designee must contact the member by phone.

STANDING COMMITTEES

Certification, Accreditation, and Compliance Committee

The Certification, Accreditation, and Compliance Committee drafts recommendations for consideration by the Board concerning the applicability, certification, accreditation and compliance sections of the organic regulations [7CFR Part 205]

Crops Committee

The Crops Committee drafts recommendations for consideration by the Board concerning the crop production section of the organic regulations as contained in [7CFR Part 205]. The Crops Committee reviews 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 drafts recommendations for consideration by the Board concerning the livestock and livestock feed sections of the organic regulations as contained in [7CFR Part 205]. The Livestock Committee reviews 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 drafts recommendations for consideration by the Board concerning the National List section of the organic regulations as contained in [7CFR Part 205] and OFPA. The Materials Committee works 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 makes draft recommendations for consideration by the Board concerning the handling and labeling sections of the organic regulations as contained in [7CFR Part 205]. The Handling Committee reviews 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 works 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 non-Board members of the public. 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 or when the Board determines the task force is no longer necessary.

SECTION V

This section starts by defining the responsibilities of the different committee chairs and respective vice chairs. In addition, this section covers the general and specific collaboration procedures between NOSB and NOP.

DUTIES OF COMMITTEE CHAIRS

Committee chairs are responsible for the following duties:

- Schedule committee meetings as needed.
- Draft committee meeting agendas and work plans in consultation with committee members and NOP staff.
- Convene and preside at committee meetings.
- Ensure that minutes are taken of committee meetings.
- Review committee meeting minutes for accuracy.
- Report the actions of the committee to the Board.
- Name a committee vice-chair.
- Serve a mentor/trainer for new committee chair during transition periods

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

DUTIES OF COMMITTEE VICE-CHAIR

Committee vice-chairs are responsible for the following duties:

- Provide support in developing and completing committee work plans.
- Represent the committee chair in the absence of the chair.
- Vice Chairs of the Crops, Livestock and Handling Committees will serve on the Materials Committee as a liaison for all petitioned substances.

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

PROCEDURES FOR THE TRANSITION OF COMMITTEE CHAIRS

In order to avoid disruption in the quality and volume of work produced by the NOSB, the appointment of committee chairs will follow these procedures:

- Ideally, the Board Chair should appoint committee chairs from members with at least one year of NOSB experience. It is recommended that a new committee chair should have experience as committee vice-chair.
- Upon appointment, new and outgoing committee chairs should have a formal meeting to exchange all files related to the committee's work and to complete the first committee work plan.
- New committee chairs should review all work plan items and active files involving committee work.
- The outgoing committee chair should work as mentor for the new committee chair and vice-chair for a period of at least two months after transition.

COMMITTEE AND BOARD PROCEDURES ON RECOMMENDATIONS

Committee recommendations are developed as follows:

1. The committee drafts a recommendation;
2. The draft recommendation is posted for public comment;
3. Public comments are considered by the committee when making recommendation to the Board; and
4. The Board takes action on the committee recommendation.

All draft recommendations must be submitted to the NOP at least thirty (30) days prior to the next upcoming NOSB meeting in order to be considered at that meeting.

The Board may take the following actions based on the committee's recommendation:

1. Adopt the recommendation as presented by the committee;
2. Amend and adopt the amended recommendation;
3. Reject the recommendation; or
4. Refer the recommendation back to the committee for further development.

PROCEDURES TO PRESENT COMMITTEE RECOMMENDATIONS

NOSB committees and task forces will follow the outline presented below in order to present draft policy and/or material recommendations for consideration by the Board:

- Introduction—A brief summary of the issue or statement of the problem.
- Background—An explanation with sufficient detail and rationale to support a proposed recommendation, including reasons why the recommendation should be adopted, historical context, and the regulatory framework pertinent to the issue.
- Recommendation—The concise text of the recommended action.
- Committee vote—The vote of the committee or task force shall be reported.
- Minority opinion – If applicable, the dissenting opinion(s) of committee or task force members shall be reported.

NOSB AND NOP COLLABORATION PROCESS

Formal Collaboration Procedures between the NOSB and the NOP

Formal collaboration consists of an interactive relationship between the NOP and the NOSB in ways that ensure that NOSB input and feedback is received by the NOP. Further processes may be needed for the NOP for more than one means of collaborating *with,* or receiving input *from,* the NOSB, depending on the type of issues that arise and the type of action being contemplated.

A single approach to collaborating and receiving input from the NOSB may not suffice to ensure effective program administration. This observation is based on the following factors:

- The NOSB is a FACA advisory committee, and as such, must conduct business in the open, under the requirements of P.L. 94-409, also known as "Government in the Sunshine Act" (5 U.S.C.552b).
- USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice.
- However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.
- The NOSB cannot direct USDA or bind the Secretary through its actions; for example, it can not obligate funds, contract, or initiate policies on its own accord.

General Procedures for Formal Collaboration

1. NOP alerts NOSB of the issue and asks for input, or NOSB alerts NOP of the issue and formulates input.
2. Necessary information, including the issue in writing, research, TAP reports or other studies shall be provided by the NOP or other organizations regarding the issue prior to collaborative discussion.
3. The issue may be placed on the agenda for the next upcoming NOSB meeting.
4. NOSB or NOP may ask for public comment on the issue.
5. NOSB may make a formal recommendation to NOP on the issue.
6. NOP acts on the recommendation (administratively addresses the issue or initiates rule making).

Special Circumstances

There are specific areas in which the formal collaborative process needs to be tailored or modified. Examples below include categories of communications between NOP and NOSB to address the specific issues accompanied by specific procedures to be followed:

1. Materials proposed to be added to or removed from the National List;
2. Standards development or modification;
3. Standards interpretation and questions and answers submitted to the NOP; and
4. Compliance and enforcement.

