

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

Date: April 29, 2010
Subject: Policy and Procedures Manual Changes
Chair: Daniel G. Giacomini

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other: X

Summary Statement of the Recommendation (including Recount of Vote):

Recommendation that a two tiered voting approach for materials petitioned to the National List be established and that the PPM be revised to incorporate the change.

NOSB Vote: **Motion:** Steve DeMuri **Second:** Tracey Miedema

Board vote: Yes - 14 No- 0 Abstain- 0 Absent - 1

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

During the petitioned material evaluation process, it is important that the reviewing committee first properly classify the material as non-synthetic or synthetic.

Response by the NOP:

National Organic Standards Board Policy Development Committee

Materials Petitioned for Addition to the National List Two Tiered Voting

February 22, 2010

I. Introduction

In order to align NOSB material reviewing committees (Crops, Livestock, and Handling) with classification of materials definitions and procedures, and to correctly categorize materials petitioned to be included on the National List, the Policy Development Committee recommends establishment of a two tier voting process for materials petitioned to be added to the National List.

II. Background

During board discussions regarding the Definition of the Classification of Materials, the importance of a synthetic or non-synthetic determination for petitioned materials has proven to be a critical component of material classification. According to archived NOSB meeting transcripts and written recommendations, in the past, material reviewing committees and the NOSB voted in two stages, the first for whether a petitioned material was synthetic or non-synthetic, and the second for or against listing of that petitioned material. At some point in time, this two tier voting procedure was abandoned, and only the vote to list or not currently remains. The reason for this change is not clear, but the Policy Development Committee was asked to consider re-establishment of a two tier voting process for materials petitioned for addition to the National List.

III. Relevant Areas in the Rule:

Sections §205.600, §205.601, §205.602, §205.603, §205.604, §205.605, and §205.606.

IV. Discussion:

During the petitioned material evaluation process, it is important that the reviewing committee, to the best of it's ability, classify substances as non-synthetic or synthetic to provide for correct placement on the National List, and to provide direction to the organic industry on matters impacted by material classification, such as commercial availability scrutiny. Since this determination can be complex at times, a vote of reviewing committee members, and then the full NOSB, will help assure that the majority opinion regarding classification will rule. In this recommendation, applicable sections of the NOSB Policy and Procedure Manual have been revised to include a two-tier voting procedure for materials petitioned to be added to the National List for crop production, livestock production, or for handling operations. Sunset material recommendations and petitions to remove materials from the National List would not be impacted by this recommendation. Additionally, the form used by the NOSB to transmit material recommendation results to the National Organic Program has been modified to include the

synthetic / non-synthetic vote. The vote tally format for the listing / non-listing recommendation remains the same.

V. Recommendation:

The Policy Development Committee recommends that a two tiered voting approach for materials petitioned to the National List be re-established, and that the Policy and Procedure Manual be revised to incorporate this change, as attached.

VI. Committee Vote:

Motion:	Steve DeMuri	Second:	Barry Flamm
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Yes: 4	No: 0	Absent: 1	Abstain: 0
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NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

Adopted October 19, 2002
Revised August 18, 2005
Revised March 29, 2007
Revised November 30, 2007
Revised May 22, 2008
Revised November 19, 2008
Revised May 6, 2009

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 or deletion from 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 provide timely information and education on the NOP, making reasonable use of a variety of communication channels.
- Communicate, support and coordinate with the NOP staff;

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**

- o Public service is a public trust, requiring ethical principles above private gain.
- o NOSB members shall put forth honest effort in the performance of their NOSB duties.
- o NOSB members shall make no commitments or promises of any kind purporting to bind the Government.
- o NOSB members shall act impartially and not give preferential treatment to any organization or individual.
- o 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.
- o 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.”
- o NOSB members, committee members and task force members shall keep confidential all¹ information identified by petitioners as confidential business information.
- o 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.
- o 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

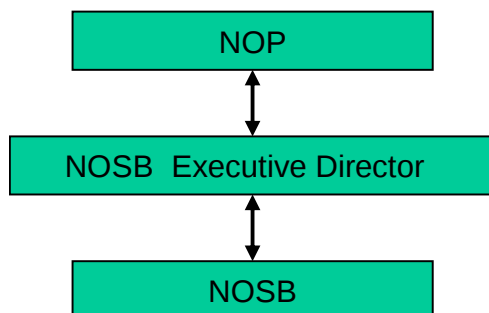
- Quorum—As specified in OFPA, a majority of the members of the Board shall constitute a quorum for the purpose of conducting business. [§2119(h)] A majority of the members of a Committee, including the Executive Committee, shall constitute a quorum for the purpose of conducting business.
- Decisive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



- Assist in the implementation of policies, goals, objectives, strategic plans, committee work plans, and recommendations set by the NOSB and NOP.
- Draft initial NOSB meeting agendas with NOSB Chair based on committee work plans for NOSB and NOP discussion, then finalizes agenda.
- Coordinate Board and committee meetings, and manage information reporting and communications between Board and NOP.
- Arrange, facilitate, and record the minimum number of NOSB Committee conference calls necessary to achieve the most efficient workings of the Board. Minutes are distributed to committees for confirmation they are accurate. Final minutes are timely distributed to Board committees.
- Provide training and information to NOSB and task forces on compliance with all pertinent Acts and regulations (e.g., FACA, OFPA, NOP), including their role in advising the Secretary.
- Establishes and monitors Board adherence to timelines which ensure NOP has sufficient time to publish related Federal Register notices and Board/Committee recommendations that meet deadlines for public comment.
- Manage Board calendar and tracking databases in a manner that facilitates clarity of activities to the Board and the NOP.
- Work as liaison with NOP staff, TAP & technical review contractors and other government agencies (e.g., EPA, FDA, AAFCO).
- Ensure Board members have all materials and information necessary to provide informed, structured and timely recommendations to the NOP for proposed amendments and guidances to NOP regulation 7 CFR 205. This includes the provision of petitions, TAP and technical reviews, and historic discussions of substances proposed for inclusion on the National List, as well historic discussions and recommendations regarding issues.
- 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.

