UPDATE from the Policy Development Subcommittee August 11, 2015

The PDS collaborated with the NOP to draft revisions to the NOSB Policy and Procedures Manual. The goal is to update and streamline the document. This draft is presented for public comment and further NOSB review. There will be no vote on this document at the October 2015 meeting of the NOSB.

NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

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NATIONAL ORGANIC STANDARDS BOARD (NOSB) POLICY AND PROCEDURES MANUAL

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I. INTRODUCTION/PURPOSE

This document provides procedures for the functioning of the National Organic Standards Board (NOSB) and is designed to assist the NOSB in its responsibilities. New NOSB members are encouraged to review this manual in depth as well as to become familiar with the <u>Organic Foods</u> <u>Production Act</u> (OFPA), the USDA organic regulations at <u>7 CFR Part 205</u>, and the NOSB Member Guide. Members are advised to periodically review the contents to refresh their understanding of the NOSB's role and duties. NOSB members are entrusted with the responsibility to act in the best interests of all members of the organic community and the public at large. The NOSB's success relies upon the ability to understand each other's respective roles, and to develop successful working relationships.

The primary roles and duties of the National Organic Standards Board (NOSB):

- Serve as a link to the organic community
- Advise USDA on the implementation of OFPA
- Propose amendments to the National List of Allowed and Prohibited Substances
- Protect and defend the integrity of organic standards

A. NOSB VISION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007). 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.

B. NOSB STATUTORY MISSION

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007). 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))

C. NOSB MISSION STATEMENT

(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007). To provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program (NOP), and the consensus of the organic community.

Key activities of the Board include:

- Assisting in the development and maintenance of organic standards and regulations
- Reviewing petitioned materials for inclusion on or removal from the National List of Approved and Prohibited Substances (National List)
- Recommending changes to the National List

- Communicating with the organic community, including conducting public meetings, soliciting and accepting public comments
- Communicating, supporting and coordinating with the NOP staff

II. AUTHORIZATION

The National Organic Standards Board (NOSB) is authorized under Section 2119 of the Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6519), part of the Food, Agriculture, Conservation, and Trade Act of 1990 (FACT Act). The OFPA specified that the NOSB be established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App. 2.

A. ORGANIC FOODS PRODUCTION ACT OF 1990

The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary of Agriculture to establish a National Organic Standards Board (NOSB) in accordance with the Federal Advisory Committee Act 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 OFPA (OFPA, 7 U.S.C. Section 6518(a)).

B. FEDERAL ADVISORY COMMITTEE ACT

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.

C. NATIONAL ORGANIC STANDARDS BOARD CHARTER

The Federal Advisory Committee Act requires advisory committees to have an official charter prior to meeting or taking any action. An advisory committee charter is intended to provide a description of an advisory committee's mission, goals, and objectives. The <u>NOSB charter</u> is renewed every two years as a requirement of FACA. The NOSB charter describes the purpose of the NOSB 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 OFPA."

III. NOSB ADMINISTRATION

A. NOSB Membership

OFPA specifies the membership composition of the NOSB as follows. The NOSB shall be composed of 15 members, of which:

- Four shall be individuals who own or operate an organic farming operation;
- Two shall be individuals who own or operate an organic handling operation;
- One shall be an individual who owns or operates a retail establishment with significant trade in organic products;
- Three shall be individuals with expertise in areas of environmental protection and resource conservation;
- Three shall be individuals who represent public interest or consumer interest groups;

- One shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry; and
- One shall be an individual who is a certifying agent as identified under OFPA, 7 U.S.C. § 6518(b)

B. Nomination and appointment process

(NOSB recommendation adopted June 10, 1999)

NOSB members are appointed by the Secretary of Agriculture to a five year term. The terms are staggered and the USDA periodically requests nominations to fill upcoming vacancies. Selection criteria include the following:

- A general understanding of organic principles, and practical experience in the organic community, particularly in the sector for which the person is applying
- Demonstrated experience in the development of public policy such as participation on public or private advisory boards, boards of directors or other comparable organizations
- Participation in standards development and/or involvement in educational outreach activities
- A commitment to the integrity and growth of the organic food and fiber industry
- The ability to evaluate technical information and to fully participate in Board deliberation and recommendations
- The willingness to commit the time and energy necessary to assume Board duties
- Not currently serving (or have been elected to serve) on another USDA advisory committee or research and promotions council/board during your term
- Not registered as a lobbyist with the federal or state government

NOSB members serve without compensation. NOSB members are reimbursed by the USDA for approved travel and associated lodging expenses as determined by official federal government guidelines and regulations. In accordance with USDA policies, equal opportunity practices are followed in all appointments to the NOSB. Membership shall include to the extent possible the diverse groups served by USDA, including minorities, women, and persons with disabilities. The USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, age, disability, and where applicable, sex, marital status, familial status, parental status, religion, sexual orientation, political beliefs, genetic information, reprisal, or because all or part of an individual's income is derived from any public assistance program.

C. Responsibilities of the NOSB

(OFPA, 7 USC 6518(k)):

(1) **In General**. The Board shall provide recommendations to the Secretary regarding the implementation of this chapter.

(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 6517 of this title.

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

(4) **Special Review of Botanical Pesticides**. The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticides 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 chapter (except the provisions of section 6511 of this title) 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.

Requirements. (OFPA 6518(I)) In establishing the proposed National List or proposed amendments to the National List, the Board shall

- review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List;
- (2) work with manufacturers of substances considered for inclusion in the proposed National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced; and
- (3) submit to the Secretary, along with the proposed National List or any proposed amendments to such list, the results of the Board's evaluation and the evaluation of the technical advisory panel of all substances considered for inclusion in the National List.

Evaluation. (7 USC 6518(m)) In evaluating substances considered for inclusion on the National List the NOSB shall consider:

- 1. the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
- 2. the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
- 3. the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
- 4. the effect of the substance on human health;
- the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
- 6. the alternatives to using the substance in terms of practices or other available materials; and
- 7. compatibility with a system of sustainable agriculture.

