National Organic Standards Board Policy Development Subcommittee Policy and Procedures Manual Revision – Proposal February 23, 2016

Introduction and Background

The Policy and Procedures Manual (PPM) of the National Organic Standards Board (NOSB) was first adopted on October 19, 2002. Since its adoption the PPM has been revised 12 times with 11 revisions occurring from 2007-2011. Since April 11, 2012 this document has not been revised. The PPM was establish to assist the board in the implementation of its duties under OFPA and to establish operating procedures and policies for the board. In order to bring the PPM in line with the current operations of the board the PDS has been undertaking revisions to the PPM and presented a draft version at the October 2015 NOSB meeting for discussion. Public comments were received and full board discussion occurred on the proposed revised PPM. The PDS has revised these comments, made revisions where necessary and is presenting this revised PPM for Board approval.

Objective

The objective of this proposal to revise the April 11, 2012 version of the PPM to reflect the current procedures for the collaborative and productive functioning of the NOSB. It is designed to assist the NOSB in its responsibilities to 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 and protect/defend the integrity of organic standards. It compliments and aligns with other governing documents including the Organic Foods Production Act (OFPA), the USDA organic regulations at 7 CFR Part 205, the NOSB Charter, FACA procedures and other government laws and regulations (ie FOIA) as applicable.

Public Comment Discussion

Brief summary of comments	PDS Response
Proposed changes to the PPM	The PDS acknowledges there were a number of formatting,
need to be more transparent. (6	ordering, grammatical as well as content changes that make
comments)	comparing the April 2011 version to the proposed version difficult.
	The PPM was revised 11 times in a 5 year period and then not
	touched for 4 years - clearly a number of edits are needed bring
	this document up to date. To make the changes to the PPM more
	transparent a redline version of the document as well as a table of
	contents comparison are provided. Due to the global nature of the
	changes, the redline version provides limited value in comparing
	the two documents.
The PPM should reflect the public	The PDS agrees that the PPM should align and comply with other
information disclosure	governing documents the PDS has revised Section III I Additional
requirements of FACA in addition	Administrative Items bullet fourth and fifth bullet points to include
to FOIA. (4 comments)	FACA disclosure requirements along with FOIA.
Conflict of Interest policy of	The PDS agrees that the procedures for disclosing conflicts of
Technical Reviews (TR) and	interest are important and need to be transparent as well as
Technical Advisory Panels (TAP)	aligned with the contracting procedures of the federal
need to be transparent and the	government. It is clarified in section VI H 3 in the sixth bullet point
authoring party needs to be listed	that the contracting party will be named on the TR/TAPs and the
on the TR/TAP. (4 comments)	conflict of interest protocols to be followed for the contracting of
	TR/TAPs.

FACA definition of non-public information should be used in place of the FOIA definition. (3 comments) Changes to the PPM need to be approved by the full board. (1 comment)	The PDS agrees that the PPM should align and comply with other governing documents the PDS has revised Section III I Additional Administrative Items bullet fourth and fifth bullet points to include FACA disclosure requirements along with FOIA. The PDS agrees and added section IX to reflect this clarification.
NOSB and NOP collaboration section less collaborative than older version. (1 comment)	The PDS revised Section III E to reflect the importance of both NOP-NOSB collaboration as well as NOP-NOSB mutuality in their respective roles in the organic community.
The PDS's responsibilities do not reflect its role in reviewing and proposing changes to the PPM. (1 comment)	The PDS has revised Section IV A to reflect the PDS's role in revising the PPM and other internal policy documents.
Does not address section §6518(j) of OFPA, "The Secretary shall authorize the Board to hire a staff director." (1 comment)	The PPM should reflect the current operating procedures of the NOSB. Since the NOSB has never had the budget or the recognized authority to hire a staff director due to conflicting government regulations and laws - this is not included in this revision.
Removes NOSB authority to initiate agenda items. (1 comment)	The PDS revised Section III F to reflect the collaborative nature under which work plans are set with the program. The NOSB has the authority to initiate work agenda items and bring them to the Executive Committee and the NOP for confirmation. The proposed revisions bring the PPM into alignment with the NOSB Charter.
The section on the Advisory Committee Specialist (ACS) deletes this sentence: "The most important function of the ED is to facilitate the operation of the Board, while helping to maintain and strengthen its independence." (1 comment)	The PDS agrees that the most important function of the ACS is to facilitate the operations of the board along with facilitating communication and collaboration with the program. These section have remained. It is unfair and a conflict of interest to have this position take on the role of maintaining the board's independence.
Changes to the requirements for minority reports decrease the full understanding of the NOSB and the public. (1 comment)	The PDS disagrees with this comment. The minority view section was revised to better integrate the minority view into the final NOSB proposal and discussion as well as to facilitate a collaborative NOSB process. Objections raised by this commenter advocate for the NOSB to maintain an uncollaborative and potentially unproductive process with its own members - this is opposite to the objective of the PPM.
NOSB and NOP Conflict of Interest (COI) policies for NOSB members. (1 comment)	The PDS believe the COI procedures for NOSB members is clear and aligned with other governing documents.
NOSB policy for forced resignations needs to be better defined. (1 comment)	The NOSB has no authority to force the resignation of any of its members, this authority lies with the Secretary. This section only details circumstance where members should be encouraged to resign if they are not participating in the work of the NOSB.

Objections to greater meeting accessibility. (1 comment)	The NOSB strives to increase access to its meetings to members of the public and to its own members, regardless of their abilities to travel to the NOSB meeting. It would not be in the interest of the public, the NOSB and people of all abilities to limit access and refuse to use current common communication technology where the medical need is present.
The PPM should not adopt current	The PPM should reflect the current operating procedures of the
Sunset procedures used by the	NOSB.
Board.	

Attachments

Proposed Policy and Procedures Manual Draft February 23, 2016 (Clean)
Redline Policy and Procedure Manual comparing Draft February 23, 2016 to April 11, 2012 version
Table of Contents Comparison February 23, 2016 to April 11, 2012 version

Proposal

The NOSB moves to adopt the February 23, 2016 drafted version of the Policy and Procedures Manual.

Subcommittee Vote

The NOSB PDS subcommittee approves the three sections of this proposal as stated above.

Motion by: Tom Chapman Second: Lisa de Lima

Yes: 5 No: 0 Abstain: 0 Absent: 1 Recuse: 0

PPM Change Table

Last revised PPM (April 11, 2012)	Proposed PPM (Mar 1 2016	Change
I Introduction	I. Introduction	Updated
I NOSB Vision Statement	I.A NOSB Vision Statement	No material change
I NOSB Statutory Mission	I.B NOSB Statutory Mission	No material change
I NOSB Mission Statement	I.C NOSB Mission Statement	No material change
	III.C Responsibilities of the Board	
I Duties of Board and Officers	Appendix I: Foundations	Updated
I Maintaining Professional and Ethical	III.J Professional and Ethical Standards	
Standards	III.K Conflict of Interest	Updated
	I. Introduction	
II Board Member Job Descriptions	III.A NOSB Membership	Updated
II Board Member Standards	III.J Professional and Ethical Standards	Updated
II Conducting Business	VIII.B Conducting Business	Updated
III Role of Executive Director	III.H Advisory Committee Specialist	Updated
III Officer Responsibilities	III.D NOSB Officers	Updated
III Election of Officers	VIII.F Election of Officers	Updated
III Executive Committee	IV.A Standing Subcommittees	Updated
III Meetings	VIII.A Board Meetings	Updated
IV Board Committees	IV.A Standing Subcommittees	Updated
IV Committee Meetings	IV.C Subcommittee Meetings	Updated
IV Standing Committees	IV.A Standing Subcommittees	Updated
IV Task Forces	IV.D Task Forces	Updated
IV Ad Hoc Committees	IV.B Ad Hoc Subcommittees	Updated
	IV.E Duties of Subcommittee Chairs and	
V Duties of Committee Chairs	Vice Chairs	Updated
	IV.E Duties of Subcommittee Chairs and	
V Duties of Committee Vice Chairs	Vice Chairs	Updated
V Procedures for transitioning of	IV.F Transition of Subcommittee Chairs, Vice Chairs and Members (New and	
Committee Chairs	Continuing)	Updated
	IV.G Procedures for completing	
V Procedures for completing	Subcommittee Proposals and Discussion	
Committee Recommendations	Documents	Updated
V NOSB-NOP Collaboration	III.E NOSB-NOP Collaboration	Updated
	VIII.G Miscellaneous Procedures	
VI Miscellaneous Policies	VIII.E Public Comment	Updated
VII NOSB Principles of Organic		
Production and Handling	Appendix I: Foundations	Moved
VII NOSB Guidance of Compatibility with a System of Sustainable		
Agriculture and Consistency with		
organic Farming and Handling	Appendix I: Foundations	Moved

VIII Committee Work Plans	III.F NOSB Work Agendas	Updated
VIII Materials Review Process	IV.H Substance/Materials Review Process	Updated
VIII Procedures for Handling Technical		
Reviews	IV.H Substance/Materials Review Process	Updated
VIII Handling Withdrawals of Petitions	VI. Withdrawal of a Petition by a	
by the Petitioner	Petitioner	Updated
VIII Technical Advisory Panel Contract		
Procedures	IV.H Substance/Materials Review Process	Updated
VIII Information to be Included in a		
Petition	IV.H Substance/Materials Review Process	Updated
VIII Priority of Petitions Guideline	V. Prioritization of Petitions	Updated
VIII NOSB Committee		Moved to Member
Recommendation	-removed-	Guide
VIII Evaluation Criteria for Substance		Moved to Member
added to the National List	-removed-	Guide
VIII NOSB Recommended Decision	VIII.D NOSB Deliberations and	Updated/Moved to
Form	Recommendations	Member Guide
VIII Procedures for the Materials		
Review Process for NOSB Members	IV.H Substance/Materials Review Process	Updated
VIII Sunset Review Process	VII Sunset Review Process	Updated
VIII Handling Technical Errors After an	VII SUIISCE NEVIEW 1 10ccss	Opuateu
Item has been Placed in the Federal		
Register	-removed-	Removed
Appendix A Decision Making		
Procedures for the NOP	-removed-	Removed
Appendix B FACA Facts	Appendix II: Faca Facts	No material change
Appendix C Duties of the Designated	Tipperiam in vaca racte	Tro material enange
Federal Officers	III.G Designated Federal Officer	Updated
Appendix D Parliamentary Procedures		
at a Glance	VIII.C Parliamentary Procedures	Updated/Removed
Appendix E Basic Chemistry	-removed-	Removed
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	II.A OFPA	Added
	II.B FACA	Added
	II.C NOSB Charter	Added
	III.B Nomination and Appointment	Added
	III.I Additional Administrative Items	Added
	IX. Revisions to the Policy and Procedures	
	Manual	Added

NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

Adopted October 19, 2002
Revised August 18, 2005
Revised March 29, 2007
Revised November 30, 2007
Revised May 22, 2008
Revised November 19, 2008
Revised May 6, 2009
Revised November 9, 2009
Revised April 29, 2010
Revised October 28, 2010
Revised April 29, 2011
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Revised April 11, 2012

Draft Feb. 23, 2016

NATIONAL ORGANIC STANDARDS BOARD (NOSB) POLICY AND PROCEDURES MANUAL

Contents

I.	INTRODUCTION/PURPOSE	4
A.	NOSB VISION STATEMENT	
В.	NOSB STATUTORY MISSION	
C.	NOSB MISSION STATEMENT	
**	AUTHORIZATION	
II.		
A.	ORGANIC FOODS PRODUCTION ACT OF 1990	
В.	FEDERAL ADVISORY COMMITTEE ACT	
C.	NATIONAL ORGANIC STANDARDS BOARD CHARTER	5
III.	NOSB ADMINISTRATION	5
A.	NOSB Membership	5
В.	NOMINATION AND APPOINTMENT PROCESS	6
C.	RESPONSIBILITIES OF THE NOSB	6
D.	NOSB OFFICERS	8
	CHAIR	8
	VICE CHAIR	
	SECRETARY	
	ADMINISTRATIVE TEAM	
E.	NOSB-NOP COLLABORATION	
F.	NOSB WORK AGENDAS	
G.	DESIGNATED FEDERAL OFFICER	
H.	ADVISORY COMMITTEE SPECIALIST	
l.	ADDITIONAL ADMINISTRATIVE ITEMS	
J.	PROFESSIONAL AND ETHICAL STANDARDS	
	NOSB Member Professional Conduct Standards	
	2) Additional Standards of Conduct	
K.	DECLARATION OF INTERESTS/CONFLICT OF INTEREST	
	·	
IV.	SUBCOMMITTEES	
A.	STANDING SUBCOMMITTEES	
В.	AD HOC SUBCOMMITTEES	-
C.	SUBCOMMITTEE MEETINGS	
D.	TASK FORCES	
E.	DUTIES OF SUBCOMMITTEE CHAIRS AND VICE CHAIRS	
F.	TRANSITION OF SUBCOMMITTEE CHAIRS, VICE CHAIRS, AND MEMBERS (NEW AND CONTINUING)	
G.	PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS	
	1. Development of proposals	
	2. Types of Proposals	
	3. Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings	
Н.	SUBSTANCE/MATERIALS REVIEW PROCESS	
	1. Steps in the material review process for a new petition:	
	2. Changes to annotations or classification of materials	

	3. Additional considerations concerning Technical Reviews	28
	4. Definitions	
V.	PRIORITIZATION OF PETITIONS	28
VI.	WITHDRAWAL OF A PETITION BY A PETITIONER	29
VII.	SUNSET REVIEW PROCESS	30
VIII.	NOSB PROCEDURES	31
A.	BOARD MEETINGS	31
В.	CONDUCTING BUSINESS	31
C.	PARLIAMENTARY PROCEDURES	32
D.	NOSB DELIBERATIONS AND RECOMMENDATIONS	32
E.	PUBLIC COMMENT	
F.	ELECTION OF OFFICERS	34
G.	MISCELLANEOUS PROCEDURES	35
	1. Invited Speakers	35
	2. Surveys Conducted on Behalf of NOSB Subcommittees	36
IX.	REVISIONS TO THE POLICY AND PROCEDURES MANUAL	36
X.	APPENDICES	37
Α.	APPENDIX 1: FOUNDATIONS	37
	1. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING	
	2. NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND	
	CONSISTENCY WITH ORGANIC FARMING AND HANDLING	39
	3. NOSB MEMBER DUTIES	39
В.	APPENDIX 2 – FACA FACTS	41

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. This policy and procedures manual does not supersede authority or responsibilities as specified in the Federal Advisory Committee Act or the Organic Foods Production Act (OFPA). NOSB members are encouraged to review this manual in depth as well as to become familiar with the 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 reviewing 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 NOSB charter 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

- (1) 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;
- 5. 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 Advisory Committee Specialist (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 Designated Federal Official/Advisory Committee Specialist. 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

In 1990, the Organic Foods Production Act (OFPA: 7 U.S.C. 6518 (a)) directed the Secretary of Agriculture to "establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (FACA)) ... 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. Section 6503 (a) of the OFPA requires that the Secretary "shall establish an organic certification program ... and shall consult with the NOSB" (6503(c)). The National Organic Program (NOP) is the governmental institution responsible for implementing the OFPA and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture. The NOSB, as a FACA advisory committee, 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. Therefore, 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

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 unique nature of the NOSB and its relationship with the NOP, as established through OFPA, requires that the volunteer Board, which regularly receives stakeholder input through public comment, must work collaboratively with the NOP.

Similarly the NOP, as required through OFPA, must consult and collaborate with the NOSB

Team work and collaboration between the NOSB and the NOP, as well as others in the organic community, is needed to maintain, enhance and promote the integrity of organic principles and products. 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.

The work of the NOP and NOSB since the 1990 passage of the OFPA clearly demonstrates the

need for the high level of collaboration and consultation described above. NOP, NOSB and its associated stakeholders must continuously work to seek common ground, collaborate and consult in order to build organics and maintain organic integrity. Every aspect of this work must take place in a manner which clearly demonstrates mutual respect and positive intent.

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 confirms the final NOSB work agenda, and provides written confirmation. .

Work agenda items should be prioritized accordingly:

- **1.** Substance evaluations (e.g., 5-year sunset review, petitions)
- 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:

http://www.ams.usda.gov/rules-regulations/organic/nosb

While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of NOSB meetings and to support subsequent rulemaking activities. Minutes of each NOSB meeting, as approved by the DFO and the NOSB Chair and Secretary, shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions, and the outcome of voting.

FACA requires (5 U.S.C. App. Section 10 (b)): "Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist."

Any request for FACA records must be made to the NOP.

While requests for FACA Board records do not have to go through the formal FOIA request process, those records must be reviewed by AMS/NOP before release, to determine whether any FOIA exemptions apply (e.g., personal information, business proprietary information). In addition, OFPA itself requires that no confidential business information be released, so emails and documents need to be reviewed before release to ensure that this requirement is met.

• 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 (including email) are subject to these requests, with limited exemptions. Some USDA 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:

- Do not accept improper gifts (from those seeking actions from the Board).
- Do not use board appointments for private gain.
- Do not misuse internal non-public government information.
- Do not use government property and time improperly.
- Do not accept compensation for teaching, speaking, and writing related to your board duties.

- Do not 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 working documents with the public. Working documents are
 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.
- Do not circulate draft Subcommittee documents until they are finalized and publicly available to all on the AMS/NOP website.
- 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 DFO 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 DFOto 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 DFO 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 clarification and proposed changes for NOSB internal policies, and procedures as needed, in collaboration with the NOP. The PDS, in collaboration with the NOP, also updates and revises the NOSB Policy and Procedures Manual and the Member Guide.

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 agenda 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 agendas 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 agendas
- 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 agenda 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;

- o 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.
- o 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. If the Board then determines that the minority view has merit, it may send the proposal back to Subcommittee for further work, since it would be a substantive change to the proposal as presented.

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:

- 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. The name of the contracted party will appear on the Technical Review. All Federal contracts, including those issued by USDA/NOP to Technical Report contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a "Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions," which requires contractors to identify and prevent personal conflicts of interest for their covered employees. "Personal conflict of interest" means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract.

Link: https://www.acquisition.gov/far/current/pdf/FAR.pdf

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. The NOSB observes the following procedure.

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 includes 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**, which are posted on the NOP website.

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, non-arbitrary, 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.

Calculation of Decisive Votes

# 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

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 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.
- 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, unless invited by the NOSB Chair.

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. REVISIONS TO THE POLICY AND PROCEDURES MANUAL

- The PDS will review the PPM each year and, working in collaboration with the NOP, determine if any updates are necessary.
- Proposed changes will be subject to review and approval by the NOP and the full NOSB.

X. 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 non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
- Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- Does the substance allow for an increase in the long-term viability of organic farm operations?
- Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- Is there adequate information about the substance to make a reasonable determination on the substance's compliance with each of the other applicable criteria? If adequate information has not been provided, does an abundance of caution warrant rejection of the substance?
- Does use of the substance have a positive impact on biodiversity?

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
 - o Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to hegin
 - 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 provides transcripts or
 meeting notes to support the transparency of Board meetings and to support subsequent
 rulemaking activities. The NOP also issues a short meeting summary, which is required by
 FACA, after each biannual meeting that summarizes the key issues discussed, and the
 outcome of voting.
- Advisory committee documents must be available for public inspection and copying until the committee ceases to exist.
- Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.
- Additional information may be found at the FACA homepage: http://www.gsa.gov/portal/content/100916

This is a comparison document between the currently posted version of the NOSB Policy and Procedures Manual (April 11, 2012) and the new Feb. 29, 2016 draft. Revisions are shown in strikeout for deletions, and with underline for additions or rearranging.

NATIONAL ORGANIC STANDARDS BOARD

POLICY AND PROCEDURES MANUAL

Adopted October 19, 2002
Revised August 18, 2005
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Revised April 29, 2011
Revised December 2, 2011
Revised April 11, 2012
Draft Feb. 29, 2016

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NATIONAL ORGANIC STANDARDS BOARD (NOSB-)

POLICY AND PROCEDURES MANUAL

TABLE OF CONTENTS

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Contents

<u>INTRODUCTION</u>	Formatted: Font: +Headings (Calibri)
SECTION I	6
NOSB VISION STATEMENT	 6
NOSB STATUTORY MISSION	 7
"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))	 7
NOSB MISSION STATEMENT	 7
DUTIES OF THE BOARD AND OFFICERS	 7
Duty of Care	 14
Duty of Loyalty	 15
Duty of Obedience	 15
MAINTAINING PROFESSIONAL AND ETHICAL STANDARDS	 16
◆Professional Conduct	 18
Conflict of Interest	35
SECTION II	35
BOARD MEMBER 10B DESCRIPTIONS	37
Composition of the Board	37
BOARD MEMBER STANDARDS	
CONDUCTING BUSINESS	38
SECTION III	38
ROLE OF THE EXECUTIVE DIRECTOR	 39
OFFICER RESPONSIBILITIES	 4 0
ELECTION OF OFFICERS	 4 1
EXECUTIVE COMMITTEE	 4 3
MEETINGS	 44
SECTION IV	4 4
BOARD COMMITTEES	44
COMMITTEE MEETINGS	45
STANDING COMMITTEES.	 4 5
Certification, Accreditation, and Compliance Committee (CACC)	 4 5
Crops Committee (CC)	
Handling Committee (HC)	 4 5
Livestock Committee (LC)	
Materials Committee (MC)	 46
Policy Development Committee (PDC)	 46
TASK FORCES	 4 6
AD HOC COMMITTEES	 4 6
SECTION V.	46