- Prepare and clear Federal Register Meeting Notice and News Release, ensuring publication 45 days prior to meeting.
- Ensure proposed additions to the National List, or other recommendations, are posted on the NOSB website for 45 days prior to an NOSB meeting to allow for public comment.
- Provide accurate, clear pre-meeting information to public regarding questions on recommendations.
- Ensure NOSB members have timely access to public comments.
- Schedule public comment according to issues, and accommodates commenters' travel schedules, where possible.
- Ensure that Board members and NOP staff at NOSB meetings have access to relevant documents related to petitions, materials due to sunset, technical reviews, etc. The format could be electronic (CD version) or hard copy.
- Track recommendations, changes, and votes during meeting to ensure accurate meeting transcripts.
- Assist the NOSB Officers as needed, including scheduling and participating in Officer calls, and assisting the Secretary during Board meetings in managing public comments, summary of minutes, committee votes, election of officers, Board meeting breaks. Also stays apprised and assist as needed in committee meetings scheduled before, during and after Board meetings.

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;
- Review meeting minutes for accuracy, and
- Assist with the annual election of NOSB officers.

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 of the Board, with the assistance of the Executive Director, shall review all additions to the Federal Register and report to the Board any discrepancies between the Board recommendation and those published in the Federal Register. 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;
- Transfer custody of the Board minutes to the Secretary's successor, and
- Assist with the annual election of NOSB officers.

The Secretary may delegate tasks to others, but retains responsibility for the official record.

ELECTION OF OFFICERS

A. NOMINATION

- All interested NOSB members are eligible for consideration for any officer position.
- Candidates may be self-nominated or nominated by another member of the Board.
- Should the Vice Chair or Secretary 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.
- Members interested in serving more than one consecutive term in an officer position can if the Board is in favor; however it is recommended that an officer not serve for more than two consecutive terms.

B. VOTING SCHEDULE

- Officers shall be elected for terms of one year by majority vote at the annual fall meeting of the Board.
- Newly appointed officers will assume their positions at the conclusion of the fall Board meeting pursuant to the election.
- Acting Board officers will assist the new officers to transition into their new role.

C. ELIGIBILITY TO VOTE

- Only NOSB Board Members present are eligible to vote for nominated officers.
- Absent NOSB members will not be eligible to vote.
- Board members shall be entitled to cast one vote per nomination.

D. COUNTING OF VOTES

- Voting will be by ballot immediately following nominations for each office.
- Ballots for officers will be cast in the following order:
 1. Chair
 2. Vice-Chair
 3. Secretary
- The ballots will be counted for one office and the acting Chair will announce the tally before the next office is opened for nominations
- The acting Secretary will prepare and distribute the ballots and will gather the votes by secret ballot.
- The acting Chair will tally the votes after each officer nomination and the acting Secretary will verify the vote results.
- The candidate receiving the largest number of votes will be elected.
- In the event of a tie there will be a revote until a nominee obtains majority. All nominees will be included in the revote or may be given the opportunity to withdraw at their discretion. .

- Member vote counts will remain confidential. Other NOSB members will not be allowed to determine how the members voted.
- Votes will be disposed of by the Chair or Secretary.
- The acting Secretary will record newly elected officers into the NOSB Meeting Summary of Minutes.

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. Only the full Board may take decisive action on guidance and other policy recommendations from committees, including the status of materials proposed for addition or deletion on the National List. The Executive Committee will provide guidance and feedback to Committees on their proposed work plans.

MEETINGS

All Board meetings, conference calls, and bulletin board assembled for the purpose of making recommendations to the NOP are subject to FACA (see appendix B for FACA facts). In particular, these must be open to the public and must meet public notification requirements. Not all meetings are subject to FACA and do not require public notification. Examples are: assemblies for completing work, planning retreats, training and sharing information. At this time, full Board conference calls or full Board assembly via electronic bulletin board are not permitted. The date and location of periodic full in person Board Meetings (normally twice a year), will to the extent possible, be set by consensus of the Board in consultation with the NOP.

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.

1. Committee recommendations are finalized by the NOSB according to the following process:
2. Committee drafts the recommendation.
3. Draft recommendation is posted for public comment.
4. Public comments are considered by committee when making recommendation to the Board.
5. 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 (CACC) The Certification, Accreditation, and Compliance Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of certification, accreditation and compliance sections of the organic regulations [7CFR Part 205] and OFPA. The CACC occasionally works with other committees to develop joint recommendations where certification and compliance issues are involved.

Crops Committee (CC) The Crops Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the crop production section of the organic regulations as contained in [7CFR Part 205] and OFPA. The CC reviews petitions, substances scheduled to sunset, 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. The CC occasionally works with other committees to develop joint recommendations where crop issues are involved.

Handling Committee (HC) The Handling Committee makes draft recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the handling and labeling sections of the organic regulations as contained in [7CFR Part 205] and OFPA. The HC reviews petitions, substances scheduled to sunset, 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. The HC occasionally works with other committees to develop joint recommendations where handling issues are involved.

Livestock Committee (LC) The Livestock Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the livestock and livestock feed sections of the organic regulations as contained in [7CFR Part 205] and OFPA. The LC reviews petitions, substances scheduled to sunset, 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. The LC occasionally works with other committees to develop joint recommendations where livestock issues are involved.

Materials Committee (MC) The Materials Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the National List section of the organic regulations as contained in [7CFR Part 205] and OFPA. The MC works with the NOP, NOSB Committees and TAP Contractors in managing the Materials Review Process including tracking petitions, sufficiency reports, materials scheduled to sunset and sunset review process. In addition to a chair appointed by the Board Chair, the MC 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. The MC occasionally works with other committees to develop joint recommendations where materials are involved.