1. Materials proposed to be added to or removed from the National List

   The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances. Formalized procedures to facilitate the NOSB's role in reviewing and approving materials for the National List include:

   - New petition procedures.
   - Formalized Decision Criteria Forms from the NOSB for providing feedback to NOP on their recommended decisions.
   - Sunsetting of materials every five years.
   - New Technical Advisory Panel (TAP) contractor training for TAP contractors to facilitate quality TAP reviews to provide essential information.
   - Proposed rules to amend the National List based on NOSB recommendations, receive and address comments, and publish the final rule amending the National List.

- Collaborative processes for the review of petitioned substances, including utilization of the Decision Tree.
- Collaboration to determine if draft reports submitted by TAP contractors are sufficient (complete, relevant and understandable.)

2. Standards development or modification for formal recommendation.

   NOSB initiates, through a formal recommendation to NOP, a request for the development of new standards or changes to existing standards. The NOSB will use the Decision Making Procedures as outlined on page 53 to assist in explaining rationale for modifying the existing standards or why new standards are needed. NOP will work with the NOSB to develop proposed regulatory language that expresses the NOSB's desired modification. The NOSB should make a formal recommendation, during a public Board meeting, to the NOP to prompt rule making activity by the NOP. (See examples following this section of formal recommendations.)

3. Standards interpretation and handling questions and answers submitted to the NOP

   In many cases, questions arise from accredited certifying agents (ACA's) and others directed to the NOP about interpreting the existing standards. The follow procedures are to be used to handle these questions:

   - Questions submitted to the NOP will be forwarded to the NOSB electronically as soon as possible.
   - NOP will alert the NOSB as to how NOP would address the incoming question.
   - The Board will assign the appropriate committee to address the question.
   - This committee will receive necessary information from the NOP to help resolve the standards interpretation and questions or will be given the authority to conduct research.
   - Draft answers to standards interpretation or submitted questions developed by committees will be shared with the NOSB and the NOP.
   - The NOSB will act on the committee's recommended response during its next regularly scheduled meeting.
   - If there is a significant difference between NOP and NOSB regarding the interpretation or answer to the incoming question, NOP will be formally address this at the next public Board meeting.
   - If there is not significant difference between NOP and NOSB on the question and answer, NOP will post the question and answer on the NOP web site.

4. Compliance and Enforcement

Compliance and enforcement are the authority of the regulatory body, (NOP). However, there may be significant or sensitive issues that arise as a result of compliance and enforcement actions that should prompt NOP to alert the NOSB for further discussion. In these instances, the NOP will follow the General Procedures for Formal Collaboration as outlined in the beginning of this section.

FORM FOR FORMAL RECOMMENDATION

In submitting formal recommendations to the NOP, the NOSB will utilize the following cover sheet to the greatest extent possible:

Formal Recommendation by the
National Organic Standards Board (NOSB)
to the National Organic Program

Date _____

Subject _____

Chair _____
(Sign)

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action ____
Guidance Statement ____
Other ____

Statement of the Recommendation (Including Recount of Vote):

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

Response by the NOP:

EXAMPLE FORM FOR FORMAL RECOMMENDATION

FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)

Date: March 18, 2006

Subject: ___Calcium Carbonate G & Ac_____

Chair: ___Jim Riddle_____
(sign)

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: _____
Guidance Statement: ____X___
Other: _____

Statement of the Recommendation (Including Recount of Vote):

Question # 1: Does the NOP regulation permit livestock producers to use calcium carbonate as a feed supplement for livestock intended to be sold, labeled, or represented as organically produced? Please provide your rationale.

NOSB Recommended Answer: Yes. Mined calcium carbonate is a nonsynthetic substance allowed for use as a feed supplement or feed additive.

Question # 2: Can a mineral product, such as calcium carbonate, carry the term organic on its label? Please provide your rationale.

NOSB Recommended Answer: No. Section 205.2 defines "organic" as "a labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part."
Calcium carbonate is not an agricultural product and therefore does not qualify to carry the term "organic" under the NOP regulation.

NOSB vote: 14 yes, 0 no, 0 abstain

Rationale Supporting Recommendation (Including consistency with OFPA and NOP):
Rationale explained in attached recommendation.

Response by the NOP:

Updated 2/25/05

SECTION VI

MISCELLANEOUS POLICIES

NOSB Policy for Presenters Invited by Committees

1. Need for presentation established within the appropriate committee by the committee chairperson.

2. The committee chairperson should notify the NOSB Chair with a request to issue an invitation at least 45 days prior to meeting. Exceptions are at the discretion of the NOSB Chair.

3. Presenter(s) must be invited by committee chair and/or NOSB Chair and approved by the NOSB Chair.

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 surveys, including electronic surveys, conducted in the name of any NOSB Committee, must be approved by the NOSB Executive Committee before they are submitted for approval to USDA, which must submit for approval to the Office of Management and Budget (OMB); 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
Amended March 2, 2005

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 sign up.

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.

7. Individuals providing public comment will refrain from any personal attacks and from remarks that otherwise impugn the character of any individual.

Adopted October 19, 2002
Amended March 2, 2005

SECTION VII

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 and 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.

NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND CONSISTENCY WITH ORGANIC FARMING AND HANDLING

A significant task of the NOSB is to determine the suitability of materials for use in organic production and handling. Among the criteria the Board must consider, OFPA requires the NOSB to determine the compatibility of a material with organic practices. The following questions were developed by the NOSB to assist in determining the compatibility of materials with organic practices.