DUTIES OF COMMITTEE CHAIRS	4 /
DUTIES OF COMMITTEE VICE-CHAIRS	 4 7
PROCEDURES FOR THE TRANSITION OF COMMITTEE CHAIRS	
PROCEDURES FOR COMPLETING COMMITTEE RECOMMENDATIONS	
Writing Committee Recommendations	
Presenting Committee Recommendations at NOSB Meetings	
NOSB-NOP COLLABORATION	 12
SECTION VI	 57
MISCELLANEOUS POLICIES	57
NOSB Policy for Presenters Invited by Committees	57
NOSB Policy for Surveys Conducted on Behalf of NOSB Committees	57
NOSB Policy for Public Comment at NOSB Meetings:	
SECTION VII	61
NOSE PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING	61
NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND	01
CONSISTENCY WITH ORGANIC FARMING AND HANDLING.	64
SECTION VIII	6 5
PROCEDURES OF THE NOSB.	65
COMMITTEE WORK PLANS	65
MATERIALS REVIEW PROCESS	
Evaluation Procedures for Substances Petitioned for Addition or Removal from the National	
List	67
Definitions	
Phase 1: Receipt of Petition and Examination of Petition for Completeness and Eligibility	 67
Phase 2: Determine if a Third Party Technical Review is Required	 68
Phase 3: Evaluation by a Third Party Expert	 68
Phase 4: Sufficiency Determination	
Phase 5: Action by NOSB Materials Chair and the Committee that the Substance Is Being	
Petitioned for Addition or Prohibition from the National List (Crops, Livestock or Handling)	 70
Phase 6: Action by Full NOSB	 70
PROCEDURES FOR HANDLING TECHNICAL REVIEWS	
HANDLING WITHDRAWALS OF PETITIONS BY THE PETITIONER.	 72
TECHNICAL ADVISORY PANEL (TAP) CONTRACT PROCEDURES	72
STATEMENT OF WORK	
AGENCY NEED	
Phase 1: Data Gathering and Compilation (120 days)	
Phase 2: Evaluation against Criteria (100 days)	
Phase 3: Recommendation (42 days)	75
Evaluation Factors for Award	
OTHER EVALUATION FACTORS	
Reporting Requirements	7 6
INFORMATION TO BE INCLUDED IN A PETITION	
PRIORITY OF PETITIONS GUIDELINE.	82
NOSB COMMITTEE RECOMMENDATION	83
EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST	85
NOSB RECOMMENDED DECISION FORM	
PROCEDURES FOR THE MATERIALS REVIEW PROCESS FOR NOSB MEMBERS.	
SUNSET REVIEW PROCESS	
Chart 1: Sunset Review - NOP Posts an ANPR	
	0 1

	Chart 3: Sunset Review – NOSB Committee Reviews Evidence for Delisting	94
	Chart 4: Sunset Review — NOSB Committee Reviews Evidence for Delisting	
	Final Rule Process Error! Bookmark not	
HANI	DLING TECHNICAL ERRORS AFTER AN ITEM HAS BEEN PLACED IN THE FEDERAL REGISTER	95
	INDICES AND RESOURCES	
APPE	NDIX A - DECISION MAKING PROCEDURES FOR THE NOP	96
	NDIX B - FACA FACTS	
	NDIX C - DUTIES OF THE DESIGNATED FEDERAL OFFICER	
	NDIX D - PARLIAMENTARY PROCEDURE AT A GLANCE	
APPE	NDIX E - BASIC CHEMISTRY	 100
I.	INTRODUCTION/PURPOSE	<u></u> 6
Α.	NOSB VISION STATEMENT	6
<u>л.</u> В.	NOSB STATUTORY MISSION	
C.		
II.		
A.	ORGANIC FOODS PRODUCTION ACT OF 1990	7
B.	FEDERAL ADVISORY COMMITTEE ACT	
c.	NATIONAL ORGANIC STANDARDS BOARD CHARTER	8
III.	NOSB ADMINISTRATION	c
111.		
Α	NOSB MEMBERSHIP	
В	NOMINATION AND APPOINTMENT PROCESS.	
<u>C.</u>	RESPONSIBILITIES OF THE NOSB	
D.	NOSB OFFICERS	
	CHAIR	
	VICE CHAIR	
	SECRETARYADMINISTRATIVE TEAM	
E.	NOSB-NOP COLLABORATION	
F.	NOSB WORK AGENDAS	
G.	DESIGNATED FEDERAL OFFICER	
H.	ADVISORY COMMITTEE SPECIALIST	
i.	ADDITIONAL ADMINISTRATIVE ITEMS.	
J.	PROFESSIONAL AND ETHICAL STANDARDS	
	1) NOSB Member Professional Conduct Standards	18
	2) Additional Standards of Conduct	19
	3) Failure to participate	20
K.	DECLARATION OF INTERESTS/CONFLICT OF INTEREST.	<u></u> 20
IV.	SUBCOMMITTEES	22
<u>A.</u>	STANDING SUBCOMMITTEES.	
<u>B.</u>	AD HOC SUBCOMMITTEES.	
<u>C.</u>	SUBCOMMITTEE MEETINGS	
<u>D.</u> E.	TASK FORCES DUTIES OF SUBCOMMITTEE CHAIRS AND VICE CHAIRS	
<u>E.</u> F.	TRANSITION OF SUBCOMMITTEE CHAIRS, VICE CHAIRS, AND MEMBERS (NEW AND CONTINUING)	
<u>r.</u> G.	PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS	
<u>u.</u>	1. Development of proposals	
	2. Types of Proposals	
	3 Presenting Subcommittee Proposals and Discussion Documents at NOSR Meetings	

н.	SUBSTANCE/MATERIALS REVIEW PROCESS	28
	SUBSTANCE/MATERIALS REVIEW PROCESS	28
	2. Changes to annotations or classification of materials.	32
	3. Additional considerations concerning Technical Reviews	<u></u> 32
	4. Definitions	
٧.	PRIORITIZATION OF PETITIONS	<u></u> 33
VI.	WITHDRAWAL OF A PETITION BY A PETITIONER	<u></u> 34
VII.	SUNSET REVIEW PROCESS	34
VIII.	NOSB PROCEDURES	<u></u> 37
Α.	BOARD MEETINGS	
В.	CONDUCTING BUSINESS	
<u>C.</u>	PARLIAMENTARY PROCEDURES	<u></u> 43
D.	NOSB DELIBERATIONS AND RECOMMENDATIONS.	<u></u> 43
Ε.	PUBLIC COMMENT.	<u></u> 54
F.	ELECTION OF OFFICERS.	
G.	MISCELLANEOUS PROCEDURES	<u></u> 60
	1. Invited Speakers	<u></u> 60
	2. Surveys Conducted on Behalf of NOSB Subcommittees	<u></u> 60
IX.	REVISIONS TO THE POLICY AND PROCEDURES MANUAL	<u></u> 60
<u>X.</u>	APPENDICES	<u></u> 61
Α.	APPENDIX 1: FOUNDATIONS	
	1. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING	<u></u> 61
	2. NOSB GUIDANCE ON COMPATIBILITY WITH A SYSTEM OF SUSTAINABLE AGRICULTURE AND	
	CONSISTENCY WITH ORGANIC FARMING AND HANDLING	
	3. NOSB MEMBER DUTIES	
B.	APPENDIX 2 – FACA FACTS	96

INTRODUCTION/PURPOSE

This document is intended as a guideprovides procedures for all membersthe functioning of the National Organic Standards Board (NOSB). Board members are entrusted with a strong responsibility to treat the business of the Board as fiduciaries for all members of the organic community and the public at large.

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

This manual) and is designed to assist the BoardNOSB in its responsibilities. New BoardThis policy and procedures manual does not supersede authority or responsibilities as specified in the Federal Advisory Committee Act or the Organic Foods Production Act (OFPA). NOSB members are encouraged to review this manual in depth as well as to become familiar with the Organic Foods Production Act (OFPA), 7 CFR Part 205, and the NOSB NewOFPA, the USDA organic regulations at 7 CFR Part 205, and the NOSB Member Guide. Existing members are advised to periodically review the contents to refresh their understanding of the Board's NOSB's role and their 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

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

SECTION I

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

- 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.

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B. NOSB STATUTORY MISSION

<u>"(NOSB Recommendation adopted October 19, 2002, revised November 30, 2007).</u>

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.

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

Accist

- Assisting in the development and maintenance of organic standards and regulations;
- REVIEWReviewing petitioned materials for inclusion on or DELETION removal from the National List of Approved and Prohibited Substances (National List);).
- RECOMMEND Recommending changes to the National List;
- COMMUNICATECommunicating with the organic community, including conducting public meetings, soliciting and TAKING reviewing public comments PROVIDE TIMELY INFORMATION AND EDUCATION ON THE NOP, MAKING REASONABLE USE OF A VARIETY OF COMMUNICATION CHANNELS.
- COMMUNICATE, SUPPORT AND COORDINATE Communicating, supporting and coordinating with the NOP staff fx

DUTIES OF THE BOARD AND OFFICERS

II. - AUTHORIZATION

The National Organic Standards Board (NOSB) is authorized under Section 2119 of the 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

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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 NOSB charter 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 defines 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 specific responsibilities for the Board starting at Sec 2119:

 A general understanding of organic principles, and practical experience in the organic community, particularly in the sector for which the person is applying Formatted: level-1, Indent: Left: 0.25"

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- 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. In General. The Board shall provide recommendations to the Secretary regarding the implementation of this titlechapter.

(2) NATIONAL LIST.—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 21186517 of this title.

(3) TECHNICAL ADVISORY PANELS. 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. (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. 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.—Emergency Spray Programs. The Board shall advise the Secretary concerning rules for exemptions from specific requirements of this TITLEchapter.

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(except the provisions of section 21126511 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.

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

-6518(n) PETITIONS. The |) In establishing the proposed National List or proposed amendments to the National List, the Board shall establish procedures under which persons may petition the Board for the purpose

(1) 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.