Policy Development Committee (PDC) The Policy Development Committee makes draft recommendations for consideration by the Board to provide guidance, clarification or proposed standards of Board operations, policies and procedures. The PDC maintains the content and updates to the NOSB Policy and Procedures Manual and New Member Guide. The PDC occasionally works with other committees to develop joint recommendations where policy issues are involved.

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.

OUTLINE FOR WRITING COMMITTEE RECOMMENDATIONS

This section provides an outline to be used by committees in writing a recommendation document. These guidelines not only allow consistency in the content of NOSB recommendations, but should also provide the NOSB, and the public, a fast manner to weigh the advantages and disadvantages of a proposal.

Recommendations not related to material petitions or sunset reviews, should include the following sections:

I. Introduction:

This section consists of a brief summary of the recommendation, its main issues and its relevance to the organic community. This section should also mention the goals and intent of the proposed recommendation.

II. Background:

This section should present the issues that justify the development of the recommendation as well as any relevant work done by the NOSB in the past.

III. Relevant areas in the Rule:

This section should mention any areas of the Rule or OFPA which provide the basis for the recommendation.

IV. Discussion:

This section should be used to expand on the intent of the recommendation. It is also a place to emphasize the SWOT of the recommendation (strength, weaknesses, opportunities and threats). No recommendation is 100% perfect and this section can serve to clarify the tradeoffs and advantages of a recommendation. Thus, it is advisable to mention all major alternatives reviewed by the committee. If appropriate, different stakeholders groups should be identified indicating how each group's needs are met or affected.

V. Recommendation:

This is the core, or deliverable, of the recommendation.

VI. Committee Vote:

This section should present the names of the members who moved and second the motion to approve the recommendation. As a norm, a motion should always be presented in the affirmative. In the case of recommendations for petitions to add materials to the National List, two votes should be taken and recorded, the first for a synthetic or non-synthetic material classification, and the second to list or not list the material. The record should list the number of synthetic and non-synthetic votes, and yes and no votes for listing, and the number of abstentions and absences.

Minority opinion:

If applicable, the dissenting opinion(s) of committee or task force members shall be reported. A member of a committee can present a minority report to the committee recommendation. Such document should include reasons for opposing a proposed recommendation and cite where the opposition points are in the recommendation. In addition, the minority report could, provide alternative approaches or solutions

from those given in the recommendation, or recommend an amendment to the recommendation. The minority opinion will be included as a separate document at the end of the recommendation.

PROCEDURES FOR PRESENTING COMMITTEE RECOMMENDATIONS

NOSB committees and task forces will follow the outline presented below in order to present draft policy and/or material recommendations at meetings of 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. In the case of recommendations for petitions to add materials to the National list, two votes will be recorded, one for synthetic or non-synthetic material classification, and the other for listing or not.

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 cannot 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

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:

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

- o Questions submitted to the NOP will be forwarded to the NOSB electronically as soon as possible.
- o NOP will alert the NOSB as to how NOP would address the incoming question.
- o The Board will assign the appropriate committee to address the question.
- o 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.

- o Draft answers to standards interpretation or submitted questions developed by committees will be shared with the NOSB and the NOP.
- o The NOSB will act on the committee's recommended response during its next regularly scheduled meeting.
- o 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.
- o 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) <u>Recommendation</u> 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 (NOBB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: March 18, 2006

Subject: Calcium Carbonate G & As

Chair: Jim Riddle
(sign)

Recommendation

The NOBB 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.

NOBB 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.

NOBB 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.

NOBB 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.

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.

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 per the instructions in the Federal Register Notice for the Meeting.
2. All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. Advance submissions allow NOSB members the opportunity to read comments in advance electronically, and decrease the need for paper copies to be distributed during the meeting.
3. Persons will be called upon to speak in the order they sign up. Persons called upon who are absent from the room could potentially miss their opportunity for public comment.
4. Each person will be given 5 minutes to speak, unless otherwise indicated by the Chair.
5. Persons must give their names and affiliations for the record at the beginning of their public comment.
6. A person may submit a written proxy to the NOP or NOSB requesting that another person speak on his or her behalf.
7. No person will be allowed to speak during the public comment period for more than 10 minutes, unless otherwise indicated by the Chair.
8. Individuals providing public comment will refrain from any personal attacks and from remarks that otherwise impugn the character of any individual.

Other suggestions that would be appreciated by NOSB members:

- The NOSB will attempt to accommodate all persons requesting public comment time, however, persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOSB Chair depending on availability of time. Similarly, persons who have signed up to address the NOSB for their 5-minute slot and have also served as a proxy for another person will be placed on a waiting list if they wish to speak for a third time on the same topic, and will be considered at the discretion of the NOSB Chair depending on availability of time. This should allow more members of the public time to present.
- Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.
- Members of the public should be considerate about - speaking more than once on the same topic - to allow more members of the public the opportunity to speak

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

COMMITTEE WORK PLANS

At the end of every NOSB meeting, each committee chair is required to present the committee's work plan. Given the nature, and number, of the issues the Board handles, it is important for a committee to follow a structured procedure for assigning priorities in the work plan. The following provides a guideline on how to develop a committee work plan. The committee chair, working with the committee, should follow three general steps in producing a work plan: 1) List all issues before the committee; 2) Prioritize each issue; 3) set a calendar; and 4) Obtain feedback from the Executive Committee and the Program.

Step 1: Identifying all issues

The committee work plan rises out of these main situations:

- Items committed, or assigned to a committee, by the Board during an official session.
- Items that are reviewed by a committee on a regular basis such as materials sunset review or petitions submitted by members of the public.
- Requests or suggestions from the National Organic Program such as clarifications on a particular issue or guidance on enforcement.
- Proposals stemming from the committee members' contact with the organic community.

In many cases not all issues should be the responsibility of the committee. Selecting what the committee should be reviewing can be done based on the following criteria:

- Relevance to the organic community (Is this an important issues? vs. Is this an interesting issue?)
- Criticality regarding mandate (is the issue within the committee's or the NOSB's realm?)
- Feasibility in terms of the Rule (can a proposal by the committee be realistically enforced by the NOP?)

