

**National Organic Standards Board
Policy Development Subcommittee
Administrative updates to the NOSB Policy and Procedures Manual (PPM)**

August 13, 2013

Introduction

The Policy Development Subcommittee (PDS) proposes to update and revise various administrative components of the PPM, including organization, formatting, sentence structure, grammar and syntax.

Background

The NOSB Policy and Procedures Manual (PPM) is a guide meant to assist the Board members with operational procedures, roles, and responsibilities. The Policy Development Subcommittee revises the PPM as necessary to reflect changes in procedure, and less frequently, policy. Since its adoption on October 19, 2002, bi-annual updates have been made to isolated components of the PPM by a diverse array of writers. As such, the organization, structure and style of the document have become unsystematic.

Relevant Areas in the Rule

The Organic Foods Production Act of 1990, 7 USC 6518 (a), directed the Secretary of Agriculture to establish the National Organic Standards Board and described its composition, authority and duties.

Discussion

The PPM contains guidance about the Board's standard operating procedures and policies, and the Policy Development Subcommittee in collaboration with the NOSB Vice Chair is charged with its ongoing review and maintenance. Because various writers have contributed updates over the course of 11 years, the PPM has become a mix of styles, formatting and structure. In an effort to make it easier to read, the PDS proposed the following types of changes throughout the document, as illustrated by the following representative examples:

Example #1: Original Introduction

INTRODUCTION (page 4)

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.

Example #1: Revised Introduction

The primary roles and duties of the National Organic Standards Board (NOSB) members include but are not limited to:

- Serve as a link to the organic community
- Advise the NOP on the implementation of OFPA
- Approve all materials which appear on the National List
- Protect and defend the integrity of organic standards

Board members are entrusted with the responsibility to act as fiduciaries to act in the best interests of all members of the organic community and the public at large. The Board's success relies upon the ability to understand each other's respective roles, and to develop successful working relationships.

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 periodically, as determined by the Board.

The bulleted items above didn't appear until Section II, page 10 under a section mistitled "Board Members Job Descriptions". I thought it was more important and more impactful for it to be right up front.

Example # 2: Original text and formatting

OFFICER RESPONSIBILITIES

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 Subcommittee;
- Draft meeting agendas in consultation with Subcommittee chairs and NOP staff;
- Convene and preside at meetings;
- Review Subcommittee 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 serve as a member of the Policy Development Subcommittee, and work collaboratively with the PDS's members on the maintenance and upkeep of the Policy and Procedures Manual.

Example # 2: New text and formatting

Chair

The Chair is responsible for ensuring the integrity of the Board process, effectiveness of meetings and adherence to Board policies and procedures. The primary duties of the Chair are as follows:

- Schedules meetings of the Executive Subcommittee, in cooperation with the NOP
- Serves as a member of the Executive Subcommittee
- Convenes and facilitate Executive Subcommittee meetings
- Convenes and preside over NOSB meetings
- Participates in the administrative team meetings
- Drafts NOSB meeting agendas in consultation with Subcommittee chairs and NOP staff
- Reviews Subcommittee work plans
- Reviews NOSB meeting minutes for accuracy
- Assists with the annual election of NOSB officers and announces the new officers

Vice Chair

The Vice Chair acts in the absence of the Chair. The primary duties of the Vice Chair are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Serves as a member of the Policy Development Subcommittee
- Works collaboratively with the PDS's members on the maintenance of the Policy and Procedures Manual

Example # 3: Reorganization of various topics/sections.

Several topics were found in various locations within the document and those that pertained to the same subject were moved to a more logical and functional location. For example information about Subcommittees was found in both Sections IV and V, and was combined into one section (IV).

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Summary of recommendation

The Policy Development Subcommittee (PDS) proposes to update and revise various administrative components of the PPM, including organization, formatting, sentence structure, grammar and syntax.

Subcommittee Vote

Motion: To accept the proposed amendments to the Policy and Procedures Manual described above.

Motion by: John Foster

Seconded by: Jay Feldman

Yes: 4 No: 1 Abstain: 0 Absent: 1 Recuse: 0

Approved by Colehour Bondera, Subcommittee Chair, to transmit to NOSB August 13, 2013

NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

Adopted October 19, 2002

DRAFT Revision August 13, 2013.

Administrative updates are described in the accompanying proposal and are incorporated into the draft PPM presented here.

Miscellaneous updates are described in the accompanying proposal and are also illustrated in the draft PPM as follows: Text highlighted in yellow and struck out indicates original text. Text highlighted in green indicates the new proposed text.

Previous revisions: August 18, 2005; March 29, 2007; November 30, 2007; May 22, 2008; November 19, 2008; May 6, 2009; November 9, 2009; April 29, 2010; October 28, 2010; April 29, 2011; December 2, 2011; August 13, 2013.

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INTRODUCTION

The primary roles and duties of the National Organic Standards Board (NOSB) members include but are not limited to:

- Serve as a link to the organic community
- Advise the NOP on the implementation of OFPA
- Approve all materials which appear on the National List
- Protect and defend the integrity of organic standards

Board members are entrusted with the responsibility to act as fiduciaries to act in the best interests of all members of the organic community and the public at large. The Board's success relies upon the ability to understand each other's respective roles, and to develop successful working relationships.

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 periodically, as determined by the Board.

SECTION I

NOSB VISION STATEMENT

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

NOSB 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 its implementation, and to represent the consensus of the organic community.

To carry out the mission, the Board will:

- 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 to provide timely information concerning the NOP, making reasonable use of a variety of communication channels, including but not limited to conducting public meetings and soliciting and receiving public comments.
- Communicate and coordinate with, and provide support to, 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 on 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 the following Duties as described in this Manual--Duty of Care, Duty of Loyalty, and 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 requires Board members to exercise the 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 organic community and the public at large, and not in their own interest or the interest of another entity or person. 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. Because Board members may have interests in conflict with those of the public they must be conscious of the potential for such conflicts and act with candor and care. 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.)
- Adhere to the responsibilities of the Board as defined by the Organic Foods Production Act of 1990
- Adhere to the requirements specified in the NOSB Policy and Procedures Manual

Professional and Ethical Standards

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

- **Professional Conduct**

NOSB members shall:

- Observe ethical principles above private gain in the service of public trust
- Put forth an honest effort in the performance of their NOSB duties
- Make no commitments or promises of any kind purporting to bind the Government
- Act impartially and not give preferential treatment to any organization or individual
- Along with task force members, refrain from engaging in any financial transactions using nonpublic information*, must not allow the improper use of nonpublic information to further his/her own private interest or that of another, whether through advice or recommendation, or allow the unauthorized disclosure of nonpublic information

*Nonpublic information is defined as information that a Board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should be expected to 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.”

- Along with task force members shall keep confidential all information identified by petitioners as confidential business information.
- Speak with one voice to the maximum extent possible. Although there may be disagreements, NOSB members 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
- Represent the segments of the population from which they were selected, while also representing 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 are appointed because they have professional expertise that enables them to advise the Secretary. This professional expertise may, at times, present a perceived 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.

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 parties who manufacture, distribute or hold exclusive title to a formula

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)]

BOARD MEMBER STANDARDS

- Participate in meetings - Members must make a commitment to attend meetings of the Board.
- Serve on Subcommittees, as assigned - Each member must be willing to serve on Subcommittees as assigned by the Chair, and to participate in the work of those Subcommittees.
- Be informed about Board business - Board members are expected to seek and study the information needed to make reasoned decisions and/or recommendations on all business brought before the Board.
- Fully disclose any conflicts of interest - Members having any commercial or immediate family interests that pose a potential or perceived conflict of interest must disclose that conflict to the Board and abide by any decision of the Board regarding 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 Subcommittee, including the Executive Subcommittee, 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 be counted towards the total number of votes cast. Both abstentions and recusals will be considered in order to establish a quorum.

# Votes Cast	# Recusals and Abstentions	2/3 Majority*
15	0	10
14	1	10
13	2	9
12	3	8
11	4	8
10	5	7
9	6	6
8	7	6

DRAFT

SECTION III

ROLE OF THE DESIGNATED FEDERAL OFFICER (DFO)/ADVISORY BOARD SPECIALIST (ABS)

The Designated Federal Officer assigned to the National Organic Standards Board and its Subcommittees, 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 Advisory Board Specialist (ABS). The position of Advisory Board Specialist (ABS) (formerly the Executive Director) was added in 2005 to facilitate contact between the NOP and the NOSB.