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

- 1. __6509(d) (2) STANDARDS.-the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
- the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
- 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;
- 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

<u>Sunset Provision.</u> (7 USC 6517 (e)) No exemptions or prohibition contained in the National List shall be valid unless the National Organic Standards Board <u>SHALL RECOMMEND TO-has</u> reviewed such exemption or prohibition as provided in this section within 5 years of such

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<u>exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.</u>

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D. NOSB OFFICERS

<u>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.</u>

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 Advisory Committee Specialist (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 Designated Federal Official/Advisory Committee Specialist. 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

In 1990, the Organic Foods Production Act (OFPA: 7 U.S.C. 6518 (a)) directed the Secretary of Agriculture to "establish a National Organic Standards Board (in accordance with the Federal Advisory Committee Act (FACA)) ... 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. Section 6503 (a) of the OFPA requires that the Secretary "shall establish an organic certification program ... and shall consult with the NOSB" (6503(c)). The National Organic Program (NOP) is the governmental institution responsible for implementing the OFPA and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture. The NOSB, as a FACA advisory committee, 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. Therefore, 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

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 unique nature of the NOSB and its relationship with the NOP, as established through OFPA, requires that the volunteer Board, which regularly receives stakeholder input through public comment, must work collaboratively with the NOP.

Similarly the NOP, as required through OFPA, must consult and collaborate with the NOSB

Team work and collaboration between the NOSB and the NOP, as well as others in the organic community, is needed to maintain, enhance and promote the integrity of organic principles and products. 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.

The work of the NOP and NOSB since the 1990 passage of the OFPA clearly demonstrates the need for the high level of collaboration and consultation described above. NOP, NOSB and its associated stakeholders must continuously work to seek common ground, collaborate and consult in order to build organics and maintain organic integrity. Every aspect of this work must take place in a manner which clearly demonstrates mutual respect and positive intent.

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:

- NOSB Subcommittees submit to the Executive Subcommittee draft work agenda items based on AMS-NOP requests, NOSB priorities, and requests from public comment.
- 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 confirms the final NOSB work agenda, and provides written confirmation. .

Work agenda items should be prioritized accordingly:

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

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• 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 IN ADDITION TO THOSE IN PARAGRAPH (1) FOR THE CARE OF

The NOSB may review the quality management system and internal audits to ensure that SUCH LIVESTOCK IS ORGANICALLY PRODUCED—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.

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

- Duty of Care
- Duty of Loyalty
- Duty of Obedience

-Duty of Care

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

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

Duty of Loyalty

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

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

Duty of Obedience

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

G. Act within the requirements of the law—Board members must uphold all state and federal statutes, including the Designated Federal Advisory Committee Act (Officer

• FACA —and its implementing regulations (5 U.S.C. App. 2—t seq.,) 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.

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Follow the responsibilities of the Board as defined by the Organic Foods Production Act of 1990.

Follow the 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 SPECIFIED IN THE NOSB POLICY AND PROCEDURES MANUAL are implemented

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Maintaining Professional and Ethical Standards

- 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:

http://www.ams.usda.gov/rules-regulations/organic/nosb

While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes to support the transparency of NOSB meetings and to support subsequent rulemaking activities. Minutes of each NOSB meeting, as approved by the DFO and the NOSB Chair and Secretary, shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions, and the outcome of voting.

FACA requires (5 U.S.C. App. Section 10 (b)): "Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist."

Any request for FACA records must be made to the NOP.

While requests for FACA Board records do not have to go through the formal FOIA request process, those records must be reviewed by AMS/NOP before release, to determine whether any FOIA exemptions apply (e.g., personal information, business proprietary information). In addition, OFPA itself requires that no confidential business information be released, so emails and documents need to be reviewed before release to ensure that this requirement is met.

 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 (including email) are subject to these requests, with limited exemptions. Some USDA 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 for the conduct of all activities both within and outside of the NOSB. Areas of particular concern include professional conduct and conflict of interest.

•1) NOSB Member Professional Conduct Standards

Public service is a public trust, requiring NOSB members shall:

- → Observe ethical principles above private gain in the service of public trust.
- NOSB members shall putPut forth an honest effort in the performance of their NOSB duties.
- •• NOSB members shall make Make no commitments or promises of any kind purporting to bind the Government.

<u>Act</u>

- NOSB members-shall 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,

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relatives, business partners, or employer would be directly seeking to financially benefit from the Board's recommendations.

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

Nonpublic information ismembers 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:

- Do not accept improper gifts (from those seeking actions from the Board).
- Do not use board appointments for private gain.
- Do not misuse internal non-public government information.
- Do not use government property and time improperly.
- Do not accept compensation for teaching, speaking, and writing related to your board duties.
- Do not 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 working documents with the public. Working documents are defined as information that THEa board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should know, has not been made available to the general public. THIS INCLUDES INFORMATION THAT IS "ROUTINELY EXEMPT FROM DISCLOSURE IN 5 U.S.C. 552 (FREEDOM OF INFORMATION ACT) OR OTHERWISE PROTECTED FROM DISCLOSURE BY STATUTE, EXECUTIVE ORDER OR REGULATION; IS DESIGNATED AS CONFIDENTIAL BY THE AGENCY OR PROGRAM; OR HAS NOT ACTUALLY BEEN DISSEMINATED TO THE GENERAL PUBLIC AND IS NOT AUTHORIZED TO BE MADE AVAILABLE TO THE PUBLIC UPON REQUEST." -: e.g. is not on the NOP or other public websites, or is a draft document under development by an NOSB Subcommittee.
- Do not circulate draft Subcommittee documents until they are finalized and publicly available to all on the AMS/NOP website.
- Use a professional, respectful tone in NOSB email correspondence; remember that all correspondence with government officials is subject to FOIA requests.

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NOSB—members, committee members and task force members shall keep confidential all information identified by petitioners as confidential business information.

To the maximum extent possible, NOSB members should speak with one voice.

Although there may be disagreements within NOSB COMMITTEE 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.

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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.

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

- 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 DFO 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 DFOto 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:

- 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 DFO 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

<u>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</u>

A. STANDING SUBCOMMITTEES

The current standing Subcommittees are:

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- 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)

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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 clarification and proposed changes for NOSB internal policies, and procedures as needed, in collaboration with the NOP. The PDS, in collaboration with the NOP, also updates and revises the NOSB Policy and Procedures Manual and the Member Guide.

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 agenda approved by the NOP
- Have a clearly articulated project deliverable

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- Include at least one current member of the NOSB
- Record and maintain meeting or conference call minutes, made available to the <u>NOSB and the NOP</u>
- 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 agendas 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 agendas
- 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:

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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

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

3. Appointment of Subcommittee Vice Chair

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

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 agenda 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.

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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;
- o 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:
 - I. Introduction: A brief summary of the issue or statement of the problem.
 - 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. If the Board then determines that the minority view has merit, it may send the proposal back to Subcommittee for further work, since it would be a substantive change to the proposal as presented.

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:

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- 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.
- TR sufficiency is determined by SC, and the TR is posted on the NOSB website by the NOP.
- SC reviews substance, develops proposal, discusses proposal and votes, and submits for posting 45 days prior to public meeting.
- 5. 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

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

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<u>During this phase, the applicable NOSB Subcommittee has 60 days to review the petition and determine whether a third party technical review is required.</u> 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

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.

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 Ensure that TRs/TAP reports are sufficient and complete when they are distributed to the Subcommittee

<u>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.</u>

Step 4: Technical Review Sufficiency Determination

<u>During this phase the Subcommittee (Crops, Livestock or Handling) will:</u>

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.

<u>If necessary, the NOP will seek improvements or supplemental information from the contractor.</u>

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.

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 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. The name of the contracted party will appear on the Technical Review. All Federal contracts, including those issued by USDA/NOP to Technical Report contractors, are governed by the Federal Acquisition Regulations (FAR). The FAR includes a "Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions," which requires contractors to identify and prevent personal conflicts of interest for their covered employees. "Personal conflict of interest" means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract.

Link: https://www.acquisition.gov/far/current/pdf/FAR.pdf

4. Definitions

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

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

V. Prioritization of Petitions

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

<u>Priority 1:</u> A petition to <u>remove</u> 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 - <u>Priority 1</u>, above all other petitions in the queue of the reviewing Subcommittee (Crops, Handling, or Livestock).

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

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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.

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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.

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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.

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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.

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

Conflict of Interest

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

Be it resolved by the National Organic Standards Board:

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

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

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

SECTION II

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

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. The NOSB observes the following procedure.

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.

<u>Step 2: The public submits written comments, which are analyzed by Subcommittees.</u>

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 includes 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, which are posted on the NOP website.

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.

<u>Step 8: AMS issues Federal Register Notice announcing renewal of applicable substances</u>

Note: 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, non-arbitrary, based on the best current information and in the interest of the organic community and public at large.

VIII. NOSB PROCEDURES

A. BOARD MEMBER JOB DESCRIPTIONS 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.

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

- The Board serves as the primary linkage to the organic community. In that regard, the Board must advise the NOP on the implementation of OFPA.
- The Board must approve all materials which appear on the National List.
- The Board maintains the responsibility to protect and defend the integrity of organic standards.

Composition of the Board 6518 (b)

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

- (1) four shall be individuals who own or operate an organic farming operation;
- (2) two shall be individuals who own or operate an organic handling operation;
- (3) one shall be an individual who owns or operates a retail establishment with significant trade in organic products;
- (4) three shall be individuals with expertise in areas of environmental protection and resource conservation:
- (5)—three shall be individuals who represent public interest or consumer interest groups;
- (6) one shall be an individual with expertise in the fields of toxicology, ecology, or biochemistry; and
- (7) one shall be an individual who is a certifying agent as identified under section 2116 of OFPA. [§2119(b)]

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

BOARD MEMBER STANDARDS

Participate in meetings Members must make a commitment to attend meetings

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of the Board. 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.

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- <u>Serve on committees, as assigned</u>—Each member must be willing to serve on committees as assigned by the Chair, and to participate in the work of those committees.
- Be informed about the decisions to be made—Board members are expected to seek and study the
 information needed to make a reasoned decision and/or recommendation on all business brought
 before the Board.
- <u>Fully disclose any conflict of interest positions</u>—Members having any commercial or immediate
 family interest that poses a potential or perceived conflict of interest must disclose that conflict to
 the Board and abide by any decision of the Board in dealing with the situation.

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 Board shall constitute a quorum for the purpose of conducting business. [§2119(h)] A majority of the members of a Committee, including the Executive Committee, 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 boardNOSB at which a quorum is present shall be decisive of any motion [§2119(i)].

Following Robert's Rules of Order, all(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 BoardNOSB 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.