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:

1. Does the substance promote plant and animal health by enhancing the soil's physical chemical, or biological properties?
2. Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
3. 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?
4. Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
5. Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
6. Does the substance allow for an increase in the long-term viability of organic farm operations?
7. Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
8. If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
9. Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
10. Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
11. 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?
12. Does use of the substance have a positive impact on biodiversity?

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

SECTION VIII

PROCEDURES OF THE NOSB

This section presents the procedures followed by the NOSB to evaluate petitions. First, the NOP material review process is presented. Second, a review of the NOSB process for selecting and reviewing the work of technical advisory panels is provided followed by a description needed in a formal petition. Third, the process for NOSB material review is provided. This section concludes by providing a graphical description of the sunset review process.

NATIONAL ORGANIC PROGRAM MATERIALS REVIEW PROCESS

Evaluation Procedures for Substances Petitioned for Addition or Removal from the National List.

Phase 1: Receipt of Petition

During this phase the National Organic Program (NOP) will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.

Phase 2: Examination of Petition for Completeness and Eligibility

During this phase the NOP will:

- Determine whether the petition is complete
- Determine if the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations; document this review using the NOP-OFPA checklist.
- Determine whether the petitioned use is approved under the statutory and regulatory authority of the Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA), if applicable;
- Identify and secure any confidential business information (CBI) designated by the petitioner;
- Notify, as applicable, the petitioner via letter and/or electronic mail of determination of completeness and eligibility, and acknowledge the designation of certain information as CBI.
- Upon determination of completeness and eligibility, the following actions will be taken:
  - Publish the petition on NOP website; and
  - Notify the National Organic Standards Board (NOSB) materials committee chairperson and the chairperson of the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling). This notification will be sent via letter and/or electronic mail and inform the chairs that the petition is complete, provide

OFPA review and EPA/FDA determination checklist, and request identification of any questions the appropriate committee wishes to be specifically addressed in the contractor's report. The NOSB materials committee, working with other applicable NOSB committees, has 21 working days to submit any questions to the NOP. The questions requested by the committee should include items that need specific background information provided and be based on the OFPA criteria.

  - Notify the contractor of the determination of completeness and eligibility via letter and/or electronic mail. This letter will constitute official notice to the contractor to perform an evaluation of the petitioned substance.

- Notify, as applicable, the petitioner via letter and/or electronic mail of determining the petition to be incomplete or ineligible.

Phase 3: Evaluation by Contractor

During this phase the contractor will:

- Conduct activities necessary to provide responses to evaluation questions contained in the Statement of Work (SOW) and any additional questions identified by the NOSB as described above;
- Use the evaluation report template to prepare and distribute to the NOP a draft evaluation report in electronic format.

Phase 4: Sufficiency Determination

During this phase the NOP will:

- Submit a copy of the draft evaluation report for review to the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling);
- Review the draft evaluation report against the following performance criteria. The report will be acceptable when it:

  - Is consistent in format, level of detail and tone;
  - Is technically objective and free from opinions or conjecture;
  - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
  - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
  - Is based on the best available information that can be obtained within the designated time frame;
  - Is thoroughly supported using literature citations; and,
  - Addresses all evaluation questions as set out in the SOW.

During this phase the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling) will:

- Review the draft evaluation report against the following performance criteria. The report will be acceptable when it:
  - Is consistent in format, level of detail and tone;
  - Is technically objective and free from opinions or conjecture;
  - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
  - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
  - Is based on the best available information that can be obtained within the designated time frame;
  - Is thoroughly supported using literature citations; and,
  - Addresses all evaluation questions as set out in the SOW.
- Notify the NOP in letter and/or electronic mail the acceptance of the report within 21 days of receiving the draft report. If the report is not accepted by the NOSB materials and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling), the committees must provide to the NOP in letter and/or electronic mail the specific areas of the report that were concluded to be insufficient, the rationale for drawing such a conclusion and the improvements to be made so that the document can be determined sufficient.
- Upon concurrence by the NOP that the report is insufficient, the NOP will notify the contractor by letter and/or electronic mail of the areas of the report that are insufficient, the rationale for drawing such a conclusion and the improvements to be made so that the document can be determined sufficient. The time frame required for the completion of the changes will be determined through mutual agreement between the contractor and the NOP.

Phase 5: Action by NOSB Materials Chair and the Committee that the Substance Is Being Petitioned for Addition or Prohibition from the National List (Crops, Livestock or Handling)

During this phase the NOSB materials Chair and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling) will:

- Convene at a mutually convenient time to review, discuss and recommend an action on the petitioned substance. The committee may convene a Technical Advisory Panel by electronic mail or conference call to provide scientific evaluation of the petitioned substance, as provided by OFPA 6518(k)(3). The NOSB materials committee or delegated committee must convene and recommend an action on the petitioned substance no later than 30 days before a scheduled meeting of the full NOSB.

During this phase the NOP will:

- Publish the recommendation of the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling) on the NOP website and request public comment on the recommendation.

Phase 6: Action by Full NOSB

During this phase the NOP will:

- Set as an agenda item for the next meeting of the NOSB time sufficient to discuss and make a recommendation by the full NOSB on the petitioned substance.

TECHNICAL ADVISORY PANEL (TAP) CONTRACT PROCEDURES

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.

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 Federal Register 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)(l-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:

- Processing aid or adjuvant cannot be produced from a natural source and has no organic ingredients as substitutes;
- 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;

- The 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 1: 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 2: 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 substance should be added to or removed from the National List.

Phase 3: 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

Any person may petition to add a substance to or remove a substance from the National List of Allowed and prohibited Substances by submitting the information and following the procedures identified below.