Advisory Board Specialist duties include but are not limited to:

- Ensuring that all FACA and OFPA requirements are implemented.
 - Managing calendars and workplans to facilitate Subcommittee and Board activities
 - Arranging, facilitating, and documenting the NOSB Subcommittee conference calls
 - Ensuring Board members have all necessary materials and information to provide informed, structured and timely recommendations to the NOP
 - Conducting meeting planning activities for the semi-annual Board meetings, including preparation of Federal Register notices and press releases, and facilitation of public comments
- Approving and calling the meeting of the NOSB
- Approving the Semi-annual meeting agenda
- Attending the meetings
- Adjourning the meetings when such adjournment is in the public interest
- Chairing the meeting when directed by the Secretary of Agriculture or the Secretary's designee
 - Coordinating the Board nomination and chartering process
 - Facilitating training of Board members
 - Managing information reporting and communication between the NOSB and NOP
 - Administering and maintaining a year-round public communication mechanism

ROLE OF THE Designated Federal Officer (DFO)/Advisory Board Specialist (ABS)

A Designated Federal Officer is assigned to the National Organic Standards Board and its Subcommittees under the Federal Advisory Committee Act (U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10)., The DFO's duties include but are not limited to:

- Approving and calling the meeting of the NOSB
- Approving the Semi-annual meeting agenda
- Attending the meetings
- Adjourning the meetings when such adjournment is in the public interest
- Chairing the meeting when directed by the Secretary of Agriculture or the Secretary's designee

The position of Advisory Board Specialist (ABS) (formerly the Executive Director) was added in 2005 to facilitate communication and collaboration between the NOP and the NOSB. Advisory Board Specialist duties include but are not limited to:

- Ensuring that all FACA and OFPA requirements are implemented.
- Managing calendars and workplans to facilitate Subcommittee and Board activities
- Arranging, facilitating, and documenting the NOSB Subcommittee conference calls
- Ensuring Board members have all necessary materials and information to provide informed, structured and timely recommendations to the NOP
- Conducting meeting planning activities for the semi-annual Board meetings, including preparation of Federal Register notices and press releases, and facilitation of public comments
- Coordinating the Board nomination and chartering process
- Facilitating training of Board members
- Managing information reporting and communication between the NOSB and NOP
- Administering and maintaining a year-round public communication mechanism

Please note: The DFO and ABS may or may not be the same person as designated by the NOP

NOSB OFFICER RESPONSIBILITIES

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

Chair

The Chair is responsible for ensuring the integrity of the Board process, effectiveness of meetings and adherence to Board policies and procedures. The Chair:

- Schedules meetings of the Executive Subcommittee, in cooperation with the NOP
- Serves as a member of the Executive Subcommittee
- Convenes and facilitate Executive Subcommittee meetings
- Convenes and preside over NOSB meetings
- Participates in the administrative team meetings
- Drafts NOSB meeting agendas in consultation with Subcommittee chairs and NOP staff
- Reviews Subcommittee work plans
- Reviews NOSB meeting minutes for accuracy
- Assists with the annual election of NOSB officers and announces the new officers

Vice Chair

The Vice Chair acts in the absence of the Chair, and:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Serves as a member of the Policy Development Subcommittee
- Works collaboratively with the PDS's members on the maintenance of the Policy and Procedures Manual

Secretary

The Secretary works with the Advisory Board Specialist to maintain the integrity of all legal and governing documents of the Board. The Secretary:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Ensures that official NOSB transcripts are posted for the public
- Records all Board member votes at NOSB meetings and circulates that record to NOSB members for approval
- Reviews all additions to the Federal Register to report any unexplained discrepancies between Board recommendations and proposed rules published in the Federal Register
- Transfers custody of the Board's voting records to the incoming Secretary
- Assist with the annual election of NOSB officers

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

Administrative Team

The Administrative Team consists of the Chair, Vice Chair, Secretary and DFO/ABS. This group is responsible for coordinating logistics and operations of the Board. The Administrative team will meet via teleconference on an as-needed basis, to be determined by the Administrative Team.

ELECTION OF OFFICERS

A. NOMINATIONS

- Any NOSB member is eligible for consideration for any officer position
- A Board member may nominate his or her self or may be nominated by another member of the Board
- Should the Chair, Vice Chair, or Secretary resign or fail to serve the full term, the Executive Subcommittee shall appoint an interim officer. The interim officer shall serve in that 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 may serve more than one consecutive term in an officer position. However, more than two consecutive terms are not recommended.~~
- Members may serve more than one term in any officer position; However, historically more than two consecutive terms in any given officer position has not been recommended.

B. VOTING SCHEDULE

- Officers shall be elected for terms of one year by majority vote at the fall Board meeting.
- Newly elected officers will assume their positions at the conclusion of the fall Board meeting, and assume the responsibilities thereof at that time
- Outgoing Board officers will assist the incoming officers in the transition into their new roles, to be completed no later than January 23rd of the following year.

C. ELIGIBILITY TO VOTE

- Only NOSB Board Members present are eligible to vote for nominated officers
- Board members are entitled to cast one vote for each officer position

D. COUNTING OF VOTES

- Voting will be by secret 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 Chair will announce the tally before the next office is opened for nominations
- The Secretary and NOP representative will prepare and distribute the ballots, then collect them after each vote
- The Chair will tally the votes after each officer nomination and the Secretary will verify the results
- The candidate receiving the greatest number of votes will be elected
- In the event of a tie there will be a revote until a nominee obtains a majority. All nominees will be included in the revote or may be given the opportunity to withdraw at their discretion
- Votes will remain confidential, and ballots will be disposed of by the Chair or Secretary

EXECUTIVE SUBCOMMITTEE

The Executive Subcommittee of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the chairs of each of the standing Subcommittees. The Executive Subcommittee, the DFO/ABS, and the NOP Deputy Administrator, 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 proposals from Subcommittees, including the status of materials proposed for addition or deletion on the National List. The Executive Subcommittee will provide guidance and feedback to the Subcommittees on their proposed work plans.

BOARD MEETINGS

All Board meetings, assembled for the purpose of making recommendations to the NOP, are subject to FACA (see appendix B for FACA facts) and as such 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 of these exempted meetings include: Subcommittee calls, assemblies for completing work, planning retreats, training or sharing information. Full Board conference calls are not currently practiced. The date and location of in-person Board Meetings-currently held twice each year in spring and fall), will to the extent possible, be set at the mutual scheduling convenience of the NOSB and the NOP.

Board actions include but are not limited to; adoption of the proposal as presented by the Subcommittee, amendment and then adoption of the proposal, rejection of the proposal, or referral of the proposal back to Subcommittee for further development.

The Board, through the Board Chair, communicates its recommendations to the NOP using standardized forms and procedures.

SECTION IV

BOARD SUBCOMMITTEES

Subcommittees play an important role in administering the Board's responsibilities to make informed decisions. The Subcommittees are responsible for conducting research and analyses, and drafting discussion documents, guidance documents or proposals to be considered by the full Board. Except for the Executive Subcommittee, no Subcommittees are authorized to act in place of the Board. Subcommittees are empowered to analyze information and bring draft proposals to the Board for action.

Subcommittee chairs are appointed by the Board Chair. The current standing Subcommittees are:

- Certification, Accreditation, and Compliance (CACS)
- Crops (CS)
- Handling (HS)
- Livestock (LS)
- Materials (MS)
- Policy Development (PDS)

The Livestock, Crops, and Handling Subcommittees will each have two Co-Chairs. One will guide all Subcommittee discussion and will oversee the Subcommittee's workplan. The other will be responsible for the Subcommittee's consideration of materials and will serve as the liaison to the Materials Subcommittee.

STANDING SUBCOMMITTEES

Certification, Accreditation, and Compliance Subcommittee (CACS) The Certification, Accreditation, and Compliance Subcommittee drafts proposals for consideration by the Board to provide guidance, clarification or proposed standards of the certification, accreditation and compliance sections of the organic regulations [7CFR Part 205] and OFPA. The CACS occasionally works with other Subcommittees to develop joint proposals where certification and compliance issues are involved

Crops Subcommittee (CS) The Crops Subcommittee drafts proposals 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 CS 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 CS occasionally works with other Subcommittees to develop joint proposals where crop issues are involved.

Handling Subcommittee (HS) The Handling Subcommittee drafts proposals 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 HS 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 HS occasionally works with other Subcommittees to develop joint proposals where handling issues are involved.

Livestock Subcommittee (LS) The Livestock Subcommittee drafts proposals 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 LS 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 LS occasionally works with other Subcommittees to develop joint proposals where livestock issues are involved.