Petitions. (7 USC 6518(n))

The board shall establish procedures for receiving petitions to evaluate substances for inclusion on the List

Sunset Provision. (7 USC 6517 (e)) No exemptions or prohibition contained 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 or reviewed and the Secretary has renewed such exemption or prohibition.

D. NOSB OFFICERS

Three principal officers, Chair, Vice Chair and Secretary, guide the NOSB. The NOSB members hold an election each fall at the public meeting to elect these three members.

CHAIR

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

- Schedules meetings of the Executive Subcommittee, in collaboration with the NOP
- Serves as a member of, convenes, and facilitates Executive Subcommittee meetings
- Convenes and presides over NOSB meetings
- Participates in the administrative team meetings
- Drafts NOSB meeting agendas in consultation with Subcommittee chairs and the NOP
- Reviews Subcommittee work agendas
- 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
- Helps maintain the Policy and Procedures Manual and ensures its accuracy

SECRETARY

The primary duties of the Secretary are as follows:

- Serves as a member of the Executive Subcommittee
- Participates in the administrative team meetings
- Records all NOSB member votes at NOSB meetings, and in collaboration with the ACS, circulates that record to NOSB members for approval

- Assists with the annual election of NOSB officers
- 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/ACS. This group is responsible for coordinating logistics and operations of the Board. The Administrative team meets via teleconference once or twice a month on an as-needed basis, to be determined by the Administrative Team.

E. NOSB-NOP COLLABORATION

The Organic Foods Production Act (7 U.S.C. 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 Section 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 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. Communication is facilitated by the Advisory Committee Specialist, 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 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.

F. NOSB WORK AGENDAS

The NOSB Work agenda is a list of projects for the upcoming semester or year for each of the Subcommittees. Agendas are developed via collaboration between the NOSB and the NOP and

are revised based on AMS-NOP requests, NOSB priorities, and public comment.

Work agendas are developed based on the following criteria:

- Within Scope: Item must be within the scope of OFPA. NOP must have a clear sense of the intent and scope of the work agenda item. The public may petition additions or deletions from the National List that will be added to the work agenda. In addition, the public may submit comments to the NOSB or write to the NOP for potential additions to the work agenda. For the NOSB, work agenda items may emerge from discussions on current issues.
- **USDA and NOP Priority**: Item must be a priority for the USDA/NOP; something that the NOP is able to implement in a reasonable timeframe.
- **Clear Need**: Item must reflect a clear need for the NOP and/or organic community, for which new or additional information or advice is needed.

The NOSB work agenda establishes Subcommittee work for the upcoming semester or year, and is developed through the following process:

- **1.** NOSB Subcommittees submit to the Executive Subcommittee draft work agenda items based on AMS-NOP requests, NOSB priorities, and requests from public comment.
- **2.** The NOP and Executive Subcommittee review the draft NOSB work agenda. The content and schedule will be reviewed on an ongoing, as needed basis.
- **3.** NOP approves NOSB work agenda.

Work agenda items should be prioritized accordingly:

- 1. Substance evaluations (e.g., petitions, 5-year sunset review)
- **2.** NOP requests to the NOSB
- 3. NOSB requests to NOP
- 4. Other projects

Below are descriptions of common NOSB work agenda items and the corresponding NOP and NOSB responsibilities.

- Review of 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. The NOSB may also make recommendations to add, remove, or modify annotations restricting the use of such listed materials.
- Changes to annotation or classification of materials The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or

reclassification of the substance. This may happen as a result of the sunset review process, or as new information is provided in a Technical Review, or from public comment.

• Recommendation for modification of existing standards or new standards

The NOP may request that the NOSB develop recommendations for new or existing standards. The request should be in writing and include a statement of the problem to be addressed, background, including the current policy or situation, statutory/regulatory authority, legal context, and desired timeframe for receiving the recommendation. The request will be posted on the NOP web site.

• Advice on NOP policy and interpretation of standards

The NOSB may provide comments on guidance or policy memos included in the Program Handbook, or may also make recommendations for new guidance or policies.

• Compliance and Enforcement

The NOP is responsible for compliance and enforcement. The NOP welcomes NOSB input on standards, but NOSB involvement in active investigations or enforcement actions is not appropriate. When timely and appropriate, the NOP reports to the NOSB 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 work agenda items that relate to the development or implementation of audit corrective actions.

G. Designated Federal Officer

FACA and its implementing regulations (5 U.S.C. App. 2) govern the roles and responsibilities of NOSB management including meeting coordination and facilitation. The Designated Federal Officer (DFO) is the individual designated to implement advisory committee procedures. The AMS/NOP Deputy Administrator is the DFO for the NOSB.

The NOP Deputy Administrator or designee acts as the Designated Federal Officer (DFO) during public meetings of the NOSB and meetings of the Executive Subcommittee. The Advisory Committee Specialist (ACS) or designee acts as the DFO for all other NOSB Subcommittee meetings. The DFO holds the authority to chair meetings when directed to do so by the official to whom the advisory committee reports.

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 semi-annual meetings

• Adjourning the meetings when such adjournment is in the public interest

H. Advisory Committee Specialist

The Advisory Committee Specialist (ACS) is an NOP staff member who is assigned to support the NOSB. The Advisory Committee Specialist prepares the Advisory Committee's and Subcommittees' meeting agendas and notes, and attends all meetings. The position of Advisory Committee Specialist (formerly called Executive Director) was added in 2005 to facilitate communication and collaboration between the NOP and the NOSB. Advisory Committee Specialist duties include but are not limited to:

- Ensuring that all FACA and OFPA requirements are implemented
- Managing calendars and work agendas to facilitate Subcommittee and NOSB activities
- Arranging, facilitating, and documenting the NOSB Subcommittee conference calls
- Ensuring NOSB 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 NOSB meetings, including preparation of Federal Register notices and press releases, and facilitation of public comments
- Coordinating the NOSB nomination and chartering process
- Facilitating training of NOSB members
- Managing information reporting and communication between the NOSB and NOP

I. ADDITIONAL ADMINISTRATIVE ITEMS

- Official to whom the Committee Reports
 The NOSB shall provide recommendations to the USDA Secretary through the Designated
 Federal Officer, the Agricultural Marketing Service's NOP Deputy Administrator.
- Staff Support

The NOP shall provide administrative support to the NOSB through the work of an Advisory Committee Specialist, who is a permanent NOP staff member. The NOP may also provide technical support to the NOSB based on need and available resources.