ITEM A

The petitioner should identify which of the following categories the 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;
5. Nonagricultural (nonorganic) substances allowed in or on processed products labeled as “organic'' or “made with organic (specified ingredients)'; or
6. Nonorganic agricultural substances not commercially available in organic form.

ITEM B

The petitioner must submit the following information:

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:

- 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.
- “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.
- 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."
- 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 CBI-deleted copy.
- 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."
- 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.")
- 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.

National List substance evaluations conducted by the NOSB 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.

NOSB COMMITTEE RECOMMENDATION

Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meeting: _____ **Substance:** _____

Committee: Crops ☐ **Livestock** ☐ **Handling** ☐ **Petition is for:**_____

_____ **on the National List § 205.**_____

A. Evaluation Criteria (Applicability noted for each category; Documentation attached) **Criteria Satisfied? (see B below)**

1. Impact on Humans and Environment Yes ☐ No ☐ N/A ☐
2. Essential & Availability Criteria Yes ☐ No ☐ N/A ☐
3. Compatibility & Consistency Yes ☐ No ☐ N/A ☐
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for 606) Yes ☐ No ☐ N/A ☐

B. Substance Fails Criteria Category: _____ Comments: _____

_____

C. Proposed Annotation (if any): _____

_____

Basis for annotation: To meet criteria above: _____ Other regulatory criteria: _____ Citation:_____

D. Recommended Committee Action & Vote (State Actual Motion): _____

_____

Motion by: _____ *Seconded:*_____ *Yes:* _____ *No:* _____ *Absent:* _____ *Abstain:* _____

Crops		Agricultural		Allowed[1]	
Livestock		Non-Synthetic		Prohibited[2]	
Handling		Synthetic		Rejected[3]	
No restriction		Commercially Un-Available as Organic[1]		Deferred[4]	

1) Substance voted to be added as "allowed" on National List to § 205._____with Annotation (if any) _____

_____

2) Substance to be added as "prohibited" on National List to § 205._____with Annotation (if any) _____

_____

Describe why a prohibited substance:_____

_____

3) Substance was rejected by vote for amending National List to § 205. _____ Describe why material was rejected:_____

_____

4) Substance was recommended to be deferred because _____

_____

If follow-up needed, who will follow up _____

E. Approved by Committee Chair to transmit to NOSB:

_____ _____

Committee Chair **Date**

EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

Category 1. Adverse impacts on humans or the environment? Substance _____

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on 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]				
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 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]				

[1] 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[1]	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]				
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]				
9. Is there any alternative substances? [§6518 m.6]				
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]				

[1] 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[1]	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?				

[1] 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 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]

Substance _____

Question	Yes	No	N/A[1]	Documentation (TAP; petition; regulatory agency; other)
1. Is the comparative description provided as to why the non-organic form of the material /substance is necessary for use in organic handling?				
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?				
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?				
5. Does the industry information provided on material / substance non-availability as organic, include (but not limited to) the following: a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Are there other issues which may present a challenge to a consistent supply?				

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOP

For NOSB Meeting: _____ | Substance: _____

A. Evaluation Criteria (Documentation attached; committee recommendation attached)

	Criteria Satisfied?
1. Impact on humans and environment	Yes No (see B below)
2. Availability criteria	Yes No (see B below)
3. Compatibility & consistency	Yes No (see B below)

B. Substance fails criteria?

Criteria category: _____

Comments:

C. Proposed Annotation: _____

_____

Basis for annotation:

To meet criteria above: ____ Criteria: _____

Other regulatory criteria: ____ Citation:_____

D. Final Board Action & Vote: Motion by: _____ Second:_____

Vote:

Yes:

No:

Abstain:

Agricultural		Nonagricultural		Crops	
Synthetic		Not synthetic		Livestock	
Allowed[1]		Prohibited[2]		Handling	
No restriction		Deferred4		Rejected[3]	

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:

Return to NOSB Reason: _____

_____ _____

Richard H. Mathews, Program Manager 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.

4. 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.

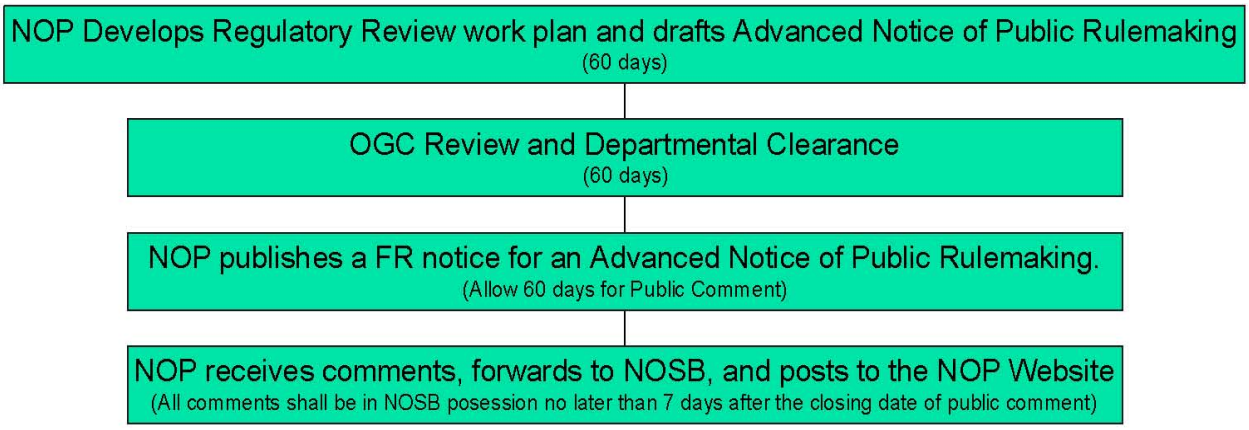
5. The Chair of each committee will present the Board with the committee's written votes and recommendations during the Materials Review process at the NOSB meeting. The recommendation should come in the form of a motion which must be seconded by an NOSB member to move forward. The process will follow 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.