Materials Subcommittee (MS) The Materials Subcommittee drafts proposals 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 MS works with the NOP and, other NOSB Subcommittees in managing the Materials Review Process, which includes tracking petitions, sufficiency reports, materials scheduled to sunset and the sunset review process. In addition to a Chair appointed by the Board Chair, the MS shall include in its membership a representative from each of the Livestock, Crops, and Handling Subcommittees. Other members may be appointed as needed. The MS occasionally works with other Subcommittees to develop joint proposals where materials are involved.

Policy Development Subcommittee (PDS) The Policy Development Subcommittee drafts proposals for consideration by the Board to provide guidance, clarification or proposed standards of Board operations, policies and procedures. The PDS maintains and updates the NOSB Policy and Procedures Manual (in collaboration with the NOSB Vice Chair and the Advisory Board Specialist), as well as the New Member Guide. The PDS occasionally works with other Subcommittees to develop joint proposals where policy issues are involved.

SUBCOMMITTEE MEETINGS

Subcommittees hold meetings via telephone conference calls. Calls should be scheduled at least 2 weeks in advance and should be the result of Subcommittee dialog regarding the most conducive dates and times. This dialog may occur on a previous conference call or through email. A minimum of 48 hours should be allowed for responses to email requests.

Emergency calls may be scheduled with less notice only after each member is contacted. If the members do not respond to email requests, the Chair or their designee must contact the member by phone.

TASK FORCES

~~As determined by the Board or Executive Subcommittee and with approval/support from the NOP, task forces shall be appointed to explore specific issues and present draft proposals to the Board or to a Subcommittee, and may include non-Board members. Each task force shall:~~

- ~~• Include at least one member of the NOSB~~
- ~~• Record and maintain meeting minutes~~
- ~~• Submit a final report to the Board~~

- Disband when its work has concluded or when the Board determines the task force is no longer necessary.

With approval from the NOP, Task Forces may be appointed by either the Board or Executive Subcommittee to explore specific issues or concerns relevant to the organic community and industry and present to the Board draft proposals, discussion documents, or reports. Each task force shall:

- Have a specific Work Plan approved by the Board or Executive Subcommittee
- Have a clearly articulated project deliverable identified
- Include at least one current member of the NOSB
- Record and maintain meeting or conference call minutes, made available to the Board and the NOP
- Submit a final report to the Board
- Disband when its work has concluded or when the Board determines the task force is no longer necessary

AD HOC SUBCOMMITTEES

At the discretion of the NOSB Chair, and with approval of the Executive Subcommittee, ad hoc NOSB Subcommittees may be formed to develop policy and guidance on specific issues that involve multiple standing Subcommittee jurisdictions, or for issues or tasks that are very large and require additional resources to complete. Ad hoc Subcommittees must be comprised of current NOSB members, and may be either a combination of two or more standing Subcommittees to form a “joint” Subcommittee, or may be a completely new Subcommittee comprised of selected NOSB members from various standing Subcommittees. Ad hoc Subcommittees can be dissolved at the recommendation of the NOSB chairperson with the approval of the Executive Subcommittee. Ad hoc Subcommittee chairpersons are non-voting members of the Executive Subcommittee.

SECTION V

DUTIES OF SUBCOMMITTEE CHAIRS

Subcommittee Chair duties:

- Appoint a Subcommittee Vice Chair in consultation with Board Chair
- Consult with Board Chair regarding Subcommittee appointments
- Schedule Subcommittee meetings as needed
- Draft Subcommittee meeting agendas and work plans in consultation with Subcommittee members, the Executive Subcommittee, and NOP staff
- Convene and preside over Subcommittee meetings
- Ensure Subcommittee meeting notes are recorded
- Ensure that the Subcommittee meeting notes are reviewed for accuracy
- Report actions of the Subcommittee to the Board
- Serve as mentor/trainer for new Subcommittee chair during transition periods

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

DUTIES OF SUBCOMMITTEE VICE CHAIRS

Subcommittee Vice Chair duties:

- Provide support in developing and completing Subcommittee work plans
- Assist in reviewing Subcommittee meeting notes for accuracy
- Represent the Chair in the event of the Chair's absence
- The Vice Chairs of the Crops, Livestock and Handling Subcommittees will serve on the Materials Subcommittee as liaisons for reviewing all petitioned substances.

Subcommittee Vice Chairs shall not act unilaterally, especially concerning issues which involve statutory responsibilities of the Board.

TRANSITION OF SUBCOMMITTEE CHAIRS, VICE CHAIRS, AND MEMBERS (NEW AND CONTINUING)

Subcommittee Chairs, Vice Chairs and members shall be appointed to serve annually by the Chair of the Board. The annual Subcommittee term shall be concurrent with the one-year term established by the Secretary (beginning on January 24 and ending on the following January 23). Newly appointed Chairs, Vice Chairs and Subcommittee members will assume their positions at the beginning of the new term, after a period of orientation and mentorship

provided by the outgoing Chair, Vice Chair, and members.

To avoid disruption in the quality and volume of work produced by the NOSB, the following procedures will be observed:

After the election of NOSB Officers at the Fall Meeting:

Appointment of Subcommittee Chairs

The Board Chair should appoint Subcommittee Chairs from members with at least one year of NOSB experience. It is recommended that a new Subcommittee Chair have experience as Subcommittee Vice Chair

Appointment of Subcommittee Vice Chairs

Vice Chairs shall be appointed by the incoming Subcommittee Chair and should be someone who has expressed interest in eventually serving as Subcommittee Chair

Time Frame for Appointments

Subcommittee Chairs shall be appointed and seated not more than 30 days after the newly elected NOSB Chair takes office (or continues in office), and Vice Chairs shall be appointed by Subcommittee Chairs no more than two weeks after that

Exchange of Subcommittee Files

Upon appointment, new and outgoing Subcommittee Chairs should have a formal meeting to exchange all files related to the Subcommittee's work and to complete the first Subcommittee work plan under the new leadership

Review of Subcommittee Files

New Subcommittee Chairs should review all work plan items and active files involving Subcommittee work

Mentorship Period

The incoming Chair and Vice Chair of each Subcommittee shall participate in an orientation and mentorship period with the outgoing Chair and Vice Chair of their Subcommittee until seated in their positions at the beginning of the new term on January 24

Appointment of the New NOSB Members (prior to January 24):

The Board Chair will appoint each new NOSB member(s) to appropriate Subcommittees no more than two weeks after his or her appointment, after consulting with outgoing and incoming Subcommittee Chairs, and other Board officers, with due consideration of the member interest, expertise, and background, and well as composition and needs of the new Board.

Once appointed, incoming Subcommittee members shall be included in all email communication pertaining to the Subcommittees on which they serve.

Incoming members of the Subcommittee are encouraged and advised to participate in observer status on Subcommittee conference calls, and should be encouraged to attend the full Board meetings, if the selection precedes the fall meeting prior to the beginning of his or her term.

To facilitate an effective transition for new Board members and to ensure effective participation in Subcommittee and board deliberations, the Board Chair shall ask incoming Board members to identify a mentor from existing Board members no later than two weeks after his or her appointment, or, if the Board member prefers or the Board member takes no action, the Board Chair shall assign a mentor

Between Board Appointments and Board Meetings:

Changing Subcommittee Appointments

Board members who would like to join or leave a Subcommittee, shall submit a written request to the Board Chair. If the request does not alter the preferred number of Subcommittee members, in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair states in writing that such a change will interfere with the functioning of the Subcommittee or the Board. The Chair's determination should be made in consultation with Subcommittee Chairs and the Executive Subcommittee.

Filling a Subcommittee Chair and/or Vice Chair vacancy

If a Subcommittee Chair position becomes vacant, the Subcommittee Vice Chair shall assume the position as Chair and the new Subcommittee Chair shall appoint a new Vice -Chair in accordance with the consultation procedures cited above.

PROCEDURES FOR COMPLETING SUBCOMMITTEE RECOMMENDATIONS

Developing committee recommendations follows these broad steps:

1. The committee prepares a recommendation or discussion document as agreed to in the committee work plan (see p. 32 PPM).
2. The recommendation or discussions document is posted for public comment.
3. During the Board meeting, the committee presents its recommendation for discussion by the full Board.
4. At any point in the process prior to the Board's vote on the status of the recommendation, the presenting committee may convene and vote to withdraw its recommendation, based on approval of this action by the majority of the members of the committee.
5. Once presented, the Board votes on the committee recommendation.

In order to be considered a voting item, all recommendations must be submitted to the NOP at least forty five (45) days prior to a scheduled NOSB meeting. This time is needed in order to allow the Program to publish a meeting notice and allow for public comment.

PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS

Subcommittee proposal and Discussion document process:

1. The Subcommittee drafts the proposal or discussion document based on workplan items (See Section V for detailed discussion about workplans)

2. The draft proposal or discussion document is voted upon by the Subcommittee members in order for it to pass from the Subcommittee to the full Board
3. The draft proposal or discussion document is posted for public comment
4. At any point in the process prior to the Board's vote a Subcommittee may convene and, by simple majority, vote to withdraw its proposal.
5. During a subsequent Board meeting, the Subcommittee presents the proposals and discussion documents, as well as a summary of public comments, for discussion by the full Board.

In order to be considered for a vote during an NOSB meeting, all proposals must be voted on by the Subcommittee and submitted to the NOP at least forty five (45) days prior to a scheduled NOSB meeting. This will allow the Program to publish a meeting notice and accept public comment.

Guidelines for Writing Subcommittee Proposals and Discussion Documents

(See Appendix E for examples of proposals and discussion documents)

There are several formats for writing proposals and discussion documents, based on the subject under review:

- Proposals related to material petitions or sunset reviews
- Proposals for policy or procedure changes
- Discussion documents

Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings

NOSB Subcommittees and task forces should follow the outline presented below when presenting proposals or discussion documents for consideration by the Board:

- I. **Introduction:** A brief summary of the issue or statement of the problem.
- II. **Background:** An explanation with sufficient detail and rationale to support the proposal, including reasons why the proposal should be adopted, historical context, and the regulatory framework pertinent to the issue.
- III. **Proposal:** A concise explanation of the recommended action.
- IV. **Subcommittee Vote:** The Subcommittee or task force vote shall be reported. In the case of petitions to add materials to the National list, two votes will be reported; one for classification of the material as a synthetic or non-synthetic, and the other a motion to list or not.
- V. **Public Comment:** A brief summary of the public comments
- VI. **Minority opinion:** If applicable, the dissenting opinion(s) of Subcommittee or task force members shall be reported.

NOSB-NOP COLLABORATION

The Organic Foods Production Act (6518 (a)) directed the Secretary of Agriculture to establish a National Organic Standards Board 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 the Act. In 6503 (a) of the Act, the Secretary was directed to establish an organic certification program. The National Organic Program (NOP) has become the governmental institution responsible for this and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture.

Maintaining, enhancing, and promoting integrity of organic products, principles and products is accomplished through team work and collaboration of the NOSB and the NOP, as well as others in the organic community. Successful collaboration is dependent on effective communication and constructive feedback. Collaboration is facilitated by the Advisory Board Specialist (ABS), who participates in all NOSB calls. Additionally, the NOP Deputy Administrator or designee will participate in all ES calls, and in other standing subcommittee calls upon request and mutual agreement. In addition, each standing subcommittee will be assigned an NOP staff person to provide additional technical, legal, and logistical support.

Several factors to keep in mind with regard to the working relationship between the NOP and the NOSB:

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).

The 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, make NOP staffing decisions, or initiate policies of its own accord.

WORK PLANS

Workplans are developed by the Board and NOP in advance of each public Board meeting, where they are presented, discussed and potentially revised based on public comments, Board discussion, and NOP priorities and resources. Workplan procedures are described in detail in Section VI.

The NOSB expects that requests from the NOP regarding work plan items will be made publicly, either in written form or oral form made at an NOSB meeting. Requests made orally to the NOSB are to be followed up in writing stating the problem to be addressed, background, statutory authority and the time frame for response. The proposed Subcommittee work plans will be reviewed at the next ES call following the Board meeting, with participation by the NOP Deputy Administrator. This participation in the development of work plans is vital for effective NOSB/NOP collaboration. Due to change in circumstances, these work plans may need to be revised prior to the posting of the final agenda of the upcoming Board meeting. Subcommittee work plan changes must be approved by the ES and NOP.

Below are descriptions of common NOSB workplan items and the corresponding NOP and NOSB responsibilities. In all cases, the end product should be a recommendation by the Board to the NOP. Each recommendation should be accompanied by a cover sheet (See Appendix

E)

- **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, or to add, remove, or modify annotations restricting the use of such listed materials.
- **Recommendations for modification of existing standards or new standards.**
The NOSB will use the decision making procedures outlined in Section VI to justify modification of existing standards or proposal of new standards. The NOP may request that the NOSB develop recommendations in support of this. The request should be in writing and should include: a statement of the problem to be addressed; background, including the current policy or situation; statutory/ regulatory authority; legal issues; and the desired timeframe for receipt of the recommendation. The request will be posted on the NOP web site.
- **Advice on NOP policy and interpretation of standards.**
The NOSB periodically provides advice about specific NOP policies and actions, such as the yeast and compost policies.
- **Compliance and Enforcement.**
The NOP is responsible for compliance and enforcement of the Organic Standards. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. The NOP reports to the NOSB and the public the status of enforcement actions and also posts the status on the NOP web site
- **Management Review.**
The NOSB may review the quality management system and internal audits to ensure that the NOP is managed effectively and efficiently. For example, the NOSB may be asked for informal feedback or to work on specific workplan items that relate to the development or implementation of audit corrective actions,

Adopted October 2010 Yes: 14 No: 0 Abstain: 0 Absent: 0 Recusal: 0

SECTION VI

NOSB PROCEDURES

SUBCOMMITTEE WORKPLANS

At the end of every NOSB meeting, each Subcommittee chair is required to present the Subcommittee's workplan. Each Subcommittee should follow four general steps to develop their workplan: 1) Identify all issues before the Subcommittee; 2) Prioritize each issue; 3) Set a calendar for reviewing items; and 4) Obtain feedback from the Executive Subcommittee and the NOP.

Step 1: Identify all issues

The Subcommittee workplan will be based on:

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

Selection criteria for workplan items:

- Relevance to the organic community (Is it an important issue or is it an interesting issue?)
- Criticality regarding mandate (Is the issue within the Subcommittee's or the NOSB's realm?)
- Feasibility. Can a proposal realistically be implemented and enforced by the NOP?

Step 2: Prioritize the issues

Workplan items should be prioritized according to the following criteria:

- Petitioned materials are given preference
- 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

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

Step 3: Set a calendar for completing reviews

Once the workplan items are prioritized, the Subcommittee chair should define a calendar for

discussion of each issue. The calendar should include deadlines and the posting/publication target dates mandated by the Program and the Federal Regulation.

Step 4: Incorporate input from the Executive Subcommittee, NOP, and finalize work plan.

Subcommittees propose work plans to the Exec Subcommittee and NOP before the NOSB biannual meeting. The NOP provides formal comments and feedback. Subcommittees revise work plans as deemed appropriate. The NOP displays final work plans at the NOSB meeting for discussion and finalization. Final workplans are validated at first ES call after the NOSB meeting. These work plans encompass the work that is planned to be done for subsequent meetings.

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SECTION VII

MISCELLANEOUS PROCEDURES

Invited Speakers

- Subcommittees identify the possible need for a presentation at the NOSB meeting. NOP may also identify needs for presentations and candidate speakers.
- The Subcommittee chairperson should send a request to the NOP, through the NOSB Chair, at least 60 days prior to meeting.
- Speakers must be approved and invited by the NOP.
- The purpose for the presentation, the subject area and the bio/resume of speaker should be circulated via email to the entire Board at least 2 weeks prior to the Board meeting.
- Invited speakers must provide objective information.
- Current petitioners cannot be invited to speakers about the topic under discussion.
- Speakers must disclose any actual or perceived conflict of interest including information about who may have provided funding for the presentation.

MISCELLANEOUS PROCEDURES

Invited Speakers

- Subcommittees, the NOSB or the NOP may identify the need for presentations and candidate speakers regarding subjects of interest or concern to be addressed at NOSB meetings.
- Requests must be made by the NOSB chair to the NOP no less than 60 days prior to the target NOSB meeting.
- Speakers must be approved and invited by the NOP.
- If approved by the NOP, the purpose for the presentation, the subject area and the bio/resume of speaker(s) should be circulated via email to the entire Board at least 2 weeks prior to the Board meeting.
- Current petitioners cannot be invited to speakers about the topic under discussion.
- Speakers are expected to disclose any financial interests that he or she has that can be reasonably assumed to influence his or her presentation content.

Surveys Conducted on Behalf of NOSB Subcommittees

- All surveys, including electronic surveys, conducted on behalf of the NOSB, must be approved by the NOSB Executive Subcommittee before they are submitted for approval to USDA, who must then submit them for approval to the Office of Management and Budget (OMB); and
- 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.