Step 2: Prioritizing the issues

After listing the issues to review, the committee should prioritize its work plan items according to the following criteria:

- Preference given to petitioned materials
- Relevance to the organic community, public at large and the environment
- Size of the population affected by the issue
- Timeline since the issue/petition was submitted

The criteria are presented in order of importance and should be used to rank or prioritize each issue accordingly. For example, a petitioned material has priority over an issue that has been waiting to be reviewed for an extended period of time.

Step 3: Setting a calendar for reviews

Once the issues are prioritized, the committee chair should define a calendar for discussion of each issue. The calendar should allow committee members to understand specific deadlines and should reflect the posting/publication target dates mandated by the Program and the Federal Regulation.

Step 4: Incorporating Input from the Executive Committee

The committee chair must present the finalized work plan at the first Executive Committee conference call following a normal NOSB meeting. This event is not only an opportunity for the EC to provide guidance to the committee chair, but it is also an opportunity to obtain input from the NOP regarding the feasibility of implementing the committee's recommendation.

MATERIALS REVIEW PROCESS

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.

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

A petition to change the annotation to a listed material is in effect the addition or removal of one or more materials.

Definitions:

Technical Advisory Panel (TAP) - Group of third party experts convened by the Board to provide a technical review related to a material petition under review by the NOSB.

Technical Review – A report prepared by a third party expert under contract addressing the environmental, human, and industrial impact of a petitioned material per the OFPA and regulatory evaluation criteria to aid in the thorough evaluation of that material by the NOSB.

Phase 1: Receipt of Petition and Examination of Petition for Completeness and Eligibility

During this phase the NOP will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition. 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); the Food and Drug Administration (FDA); or other appropriate federal agency 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:

- o Publish the petition on NOP website; and
- o 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, Handling or other pertinent committees). 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.

Phase 2: Determine if a Third Party Technical Review is Required

During this phase:

- The NOSB materials committee, working with other applicable NOSB committees, has 60 days to submit any questions to the NOP. The questions requested by the committee should include items that need specific background information, recommended technical expertise, and be based on the OFPA criteria.
- Per the NOP materials review process, the NOSB should review the petition and using the NOP checklists for the material determine the following:
 - 1) If the material is deemed appropriate for consideration on the National List (pending criteria). If the answer is no to this question, an explanation is required.
 - 2) If the answer to question #1 is yes, the NOSB committee assigned for the review (as identified by the Materials Committee Chair) must decide if
 - a) there is sufficient information in the petition,
 - b) the committee can reasonably research any pending technical information, or
 - c) there is the need to secure a technical review from a third party expert (see section titled Procedures for Handling Technical Reviews)
 - 3) If the answer to question #1 is no, the Materials Committee Chair will inform the NOP that the petition is incomplete and will include an explanation. If the reviewing committee concludes there is a need for a third party technical review, the Materials Committee Chair will proceed to make the request to the Program.
- Notify the petitioner, via letter and/or electronic mail, that the petition is incomplete or ineligible; or

Phase 3: Evaluation by a Third Party Expert

During this phase the NOP will:

- Notify the third party expert of the petition's determination of completeness and eligibility. This third party will have technical expertise relevant to the petition and the notification will constitute official notice of the need for a technical review.

During this phase the Third Party Expert 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 TR template to prepare and distribute to the NOP a draft technical report (TR) in electronic format.

Phase 4: Sufficiency Determination

During this phase the NOP will:

- Submit a copy of the draft TR 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 TR against the following performance criteria. The report will be acceptable when it:
 - o Is consistent in format, level of detail and tone;
 - o Is technically objective and free from opinions or conjecture;
 - o Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
 - o Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
 - o Is based on the best available information that can be obtained within the designated time frame;
 - o Is thoroughly supported using literature citations; and,
 - o 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 TR against the following performance criteria. The report will be acceptable when it:
 - o Is consistent in format, level of detail and tone;
 - o Is technically objective and free from opinions or conjecture;
 - o Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
 - o Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
 - o Is based on the best available information that can be obtained within the designated time frame;
 - o Is thoroughly supported using literature citations; and,
 - o Addresses all evaluation questions as set out in the SOW.
- Notify the NOP in letter and/or electronic mail the acceptance of the TR within 60 days of receiving the TR. If the TR 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 TR 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 TR is insufficient, the NOP will notify the contractor by letter and/or electronic mail of the areas of the TR 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 as the TAP by electronic mail or conference call to provide complete 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 60 days before a scheduled meeting of the full NOSB.

Phase 6: Action by 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 a minimum of 60 days of written public comment on the recommendation prior to the public NOSB business meeting.
- 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.

PROCEDURES FOR HANDLING TECHNICAL REVIEWS

The NOSB's role involves reviewing specific materials; however, a petition could involve a wide range of topics. Although members of the Board represent several areas of the organic community and hold advanced degrees in different scientific areas, they might lack the expertise, or time, required to address the data needs of a petition. In such cases the Board has the option of requesting the assistance of third party experts and expecting from these experts a written technical review or report.

Third party experts can consist of the following:

1. Employees of the USDA such as AMS Science & Technology, Agriculture Research Service, or other federal agencies with appropriate expertise, as needed.
2. Consultants or contractors.

A committee should follow these steps in deciding the need for third party expert:

1. Define if the committee has the expertise needed to address the questions related to the petition, mainly:
 - a. Impact on the environment
 - b. Impact to human health
 - c. Sustainability and compatibility with organic principles.