SECTION III

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

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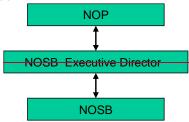
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ROLE OF THE EXECUTIVE DIRECTOR

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



The most important function of the ED is to facilitate the operation of the Board, while helping to maintain and strengthen its independence. Other specific functions of the ED are:

- Assist in the implementation of policies, goals, objectives, strategic plans, committee work plans, and recommendations set by the NOSB and NOP.
- Draft initial NOSB meeting agendas with NOSB Chair based on committee work plans for NOSB and NOP discussion, then finalizes agenda.
- Coordinate Board and committee meetings, and manage information reporting and communications between Board and NOP.
- Arrange, facilitate, and document in the form of written minutes the NOSB Committee
 conference calls necessary to achieve the most efficient workings of the Board. Minutes are
 distributed to committees for confirmation of accuracy and approval. Committee minutes must
 fully capture the discussion, reflect the diversity of opinions expressed during meetings in order
 that transparency exist and content remain useful for committee members, board members and
 our stakeholder public.
- Provide training and information to NOSB and task forces on compliance with all pertinent Acts and regulations (e.g., FACA, OFPA, NOP), including their role in advising the Secretary.
- ESTABLISHES AND MONITORS BOARD ADHERENCE TO TIMELINES
 WHICH ENSURE NOP HAS SUFFICIENT TIME TO PUBLISH RELATED
 FEDERAL REGISTER NOTICES AND BOARD/COMMITTEE
 RECOMMENDATIONS THAT MEET DEADLINES FOR public comment.
- Manage Board calendar and tracking databases in a manner that facilitates clarity of activities to the Board and the NOP.
- Work as liaison with NOP staff, TAP & technical review contractors and other government agencies (e.g., EPA, FDA, AAFCO).
- ENSURE BOARD MEMBERS HAVE ALL MATERIALS AND INFORMATION NECESSARY TO PROVIDE INFORMED, STRUCTURED AND TIMELY RECOMMENDATIONS TO THE NOP FOR PROPOSED AMENDMENTS AND GUIDANCE DOCUMENTS TO NOP REGULATION 7 CFR 205. THIS INCLUDES THE PROVISION OF PETITIONS, TAP AND TECHNICAL REVIEWS, AND HISTORIC DISCUSSIONS OF SUBSTANCES PROPOSED FOR INCLUSION ON THE NATIONAL LIST, AS WELL HISTORIC DISCUSSIONS AND RECOMMENDATIONS REGARDING ISSUES.

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- Maintain executive committee meeting minutes and committee meeting minutes, committee records, reports, transcripts, appendices, working papers, drafts, studies, agendas and other documents which were made available to or prepared for or by the NOSB or its committees, and make such documents available for public inspection and copying at the Agency, electronically via the World Wide Web; and/or, upon written request in printed form.
- Prepare and clear Federal Register Meeting Notice and News Release, ensuring publication 45 days prior to meeting.
- Ensure proposed additions to the National List, or other recommendations, are
 posted on the NOSB website for 45 days prior to an NOSB meeting to allow for
 public comment.
- Provide accurate, clear pre-meeting information to public regarding questions on recommendations.
- Ensure NOSB members have timely access to public comments.
- Schedule public comment according to issues, and accommodates commenters' travel schedules, where possible.
- Ensure that Board members and NOP staff at NOSB meetings have access to relevant documents related to petitions, materials due to sunset, technical reviews, etc. The format could be electronic (CD version) or hard copy.
- Track recommendations, changes, and votes during meeting to ensure accurate meeting transcripts.
- Assist the NOSB Officers as needed, including scheduling and participating in
 Officer calls, and assisting the Secretary during Board meetings in managing
 public comments, summary of minutes, committee votes, election of officers,
 Board meeting breaks. Also stays apprised and assist as needed in committee
 meetings scheduled before, during and after Board meetings.

OFFICER RESPONSIBILITIES

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

Chair

The Chair is responsible to assure the integrity of the Board process, including effectiveness of meetings and the board's adherence to its own rules. The Chair shall:

- Schedule meetings of the Board and the Executive Committee;
- Draft meeting agendas in consultation with committee chairs and NOP staff;
 - CONVENE AND PRESIDE AT MEETINGS;
- Review committee work plans;
- Review meeting minutes for accuracy, and
- Assist with the annual election of NOSB officers.

Vice Chair

The Vice Chair shall act in the absence of the Chair. The Vice Chair shall serve as a member of the Policy Development Committee, and work collaboratively with the PDC's members on the maintenance and upkeep of the Policy and Procedures Manual.

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Secretary

The Secretary will work with the NOP Executive Director (ED) to assist in maintaining the integrity of all legal and governing documents of the Board. It is the Secretary's responsibility to help the ED:

- Make sure official NOSB transcripts are posted for the public:
- Record all committee votes at NOSB meetings and circulate to the NOSB for approval;
- -Review all additions to the Federal Register to report any discrepancies between Board recommendations and those published in the Federal Register;
- Transfer custody of the Board's vote records to the Secretary's successor, and
- Assist with the annual election of NOSB officers.

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

Administrative Team

The Administrative Team consists of the Chair, Vice Chair, Secretary and Executive Director. This group may meet on a weekly basis or as needed by teleconference or correspond by email in order to coordinate the overall logistics and operations of the board, the officer responsibilities noted above, and the overall support provided to the Board by the Executive Director.



A. NOMINATION

- ALLINTERESTED NOSB MEMBERS ARE ELIGIBLE FOR CONSIDERATION FOR **ANY OFFICER POSITION.**
- CANDIDATES MAY BE SELF-NOMINATED OR NOMINATED BY ANOTHER **MEMBER OF THE BOARD.**
- SHOULD THE CHAIR, VICE CHAIR, OR SECRETARY RESIGN OR FAIL TO SERVE THE FULL TERM, THE EXECUTIVE COMMITTEE SHALL APPOINT AN **INTERIM OFFICER.**
- THE INTERIM OFFICER SHALL SERVE IN THE CAPACITY UNTIL THE NEXT REGULARLY SCHEDULED MEETING OF THE BOARD, DURING WHICH AN **ELECTION WILL BE HELD TO FILL THE REMAINDER OF THE TERM.**
- MEMBERS INTERESTED IN SERVING MORE THAN ONE CONSECUTIVE TERM IN AN OFFICER POSITION CAN IF THE BOARD IS IN FAVOR; HOWEVER IT IS RECOMMENDED THAT AN OFFICER NOT SERVE FOR MORE THAN TWO **CONSECUTIVE TERMS.**

B. VOTING SCHEDULE

OFFICERS SHALL BE ELECTED FOR TERMS OF ONE YEAR BY MAJORITY **VOTE AT THE ANNUAL FALL MEETING OF THE BOARD.**

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- NEWLY APPOINTED OFFICERS WILL ASSUME THEIR POSITIONS AT THE CONCLUSION OF THE FALL BOARD MEETING PURSUANT TO THE ELECTION.
- ACTING BOARD OFFICERS WILL ASSIST THE NEW OFFICERS TO TRANSITION INTO THEIR NEW ROLE.

C. ELIGIBILITY TO VOTE

- ONLY NOSB BOARD MEMBERS PRESENT ARE ELIGIBLE TO VOTE FOR NOMINATED OFFICERS.
- ABSENT NOSB MEMBERS WILL NOT BE ELIGIBLE TO VOTE.
- BOARD MEMBERS SHALL BE ENTITLED TO CAST ONE VOTE PER NOMINATION.

D. COUNTING OF VOTES

- VOTING WILL BE BY BALLOT IMMEDIATELY FOLLOWING NOMINATIONS FOR EACH OFFICE.
 - * Pallots for officers will be cast in the following order:

1. Chair

- 2. VICE-CHAIR
- 3. SECRETARY
- THE BALLOTS WILL BE COUNTED FOR ONE OFFICE AND THE ACTING
 CHAIR WILL ANNOUNCE THE TALLY BEFORE THE NEXT OFFICE IS OPENED
 FOR NOMINATIONS
- THE ACTING SECRETARY WILL PREPARE AND DISTRIBUTE THE BALLOTS
 AND WILL GATHER THE VOTES BY SECRET BALLOT.
- THE ACTING CHAIR WILL TALLY THE VOTES AFTER EACH OFFICER NOMINATION AND THE ACTING SECRETARY WILL VERIFY THE VOTE RESULTS.
- THE CANDIDATE RECEIVING THE LARGEST NUMBER OF VOTES WILL BE ELECTED.
- IN THE EVENT OF A TIE THERE WILL BE A REVOTE UNTIL A NOMINEE OBTAINS MAJORITY. ALL NOMINEES WILL BE INCLUDED IN THE REVOTE OR MAY BE GIVEN THE OPPORTUNITY THE WITHDRAW AT THEIR DISCRETION...
- MEMBER VOTE COUNTS WILL REMAIN CONFIDENTIAL. OTHER NOSB MEMBERS WILL NOT BE ALLOWED TO DETERMINE HOW THE MEMBERS VOTED.
- VOTES WILL BE DISPOSED OF BY THE CHAIR OR SECRETARY.
 Calculation of Decisive Votes

# Votes Cast # Recusals and Abstentions	2/3 Majority*
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<u>11</u>	<u>4</u>	<u>8</u>
<u>10</u>	<u>5</u>	<u>7</u>
<u>9</u>	<u>6</u>	<u>6</u>
<u>8</u>	<u>7</u>	<u>6</u>

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 ACTING SECRETARY WILL RECORD NEWLY ELECTED OFFICERS INTO THE NOSB MEETING SUMMARY EXTENT TO WHICH THE EFFECTS OF MINUTES.

EXECUTIVE COMMITTEE

The Executive Committeethe recommendation differ from the effects of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the chairs of the standing committees. The Executive Committee, with participation of the NOP, shall meet monthly, as needed, or as called by the Chair, and shall conduct business on behalf of the Board. Only the full Board may take decisive action on guidance and other policy recommendations from

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committees, including the status of materials proposed for addition or deletion on the National List. The Executive Committee will provide guidance and feedback to Committees on their proposed work plans.proposal

MEETINGS

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

SECTION IV

BOARD COMMITTEES

Committees play an important role in administering the Board's responsibilities. Committees exist to provide greater depth and clarity in the Board's responsibility to make informed decisions. For example, at the request of the Secretary seeking advice on a matter related to the NOP, the full Board may request that a committee conduct research and analysis or draft proposed recommendations to be considered by the full Board. Except for the Executive Committee, no committees are authorized to act in place of the Board. Committees are empowered to analyze information and bring draft recommendations to the Board for action.

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

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

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

- 1.—Committee recommendations are finalized by the NOSB according to the following process:
- 2. Committee drafts the recommendation.
- 3. Draft recommendation is posted for public comment.
- 4. Public comments are considered by committee when making recommendation to the Board-
- 5.—Board takes action on the recommendation

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

COMMITTEE MEETINGS

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

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

STANDING COMMITTEES

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

Grops Committee (CC) The Crops Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the crop production section of the organic regulations as contained in [7CFR Part 205] and OFPA. The CC reviews petitions, substances scheduled to sunset, technical advisory panel reports, and public comments concerning materials used for crop production which have been requested for addition to or removal from the National List. The CC occasionally works with other committees to develop joint recommendations where crop issues are involved.