- Estimated Number and Frequency of Meetings
 The NOSB meets approximately twice per year for public meetings. Most NOSB
 Subcommittees meet approximately twice a month by conference call.
- Recordkeeping

Records of the NOSB shall be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available

for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552. Information about the NOSB is available online at: <u>http://www.ams.usda.gov/rules-regulations/organic/nosb</u>

While meeting transcripts are not required under FACA, the NOP invests in transcripts to support the transparency of NOSB 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.

Freedom of Information Act (FOIA; 5 U.S.C. 552). Under this Act, the public may request documents and other information pertaining to USDA actions. NOSB communications with USDA are subject to these requests, with some exemptions. Some information is routinely exempt from disclosure in 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. When there is a FOIA request for information, the USDA will review all relevant information and determine what qualifies for release, then provide it to the requestor.

J. 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.

1) NOSB Member Professional Conduct Standards

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.
- Participate in meetings Subcommittee conference calls as well as semi-annual meetings
- Serve on Subcommittees as assigned Each member must be willing to serve on Subcommittees as assigned by the NOSB Chair, and to participate in the work of those Subcommittees.
- Be informed about NOSB business NOSB members are expected to seek and study the information needed to make reasoned decisions and/or recommendations on all business brought before the NOSB.

To maintain the highest levels of honesty, integrity, and ethical conduct, no NOSB member shall participate in any "specific party matters" (i.e., matters that are narrowly focused and typically involve specific transactions between identified parties) such as a lease, license, permit, contract, claim, grant, agreement, or related litigation with the Department in which the member has a direct or indirect financial interest. This includes the requirement for NOSB members to immediately disclose to the NOP's Advisory Board Specialist any specific party matter in which the member's immediate family, relatives, business partners, or employer would be directly seeking to financially benefit from the Board's recommendations.

All members receive ethics training annually to identify and avoid any actions that would cause the public to question the integrity of the NOSB's advice and recommendations. The provisions of these paragraphs are not meant to exhaustively cover all Federal ethics laws and do not affect any other statutory or regulatory obligations to which advisory committee members are subject.

2) Additional Standards of Conduct

NOSB members should adhere to the following basic "standards of conduct" while in government service:

- Don't accept improper gifts (from those seeking actions from the Board).
- Don't use board appointments for private gain.
- Don't misuse internal non-public government information.
- Use government property and time properly.
- Don't accept compensation for teaching, speaking, and writing related to your board duties.
- Don't engage in partisan political activities while performing your board duties or while in a federal building.
- Alert the NOSB designated federal officer (DFO) if you or your employer enters into a lawsuit against USDA or its sub-agencies.
- Refrain from sharing nonpublic information with the public. 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 know, has not been made
 available to the general public: e.g. is not on the NOP or other public websites, or is
 a draft document under development by an NOSB Subcommittee.
- Use a professional, respectful tone in NOSB email correspondence; remember that all correspondence with government officials is subject to FOIA requests.
- To the maximum extent possible, NOSB members should speak with one voice. Although there may be disagreements within NOSB Subcommittees or working group sessions, once NOSB members leave the session, they have the responsibility to support the integrity of the process, whether or not they agree with the final outcome. While NOSB members retain the right to express minority opinions, the public airing of dissension could strain interpersonal relationships and create distrust and conflict among NOSB members. Such stresses could undermine the

NOSB's ability to effectively carry out its role as a governmental advisory board.

3) Failure to participate

The NOSB typically has a heavy work load and thus active participation by all 15 members is essential to carry out the mandates in OFPA. When one or more members fail to actively participate in Board work the entire NOSB and the organic community is negatively impacted. If a Board member finds that s/he cannot consistently attend Subcommittee meetings, take on work assignments, complete Subcommittee work in a timely manner, or cannot attend the twice-yearly public meetings and public comment listening sessions, the NOSB Chair shall discuss the matter with the Board member, bring the concerns to the attention of the Executive Subcommittee, and if necessary encourage the Board member to resign.

K. DECLARATION OF INTERESTS/Conflict of Interest

NOSB members are classified as **representatives** under the Federal Advisory Committee Act (FACA). Each representative is appointed to articulate the viewpoints and interests of a particular interest group. The Organic Foods Production Act (OFPA) prescribes these interest groups, which include farmers/growers, handlers, certifiers, environmentalists/conservationists, scientists, consumers and public interest groups, and retailers. Representatives are appointed to speak in "we" terms, serving as the voice of the group represented (e.g., "we farmers/growers believe..."). As such, NOSB members are not expected to provide independent expert advice, but rather advice based on the interests of the groups served.

NOSB members represent the interests of a particular group. As such, many of the interests are **acceptable interests**. An interest is acceptable if it is carried out on behalf of a represented group, and if a Board member receives no disproportionate benefit from expressing the interest. True **conflicts of interest** arise when an interest:

- Directly and disproportionally benefits you or a person associated with that member;
- Could impair your objectivity in representing your group; or
- Has the potential to create an unfair competitive advantage.

The appearance of a personal conflict and loss of impartiality, while not a true conflict, must be considered when conducting NOSB business.

Declarations of Interest/Conflicts of Interest Procedures

Board members are appointed in part because of their interests. As such, each NOSB member needs to actively consider their interests with respect to topics being considered by the Board, and identify whether these interests would create appearance problems. This consideration should occur at two specific points during the Board's work on a particular topic. The first consideration should occur at the Subcommittee level, when a Subcommittee begins work on material or topic. The second is when a discussion document or proposal advances from the Subcommittee to the full Board for consideration.