SUNSET REVIEW PROCESS

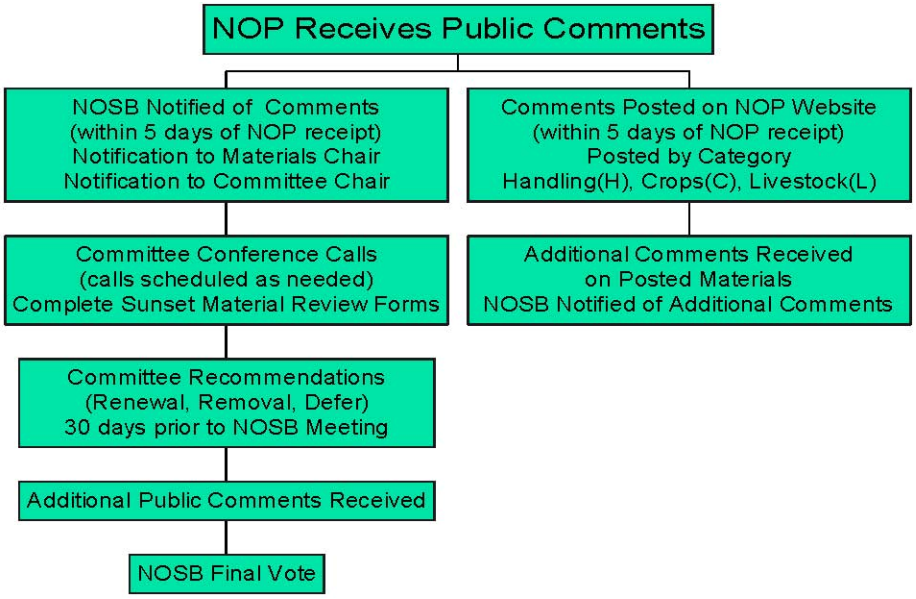
NATIONAL LIST SUNSET REVIEW PROCESS – NOP Level



OVERVIEW OF THE SUNSET PROCESS-STEPS COMPLETED

- FEDERAL REGISTER NOTICE
- RECEIPT OF PUBLIC COMMENTS
- COMMITTEES FORWARDED RECOMMENDED SUBSTANCES FOR FURTHER TECHNICAL REVIEW TO NOP

NATIONAL LIST SUNSET REVIEW PROCESS – NOSB Level



SUNSET PROCESS-IN PROGRESS

- COMMITTEES REVIEWING SUBSTANCES UNDER SUNSET REVIEW
- COMMITTEES REVIEWING PUBLIC COMMENTS
- COMMITTEES DRAFTING RECOMMENDATIONS ON SUBSTANCES
- COMMITTEES FORWARDING SUBSTANCES FOR ADDITIONAL TECHNICAL REVIEW BASED ON PUBLIC COMMENTS

Committee substance Forms

- Sunset Review Committee Forms
- Name of Substance
- National List Section, use and annotation if applicable
- Comment (s) code number (s)
- Status (record number of comments)
    - Renewal ( )
    - Removal ( )
- Summary of comment (s)
- Committee recommendation

Committee Recommendations

Committees will recommend to the full Board a determination on each substance for renewal, removal or deferral to seek specific technical information from the TAP contractors. TAP contractors shall be used to verify information provided by the commenters, research or seek additional information requested by the committee.

Since sunset is defined as the reviewing of regulations to ensure the continued relevance and not the creation of new regulation, all substance must be renewed as listed. Annotations cannot be included in a recommendation during sunset review. If there is a need to consider changing an annotation or moving a material from one list to another, this may be accomplished through the existing procedures for petition.

Clarification for deferral

A committee has the option of postponing, or deferring, a decision on a substance based on several factors including:

- Emergence of information that had not been considered and requires more time on the part of the committee members to verify such information.
- Request from the public provide more information that might affect the decision
- Concern over unknown market impact.
- Lack of information necessary to make a decision against or in favor of the

The decision to defer should be voted by the committee and should be approved with a majority of votes cast and reported to the full board while in session. The report the Board should provide the following:

- Reasons for deferral
- Deferral period – Note that the Board needs to complete a vote on deferred materials as soon as possible.
- Committee votes
- Minority opinion

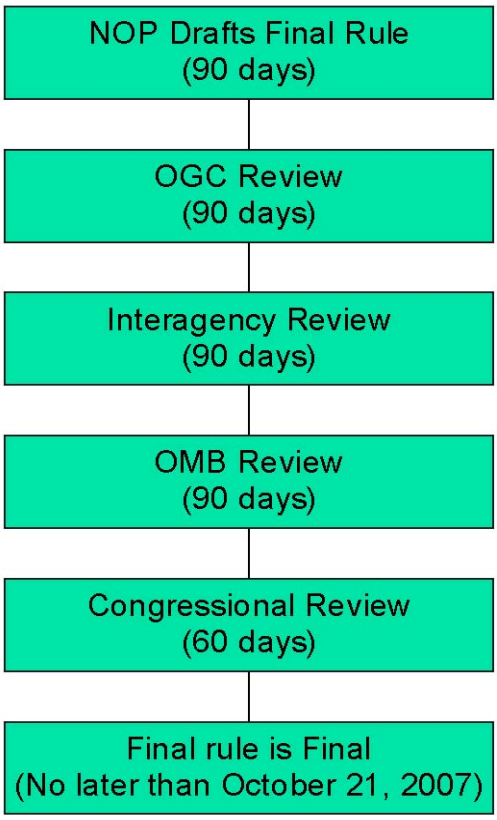
Public Comment and Final NOSB Vote on Recommendations