2. If the committee does not have the expertise or resources (e.g., time), the Committee chair should make a request to the Chair of the Materials Committee for a third party expert specifying:
 - a. The third party expert's required background and level of expertise
 - b. Existence of potential sources of conflict that could result in biased reviews.
3. When requesting the assistance of a third party expert to evaluate a material, a committee must identify the main technical issues needed to be addressed including, but not limited to:
 - a. All uses of the petitioned material beyond what the petitioner has requested
 - b. All uses of the petitioned material in combination with other material(s) that have been already approved on the same section of the National List
 - c. Interactions of the petitioned material, not addressed by the petitioner, and that may involve materials currently on the same section of the National List.
 - d. All possible manufacturing methods for a petitioned material.
 - e. Potential effects on public health and biodiversity
 - f. Environmental risks and hazards including, but not limited to potential for developing pesticide resistance, or long-term effects on sustainability
4. If required, the committee should conduct a final review of the technical report and complete an assessment on the quality of work performed by the third party expert.

These are basic principles that should be considered when dealing with a third party expert:

1. A committee cannot proceed with a recommendation on a material if it is determined that there is limited valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
2. The decision to request third party expert needs to be made independent of the availability of funds. If there is a lack of funding to secure third party expert advice, the review of the material should be placed on hold.
3. Although the Board has the final word on the approval or rejection of a petition, the decision to request a third party expert is the responsibility of the committee reviewing the material. In some cases the Materials Committee can take the initiative to request a third party expert. The logic is that a material review is an issue assigned to a committee and it is up to the committee to decide on the need for a third party expert.
4. The decision to define the expertise needed in the third party expert is the responsibility of the committee reviewing the material or issue.
5. To incorporate a diversity of opinions and to minimize the risk of bias, a committee should aim to work with a range of technical experts (individuals, or institutions).

HANDLING WITHDRAWALS OF PETITIONS BY THE PETITIONER.

When a petition involving a material is withdrawn by the petitioner, the Board should suspend its review and recommendation procedure. In the case of a petition not involving a material, Board members have the option of completing its review and providing a recommendation or guidance.

In the case a petition previously withdrawn is resubmitted, the Board should review it in the order it is received. This means that a withdrawn petition should be considered a completely new request and falls to the end of the queue of materials pending review.

The petitioner can withdraw a petition at any moment during the process of review by the Board, public comment, or prior to the Board's voting on the petition.

A petitioner should have the opportunity to withdraw a petition with the intent of improving it (e.g., conducting additional research) only. It is the hope of the Board that petitioners will not abuse this privilege with the intent of finding agreeable members in subsequent submissions.

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)(1-7)). 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: NOP Program Director, National Organic Program, USDA-AMS-TM-NOP, 1400 Independence Avenue, S.W., Room 4004-So., Ag Stop 0268, Washington, D.C. 20250-0268, 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:

A. Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)

- Explain why the synthetic substance is necessary for the production or handling of an organic product.
- Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.
- Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.

B. Removal of a Synthetic From the National List, §§ 205.601, 205.603, 205.605(b)

- Explain why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.
- Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

C. Inclusion of a Prohibition of a Non-Synthetic, §§ 205.602 and 205.604

- Explain why the non-synthetic substance should not be permitted in the production of an organic product.
- Describe other non-synthetic substances or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.

D. Removal of a Prohibited Non-Synthetic From the National List, §§ 205.602 and 205.604

- Explain why the non-synthetic substance should be permitted in the production of an organic product.
- Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the non-synthetic substance that supports its use instead of the use of other non-synthetic or synthetic substances on the National List or alternative cultural methods.

E. Inclusion of a Non-Synthetic, Non-Agricultural Substance Onto the National List, § 205.605(a)

- Explain why the substance is necessary for use in organic handling.
- Describe non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

- Describe any beneficial effects on the environment, or human health from the use of the substance that support its use instead of the use of non-synthetic or synthetic substances on the National List or alternative cultural methods.

F. Removal of a Non-Synthetic, Non-Agricultural Substance From the National List, § 205.605(a)

- Explain why the substance is no longer necessary for use in organic handling.
- Describe any non-synthetic or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.

G. Inclusion of a Non-Organically Produced Agricultural Substance Onto the National List, § 205.606

- Provide a comparative description on why the non-organic form of the substance is necessary for use in organic handling.
- Provide current and historical industry information/research/evidence that explains how or why the substance cannot be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.
- Describe industry information on substance non-availability of organic sources including but not limited to the following guidance regarding commercial availability evaluation criteria:

- (1) Regions of production, including factors such as climate and number of regions;
- (2) Number of suppliers and amount produced;
- (3) Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;
- (4) Trade related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies, and
- (5) Other issues which may present a challenge to a consistent supply.

H. Removal of a Non-Organically Produced Agricultural Substance From the National List, § 205.606

- Provide a comparative description as to why the non-organic form of the substance is not necessary for use in organic handling.
- Provide current and historical industry information/research/evidence that explains how or why the substance can be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.
- Provide new industry information on substance availability of organic sources including but not limited to the following guidance commercial availability evaluation criteria:

- (1) Region of production, including factors such as climate and number of regions;
- (2) Number of suppliers and amount produced;
- (3) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies;
- (4) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies and;
- (5) Any other issues which may present a challenge to a consistent supply.

13. A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:

- a. Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim.
- b. "Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be
 - (1) commercially valuable,
 - (2) used in the applicant's business, and
 - (3) maintained in secrecy.
- c. Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."
- d. The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy. (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy.
- e. Each page with CBI-deletions should be marked "CBI-deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI- deleted."
- f. If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBI-deleted.")
- g. All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information usually cannot be claimed as confidential.

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 Director may request additional information from the petitioner following receipt of the petition.

PRIORITY OF PETITIONS GUIDELINE

Prioritization

National List materials petitions received and deemed sufficient by the NOP / NOSB will be prioritized by the Materials Committee Chair for consideration as follows:

1. Petitions to Remove a Material From the National List:

- a. A petition to **remove** a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority - **Priority 1**, above all other petitions in the queue of the reviewing committee (Crops, Handling, or Livestock).
- b. A petition to **remove** a material presently on the National list not based on serious health, environmental, or regulatory concerns, but based on other new information, such as commercial availability status, would be assigned a **Priority 2**, behind Priority 1 petitions, but above any petitions to list materials that are in the queue of the reviewing committee (Crops, Handling, or Livestock). This priority assignment would include any removal petitions requesting reconsideration of previous board decisions, if the resubmitted petition contains substantive new information to warrant reconsideration.