At the Subcommittee Level

NOSB members represent the diverse interests of a broad stakeholder community, and make recommendations that may have wide-reaching regulatory impacts across all of these interest groups. As such, NOSB member actions are carefully scrutinized.

Given this, the NOP has provided the following guidelines for NOSB members working at the Subcommittee level:

- Avoid leading projects for which you could reasonably be viewed by others as having a particular interest that would hinder your ability to objectively and fairly represent broader group interests, and to allow other members to represent theirs. If leading a project would likely lead others to believe you are "self-dealing" to benefit yourself or someone close to you, you should refrain from leading.
- If you feel you may have an appearance problem or conflict of interest, you should inform the NOP associate deputy administrator that a conflict may exist, and describe the nature of that conflict. You should also tell the subcommittee impacted that you may have a conflict; sharing as much or as little about the nature of the conflict with other board members as you wish. After this declaration, you may continue to contribute to the discussion on the topic. As long as it is known there is a conflict of interest, the conflict does not preclude the member from contributing his or her input to the subcommittee.
- If you are uncertain as to whether an interest constitutes an appearance problem or a true conflict, then contact the NOP associate deputy administrator to discuss it. In this case, the NOP, working with the USDA office of ethics as needed, will make the determination about whether a problem exists.

At the Full Board Level

Once discussion documents and proposals are posted for public comment, each NOSB member is to review the documents across all Subcommittees, and research any potential conflicts of interest due to organizational affiliation or relationships.

The following procedures will take place at the Board level:

- 1. Approximately 2-4 weeks before the meeting, the NOP's DFO will provide a matrix to all NOSB members that lists the items being considered at the meeting.
- **2.** If you determine that you do have a conflict of interest, use the matrix to disclose that information and to declare a recusal from voting on the item(s).
- **3.** If you are not sure whether an interest is acceptable or poses a problem, or if you are uncertain whether recusal is needed, contact the NOP associate deputy administrator to discuss. The NOP working with the USDA office of ethics as needed will make the

determination about whether a conflict of interest exists, and will instruct the member accordingly as to whether to vote or not.

- **4.** Return your completed matrix approximately one week before the board meeting. The NOP will then use these to compile a list of all recusals for the meeting.
- 5. At the meeting, at the beginning of each subcommittee session or at a time designated at the discretion of the board chair, the DFO will state: "the following board members have a conflict of interest with the following documents, and will not be voting: e.g. Bob has a conflict and will recuse himself from the proposals CleanGreenA and GreatChemB (etcetera)."
- 6. Once the DFO completes listing the recusals, the NOSB Subcommittee chair leading the session may invite additional information from members on a voluntary basis, with a statement such as: "if Board members wish to disclose information about their conflict, or any other information about their interests, they are welcome to do so at this time." this is to be stated as a general and voluntary invitation; no specific NOSB member is to be called on.
- 7. For any documents deferred to the last day of the meeting, the DFO will repeat the declaration of statement above at the start of the voting session for each subcommittee. When it is time to vote, the NOSB member recusing her/his self should state "recuse" when it is his or her time to vote.

IV. SUBCOMMITTEES

Subcommittees play an important role in administering the NOSB's responsibilities to make informed decisions. The Subcommittees are responsible for conducting research and analyses, and drafting proposals for consideration by the full NOSB. No Subcommittees are authorized to act in place of the NOSB. Subcommittees are either standing or ad hoc

A. STANDING SUBCOMMITTEES

The current standing Subcommittees are:

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

Executive Subcommittee (ES)

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 provides overall coordination for the NOSB including finalizing the NOSB meeting agenda and NOSB work agendas.

Certification, Accreditation, and Compliance Subcommittee (CACS)

The CACS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the certification, accreditation and compliance sections of the USDA organic regulations and OFPA.

Crops Subcommittee (CS)

The CS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the crop production sections of the USDA organic regulations and OFPA. The CS reviews substances under sunset review and petitions for addition to, or removal from the National List of Allowed and Prohibited Substances. The CS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic crop production to draft their proposals.

Handling Subcommittee (HS)

The Handling Subcommittee drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the handling and labeling sections of the USDA organic regulations and OFPA. The HS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The HS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic handling to draft their proposals.

Livestock Subcommittee (including Aquaculture) (LS)

The LS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the livestock and livestock feed sections of the USDA organic regulations and OFPA. The LS reviews substances under sunset review and petitions for addition to or removal from the National List of Allowed and Prohibited Substances. The LS reviews technical reports (TRs), technical advisory panel reports (TAPs), and public comments concerning materials used for organic livestock and aquaculture production to draft their proposals.

Materials Subcommittee (including Genetically Modified Organisms) (MS)

The MS drafts proposals for consideration by the NOSB to provide guidance, clarification, or proposed standards for the pertinent National List sections of the USDA organic regulations and OFPA. The MS works with the NOP and other NOSB Subcommittees in managing the Materials Review Process, which may include determining which Subcommittee will conduct a review, as well as tracking technical reports and the status of reviews for petitions and sunset materials. The MS also drafts proposals and discussion documents regarding the prohibition on the use of Genetically Modified Organisms (excluded methods) under the USDA organic regulations. Research Priorities are also a critical component of the annual work agenda of the MS.

In addition to a Chair, who will be appointed by the NOSB Chair, the MS shall include in its membership a representative from each of the Livestock, Crops, and Handling

Subcommittees.

Policy Development Subcommittee (PDS)

The Policy Development Subcommittee provides guidance, clarification or proposed standards on NOSB operations, policies, and procedures as needed, in collaboration with the NOP.

B. AD HOC SUBCOMMITTEES

At the discretion of the NOSB Chair, and with approval of the Executive Subcommittee and the DFO, 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 Committee.