- Each committee will provide their recommendation to the board on each substance 30 days prior to the full Board meeting. The recommendation will be posted on the website and open to public comment.
- NOSB Final Vote

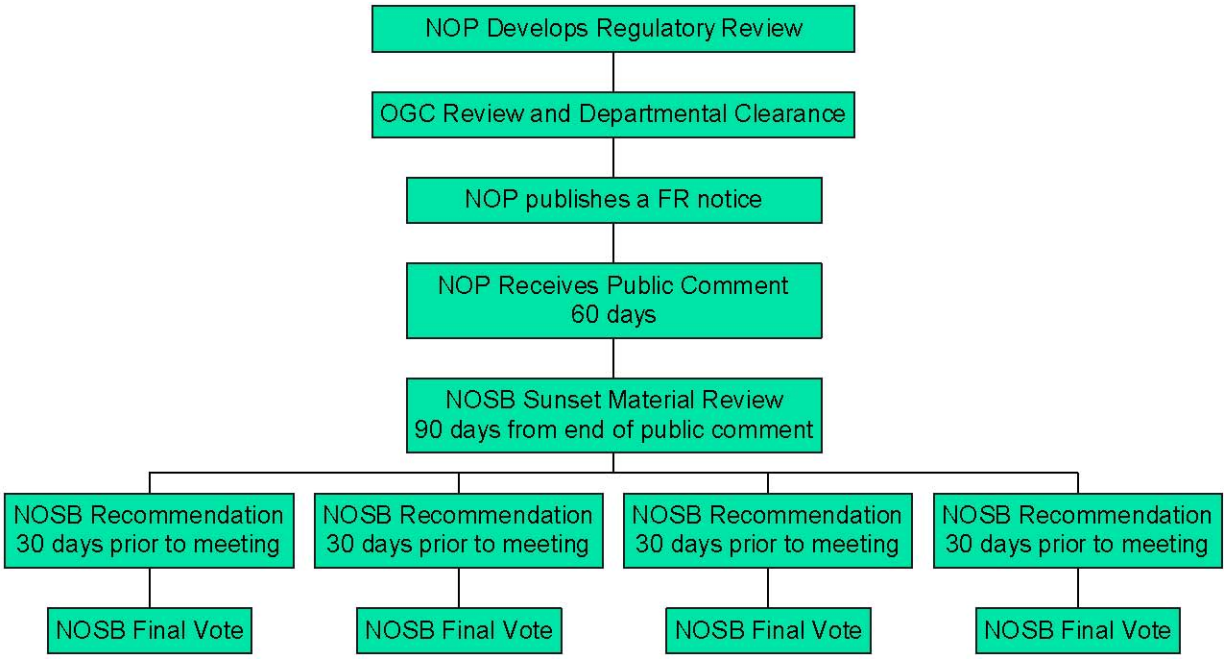
Rulemaking on NOSB Recommendations

- NOP Rulemaking
- Dockets of materials for renewal based on the assumption that deferred materials may take some additional time for review and a full board vote After each NOSB meeting, the NOP would begin rulemaking on those substances that were voted for renewal. The materials committee anticipates at least two.

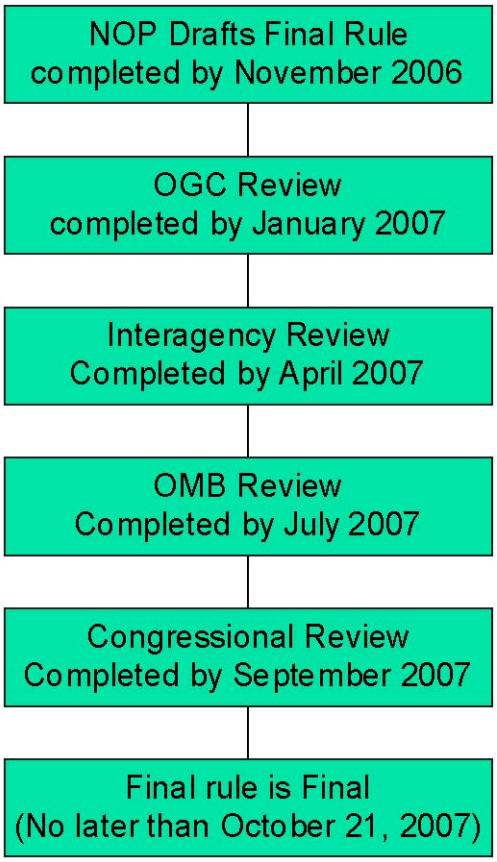
National List
Sunset Review Process



Sunset Timeline



Sunset Timeline



APPENDICES AND RESOURCES

Appendix A - 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

Appendix B - FACA FACTS

1. 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. Although not required by FACA, the NOP strives 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

Appendix C - 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:

1. Must approve or call the meeting of the NOSB;

2. Must approve the agenda;

3. Must attend the meetings;

4. Shall adjourn the meetings when such adjournment is in the public interest; and

5. Chairs the meeting when directed by the Secretary of Agriculture or the Secretary's designee.

Appendix D - 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	I 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	I appeal the decision of the chair	yes	yes	yes	majority
Table a motion - take matter from table	I move to take from the table	No	Yes	No	majority
Rescind motions – Cancel previous action	I move to rescind	No	Yes	Yes	2/3 vote

Source: Robert's Rules of Order

Appendix E - BASIC CHEMISTRY

The science of chemistry deals with the structure of matter--material things--and the changes that matter undergoes. Matter can exist in any size, shape, or color. It is solid, liquid, or gas; living or nonliving. Chemistry seeks to identify the simplest parts of matter; how they are separated and purified; how they are put together; how they are rearranged to produce new forms of matter; and what energy is absorbed or released when such rearrangements are made (Matta and Wilbraham, 1986). A distinction should be made between chemical and physical changes. The OFPA and NOS definition of synthetic specifically mentions chemical change but not physical change. A physical property is a quality or condition of a substance that can be observed or measured without changing the substance's composition. It can be specified without reference to any other substance. Other physical properties of matter include color, solubility, mass, odor, hardness, density, electrical conductivity, magnetism, melting point and boiling point. Physical properties help chemists identify substances (Matta and Wilbraham, 1986). When contractors are hired to technical review of substances for the NOSB and USDA/NOP, they typically list the physical properties of the substances in their review because this is the common way in which substances are described.