Public Comment at NOSB Meetings:

- All persons wishing to comment at NOSB meetings during public comment periods must, in general, sign-up in advance per the instructions in the Federal Register Notice for the meeting. However, the NOSB will attempt to accommodate all persons requesting public comment time. 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 NOP working closely with the NOSB Chair and will depend on availability of time.
- 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 decreases the need for paper copies to be distributed during the meeting.
- Persons will be called upon to speak according to a posted schedule. However speakers should allow for some flexibility. Persons called upon who are absent from the room could potentially miss their opportunity for public comment.
- Time allotment for public comment per person will be four (4) minutes, with the options of reducing to a minimum of three (3) and extending to a maximum of five (5) minutes at the discretion of the NOP working closely with the NOSB Chair in advance of the meeting.
- Persons must give their names and affiliations for the record at the beginning of their public comment.
- Proxy speakers are not permitted.
- Public comment requests may be scheduled according to topic.
- Individuals providing public comment will refrain from any personal attacks and from remarks that otherwise impugn the character of any individual.
- 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.

Adopted October 17 2012; 15 yes, 0 no, 0 absent, 0 abstain, 0 recuse

Policy for Public Communication between NOSB Meetings.

The NOSB and NOP seek public communication outside of Board biannual meetings and public comment periods to inform the NOSB and NOP of stakeholders' interests, and to comment on the NOSB's and NOP's work activities year around.

Adopted April 11 2013; 15 yes, 0 no, 0 absent, 0 abstain, 0 recuse

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SECTION VIII

NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

- 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.

Adopted October 17, 2001

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

A significant responsibility 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:

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

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

MATERIALS REVIEW PROCESS

Evaluation procedures for substances petitioned for addition to, 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 email of receipt of the petition
- Determine whether the petition is complete.
- Determine whether the petitioned substance is eligible for petition under the Organic Foods Production Act (OFPA) 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 email of determination of completeness and eligibility, and acknowledge the designation of certain information as CBI.
- Upon determination by the NOP of completeness and eligibility, the following actions will be taken:
 - Publish the petition on the NOP website
 - Notify the National Organic Standards Board (NOSB) Materials Subcommittee chairperson and the chairperson of the Subcommittee that will review the substance (Crops, Livestock, Handling or other pertinent Subcommittees) that the petition is complete, provide to them the OFPA review and EPA/FDA determination checklist, and request that the Subcommittee review the petition for sufficiency, and submit a request for supplemental or clarifying information.

Phase 2: Determine whether or not a third party technical review is required

During this phase:

The appropriate NOSB Subcommittee, working with other applicable NOSB Subcommittees, has 60 days to submit any questions or comments to the NOP. Comments/questions should be based on the OFPA criteria, and seek to clarify or augment specific background information.

The appropriate Subcommittee should review the petition, and using the NOP evaluation checklist for materials review (see appendix E), determine whether or not the material is appropriate to be added to, or removed from, the National List (pending detailed criteria). If the material is deemed appropriate, the Subcommittee must decide whether;

- a) there is sufficient information in the petition
- b) the Subcommittee can reasonably research any pending technical information, or
- c) there is a need to secure a technical review from a third party expert

If the material is deemed inappropriate for inclusion on, or removal from, the National List, the Subcommittee Chair will inform the NOP that the petition is ineligible, and will include an explanation. If the petition is found incomplete or insufficient, the Subcommittee may request, via the NOP, additional information from the petitioner. If the reviewing Subcommittee concludes there is a need for a third party technical review, the appropriate Subcommittee Chair will proceed to make the request to the Program.

- Notify the petitioner, via letter and/or email, that the petition is incomplete or ineligible

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. The third party must 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 Subcommittee and the pertinent Subcommittee that will conduct the review (Crops, Livestock or Handling);
- Review the draft TR using the following performance criteria. The

report will be acceptable when it:

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

During this phase the NOSB materials Subcommittee and the pertinent Subcommittee (Crops, Livestock or Handling) will:

- Review the draft TR using the following criteria. The report will be acceptable when it:
 - Is consistent in format, level of detail and tone
 - Is technically objective and free from opinions or conjecture
 - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon)
 - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance
 - Is based on the best available information that can be obtained within the designated time frame
 - Is thoroughly supported using literature citations
 - Addresses all evaluation questions as set out in the SOW
- Notify the NOP via letter and/or email, within 60 days of receiving the TR, that the TR is sufficient. If the TR is not found sufficient, the Subcommittee must provide the NOP with an explanation of why, including a request for additional information or improvements
- Upon concurrence by the NOP that the TR is insufficient, the NOP will notify the contractor by letter and/or email including 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 the Subcommittee conducting the review (Crops, Livestock or Handling)

During this phase the Subcommittee conducting the review will:

- Discuss and recommend an action on the petitioned substance. The Subcommittee may convene as the TAP by email or conference call to provide complete evaluation of the petitioned substance, as provided by OFPA 6518(k)(3). The Subcommittee 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 proposal on the NOP website and request a minimum of 30 days of written public comment on the proposal prior to the public NOSB business meeting.
- Include sufficient time on the agenda at the NOSB meeting for the Board to discuss the proposal and make a recommendation.

TECHNICAL REVIEWS

The Board has the option of requesting, through the NOP, a written technical review or report from a third party expert.

Third party experts can consist of the following:

- Employees from other USDA agencies such as AMS Science & Technology, Agriculture Research Service, or other federal agencies with appropriate expertise, as needed
- Consultants or contractors

Steps to determine the need for a third party expert:

1. Determine whether the Subcommittee has the expertise needed to address the questions related to the petition, with respect to:
 - a. Impact on the environment
 - b. Impact to human health
 - c. Sustainability and compatibility with organic principles.
2. If the Subcommittee does not have the expertise or resources (e.g., time), the Subcommittee chair should make a request to the Chair of the Materials Subcommittee 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 Subcommittee must identify the main technical issues needed to be addressed, including, but no 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 already been 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 Subcommittee should conduct a final review of the technical report and complete an assessment on the quality of work performed by the third party expert

Basic principles that should be considered when requesting third party expert advice:

- A Subcommittee cannot proceed with a recommendation on a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
- The decision to request a 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.
- 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 Subcommittee reviewing the material. In some cases the Materials Subcommittee can take the initiative to request a third party expert.
- Defining the required expertise is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee should strive to work with a range of technical experts (individuals, or institutions).

WITHDRAWAL OF A PETITION BY THE PETITIONER

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

If a petition is resubmitted, **the Board** should review it in the order in which it was received. Thus, a re-submitted petition should be considered a new request and will be placed at the end of the queue of materials pending review.

The petitioner can withdraw a petition at any time during the process.

A petitioner should have the opportunity to withdraw a petition with the intent of improving it (e.g., conducting additional research) only.

TECHNICAL ADVISORY PANEL (TAP) CONTRACT PROCEDURES

The NOSB does not hold contracting authority, and contract/SOW development is not an NOSB procedure. NOP/USDA writes and issues the SOW, and it is updated each time a new contract is announced. See Appendix G for more information regarding the contract procedures

PRIORITY OF PETITIONS GUIDELINE

Prioritization

National List materials' petitions received and deemed sufficient by the NOP/NOSB will be prioritized by the appropriate Subcommittee Chair as follows:

1. Petitions to remove a material from the National List:

- a. **Priority 1:** 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 Subcommittee (Crops, Handling, or Livestock).
- b. **Priority 2:** 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 Subcommittee (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. Priority 3: Petitions to add a material to the National List:

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

3. Priority 4: Petitions to reconsider a material for addition to the National List:

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 Subcommittee (Crops, Handling, or Livestock) queue of petitioned materials. Petitions submitted for reconsideration 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 Subcommittee, such as, but not limited to, Technical Report budgetary constraints, or a delay in the delivery of a Technical Review for a petitioned substance, the workplan may require adjustment by the NOSB and NOP.

- **BOARD PROCEDURES FOR THE MATERIALS' REVIEW PROCESS-Petitions**

- Upon receipt of the Technical Report each Subcommittee member should read it, along with the submitted petition, additional information and recommendations of the contracted panel of experts.
- Questions or clarification of the review may be answered by further review of the literature provided by the TR contractor or by the Chair of the Subcommittee who will contact the NOP, who will in turn contact the contractor directly. Questions regarding the process can be directed to the Chair of the Materials Subcommittee or NOP Material Program Director.
- The Subcommittee members will vote on whether the material is synthetic or nonsynthetic (and agricultural or non-agricultural if appropriate to handling materials) after a classification motion is made. The Subcommittee members will then vote on whether the material is to be allowed or prohibited for specific use as either a crop, livestock or handling material. Proposals may also contain an annotation which qualifies the use or context of use of the material in question.
- Subcommittee draft proposals will be submitted to the NOP at least sixty (60) days prior to the next NOSB meeting where the material will be considered.
- The Chair or Chair designate of each Subcommittee will present the proposals at the NOSB meeting. The proposals are to be presented in the form of a motion which must be seconded by an NOSB member, and following Robert's Rules of Order, the Chair will open the motion for discussion. After discussion board members will vote on the motion.
- NOSB Secretary will record the votes of each NOSB member and the Chair will announce whether or not the motion passed.
- If the motion fails the Board Chair may ask for a new motion and the procedure is repeated until a final motion is passed by a 2/3 majority (see page 11 for required votes).