Handling Committee (HC) The Handling Committee makes draft recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the handling and labeling sections of the organic regulations as contained in [7CFR Part 205] and OFPA. The HC reviews petitions, substances scheduled to sunset, technical advisory panel reports and public comments concerning materials used for processing and handling which have been requested for addition to or removal from the National List. The HC occasionally works with other committees to develop joint recommendations where handling issues are involved.

Livestock Committee (LC) The Livestock Committee drafts recommendations for consideration by the Board to provide guidance, clarification or proposed standards of the livestock and livestock feed sections of the organic regulations as contained in [7CFR Part 205] and OFPA. The LC reviews petitions, substances scheduled to sunset, technical advisory panel reports and public comments concerning materials used for livestock production which have been requested for addition to or removal from the National List. The LC occasionally works with other committees to develop joint

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recommendations where livestock issues are involved.

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

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

A. TASK FORCES

As determined by the Board or Executive Committee, task forces shall be appointed to explore specific issues and present draft recommendations to the Board or to a committee. Task forces may include non-Board members of the public. Each task force shall include at least one member of the NOSB. Minutes shall be taken of task force meetings. Each task force shall submit a final report to the Board. Each task force shall be disbanded when its work has concluded or when the Board determines the task force is no longer necessary.

<u>Procedure for submitting final recommendations to NOP</u>
Within 30 days after the completion of the NOSB meeting all final

AD HOC COMMITTEES

At the discretion of the NOSB Chairperson, with approval of the Executive Committee, an ad hoc NOSB committee may be formed to develop policy and guidance on specific issues that involve multiple standing committee jurisdictions, or for issues or tasks that are very large and require additional resources to complete. Ad hoc committees may be comprised only of current NOSB members, and could either be a combination of two or more standing committees to form a "joint" committee, or could be a totally new committee comprised of selected NOSB members from various standing committees. Ad hoc committees can be dissolved at the recommendation of the NOSB chairperson with the approval of the executive committee. The position of the ad hoc committee chairperson is a non-voting member of the executive committee.

SECTION V

This section defines the responsibilities of the different committee chairs and respective vice chairs. It also provides indications on writing committee recommendations and presenting such

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recommendations for vote at NOSB meetings, Lastly, this section covers general and specific collaboration procedures between NOSB and NOP.

DUTIES OF COMMITTEE CHAIRS

Committee chairs are responsible for the following duties:

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

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

DUTIES OF COMMITTEE VICE-CHAIRS

Committee vice chairs are responsible for the following duties:

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

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

PROCEDURES FOR THE TRANSITION OF COMMITTEE CHAIRS, VICE-CHAIRS, AND MEMBERS

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

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

AFTER ELECTION OF NOSB OFFICERS AT FALL NOSB MEETING:

APPOINTMENT OF COMMITTEE CHAIRS

THE BOARD CHAIR SHOULD APPOINT COMMITTEE CHAIRS FROM MEMBERS WITH AT LEAST ONE YEAR OF NOSB EXPERIENCE, IDEALLY. IT IS RECOMMENDED THAT A NEW COMMITTEE CHAIR SHOULD HAVE EXPERIENCE AS COMMITTEE VICE-CHAIR.

Appointment of Committee Vice-Chairs

A Committee Vice-Chair shall be appointed by the Committee Chair and should be someone who has expressed to the Chair of the Committee interest in eventually serving as Committee Chair.

Time Frame for Appointments
 Committee Chairs shall be appointed as Incoming Chairs in not more than 30 days
 after the newly elected NOSB Chair takes office (or continues in office), and
 incoming Vice Chairs shall be appointed by Committee Chairs in no more than two
 weeks after that.

Exchange of Committee Files

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

Review of Committee Files

New Committee Chairs should review all work plan items and active files involving committee work.

Mentorship Period

The Incoming Chair and Vice-Chair of each committee shall participate in an orientation and mentorship period with the outgoing Chair and Vice-Chair of their committee until being seated in their positions at the beginning of the new term on January 24.

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

New Committee Member Appointments

New incoming committee members shall be appointed by the Board Chair, in consultation with the outgoing and incoming committee Chairs, no more than two weeks after the appointment of the new NOSB members by the Secretary, with the Chair seeking and taking into account the expressed member interest, expertise, background, as well as new board composition.

- Communication with Newly Appointed Members
 Once appointed, incoming committee members shall be included in all emails pertaining to the committee assignments.
- Attendance at Committee Meetings and Fall NOSB Meeting
 New incoming members of the committee should participate in observer status in

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- committee meetings upon their appointment, and should be encouraged to attend the Fall Board meeting.
- New Member Mentorship

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 as soon after their appointment as possible, but no later than two weeks, or, if the Board member prefers or the Board member takes no action, the Board Chair shall assign a mentor in same time frame.

Between Board Appointments and Fall Board Meeting:

- Changing Committee Appointments
 - If a Board member would like to change committees, either adding to or stepping down from his/her assignments, a request shall be made to the Board Chair. If the request does not alter the preferred number of committee members in the range of five to seven, the expectation is that the request will be approved, unless the Board Chair states in writing that such change will interfere with the functioning of the committee. The Chair's determination should be made in consultation with Committee Chairs and the Executive Committee.
- Filling Vacancy of Committee Chair and/or Vice-Chair
 In the case of a vacancy in the positions of Committee Chair, the Committee Vice-Chair shall assume the Committee Chair position and the new Committee Chair shall appoint a new Vice-Chair in accordance with the consultation procedures cited above.

PROCEDURES FOR COMPLETING COMMITTEE RECOMMENDATIONS

Developing committee recommendations follows these broad steps:

- 1. THE COMMITTEE PREPARES A RECOMMENDATION OR DISCUSSION DOCUMENT AS AGREED TO IN THE COMMITTEE WORK PLAN (SEE P. 32 PPM).
- 2. THE RECOMMENDATION OR DISCUSSIONS DOCUMENT IS POSTED FOR PUBLIC COMMENT.
- 3. DURING THE BOARD MEETING, THE COMMITTEE PRESENTS ITS RECOMMENDATION FOR DISCUSSION BY THE FULL BOARD.
- 4. AT ANY POINT IN THE PROCESS PRIOR TO THE BOARD'S VOTE ON THE STATUS OF THE RECOMMENDATION, THE PRESENTING COMMITTEE MAY CONVENE AND VOTE TO WITHDRAW ITS RECOMMENDATION, BASED ON APPROVAL OF THIS ACTION BY THE MAJORITY OF THE MEMBERS OF THE COMMITTEE.

5. ONCE PRESENTED, THE BOARD VOTES ON THE COMMITTEE **RECOMMENDATION.**

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

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The Board may take Each proposal lead prepares, the following actions for each committee documents:

contain all appropriate information, including the vote recorded at the meeting.

(The NOP can provide the voting record)

2. Amend and adopt the amended recommendation;

1. Adopt the recommendation as presented by the committee;

- 3. Reject the recommendation; or
- 4. Refer the recommendation back to the committee for further development.

 - -Writing Committee Recommendations

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

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

I. Introduction:

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

II. Background:

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

III. Relevant areas in the Rule:

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

IV. Discussion:

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

V. Recommendation:

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

VI. Committee Vote:

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

Minority opinion:

If applicable, the dissenting opinion(s) of committee or task force members shall be reported. A member of a committee can present a minority report to the committee recommendation. Such document should include reasons for opposing a proposed recommendation and cite where the opposition points are in the recommendation. In addition, the minority report could, provide alternative approaches or solutions from those given in the recommendation, or recommend an amendment to the recommendation. The minority opinion will be included as a separate document at the end of the recommendation.

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

- List: This section identifies the placing of the material under review within the National List. Any annotations related to the material should be included.
- II. Committee Summary: This section should present a brief background of the material under review highlighting its uses and past NOSB decisions. It should include a short description of any current research done by the committee (e.g., review of technical reports, individual investigation, etc.) and should provide a description of the main arguments supporting the committee's final decision. This section should mention any areas of the Rule or OFPA which provide the basis for the recommendation.
- III. Committee Recommendation: The committee recommendation should be stated clearly here including any corresponding annotation.
- IV. Committee Vote: This section should present the names of the members who moved and second the motion to approve the recommendation and vote count. As a norm, a motion for a petitioned material or sunset review should always be presented in the affirmative.

Minority opinion:

-Presenting-Committee Recommendations at NOSB Meetings

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

- I. Introduction: A brief summary of the issue or statement of the problem.
- II. Background: An explanation with sufficient detail and rationale to support a proposed recommendation, including reasons why the recommendation should be adopted, historical context, and the regulatory framework pertinent to the issue.
- III. Recommendation: The concise text of the recommended action.
- IV. Committee vote: The vote of the committee or task force shall be reported. In the case of recommendations for petitions to add materials to the National list, two votes will be recorded, one for synthetic or non-synthetic material classification, and the other for listing or not.

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V. Minority opinion: If applicable, the dissenting opinion(s) of committee or task force members shall be reported.

NOSB-NOP COLLABORATION

The Organic Foods Production Act (6518 (a)) directed the Secretary of Agriculture to establish a National Organic Standards Board to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the Act. In 6503 (a) of the Act, the Secretary was directed to establish an organic certification program. The National Organic Program (NOP) has become the governmental institution to accomplish this and is the means through which the NOSB provides advice and assistance to the Secretary of Agriculture.

The mutual goals to advance the integrity of organic products, principles and products can best be accomplished through team work and cooperation between the NOSB and the NOP and is implemented regularly through two way feedback by the NOSB Executive Director and periodically at the Executive Committee's monthly calls. Especially at these calls, NOSB committee work plans and priorities are discussed and NOP requests and opinions are aired.

An effective collaboration process between the NOP and the NOSB should ensure that NOP receives NOSB input and feedback, and vice versa. The process can be complicated due to several factors like the following:

- 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 determination of materials as approved or prohibited
 substances for inclusion on the National List.
- The NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, or initiate policies on its own accord.

Several collaboration approaches may be required depending on the type of issue faced by the Board. Below are descriptions of the most common situations faced by the NOSB. In all cases, the end product should be a recommendation by the Board to the NOP and each recommendation should be accompanied by a cover sheet illustrated in figure 1.

- 1. Materials proposed to be added to or removed from the National List.
 - The NOSB has the statutory authority to consider and recommend materials for addition to, or deletion from, the National List of Approved and Prohibited Substances, or to add, remove, or modify annotations restricting the use of such listed materials.
- 2. Recommendation for modification of existing standards or new standards. The NOSB will use the decision making procedures outlined in Section VIII to justify modifying existing standards or proposing new standards. The NOP may request that the NOSB develop

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

o **Providing advice** The proposal that was voted on **NOP policy** at the meeting

The proposal leads will forward the documents to the appropriate Subcommittee Chair who will review them for accuracy and **interpretation** 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 **standards**.