C. SUBCOMMITTEE MEETINGS

Subcommittees generally hold meetings once or twice a month via telephone conference calls. Calls are scheduled well in advance on a regular reoccurring interval. Additional meetings can be held if a Subcommittee requests additional time and the NOP agrees to provide the resources to support the additional meeting. A majority of the members of a Subcommittee shall constitute a quorum for the purpose of conducting Subcommittee business.

D. TASK FORCES

The NOSB may request the establishment of a Task Force to explore specific issues or concerns relevant to the organic community and industry, and present to the NOSB draft proposals, discussion documents, or reports. Each task force shall:

- Have a specific work plan approved by the NOP
- Have a clearly articulated project deliverable
- Include at least one current member of the NOSB
- Record and maintain meeting or conference call minutes, made available to the NOSB and the NOP
- Submit a final report to the NOSB
- Disband when the NOP notifies the Task Force that its work has concluded or when the task force is no longer necessary.
- Have a specific start and end date, which may be extended by the Executive Subcommittee, with concurrence by NOP.

E. DUTIES OF SUBCOMMITTEE CHAIRS AND VICE CHAIRS

Subcommittee Chair duties:

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

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.

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

Subcommittee Chairs shall be appointed to serve annually by the Chair of the Board. Vice Chairs and Subcommittee members shall be appointed by their respective Subcommittee Chair in conjunction with the NOSB Chair. The annual Subcommittee term shall be concurrent with the one-year term established by the Secretary (beginning on January 24 and ending 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:

1. The new NOSB Chair takes Office

Immediately after the election, on the final day of the NOSB meeting, the new Chair takes office.

2. Appointment of Subcommittee Chairs

The Board Chair appoints Subcommittee Chairs preferably chosen from members with at least one year of NOSB experience.

3. Appointment of Subcommittee Vice Chair

Vice Chairs shall be appointed by the incoming Subcommittee Chair, in conjunction with the Board Chair.

4. Timeframe for Appointments

Subcommittee Chairs shall be appointed by the NOSB Chair and seated within a reasonable time after the newly elected NOSB Chair takes office (or continues in office), and Vice Chairs shall be appointed by Subcommittee Chairs as soon as possible after that.

5. Review of Subcommittee Files

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

6. 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. The Board Chair, to facilitate an effective transition for new members of the Board and ensure effective participation in Committee and Board deliberations, shall ask incoming Board members to identify a mentor from existing Board members, or, if the Board member prefers, the Board Chair shall assign a mentor.

7. Appointment of New NOSB Members:

The Board Chair will appoint each new NOSB member to appropriate Subcommittees as soon as possible, so that on January 24 all Subcommittees are in place. The NOSB Chair will consult with outgoing and incoming Subcommittee Chairs and other Board officers, with due consideration of the members interest, expertise, and background, as well as the composition and needs of the new Board and scope of Subcommittee work agendas. Once appointed, incoming Subcommittee members shall be included in all email communication pertaining to the Subcommittees on which they serve.

Changing Subcommittee Appointments

Board members who would like to join or leave a Subcommittee shall submit a 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 finds 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.

G. PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS

1. Development of proposals

Each of the NOSB Subcommittees will develop proposals, discussion documents or reports based on the current work agenda.

- A Subcommittee drafts a proposal or discussion document based on that Subcommittee's work agenda.
- By a simple majority, the Subcommittee can vote to pass a proposal or discussion document to the full Board for consideration at a subsequent NOSB meeting. 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.
- When it is not possible for a Subcommittee, during its regular deliberations on conference calls, to reach consensus on a proposed document/recommendation as it is being reviewed, and there are substantive irreconcilable differences, a minority of the Subcommittee may develop a written minority view for review by all members of the Subcommittee. The Subcommittee Chair has the responsibility to facilitate the process for the minority view.
 A minority view should:
 - Be short and concise, and include reasons for opposing the Subcommittees recommendation;
 - Should not include any data or information not introduced on a Subcommittee call;
 - Should be submitted in a timely manner, and will not be accepted after the Subcommittee has voted on its recommendation;
 - Will be included as a separate section at the end of the recommendation.
- The NOP will post the proposal or discussion document for public comment.
- At any point in the process prior to the Board's vote, a Subcommittee may convene and, by a simple majority, vote to withdraw its proposal from consideration by the Board.
- During a subsequent Board meeting, the Subcommittee presents the proposals and discussion documents as well as a summary of public comments and other relevant information for discussion and consideration by the full Board.

2. Types of Proposals

(See Member Guide for examples)

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

- Proposals related to material petitions, sunset reviews, annotation changes, or classification changes.
- Proposals for policy or procedure changes
- Discussion documents
- 3. Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings

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

- 1. **Introduction**: A brief summary of the issue or statement of the problem.
- 2. **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.
- 3. **Proposal**: A concise explanation of the recommended action.
- 4. **Subcommittee Vote**: The Subcommittee 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.
- 5. **Public Comment:** A brief summary of the public comments
- 6. **Minority View**: If applicable, the minority view of a Subcommittee or task force member shall be reported. After the Subcommittee's proposal has been presented and the motion to adopt has been made, it is usual to allow the minority to present their views. The minority report is presented for information purposes only, and it cannot be acted upon unless there is a motion to substitute it for the report of the Subcommittee.

H. SUBSTANCE/MATERIALS REVIEW PROCESS

A primary function of the NOSB is "to assist in the development of standards for substances to be used in organic production" (OFPA 6518 (a)). "The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary ..." (OFPA 6518(k)). The OFPA also establishes a petition process by which the public can request additions or deletions to the National List and also provides for a 5 –year "sunset" review by NOSB of all substances on the National List. The Materials Review Process is a collaborative effort between the NOP and NOSB. Some phases of the review process are handled exclusively by NOP and some by the NOSB.

The petition process is open to all. Petitions must be filed in accordance with the most recent Federal Register notice instructions (currently January 18, 2007 [72 FR 2167]).