BOARD PROCEDURES FOR THE MATERIALS' REVIEW PROCESS - Sunset

This 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) *or new uses of a listed substance*. 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 review of regulations to ensure the continued relevance and not the creation of new regulation, all substances 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.)

Since the sunset review process is an assessment of National List substances to ensure their

continued compliance with regulatory standards, the NOSB may determine that new restrictions in the form of annotations are necessary given changes in use patterns and scientific understanding. An annotation to expand the use of a substance does not fall within the purview of the sunset process and must only be considered through the petition process.

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 and 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.

Sunset Process (See Charts 1- 4 below)

Although not all listed materials reach sunset status at the same time, the review process remains the same:

1. An Advance Notice of Proposed Rule Making (ANPR) is placed in the Federal Register (listing the pending sunset materials. The public has 60 days from the publication date to provide written comment. A Subcommittee may request a third party technical review in anticipation of any public comments or questions.
2. Public comments are collected and forwarded to the NOSB.
3. The appropriate NOSB Subcommittee begins review of the material with the intent of providing a proposal to the entire Board for the material's removal, renewal, *or renewal with the addition of an annotation*. The review is conducted based on “Force of Evidence” as presented by Board members, public comments, and scientific data from other sources This includes the original recommendation from the Board. The Subcommittee 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 Subcommittee provides its proposal to the full Board and the public no less than 60 days prior to the Board Meeting which would include the following:
 - A simple motion to remove, add or amend an annotation, resulting in the restriction or clarification of the use of a material (if applicable).
 - A simple motion to renew the existing listing.
5. At the public NOSB business meeting, the NOSB hears additional public comment, discusses the force of evidence, and votes on the Subcommittee's proposal.
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.

The NOP will review public comment and draft the final rule. The final rule will proceed

through interagency (i.e. OGC, OMB, and department) and congressional review, and upon clearance from the appropriate parties, the NOP will publish the final rule in the Federal Register. The final rule process is illustrated in Chart 4.

Chart 1: Sunset Review – NOP Posts an ANPR

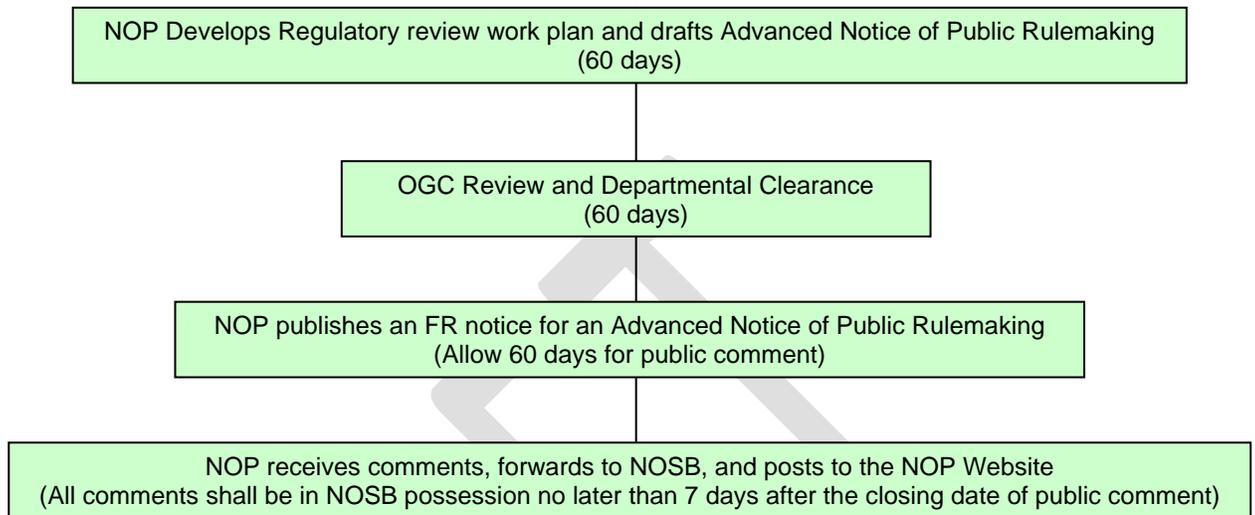
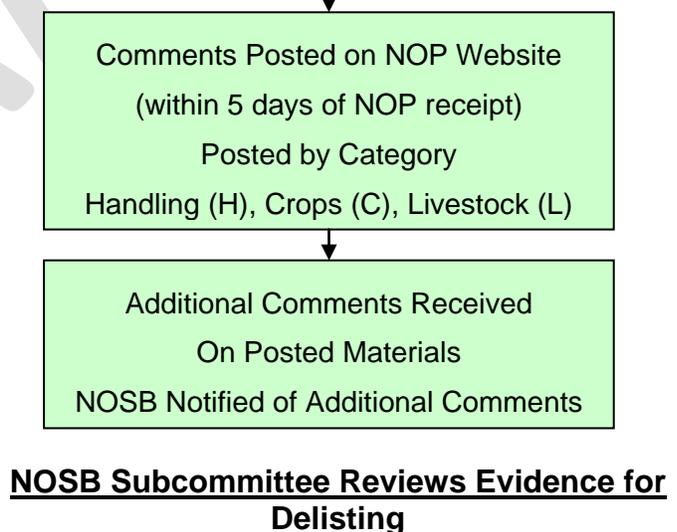
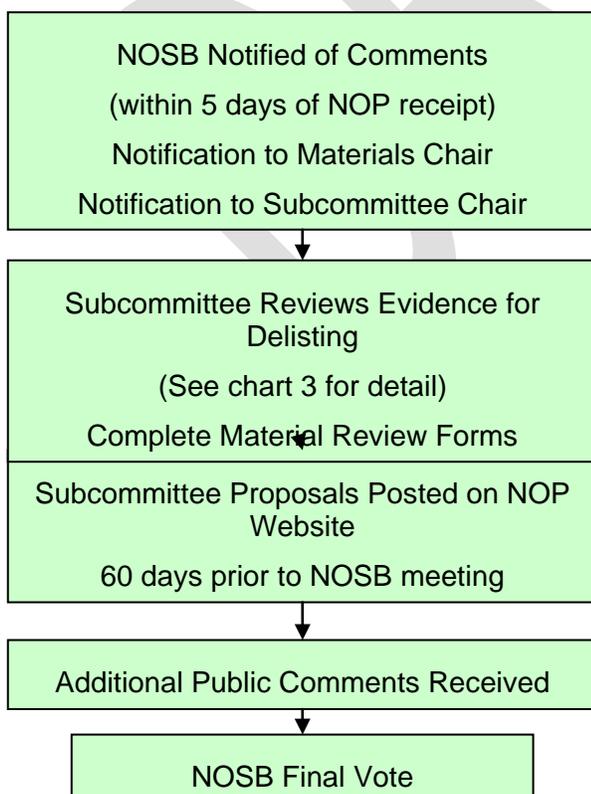