Physical changes may result when the temperature of a substance changes. Raising the temperature of a solid may turn it into a liquid (i.e., ice turns into water). A conversion without causing a change in the composition of the substance is called a physical change (Matta and Wilbraham, 1986). When ice undergoes the physical change of melting, this change does not change the nature of water. The physical properties are the same for water that has been frozen and melted as for water that has been converted into steam and then condensed (Matta and Wilbraham, 1986). Historically, the organic industry and the NOSB have acknowledged that physical changes do not render a substance synthetic.

However, there are some substances that have been identified where high temperatures during manufacturing do engender a chemical change in the substance. An example is mined minerals. Historically, the industry and NOSB has recognized that burning or excessive heating of mined mineral is considered to render them synthetic. Formerly, NOSB defined mined minerals as any naturally-occurring non-living substance derived from the earth or water. A mined mineral cannot have undergone molecular change through heating, acidification, basification or fortification with synthetic materials (NOSB Final Recommendation Addendum Number 25, Definitions and Interpretations, Austin, Texas, 1995). Therefore, heat can alter the physical properties of a substance and for other substances act as a catalyst in chemical reactions or change.

In a chemical reaction, the starting substance or substances, referred to as reactants, are changed into new substances or products. Chemists use an arrow as a shorthand form of the phrase "are changed into"; reactants products (Matta and Wilbraham, 1986). An example to distinguish between physical and chemical changes is illustrated when sulfur (a solid) is added to iron filings (a

solid). They may be separated unchanged from a mixture of the two substances mixed together. This separation is an example of a physical change. If the mixture of these two substances is heated, a chemical change takes place and the sulfur and iron are changed into a nonmagnetic substance, iron sulfide: Iron + Sulfur Iron Sulfide (Matta and Wilbraham, 1986). A substances' composition and behavior in chemical reactions--its chemical reactivity--comprise its chemical properties.

What is a substance?

In chemistry, a pure **substance** is a homogenous material that has a definite chemical composition throughout. There are two kinds of pure substances. One kind can be decomposed into two or more different substances by simple chemical change; these are called **compounds**. There are many millions of compounds.

An example of a compound is pure table salt, which can be decomposed into sodium and chlorine by an appropriate process. Many of the substances on the National Lists of Synthetic substances allowed for use in organic crop and livestock production (Sections 205.601 and 205.603) are compounds. Examples include: isopropanol, chlorine dioxide, ammonium carbonate, lime sulfur and copper sulfate.

The second kind of pure substances are called **elements**, which cannot be decomposed by chemical change. There are 90 natural elements; examples are gold, copper, oxygen, sulfur and hydrogen. Elements cannot be separated into simpler substances by chemical reactions. An example of an element on the National List is sulfur (elemental) for crop production (205.601(e)(3))(Boikess and Edelson, 1978).

Mixtures consist of a physical blend or two or more substances in which the combined substances retain their identity. Most materials found in nature are mixtures. Mixtures can be either homogeneous (same composition throughout) or heterogeneous (has non-uniform composition). A **solution** is a type of a mixture where there is a homogeneous combination of different substances. The difference between a heterogeneous mixture and a solution is that any sample of a solution has the same composition, while the composition of a mixture is not the same throughout. Solutions may be gaseous, liquid or solid. Examples of mixtures on the National List are aquatic plants and fish emulsions. The various compounds and elements that make up these products are within the plant, animal or mineral. When a particular component of the plant is desired for use in an agricultural input it typically has to be extracted and in many cases undergo additional chemical reactions to make it into a substance that is functional when combined with other substances.

A distinction should be drawn between a mixture and a compound**.** ***The elements making up a compound cannot be recovered without a chemical change*****.** The substances making up a mixture or solution can. Some mixtures

can be separated into their various components by simple physical methods. An example is a gray-colored mixture produced by stirring together powdered yellow sulfur and black iron filings. The individual particles of sulfur and iron can be readily distinguished from one another under a microscope. The mixture is easy to separate because the iron filings can be removed from the mixture with a magnet leaving sulfur behind. Both the sulfur and the iron are unchanged in composition (example from Matta and Wilbraham, 1986).

The substances making up a mixture or a solution need not be elements. For example, one can prepare a solution by dissolving salt, a compound, in water another compound. In addition, the substances making up a mixture or a solution can be combined in varying proportions. The elements in a compound have fixed proportions. (paragraph found in Boikess and Edelson, 1978). Main groups of compounds can be classified based on similar chemical properties. The following are descriptions of each group (Boikess and Edelson, 1978).