1. Steps in the material review process for a new petition:

- 1. NOP receives a petition, reviews it for completeness and eligibility according to OFPA and the petition guidelines. NOP forwards the petition to the appropriate Subcommittee with a courtesy copy to the Materials Subcommittee.
- 2. Subcommittee (SC) determines if a Technical Review (TR) is needed.
- 3. Technical Report is completed and sent to the Subcommittee for review.
- 4. TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
- 5. SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting 45 days prior to public meeting.
- 6. The NOSB members analyze comments and votes on the proposal at the public meeting.

7. The NOSB Chair delivers the final recommendations to NOP.

Step 1: Receipt of Petition

During this phase the NOP will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.
- Determine whether the petition is complete and whether the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations, and whether subject to other agency authority (e.g. EPA, FDA);
- NOP documents this review using two checklists.
 - o OFPA Checklist, NOP 3005-1
 - o Petition Checklist, NOP 3005-2

Ineligible petitions include:

- Formulated (brand name) products
- Food additive without FDA approval
- Pesticide without EPA tolerance or tolerance exemption
- Requests to add substances already allowed
- Synthetic macronutrient (e.g., NPK) fertilizers
- Materials otherwise prohibited by the USDA organic regulations (e.g., sewage sludge, GMOs, etc.)
- Previously petitioned/rejected materials (if no new information is provided)

Upon determination of completeness and eligibility, NOP will:

- Notify the petitioner, via letter and/or electronic mail, that the petition is complete and eligible;
- Publish the petition on NOP website; and
- Notify the NOSB Subcommittee that the substance is being petitioned for addition or prohibition from the National List and provide the OFPA and petition checklists.
- NOP is the primary point of contact for any correspondence between NOSB and petitioner

Step 2: Determine whether a Third Party Technical Review is Required

During this phase, the applicable NOSB Subcommittee has 60 days to review the petition and determine whether a third party technical review is required. This decision is based on the following:

- Is there sufficient information in the petition?
- Can the Subcommittee reasonably research any needed technical information?
- Can sufficient information be obtained from public comment?
- Does the Subcommittee have the expertise needed to address the questions related to the petition? This includes impact on the environment, impact on human health, and sustainability and compatibility with organic principles.

If the Subcommittee decides a Technical Review is needed, the Subcommittee Chair will make the request to the National List Manager. The SC may also submit questions for specific information based on the OFPA evaluation criteria (7 USC 6817(m)), or suggest recommended technical expertise. The NOSB may request more information from the petitioner if needed.

If the Subcommittee decides the Technical Review is not needed, the Subcommittee Chair will inform the National List Manager.

In some cases, the Subcommittee may decide the substance is ineligible for the National List without need for a Technical Review. In this case, they will develop a proposal to reject the substance at the next NOSB meeting, subject to a full board vote.

A limited scope or supplemental TR may be appropriate when the petition is to amend an existing listing, remove a listing, or for purposes of sunset review.

Option for a Technical Advisory Panel (TAP)

OFPA states: "The NOSB shall convene technical advisory panels to provide scientific evaluation of materials considered for the National List." (7 USC 6518 (k)(3)) The NOSB has not convened independent Technical Advisory Panels since 2005. Currently the NOSB is relying on information within the Technical Reports provided by the NOP and public comment to make their final recommendations

In some cases, NOSB may wish to convene a TAP instead of requesting a TR, for review of complex or controversial substances.

Step 3: Third Party Technical Review

During this phase the NOP will:

- Assign a contractor to develop a Technical Review (TR) or Technical Advisory Panel (TAP). The third party contractor must have technical expertise relevant to the petition, and will use the TR template provided by NOP.
- Review all TRs or TAP reports before they are distributed to the Subcommittee to ensure they meet the requirements of the contract.
- Ensure that TRs/TAP reports are sufficient and complete when they are distributed to the Subcommittee

Third party experts may consist of contractors, or employees of the USDA, such as AMS Science and Technology, AMS Agricultural Analytics Division, Agricultural Research Service, or other federal agencies with appropriate expertise, as needed.

Step 4: Technical Review Sufficiency Determination

During this phase the Subcommittee (Crops, Livestock or Handling) will:

Review the draft TR to ensure that 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 in the TR template

The Subcommittee chair will notify the NOP, 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.

If necessary, the NOP will seek improvements or supplemental information from the contractor.

Once the Technical Reports are deemed sufficient, the NOP will post on the NOP website.

Step 5: Review by the Subcommittee (Crops, Livestock or Handling)

During this phase the Subcommittee conducting the review will:

- Read the review, along with the submitted petition, and any additional information available, such as literature referenced in the Technical Review, personal knowledge, and recommendations of a contracted panel of experts when utilized.
- Subcommittee members will prepare a written review the substance according to the OFPA criteria.
- After discussion, the Subcommittee will vote on classification (e.g., synthetic, nonsynthetic, agricultural) for substances not previously classified, and vote on a proposed action (e.g., add to National List, remove, or amend)
- The review, including record of votes, will be finalized as a proposal for the next meeting.
- All proposals must be submitted to NOP for posting 45 days before the public meeting date.

Step 6: Action by Full NOSB

During this phase the NOP will:

- Publish the proposals on the NOP website and provide 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, listen to public comments, and make a recommendation.

At the NOSB meeting:

- The Subcommittee Chair or delegated lead reviewer for each Subcommittee will present the proposals at the NOSB meeting. The proposals are to be presented in the form of a seconded motion coming from the subcommittee, and the Chair will open the motion for discussion. After discussion board members will vote on the motion.
- Voting may be by show of hands, roll call, or by use of modern voting devices.
- The NOSB Secretary will record the votes of each NOSB member and the Chair will announce whether or not the motion passed.