2. Petitions to Add a Material to the National List:

- a. A petition to **add** a material to the National List will be considered by the reviewing committee (Crops, Handling, or Livestock) in the chronological order it is received, and will be designated as **Priority 3**.

3. Petitions to Reconsider a Material for Addition to the National List:

- a. A petition to **reconsider** adding a material that had previously been rejected by a board vote would be given the lowest priority - **Priority 4**, and would go to the bottom of the committee (Crops, Handling, or Livestock) queue of petitioned materials. Petitions for listing a substance that had been previously rejected by the board must contain substantive new information to warrant reconsideration.

This prioritization guideline is only that, a guideline. When situations occur beyond the control of the reviewing committee, such as, but not limited to, a delay in the delivery of a Technical Review for a petitioned substance, the committee chair must exercise his or her judgment in the possible reassignment of priorities and workload to make best use of resources to advance petition recommendations.

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, including classification recommendation (State Actual Motion): _____ _____ Classification of the material: Synthetic _____ Non- synthetic _____ Absent: _____ Abstain _____ Motion by: _____ Seconded: _____ Yes: _____ No: _____ Absent: _____ Abstain: _____																									
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="padding: 2px 5px;">Crops</td> <td style="width: 20px;"></td> <td style="padding: 2px 5px;">Agricultural</td> <td style="width: 20px;"></td> <td style="padding: 2px 5px;">Allowed¹</td> <td style="width: 20px;"></td> </tr> <tr> <td style="padding: 2px 5px;">Livestock</td> <td></td> <td style="padding: 2px 5px;">Non-Synthetic</td> <td></td> <td style="padding: 2px 5px;">Prohibited²</td> <td></td> </tr> <tr> <td style="padding: 2px 5px;">Handling</td> <td></td> <td style="padding: 2px 5px;">Synthetic</td> <td></td> <td style="padding: 2px 5px;">Rejected³</td> <td></td> </tr> <tr> <td style="padding: 2px 5px;">No restriction</td> <td></td> <td style="padding: 2px 5px;">Commercially Un-Available as Organic¹</td> <td></td> <td style="padding: 2px 5px;">Deferred⁴</td> <td></td> </tr> </table>		Crops		Agricultural		Allowed ¹		Livestock		Non-Synthetic		Prohibited ²		Handling		Synthetic		Rejected ³		No restriction		Commercially Un-Available as Organic ¹		Deferred ⁴	
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. <u>Is the comparative description provided</u> 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?				

Form NOPLIST2, Full Board Transmittal to NOP

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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

Background

Sunset is a regulatory process for determining the continued listing of a material already approved or prohibited on the National List for use in organic agriculture production and handling. It is not used to petition to add a new substance nor is it used to change an existing annotation. If the review and renewal process is not concluded by the expiration date, the use of the material will become prohibited.

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. 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.

The Organic Foods Production Act of 1990 (OFPA) authorized a National List of Allowed and Prohibited Substances (Section 6517). Sections 6517 (e) mandates a Sunset Provision as follows:

“No exception or prohibition in the National list shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 years of such exemption or prohibition being adopted and the Secretary has reviewed such exemption or prohibition”.

The National List that was implemented in October 21, 2002 contained over 200 substances. The first sunset review of listed materials was completed in October, 2007. Decisions made through the Sunset review must be transparent, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.

Steps followed in Sunset Process

Not all listed materials reach sunset status at the same time, but the review process includes these steps:

1. A public notice is placed in the Federal Register (Advance Notice of Proposed Rule Making or ANPR) of the pending sunset of the listed materials. The public has 60 days after the publication date to provide written comment (see Chart 1 below). The committee may request a third party technical review in anticipation of scientific evidence and claims likely to be made during public comment to the ANPR.
2. Public comments are collected and forwarded to the NOSB (see Chart 2).
3. The appropriate NOSB committee begins review of the material with the intent of providing a recommendation to the entire Board for the material’s removal or renewal. The review is conducted based on “Force of Evidence” as presented by Board members, public comments, and scientific data from other sources (see Chart 3). This includes the original recommendation from the Board to list. The committee may request a third party technical review, if needed, to verify scientific evidence and claims made during public comment to the ANPR.
4. The reviewing NOSB committee provides its recommendation to the full Board 60 days prior to the Board Meeting. At the same time, the committee recommendations are posted on the NOSB website and open to public comments.
5. At the public NOSB business meeting, the NOSB hears additional public comment, discusses the force of evidence, and votes on the committee’s recommendation.
6. The NOP reviews the NOSB recommendation and accompanying documentation and publishes a proposed rule to review the National List. The public has 90 days after the publication date to comment. All comments are made available on the NOP website.
7. NOP will review the comment and publish the final rule. The final rule process is illustrated in Chart 4