An examples 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:

3. Written comment: All members of the public are: NOSB providing encouraged to submited public comment in writing according to the Federal Register Notice. Written submissions: allow NOSB members the opportunity to read comments on specific actions by the NOP, such as the yeast and compost policies, 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.

4. 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. As timely and appropriate, the NOP reports to NOSB on the status of enforcement actions and also posts the status on the NOP web site.

5. Management Review.

NOSB may review the quality management system and internal audits to ensure that the NOP is managed effectively and efficiently. For example, the NOSB has a role to play in terms of seeing that corrective actions with OIG are completed.

In all the above situations, FACA procedures must be carefully followed to provide transparency and necessary public input.

The primary means of collaboration will be through NOP participation in Executive Committee (EC) and Standing Committee calls. The NOP Deputy Administrator or designee will participate in all EC calls. The NOSB Executive Director (ED) will participate in all NOSB calls as described in the ED duties in the PPM. Upon request and mutual agreement, the Deputy Administrator will participate in Standing Committee calls. In addition, each Standing Committee will be assigned an NOP staff person to provide additional technical, legal, and logistical support.

Work plans for action items are developed for each upcoming public board meeting. This is the

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mode for developing recommendations and discussion documents. Work plan procedures are described in detail in Section VIII, page 32. The proposed work plans are presented and discussed at each public board meeting, but may be revised based on comments and Board priorities and resources.

NOP publicly made requests at board meetings are important considerations in the development of Committee work plan. These NOP requests to NOSB will be followed up in writing stating the problem to be addressed, background, statutory authority and the time frame for response. The proposed Committee Work plans will be reviewed at the next EC call following the Board meeting, with participation by the NOP Deputy Administrator. This participation in the development of work plans is vital for effective NOSB/NOP collaboration. Due to change in circumstances, these work plans may need to be revised prior to the posting of the final agenda of the upcoming Board meeting. Committee work plan changes will be done in consultation and full knowledge of the EC and

Figure 1: Form Used to Submit NOSB Final Recommendations to the NOP (Non Materials Recommendations)

		Formal Recommendat ional Organic Standard the National Organic P	Board (NOSB)	
Date:				
Subject:				
Chair:		=		
The NOSB he	ereby recommen	ds to the NOP the follo	wing:	
Rulemaking / Guidance Sta Other	tement	= =====		
Statement o	f the Recommen	dation (Including Recou	ınt of Vote):	
	Supporting	, ,	·	consistency with
Rationale	Supporting OP):	, ,	·	consistency with
Rationale OFPA and NO	Supporting OP):	, ,	·	consistency with

SECTION VI

MISCELLANEOUS POLICIES

-NOSB Policy for Presenters Invited by Committees

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

-NOSB Policy for Surveys Conducted on Behalf of NOSB Committees

- All surveys, including electronic surveys, conducted in the name of any NOSB Committee, must be
 approved by the NOSB Executive Committee before they are submitted for approval to USDA, which
 must submit for approval to the Office of Management and Budget (OMB); and
- A written report summarizing the results of the survey must be submitted to the full Board and the NOP as soon as possible after completion.

Public Comment at NOSB

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

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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. However, the NOSB will attempt to accommodate all persons requesting public comment time. Persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP working closely with the NOSB Chair and will depend on availability of time.
- All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. AdvanceWritten 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.
- Persons must give their names and affiliations for the record at the beginning of their public comment.
- Proxy speakers are not permitted.
- Public comment requests comments may be scheduled according to topic.
- Individuals providing public comment will refrain from making any personal attacks and from or remarks that otherwise 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.
- Members of the public are asked to define clearly and suscinctly the issues they wish to present before the Board. This will give NOSB members a

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comprehensible understanding of the speaker's concerns.

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

Policy for Public Communication between NOSB Meetings-

(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:
 - Chair
 - Vice Chair
 - 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.

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G. MISCELLANEOUS PROCEDURES

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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.

<u>Current petitioners cannot be invited to be speakers about the topic under discussion, unless invited by the NOSB Chair.</u>

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.

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IX. REVISIONS TO THE POLICY AND PROCEDURES MANUAL

- The PDS will review the PPM each year and, working in collaboration with the NOP, determine if any updates are necessary.
- Proposed changes will be subject to review and approval by the NOP and the full NOSB.

<u>APPENDICES</u> Adopted April 11 2013; 15 yes, 0 no, 0 absent, 0 abstain, 0 recuse

SECTION VII

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A. Appendix 1: FOUNDATIONS

1. NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

(NOSB Recommendation Adopted October 17, 2001)

1.1_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

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

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stages of processing, handling, transport, and storage; 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; Organic products and packaging materials used for organic products do not come in contact with prohibited materials; Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained; and 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. Formatted: Default, Indent: Left: 0.38", Hanging: 0.25" 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 Formatted: Default, Indent: Left: 0.38", Hanging: 0.25" to the identification and labeling of such products. 1.7 Organic standards require that each certified operator must complete, and submit for Formatted: Default, Indent: Left: 0.38", Hanging: 0.25" 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 Formatted: Font: +Headings (Calibri), 11 pt 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. Formatted: Default, Indent: Left: 0.38", Hanging: 0.25" 1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately. -Organic certification, production, and handling systems serve to educate consumers Formatted: Default, Indent: Left: 0.38", Hanging: 0.25" regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.

practices in order to maintain the integrity and quality of organic products through all

1.11 ——Genetic engineering (recombinant and technology) is a synthetic process designed to

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.

produced by or through the use of genetic engineering are prohibited.

control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (geo/gmo'sGE/GMOs) and products

1.4.2

1.4.3

1.4.4

1.4.5

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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 taskresponsibility 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:

- 4.• Does the substance promote plant and animal health by enhancing the soil's -physical chemical, or biological properties?
- 2.• Does use of the substance encourage and enhance preventative techniques including cultural and biological methods for management of crop, livestock, and/or handling operations?
- 3.• Is the substance made from renewable resources? If the source of the product is non-renewable, are the materials used to produce the substance recyclable? Is the substance produced from recycled materials? Does use of the substance increase the efficiency of resources used by organic farms, complement the use of natural biological controls, or reduce the total amount of materials released into the environment?
- 4.• Does use of the substance have a positive influence on the health, natural behavior, and welfare of livestock?
- 5.• Does the substance satisfy expectations of organic consumers regarding the authenticity and integrity of organic products?
- 6. Does the substance allow for an increase in the long-term viability of organic farm operations?
- 7.• Is there evidence that the substance is mined, manufactured, or produced through reliance on child labor or violations of applicable national labor regulations?
- 8.• If the substance is already on the National List, is the proposed use of the substance consistent with other listed uses of the substance?
- 9.• Is the use of the substance consistent with other substances historically allowed or disallowed in organic production and handling?
- 40. Would approval of the substance be consistent with international organic regulations and guidelines, including Codex?
- 111.e 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?

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SECTION VIII

3. PROCEDURES OF THE 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

<u>Board members are bound to obey the tenants of the laws and regulations governing organic</u> production, processing and marketing.

COMMITTEE WORK PLANS

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

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Committee and the Program.

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,

Step 1: Identifying all issues

The committee work plan rises out of these main situations:

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

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

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

Step 2: Prioritizing the issues

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

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

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

Step 3: Setting a calendar for reviews

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

Step 4: Incorporating Input from the Executive Committee

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

MATERIALS REVIEW PROCESS

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

Evaluation Procedures for Substances Petitioned for Addition or Removal from the National List. A petition to change the annotation to a listed material is in effect the addition or removal of one or more materials.

Definitions:

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

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

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

During this phase the NOP will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition. Determine whether the petition is complete
- Determine if the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations; document this review using the NOP-OFPA checklist.
- -Determine whether the petitioned use is approved under the statutory and regulatory authority of the Environmental Protection Agency (EPA); the Food and Drug Administration (FDA); or other appropriate federal agency if applicable;
- Identify and secure any confidential business information (CBI) designated by the petitioner;
- -Notify, as applicable, the petitioner via letter and/or electronic mail of determination of completeness and eligibility, and acknowledge the designation of certain information as CBI.
- Upon determination of completeness and eligibility, the following actions will be taken:

PUBLISH THE PETITION ON NOP WEBSITE; AND

Notify the National Organic Standards Board (NOSB) materials committee chairperson and the chairperson of the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock, Handling or other pertinent

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committees). This notification will be sent via letter and/or electronic mail and inform the chairs that the petition is complete, provide OFPA review and EPA/FDA determination checklist, and request identification of any questions the appropriate committee wishes to be specifically addressed in the contractor's report.

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

During this phase:

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

-Phase 3: Evaluation by a Third Party Expert

During this phase the NOP will:

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

During this phase the Third Party Expert will:

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

-Phase 4: Sufficiency Determination

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During this phase the NOP will:

- Submit a copy of the draft TR for review to the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National List (Grops, Livestock or Handling);
- Review the draft TR against the following performance criteria. The report will be acceptable when it:
 - Is consistent in format, level of detail and tone;
 - OF IS TECHNICALLY OBJECTIVE AND FREE FROM OPINIONS OR CONJECTURE;
 - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
 - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
 - Is based on the best available information that can be obtained within the designated time frame;
 - Is thoroughly supported using literature citations; and,
 - Addresses all evaluation questions as set out in the SOW.

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

- Review the draft TR against the following performance criteria. The report will be acceptable when it:
 - o 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 iargon);
 - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
 - Is based on the best available information that can be obtained within the designated time frame;
 - Is thoroughly supported using literature citations; and,
 - Addresses all evaluation questions as set out in the SOW.
- Notify the NOP in letter and/or electronic mail the acceptance of the TR within 60 days of receiving the TR. If the TR is not accepted by the NOSB materials and the committee that the substance is being petitioned for addition or prohibition from the National List (Crops, Livestock or Handling), the committees must provide to the NOP in letter and/or electronic mail the specific areas of the TR that were concluded to be insufficient, the rationale for drawing such a conclusion and the improvements to be made so that the document can be determined sufficient.
- Upon concurrence by the NOP that the TR is insufficient, the NOP will notify the contractor by letter and/or electronic mail of the areas of the TR that are insufficient, the

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rationale for drawing such a conclusion and the improvements to be made so that the document can be determined sufficient. The time frame required for the completion of the changes will be determined through mutual agreement between the contractor and the NOP.

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

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

Convene at a mutually convenient time to review, discuss and recommend an action on the petitioned substance. The committee may convene as the TAP by electronic mail or conference call to provide complete evaluation of the petitioned substance, as provided by OFPA 6518(k)(3). The NOSB materials committee or delegated committee must convene and recommend an action on the petitioned substance no later than 60 days before a scheduled meeting of the full NOSB.