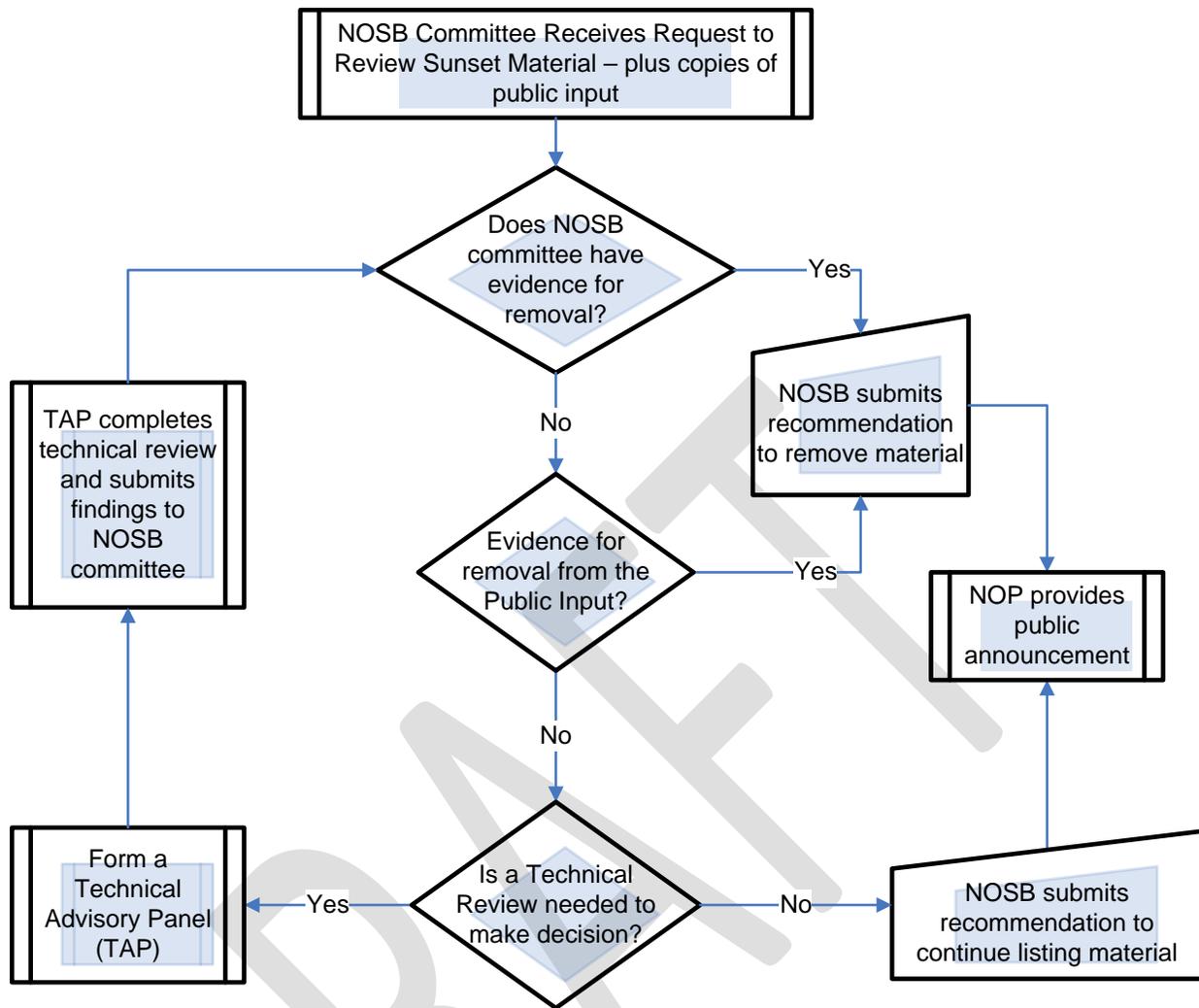
Chart 2: Sunset Review – NOP Collects and Forwards Public Comment to the NOSB



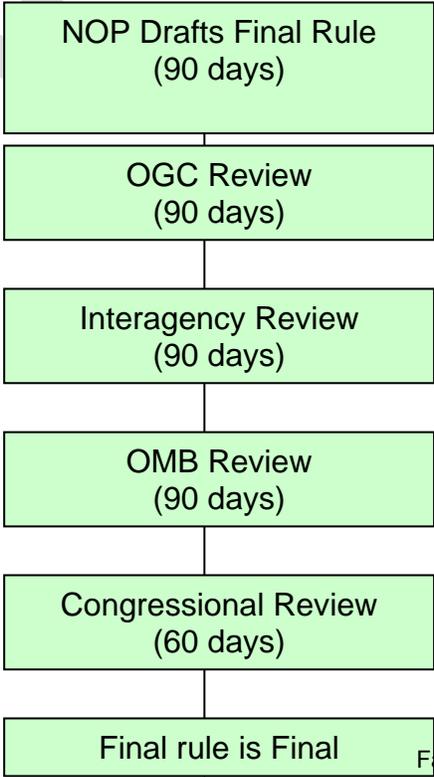
Chart 3:

Sunset Review –





**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 any discrepancies that may occur between the time an item is voted on and subsequently published in the Federal Register. Examples include:

- Annotations that differ from the original NOSB recommendation. Annotations may be changed by the Program to accommodate the requirements of other federal regulatory bodies (ex: livestock medications withholding times).
- Annotations added to address any unforeseen consequences of an NOSB recommendation, to accommodate the requirements of the organic industry. For example, the absence 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:

- The Secretary of the Board, with the assistance of the Advisory Board Specialist, shall review all additions to the Federal Register and report to the Board any discrepancies between Board recommendations and those published in the Federal Register.
- When the NOP incorporates changes to a recommendation that was voted on by the Board, the Board Officers (Chair, Vice Chair and Secretary) should be notified prior to any final action. The Board Officers will notify the Board and then work with the Program to document the reasons for such deviations in the preamble to the Rule.
- In the case of unintended consequences with a published recommendation, the Chair of the Board, with the approval of the Executive Subcommittee, will assign a Subcommittee to resolve the issue.

APPENDICES AND RESOURCES

Appendix A - DECISION MAKING GUIDELINES FOR THE NOSB

- **Define the Problem**
 - What is the problem?
 - Identify where we are now.
 - State the present condition in no more than two sentences.
 - Identify where we want to be.
 - State the future objective in no more than two sentences.

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

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

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

Appendix B - FACA FACTS

- The Federal Advisory Committee Act (FACA) (5 U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.
- 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.
- 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 the USDA to exchange facts and information, member orientation and training, and NOSB Subcommittee 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.
- Designated Federal Officers must approve all meetings and agendas, and attend meetings. The Advisory Board Specialist is the NOSB's Designated Federal Officer.
- Meeting notices and agendas must be published in the Federal Register to accommodate public participation. Although not required by FACA, the NOP strives to:
 - Post a provisional agenda on its web site no later than 90 days before the meeting is scheduled to begin
 - Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin
 - Publish notice of the meeting in the Federal Register no later than 45 days before the meeting is scheduled to begin
- While meeting transcripts are not required under FACA, the NOP invests in transcripts to support the transparency of Board meetings and to support subsequent rulemaking activities. The NOP also issues a short meeting summary, which is required by FACA, after each biannual meeting that summarizes the key issues discussed, and the outcome of voting.
- Advisory committee documents must be available for public inspection and copying until the committee ceases to exist
- Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.
- Additional information may be found at the FACA homepage:
<http://www.gsa.gov/Portal/gsa/ep/channelView.do?pageTypeld=8203&channelPage=/ep/channel/gsaOverview.jsp&channelId=-13170>

Appendix C - 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 Subcommittee	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 D - 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).

- Addition or combination reaction: Two substances combine to form one:
 - $2\text{Na} + \text{Cl}_2 \rightarrow 2\text{NaCl}$
- Decomposition reactions: One compound breaks into two or more compounds or elements.
 - $\text{CaCO}_3 \rightarrow \text{CaO} + \text{CO}_2$
- 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. $\text{AB} + \text{CD} \rightarrow \text{AD} + \text{CB}$
 - 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.
 - 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:

- Heat--most become denatured when heated above 50-60 degrees C.
- 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.
- 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.
- Organic Solvents- such as alcohols, acetone or ether.
- Mechanical treatment. Most globular proteins denatured in aqueous solution if they are stirred or shaken vigorously.
- Urea and guanidine hydrochloride- These substances can cause disruption of protein

hydrogen bonding and hydrophobic interactions.

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

References:

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

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

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

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Appendix E - FORMS

NOSB Subcommittee proposal checklists (Handling, Crops/Livestock)

Template for Subcommittee Proposal Narrative

Proposals related to material petitions or sunset reviews, should include the following:

National List reference: This section should identify the relevant Section(s) of the National List Annotations related to the material should also be included.

Background: Background should include a brief discussion of the material under review, highlighting its uses, historical context, and past NOSB decisions. It should also include a short description of any current research done by the Subcommittee (e.g., review of technical reports, individual investigation, etc.) and should provide a description of the main arguments supporting the Subcommittee's final decision, including any pertinent sections of the Regulation or OFPA.

Proposal: The motion is the core idea of the proposal and should be stated clearly including any corresponding annotation(s).

Subcommittee Vote:

This section should include the names of the members who moved and seconded the motion, as well as the number of yes votes, no votes, absences, abstentions and recusals. A motion should always be presented in the affirmative. In the case of proposals for petitions to add materials to the National List, two votes should be taken and recorded; the first a classification motion for either synthetic or non-synthetic and the second to list or not list the material.

Back-up motion:

Material Evaluation Checklist: (See appendix E)

Proposals for policy or procedure changes should include the following:

Introduction:

The introduction should include a brief summary of the proposal, key issues and relevance to the organic community, as well as the goals and intent of the proposal.