Chart 1: Sunset Review – NOP Posts an ANPR

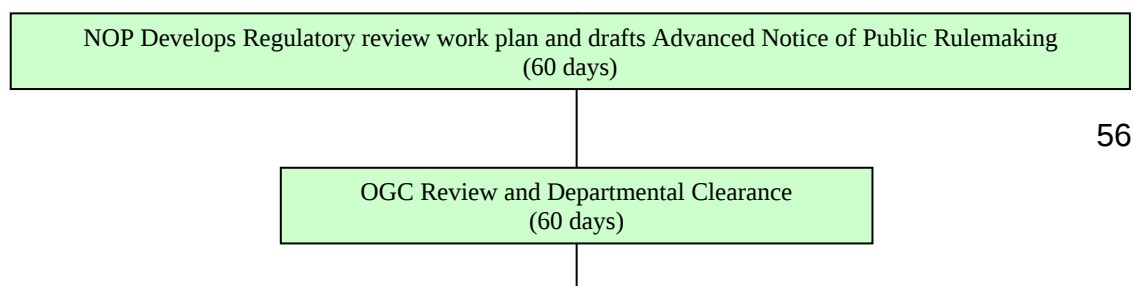


Chart 2: Sunset Review – NOP Collects and Forwards Public Comment to the NOSB

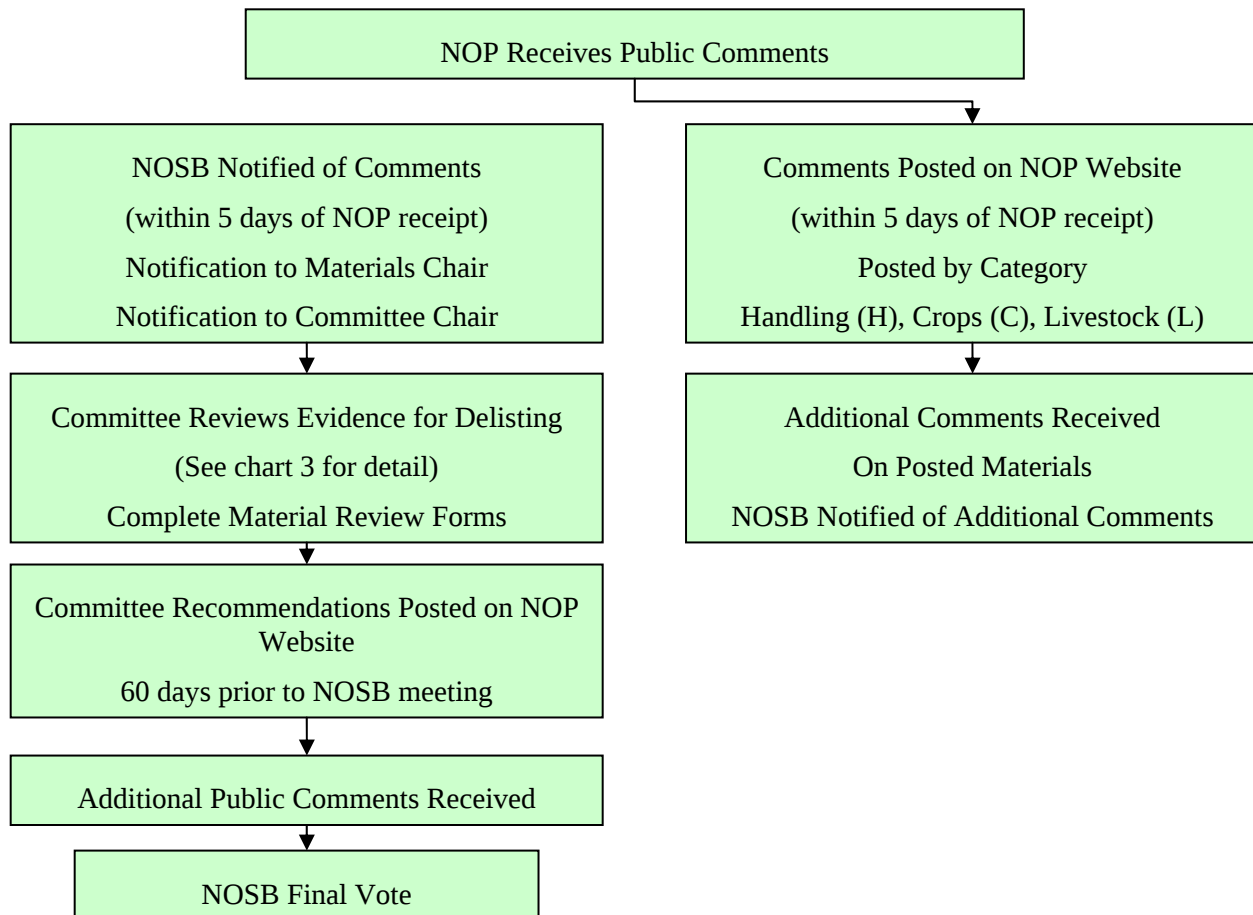
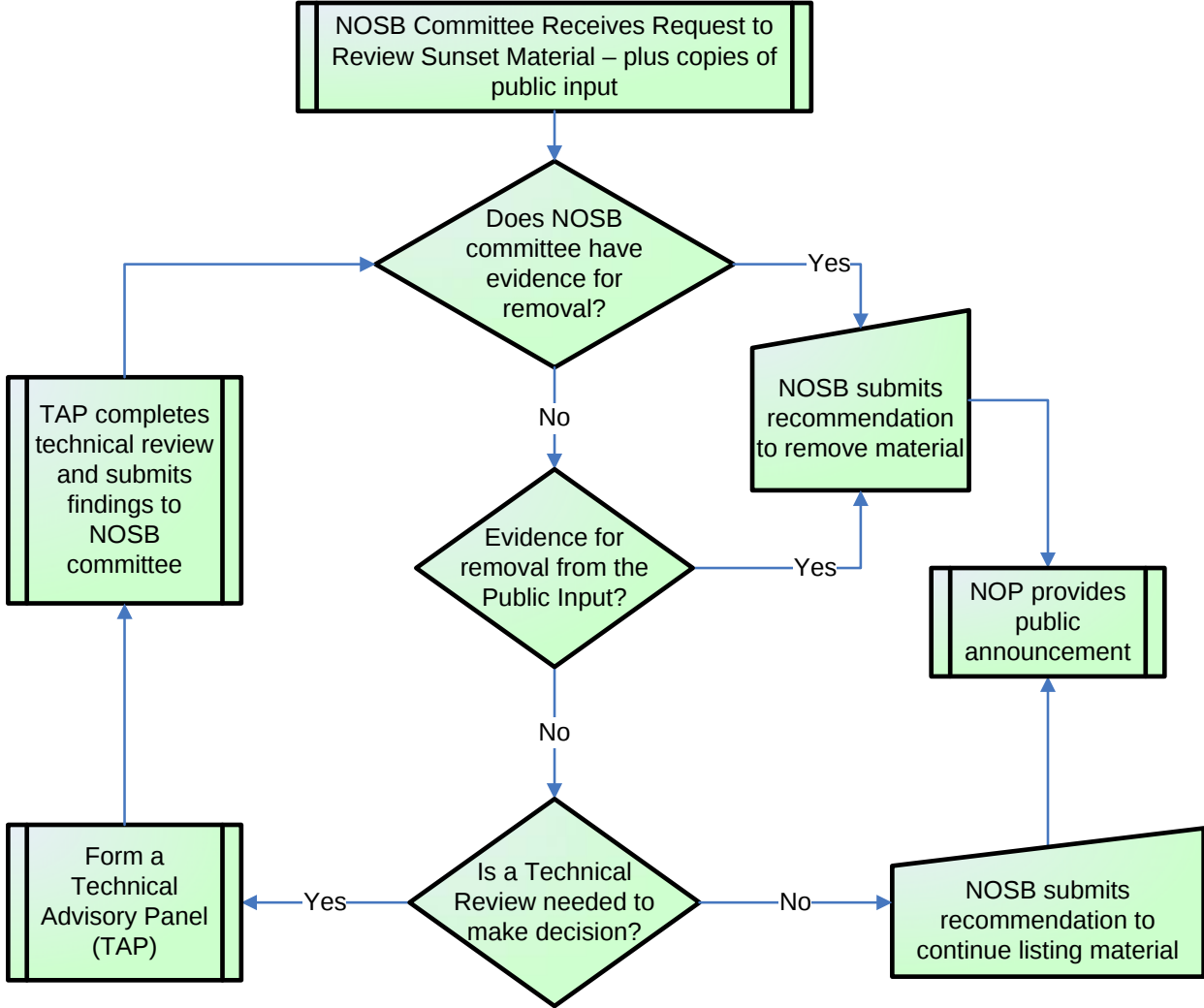
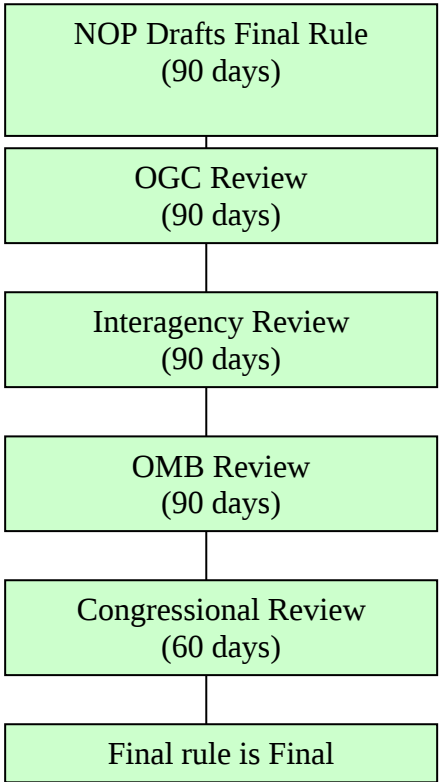