2. Changes to annotations or classification of materials.

The NOSB may request to review an existing substance on the National List without a new petition when they have justification to support a revision of the annotation or reclassification of the substance. This may happen as a result of the sunset review process, or based on new information provided in a Technical Review, or from public comment. The following procedure should be followed:

- The Subcommittee sends a written request for a new work agenda item to the Executive Subcommittee.
- The request should include a summary of the issue, brief justification for the change, and resources in hand or needed for the project.
- The ES considers the request and determines if it should go forward.
- NOP reviews the item for possible addition to the work agenda, and may propose to add to a future meeting schedule depending on NOSB workload.
- The Subcommittee develops a proposal for consideration that is separate from the sunset review of the substance. NOP will then consider rulemaking action in a timely manner, without constraints due to the sunset timeline.

3. Additional considerations concerning Technical Reviews

Basic principles that should be considered when consulting with a third party expert:

- A Subcommittee cannot proceed with a recommendation to list 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 independently of the availability of funds. If there is a lack of funding to secure third party expert advice, the Subcommittee has the option to place the review of new petitions on hold.
- The Subcommittee makes a determination on the completeness of the petition and whether a Technical Review is needed.
- The decision to define the expertise of the third party expert 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 may seek information from a range of technical experts (individuals or institutions). The

Subcommittee may also ask questions in their posted proposals, in order to gain needed information from the public.

• The NOP will seek Technical Reviews from a range of experts.

4. Definitions

<u>Technical Review</u> - 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.

<u>Technical Advisory Panel</u> (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.

V. Prioritization of Petitions

Petitions received and deemed eligible and sufficient by the NOP/NOSB will be prioritized as follows:

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).

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 <u>list</u> 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.

Priority 3: 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**.

Priority 4: 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 work agenda may require adjustment by the NOSB and NOP.

VI. Withdrawal of a petition by a petitioner

A petition may be withdrawn at any point in the process, prior to the vote by Subcommittee. Once a Subcommittee develops a proposal, the outcome will be posted for public comment and the NOSB will vote at the next public meeting. When a petition is withdrawn by the petitioner prior to Subcommittee proposal, the Subcommittee will suspend its review and recommendation procedure. Withdrawals will not be accepted after the subcommittee votes on a proposal.

If a petition is re-submitted, the NOSB will 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.

A petitioner has the opportunity to withdraw a petition with the intent of improving it (e.g., conducting additional research), and may also voluntarily submit supplemental information.

VII. Sunset Review Process

The Organic Foods Production Act of 1990 (OFPA) authorizes a National List of Allowed and Prohibited Substances (7 U.S. C. 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 renewed such exemption or prohibition."

The NOP published a Federal Register notice on Sept. 16, 2013 (78 FR 56811) describing current procedures for sunset review. Through the sunset review process, the NOSB can recommend to USDA the removal of substances based on adverse impact on human health, the environment, or other criteria under the Organic Foods Production Act (OFPA). If upon review the NOSB believes the substance no longer fits the criteria for an exemption or prohibition, the NOSB can recommend (by a decisive two thirds vote, 7 USC Section 6158 (i)) to remove the substance from the National List. After the NOSB has completed this "sunset" review, the USDA must renew or remove the substances on the National List to complete the process. All substances under sunset review will be considered over two NOSB meetings, to provide ample opportunity for public notice and comment.

A. Steps in the Sunset Review Process (See Member Guide for forms used in these steps.)

Step 1: The NOSB Subcommittees submit the initial **Sunset List Summary** for posting which may include requests for specific information. The NOP posts the list as well as the NOSB Meeting Announcement in the Federal Register which invites comments, at least 30 days prior to the first public meeting on these sunset substances.

Step 2: The public submits written comments, which are analyzed by

Subcommittees.

Step 3 (Public Meeting #1): Subcommittees summarize background and public comment & receive oral comment.

Step 4: Subcommittees analyze written and oral comments from Meeting #1 and prepare a **Preliminary Review** that may include a motion to remove the substance from the National List. The NOP publishes the next meeting announcement in the Federal Register, inviting comment on the **Preliminary Reviews**.

Step 5: Written public comments submitted and analyzed by Subcommittees

Step 6 (Public Meeting #2): Subcommittees present **Preliminary Review**, receive oral comment, and discuss the proposal with the full Board. When presented to the full NOSB, reviews will contain a motion and second taken in Subcommittee. Motions for removal based on the **Preliminary Review** are voted on by the full Board, and require a decisive two-thirds (2/3) majority to pass.

• At Meeting #2, the NOSB completes the **Sunset Review** and submits the final documents to the NOP.

Step 7: AMS reviews the NOSB Sunset Review and considers rulemaking action for any recommended removals. This will include a proposed rule open for public comment before a final rule amendment is published.

Step 8: AMS issues Federal Register Notice announcing renewal of applicable substances

<u>Note</u>: this is a regulatory process for determining whether materials already approved or prohibited on the National List should be removed. Due to regulatory process constraints, it is not possible to modify existing listings, add new uses of a listed substance during sunset review, or change annotations. If there is a need to consider changing an annotation or re-classifying a material, a subcommittee may request to develop a separate proposal that will be reviewed separately from the sunset review process. Decisions made through the Sunset review should be transparent, nonarbitrary, based on the best current information and in the interest of the organic community and public at large.

VIII. NOSB PROCEDURES

A. 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. 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.

B. CONDUCTING BUSINESS

NOSB public meetings in brief:

- Approximately 3 days long depending on workload
- Meetings are held in various venues across the country to allow for participation by stakeholders that otherwise may not be able to attend due to travel constraints
- A typical meeting agenda includes presentations by the NOP, presentations of proposals and discussion documents by the NOSB Subcommittees, discussion time and votes on each proposal, public comment, NOSB officer elections, and a review of work agendas

Quorum: As specified in OFPA, a majority of the members of the NOSB shall constitute a quorum for the purpose of conducting business. (7 USC 6518 (h)). In cases of a medical situation preventing attendance in person, a virtual presence is permitted.