Background:

The background section should include information to justify the development of the proposal as well as any relevant work done by the NOSB or former Boards.

Relevant areas in the (Regulation):

This section should include references to Sections of the Rule or OFPA which provide the basis for the proposal.

Discussion:

The discussion section should be a thorough explanation of the proposal. In this section you should emphasize the strengths, weaknesses, opportunities and threats (SWOT) of the proposal. Additionally, it is appropriate and advisable to mention any alternatives reviewed by the Subcommittee, and any stakeholders that might be affected

Proposal:

The core idea of the proposal should be stated clearly.

Subcommittee Vote:

This section should include the names of the members who moved and seconded the motion, as well as the number of yes votes, no votes, absences, abstentions and recusals. A motion should always be presented in the affirmative. In the case of proposals for petitions to add materials to the National List, two votes should be taken and recorded; the first, a classification motion for either synthetic or non-synthetic, and the second to list or not list the material.

Back-up motion:

Minority opinion:

A Subcommittee or task force member who holds a dissenting opinion can include a minority report in the Subcommittee proposal. A minority report should include the reasons for the opposition to a proposal and cite specific opposition points. In addition, alternative approaches, solutions, or suggested amendments could be included. The minority report will be included as a separate document at the end of the proposal.

Template for Subcommittee Discussion Document

Cover sheet for Final NOSB recommendations

Appendix F - 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 appropriate 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:

- Synthetic substance's allowed for use in organic crop production
- Nonsynthetic substances prohibited for use in organic crop production
- Synthetic substances allowed for use in organic livestock production
- Nonsynthetic substances prohibited for use in organic livestock production
- Nonagricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)" or
- Nonorganic agricultural substances not commercially available in organic form

ITEM B

The petitioner must submit the following information:

- The substance's common name.
- The manufacturer's name, address, and telephone number.
- The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer, or disinfectant.
- 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.
- 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.
- A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.
- Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.
- The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance.
- 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.
- Safety information about the substance including a Material Safety Data Sheet (MSDS)

and a substance report from the National Institute of Environmental Health Studies.

- 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.
- A "Petition Justification Statement" which provides justification for one of the following actions requested in the petition:
 - *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.
- A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:
 - Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim.
 - "Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be
 - commercially valuable,
 - used in the applicant's business, and
 - maintained in secrecy.
 - Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."
 - The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy. (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy.
 - Each page with CBI-deletions should be marked "CBI-deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI- deleted."
 - If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBI-deleted.")
 - All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information usually cannot be claimed as confidential.

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

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

Appendix G - 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.

- **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.

- **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)).

- **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.

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.

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.

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.

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.

Period of Performance

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

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:

- A short summary of the accomplishments for the reporting period;
- Progress on completing individual project tasks;
- The planned and actual schedules for task completion;
- Projected accomplishments for the next reporting period; and,
- 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.

Appendix H - Research Priorities Framework

March 27, 2012

Introduction

A discussion document on a Research Priorities Framework was circulated at the last National Organic Standards Board (NOSB) meeting in November 2011. Relatively little public comment was received but much of the public comment on the other issues on the agenda brought up the ongoing need for research on many topics that come before the NOSB. We are therefore proceeding to adopt criteria and a process for making the research priorities of the NOSB known to researchers, funders, and the public.

Background

Please refer to the previous (September 27, 2011) Proposed Discussion Document for most of the background about why there is a need for this recommendation.

The discussion document was generally viewed favorably by the commenters with the primary constructive points being fleshing out how the information is prioritized and disseminated and the suggested addition of one criterion about need for alternatives to materials on the National List.

Relevant areas in the Rule

The very definition of Organic Production implies a positive approach to farming and handling that would benefit from research into the integration of cultural, biological and mechanical practices:

"§ 205.2 Terms defined.

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

The National List section requires the NOSB to evaluate a variety of criteria. In doing so, the NOSB often finds gaps in the research that would be relevant to making an informed decision on whether to add a substance to the National List.

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

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

....."

Discussion

Much discussion of this topic occurred in the Discussion document from fall 2011. The goals of this recommendation are worth repeating here, with a little streamlining.

The primary goal of this framework is for the NOSB to align on criteria for prioritizing research needs and recommend a process for collecting and communicating research needs. Additional benefits include:

- Influencing where research dollars are directed and increasing the amount of research being done related to organic agriculture.
- Allowing the NOSB to be more proactive with regards to problematic or controversial National List substances by creating a mechanism to advocate for primary research ahead of material review dates
- Reducing disagreement within the organic community by increasing the amount of primary research on which decisions could be based, while satisfying many different stakeholders that the criteria have been met.
- Making the research community aware of the research needs of organic producers and handlers. Awareness could allow for USDA funding of primary research in these top priority areas and provide support for researchers submitting grants requests these research areas.

It has been recognized through the process of reviewing materials by the NOSB that it is important not only to identify the research topic, but to ask the specific questions on a topic around which research is needed.

As a recent example, oxytetracycline, indicates, the topic may be "Alternatives to Antibiotics in Organic Fruit Production", but then the supplemental research questions could include (*these are only examples*):

- Are there common elements, such as cultural or biological methods, that should be incorporated into any Organic System Plan for prevention of fireblight?
- What are the region-specific limitations of resistance to fireblight for both rootstocks and varieties?
- What strategies and characteristics can make a fireblight resistant apple or pear variety acceptable to consumers?
- Are any of the alternative materials and methods named in the TR effective in all areas of the country?
- Are there other alternative materials that have not yet been investigated?

Each one of these questions may take a considerable time to research, but each of them are important and may fit into different areas of expertise from different researchers. Therefore, the committee feels that at least some questions should be associated with each of the top group of research priorities chosen. By doing this, aspiring organic researchers from among plant breeders, laboratory scientists, livestock nutritionists, pesticide toxicologists and more can have some guidance on what is needed and justification to put into research proposals.

Recommendation

This recommendation consists of criteria for identifying research needs, a process for the NOSB to use in developing a yearly recommendation on research needs, including making the public aware of the research recommendations.

Criteria

The criteria for prioritization are for those topics that the NOSB believes will have the largest long-term impact on growth and integrity of organic agriculture. These criteria are not presented in order of importance, but will be evaluated by the Materials Committee in selecting the top research needs.

Criteria for research topics are:

- Persistent and chronic (i.e., perennial topics of debate and need)
- Challenging
- Controversial (i.e., topics on which there are widely differing perspectives or for which there have been close NOSB votes)
- Nebulous (i.e., the research need is hard to identify but the organic agriculture need is clear). For example, improved methods of weed control.
- Lacking in primary research. That is, topics for which there is no active research being conducted, primarily relating to the criteria in OFPA for review of materials..
- Relevant to assessing the need for alternative cultural, biological, and mechanical methods to materials on the National List.

Process Framework

1. The Materials Committee will collect research topics from public comment, NOP and NOSB committees on an on-going basis. Specifically, the Materials committee should review research topic needs after every NOSB meeting to ensure that public comment and NOSB discussion on new research needs are added to a 'running' list.
2. Each NOSB Committee will address the question of research priorities that have been uncovered in the course of Committee business. Committees shall identify the specific research need(s), background on the problem(s), and a description of how the research will contribute to the ability of the NOSB to carry out its function of reviewing materials in an organic systems framework. They shall submit their committee list to the Materials Committee after each NOSB meeting.
3. Research topics will be kept by the Materials committee on an all-inclusive 'running' list. The list would include a description of the research questions that need to be addressed, and how the research methods need to be applied in an organic context. It can include a preliminary list of what entities are involved in that type of research and an evaluation of funding opportunities, collaborations and endorsements.
4. On an annual basis, the committee will review the list and based on the criteria adopted above sort the list into two groups: the top research priorities for NOSB review as a recommendation, and the rest of the research suggestions to remain on an on-going list. The top priorities will not be ranked, but will have descriptions of the key questions that the NOSB wishes to see researched about each topic.
5. The Materials Committee will present the recommendation of the top research priorities to the full NOSB each year at the fall meeting. At this time public comment can be sought about the priorities and the research questions, as well as unbiased entities or individuals who may be able to conduct pressing organic research activities. The list of remaining items that the Materials Committee has chosen not to bring forward to the full Board will also be made available to the public, so that individuals with desire to research specific subjects can know what some of the broader topics are.
6. After a recommendation is finalized by the NOSB each fall the Chair of the Board will make sure it is sent to the primary organic research funders such as NIFA, ARS, NRCS, OFRF, and private foundations and other funders that may be identified. In addition all NOP staff, NOSB members and stakeholders can use the list for inspiring appropriate research.

Adopted May 2012 14 yes, 0 no, 0 abstain, 1 absent, 0 recuse