Chart 3: Sunset Review – NOSB Committee Reviews Evidence for Delisting



**Chart 4:
Sunset
Review

Final Rule
Process**



HANDLING TECHNICAL ERRORS AFTER AN ITEM HAS BEEN PLACED IN THE FEDERAL REGISTER

In order to minimize confusion in the organic community, the Board needs to monitor and correct discrepancies between items which have been voted on and their subsequent insertion in the Federal Register. Some examples of the different types of technical corrections needed are:

Annotations different than what was originally recommended by NOSB and changed by the Program in order to fit the demands of other federal regulatory bodies (ex: livestock medications withholding times).

An unforeseen consequence of a recommendation voted by the Board could require additional annotations in order to fit the needs of the organic industry. The absence, for example, of an explicit description of what methods of extraction are allowed for specific materials could result in the unwanted use of materials extracted using prohibited extraction processes.

The Board should follow these steps to monitor and correct technical discrepancies:

(1) The Secretary of the Board, with the assistance of the NOSB Executive Director, shall review all additions to the Federal Register and report to the Board any discrepancies between Board recommendation and those published in the Federal Register.

(2) When the Program incorporates changes to a recommendation voted and presented by the Board, the Program is expected to communicate these changes prior to final action by the Program to the Board Chair, Vice Chair and Secretary. The Board Chair, Vice Chair and Secretary will report such activity to the Board and then work with the Program in order to assist the Program in stating the exact reasons for such deviations in the preamble to the Rule change posted.

(3) In the cases of unintended consequences with a published recommendation, the Chair of the Board, with the approval of the Executive Committee, will assign committee to resolve the issue.

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 Director 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 90 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 45 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://www.gsa.gov/Portal/gsa/ep/channelView.do?pageTypeId=8203&channelPage=/ep/channel/gsaOverview.jsp&channelId=-13170>

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 Director. The Program Director:

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 substance's 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 of 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 at 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 $\text{Na}^+ + \text{Cl}^-$. 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 they 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.

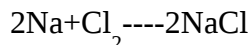
Oxides: is a binary compound of any element with oxygen, when the oxygen has an oxidation number of -2 . Almost every element forms at least one oxide. The properties of oxides vary widely- depending on the element they may resemble a salt, acid, base or non electrolyte.

What constitutes a chemical change?

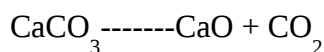
The chemical properties of a substance are those that describe the way in which it can undergo change, either alone or in interactions with other substances, to form different materials. Such changes are called chemical reactions. The chemical properties that are characteristic of any substance can be 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:



2. Decomposition reactions: One compound breaks into two or more compounds or elements.



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. $\text{AB} + \text{CD} \rightarrow \text{AD} + \text{CB}$

- 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.
3. 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.
4. Organic Solvents- such as alcohols, acetone or ether.
5. Mechanical treatment. Most globular proteins denatured in aqueous solution if they are stirred or shaken vigorously.
6. 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:

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