Decisive votes: As specified in OFPA, two-thirds (2/3) of the votes cast at a meeting of the NOSB at which a quorum is present shall be decisive of any motion (7 USC Section 6518(i)). All abstentions will be recorded as such and will not be included as part of the total vote cast in case of decisive votes. Similarly, all NOSB 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

Calculation of Decisive Votes

C. PARLIAMENTARY PROCEDURES

The NOSB adopted the use of Robert's Rules of Order in March 1992, but modified its use as only a non-mandatory guide in May 1993. Roberts Rules may be adapted to meet the special requirements of a group. Because the NOSB is also subject to the OFPA, FACA and USDA, a

designated NOP staff member may act as an informal Parliamentarian to advise the Chair.

D. NOSB DELIBERATIONS AND RECOMMENDATIONS

Board actions include but are not limited to: adoption of a proposal as presented by the Subcommittee, non-substantive amendments* and then adoption of a proposal, rejection of a proposal, or referral of the proposal back to Subcommittee for further development.

* Substantive vs. non-substantive amendments.

The following criteria shall be considered when determining if a proposal will be amended at the NOSB meeting, or must be referred back to Subcommittee and resubmitted for the next Board meeting. The DFO or designee will determine whether a proposed amendment to a proposal is substantive.

- The extent to which a reasonable person affected by the recommendation would have understood that the published proposal would affect his or her interests
- The extent to which the subject of the recommendation or the issues determined in it are substantially different from the subject or issues involved in the proposal
- The extent to which the effects of the recommendation differ from the effects of the proposal

Procedure for submitting final recommendations to NOP

Within 30 days after the completion of the NOSB meeting all final recommendations must be submitted to the NOP using the following procedure:

Each proposal lead prepares the following documents:

- A recommendation cover sheet (See Member Guide). The cover sheet should contain all appropriate information, including the vote recorded at the meeting. (The NOP can provide the voting record)
- The proposal that was voted on at the meeting

The proposal leads will forward the documents to the appropriate Subcommittee Chair who will review them for accuracy and completeness, sign and date them, and then forward them to the Board Chair and the DFO/ACS.

E. PUBLIC COMMENT

The NOP and NOSB encourage public comment and work collaboratively to increase opportunities for greater participation by a broad range of people, employing various modes of communication and modern technology whenever possible. Individuals may present oral comment at either a pre-meeting electronic webinar or at the in-person NOSB meeting. **Before Public Meetings:**

Written comment: All members of the public are encouraged to submit public comment in writing according to the Federal Register Notice. Written submissions: allow NOSB members the opportunity to read comments in advance, eliminate or decrease the need for paper copies to

be distributed during the meeting and allow each NOSB member to review and analyze data and information well ahead of the public meeting and possible voting.

Oral Comments

Oral comments: May be received via a virtual meeting/webinar. Public notice of such electronic meetings will be included in the Federal Register notice announcing the public meeting. Such electronic pre-meetings may allow individuals more time to present their data or information, reduce the need to attend the public meeting in person, reduce our carbon footprint, and give the NOSB more time to absorb the information. Such electronic meetings shall be recorded and made available to the public and to NOSB members.

Comments at In-Person Public 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. 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. Written 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 comments may be scheduled according to topic.
- Individuals providing public comment shall refrain from making any personal attacks or remarks that might 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.

Policy for Public Communication between NOSB Meetings (Adopted April 11, 2013)

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.

F. ELECTION OF OFFICERS

Nominations

- Any NOSB member is eligible for consideration for any officer position
- An NOSB member may self-nominate or may be nominated by another member of the NOSB
- 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 NOSB, during which an election will be held to fill the remainder of the term
- Members may serve more than one term in any officer position.

Voting schedule

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

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
- Ballots will be counted for one office and the Secretary will announce the tally before the next office is opened for nominations
- The Secretary and Vice chair will prepare and distribute the ballots, then collect them after each vote
- The Secretary will tally the votes after each officer nomination and the Chair 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.

G. MISCELLANEOUS PROCEDURES

1. Invited Speakers

- Subcommittees, the NOSB or the NOP may identify the need for presentations and 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 be 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.

2. 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, 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.

IX. APPENDICES

A. Appendix 1: FOUNDATIONS

1. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

(NOSB Recommendation Adopted October 17, 2001)

- 1.1 Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.
- 1.2 An organic production system is designed to:
- 1.2.1 Optimize soil biological activity;
- 1.2.2 Maintain long-term fertility;
- 1.2.3 Minimize soil erosion;
- 1.2.4 Maintain or enhance the genetic and biological diversity of the production system and its surroundings;
- 1.2.5 Utilize production methods and breeds or varieties that are well adapted to the region;
- 1.2.6 Recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources;
- 1.2.7 Minimize pollution of soil, water, and air; and
- 1.2.8 Become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.
- 1.3 The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by:
- 1.3.1 Providing good quality organically grown feed;
- 1.3.2 Maintaining appropriate stocking rates;
- 1.3.3 Designing husbandry systems adapted to the species' needs;
- 1.3.4 Promoting animal health and welfare while minimizing stress; and
- 1.3.5 Avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics.
- 1.4 Organic handling practices are based on the following principles:
- 1.4.1 Organic processors and handlers implement organic good manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage;
- 1.4.2 Organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in finished products which contain less than 100% organic ingredients;

- 1.4.3 Organic products and packaging materials used for organic products do not come in contact with prohibited materials;
- 1.4.4 Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and
- 1.4.5 Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions.
- 1.5 Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.
- 1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.
- 1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.
- 1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.
- 1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.
- 1.10 Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.
- 1.11 Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (GE/GMOs) 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.

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

(NOSB Recommendation Adopted April 29, 2004)

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 nonrenewable, 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?

3. NOSB MEMBER DUTIES

To fulfill their responsibilities, Board members agree to adhere to the following Duties

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

B. Appendix 2 – 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: <u>http://www.gsa.gov/portal/content/100916</u>

Note: the following sections have been removed from the PPM, and will be added to the NOSB Member Guide:

- A. NOP COI MEMO
- B. PARLIAMENTARY PROCEDURES AT A GLANCE
- C. BASIC CHEMISTRY
- **D.** FORMS AND TEMPLATES