Salts: a compound of a metal and nonmetal, or of a metal with a negative polyatomic group. Compounds that have an ammonium group (NH_4^+) instead of a metal are also classified as salts. Some salts are NaCl, KCl, $KMnO_4$ and NH_4Cl. A salt is an ionic solid a room temperature. Most have two ionic components (a) a cation, which can be a polyatomic group such as ammonium or a monoatomic metal such as Na^+, K^+, Ca^{2+} or Mn^{3+} and (b) an anion, which can be a negative polyatomic group or a monoatomic ion such as Cl^- or NH_3^-. A solid salt consists of ions in close association. When the salt dissolves in water, the ions are separated. Substances that exist as ions in solution are called electrolytes. When NaCl dissolves in water, the correct formula is $Na^+ + Cl^-$. This formula treats the component ions of the salts as independent entities, which is approximately how they behave in water solution. Salts are called strong electrolytes because they usually separate completely into ions in water. (Boyd text)

Acids: a compound that is a source of H^+ ions. An acid is usually a compound of hydrogen and a nonmetal or a negative polyatomic group. Unlike salts, acids usually are not aggregates of ions. An acid may be a gas (hydrochloric), liquid (sulfuric) or a solid (oxalic). Like salts, acids tend to form ions when the dissolve in water. When a substance separates into ions it is said to dissociate. Some acids dissociate completely and are called strong acids. Most acids dissociate only partially when dissolved in water. These are called weak acids, they are weak electrolytes.

Bases: a compound that is a source of OH^- ions in water solution. A compound of a cation and the OH^- anion is a base. Bases resemble salts in many ways.

They are ionic solids that dissociate into ions when dissolved in water. Bases that contain a cation and OH^- are generally dissociate completely in water and are classified as strong bases. Some strong bases are NaOH (sodium hydroxide) and KOH (potassium hydroxide). Compounds that do not contain hydroxide ions are defined as bases if they produce OH^- ions by reaction with water. An example is ammonia (NH_3) which reacts with water to produce hydroxide ions.

Nonelectrolytes: Compounds containing only nonmetals usually exist as discrete molecules, rather than collections of ions. These compounds do not dissociate into ions when they dissolve in water. Many organic compounds are nonelectrolytes and they will not dissolve appreciably in water i.e. oil. Some will dissolve in water, although they will not dissociate into ions i.e. sugar, and ethyl alcohol.

Oxides: is a binary compound of any element with oxygen, when the oxygen has an oxidation number of $^{-2}$. Almost every element forms at least on oxide. The properties of oxides vary widely- depending on the element they may resemble a salt, acid, base or non electrolyte.

What constitutes a chemical change?

The chemical properties of a substance are those that describe the way in which it can undergo change, either alone or in interactions with other substances, to form different materials. Such changes are called chemical reactions. The chemical properties that are characteristic of any substance can be described- iron combines readily with oxygen to form the compound called rust. (Boikess and Edelson, 1978). The following are common types of chemical reactions that describe what is happening when different substances and compounds interact (Boikess and Edelson,1978).

1. Addition or combination reaction: Two substances combine to form one:
   $2Na+Cl_2$----2NaCl
2. Decomposition reactions: One compound breaks into two or more compounds or elements. $CaCO_3$-------CaO + CO_2
3. Displacement reactions: Substances exchange parts. There are many types of these reactions but one of the most important is called metathesis which is the exchange of ions by two ionic compounds, with the anion of one compound joining the cation of the other compound and vice versa. AB+CD-AD + CB

   a. 1. Hydrolysis is a displacement reaction of a substance or ion with water. Water is a source of both H^+ and OH^- ions. The OH^- anion combines with the positive portion of the compound that is hydrolyzed. This positive portion may be a cation or an atom with a positive oxidation number. The H^+ cation combines with the

negative portion of the compound, which may be an anion or an atom with a negative oxidation number.

b. Acid-base reaction: an acid is a substance that can donate a proton, and a base is a substance that can accept a proton.

Since many materials used in organic agriculture are derived from plants and animals it is important to mention chemical reactions that occur in by products of these organisms. In living organisms, enzymes play the role in catalyzing a specific reaction or type of reactions. Proteins are substances extracted from living organisms that maybe utilized in materials that are petitioned for use in organic production. Proteins are sensitive to relatively small changes in pH, temperature, or solvent composition may cause them to denature. Denaturation causes physical change, the most observable result is loss of biological activity. Except for cleavage of disulfide bonds, denaturation stems from changes in secondary, tertiary, or quaternary structures through disruption of noncovalent interactions, such as hydrogen bonds, salt linkages and hydrophobic reactions. Common denaturing agents include the following:

1. Heat--most become denatured when heated above 50-60 degrees C.
2. Large changes in pH--adding concentrated acid or alkali to a protein in a aqueous solution causes changes in the charged character of ionizable side chains and interferes with salt linkages.
4. Detergents--treating a protein with sodium dodecylsulfate (SDS), a detergent, causes the native conformation to unfold and exposes the nonpolar protein side chains to the aqueous environment. These side chains are then stabilized by hydrophobic interaction with hydrocarbon chains of the detergent.
5. Organic Solvents- such as alcohols, acetone or ether.
6. Mechanical treatment. Most globular proteins denatured in aqueous solution if they are stirred or shaken vigorously.
7. Urea and guanidine hydrochloride- These substances can cause disruption of protein hydrogen bonding and hydrophobic interactions.

Denaturation can be partial or complete. It can also be reversible or irreversible. Irreversible denaturation causes a fundamental change in the protein, in particular destroying any physiological (biological) activity. In the case of reversible denaturation, the change may only be temporary (Brown, 1988).

References:

Boikess, R.S. and Edelson, E. Chemical Principles. Harper and Row, New York, 1978.

Brown, W.H. Introduction to Organic Chemistry. Brooks/Cole Publishing Company, California, 1988.

Matta, Michael, and Wilbraham, A.C. General, Organic and Biological Chemistry. Benjamin/Cummings Publishing Company, California, 1986.