-Phase 6: Action by Full NOSB

During this phase the NOP will:

- Publish the recommendation of the NOSB materials committee and the committee
 that the substance is being petitioned for addition or prohibition from the National List
 (Crops, Livestock or Handling) on the NOP website and request a minimum of 60 days
 of written public comment on the recommendation prior to the public NOSB business
 meeting.
- Set as an agenda item for the next meeting of the NOSB time sufficient to discuss and make a recommendation by the full NOSB on the petitioned substance.

PROCEDURES FOR HANDLING TECHNICAL REVIEWS

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

Third party experts can consist of the following:

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

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

- 1. Define if the committee has the expertise needed to address the questions related to the petition, mainly:
 - a. Impact on the environment
 - b. Impact to human health
 - c. Sustainability and compatibility with organic principles.
- 2. If the committee does not have the expertise or resources (e.g., time), the Committee chair should make a request to the Chair of the Materials Committee for a third party expert specifying:
 - a.—The third party expert's required background and level of expertise
 - b. Existence of potential sources of conflict that could result in biased reviews.
- 3. When requesting the assistance of a third party expert to evaluate a material, a committee must identify the main technical issues needed to be addressed including, but no limited to:
 - a.—All uses of the petitioned material beyond what the petitioner has requested
 - b.—All uses of the petitioned material in combination with other material(s) that have been already approved on the same section of the National List
 - c. Interactions of the petitioned material, not addressed by the petitioner, and that may involve materials currently on the same section of the National List.
 - d. All possible manufacturing methods for a petitioned material.
 - e. Potential effects on public health and biodiversity
 - f.—Environmental risks and hazards including, but not limited to potential for developing pesticide resistance, or long term effects on sustainability
- 4. If required, the committee should conduct a final review of the technical report and complete an assessment on the quality of work performed by the third party expert.

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

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

 To incorporate a diversity of opinions and to minimize the risk of bias, a committee should aim to work with a range of technical experts (individuals, or institutions).

HANDLING WITHDRAWALS OF PETITIONS BY THE PETITIONER.

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

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

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

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

TECHNICAL ADVISORY PANEL (TAP) CONTRACT PROCEDURES

Statement of Work

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

Agency Need

See Statement of Work, 1.0 Background.

1. Background

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

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

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

2. Mission of USDA/AMS/NOP

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

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

3. Specific Task

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

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

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

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

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

4. Minimum Skills and Experience Requirements

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

5. Place of Performance

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

6. Government Furnished Equipment and Facility

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

7. Compensation

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

8. Period of Performance

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

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9. Scope of Performance

Phase 1: Data Gathering and Compilation (120 days)

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

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

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

Phase 2: Evaluation against Criteria (100 days)

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

Phase 3: Recommendation (42 days)

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

Evaluation Factors for Award

The NOP may award multiple contracts for tasks outlined in this statement of work. Contractor(s)

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

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

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

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

Other Evaluation Factors

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

Technical Factors:

Factor 1 Overall Technical Approach; Proposed Methodology; Demonstrated Understanding of the Scope of Work and the Requirements

Factor 2 Previous Demonstrated Experience and Past Performance

Factor 3 Quality Control

Factor 4 Capability and Experience of Key Personnel

Factor 5 Project Management and Support Capability

Factor 6 Reasonableness of Cost

Reporting Requirements

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

The narrative in the progress reports should refer back to the stated objectives and timeline of the

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

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

Any deliverables required under the contract should be submitted upon completion and addressed to: NOP Program Director, National Organic Program, USDA AMS TM NOP, 1400 Independence Avenue, S.W., Room 4004-So., Ag Stop 0268, Washington, D.C. 20250-0268, Attention: Substance Evaluations.

INFORMATION TO BE INCLUDED IN A PETITION

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

ITEM A

The petitioner should identify which of the following categories the substance is being petitioned for inclusion on or removal from the National List:

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

ITEM B

The petitioner must submit the following information:

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

- 5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.
- 6.— A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.
- 7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration
- 8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance.
- 9.—The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.
- 10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.
- 11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.
- 12. A "Petition Justification Statement" which provides justification for one of the following actions requested in the petition:
 - A. Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)
 - Explain why the synthetic substance is necessary for the production or handling of an organic product.
 - Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural
 - methods that could be used in place of the petitioned synthetic substance.
 - Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.
 - B. Removal of a Synthetic From the National List, §§ 205.601, 205.603, 205.605(b)
 - Explain why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.
 - Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.
 - C. Inclusion of a Prohibition of a Non-Synthetic, §§ 205.602 and 205.604
 - Explain why the non-synthetic substance should not be permitted in the

production of an organic product.

 Describe other non-synthetic substances or synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned substance.

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

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

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

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

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

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

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

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

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

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

- Provide a comparative description as to why the non-organic form of the substance is not necessary for use in organic handling.
- Provide current and historical industry information/research/evidence that explains how or why the substance can be obtained organically in the appropriate form, appropriate quality, and appropriate quantity to fulfill an essential function in a system of organic handling.
- Provide new industry information on substance availability of organic sources including but not limited to the following guidance commercial availability evaluation criteria:
 - (1) Region of production, including factors such as climate and number of regions;
 - (2) Number of suppliers and amount produced;
 - (3) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies;
 - (4) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies and; (5) Any other issues which may present a challenge to a consistent supply.
- 13. A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:
 - a. Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim.
 - b.—"Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI.

This information must be

- (1) commercially valuable,
- (2) used in the applicant's business, and
- (3) maintained in secrecy.
- c.—Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."
- d. The CBI deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI deleted copy is paginated the same as the CBI copy. (The CBI deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBIdeleted copy.
- e. Each page with CBI deletions should be marked "CBI deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI deleted."
- f. If several pages are CBI deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBIdeleted.")
- g. All published references that appear in the CBI copy should be included in the reference list of the CBI deleted copy. Published information usually cannot be claimed as confidential.

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

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

PRIORITY OF PETITIONS GUIDELINE

Prioritization

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

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

a.—A petition to **remove** a material presently on the National list that raises serious health, environmental, or regulatory concerns, including petitions to reconsider previous decisions, will be given the highest priority—**Priority 1**, above all other petitions in the queue of the reviewing committee (Crops, Handling, or Livestock).

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

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

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

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

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

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

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NOSB COMMITTEE RECOMMENDATION Policy and Procedures Manual Form NOPLIST1. Committee Transmittal to NOSB

For NOSB Meetin	ng:		Substance	e:	
Committee: Cre	pps 🖯 Livestock 🖯 Han	dling - Petition is	for:		
				ational List § 205.	
			on the lat	ational Elot 3 Eoc.	
	criteria (Applicability noted	for each category;	Documentation a		<u> </u>
•	lumans and Environment			<u> Yes </u>	
	Availability Criteria			Yes ☐ No ☐ N/	'A-U . 🗆
	ty & Consistency Supply is Fragile or Potent	ially Unavailable ac			
4. Commercia.	rouppry to trugine or 1 occurs	nany onavanable as	Organic (only to:		— II/X- LI
Substance Fails C	riteria Category:	Comments:			
Droposed Appets	ation (if any):				
Troposcu Allisata					
- Basis for anno	otation: To meet criteria ab	nove: Ot	her regulatory cri	iteria: Citation:	
Du3.3 101 G	Addition to meet criteria aa		ner regulator,	onders.	
Pacommended Co	mmittee Action & Vote, in	cluding classification	n recommendat	ion (State Actual Motio	al.
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				
lassification of the r	naterial: Synthetic	Non- synthet	ic	Absent:	Abstain
	Seconded:				
Motion by:		<i>†</i>	es: /vu.	Absent:	Abstain:
Recommended C	ommittee Action & Vote				
Motion by:	Seconded:	γ	'es: No:-	Absent:	Abstain:
	Crops	Agricultura	4	Allowed ²	
	Livestock	Non-Synth	etic	Prohibited ²	
	Handling	Synthetic		Rejected ³	
	No	Commercia Available		Deferred ⁴	
	restriction	Available Organic ¹	as	Deferreu -	
1) Substance voted t	to be added as "allowed" o	n National List to §	205with	Annotation (if any)	
=======================================					
2) Substance to be a	idded as "prohibited" on N	ational List to § 205	with Ann	otation (if any)	
Describe udou					
Describe wity	a prohibited sub	stance:			
3) Substance was re	jected by vote for amendin	g National List to §	205 Desci	ribe why material was rej	ected:
= = = = = = = = = = = = = = = = = = =					
4) Substance was re	commended to be deferred	d because			
If follow-up needed.	who will follow up				

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EVALUATION CRITERIA FOR SUBSTANCES ADDED TO THE NATIONAL LIST

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

		[ſ	
Question	Yes	No	N/A	Documentation (TAR analysis and analysis analysis and analysis analysis and analysis analysis analysis analysis analysis analysis analysis analysis analysis anal
			,	(TAP; petition; regulatory agency; other)
1. Are there adverse effects on				omer)
environment from manufacture, use,				
or disposal? [§205.600 b.2]				
2. Is there environmental contamination				
during manufacture use misuse or				
3				
disposal? [§6518 m.3]				
3. Is the substance harmful to the environment and biodiversity?				
[\$6517c(1)(A)(i);6517(c)(2)(A)i]				
4. Does the substance contain List 1, 2, or 3				
inerts? [§6517 c (1) (B)(ii);				
205.601(m)2]				
5. Is there potential for detrimental				
chemical interaction with other				
materials used?				
[§6518 m.1]				
6. Are there adverse biological and chemical				
interactions in agro- ecosystem? [§6518				
m.5]				
7. Are there detrimental physiological				
effects on soil organisms, crops, or				
livestock? [§6518 m.5]				
8. Is there a toxic or other adverse action of				
the material or its breakdown				
products?				
[§6518 m.2]				
9. Is there undesirable persistence or				
concentration of the material or				
breakdown products in				
environment?[§6518 m.2]				
10. Is there any harmful effect on human				
health? [§6517 c (1)(A) (i) ; 6517				
c(2)(A)I; \$6518 m.4]				
11. Is there an adverse effect on human				
health as defined by applicable Federal				
regulations? [205.600 b.3]				
12. Is the substance GRAS when used				
according to FDA's good manufacturing				
practices? [§205.600 b.5]				
13. Does the substance contain residues of			i	
heavy metals or other contaminants in				
excess of FDA tolerances? [§205.600]				
b.51				
u.ɔ]				

If the substance under review is fo	r crops or livestock production, all of t	he questions from 205.600 (b) are	N/A—not applicable.	

Category 2. Is the Substance Essential for Organic Production? Substance

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

^{*} If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

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

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

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

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [56610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)]
Substance

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

NOSB RECOMMENDED DECISION FORM

Form NOPLIST2. Full Board Transmittal to NOI

For NOSB Meeting:	Substance:						
A. Evaluation Criteria (Documentation attached; committee recommendation attached) Criteria Satisfied?							
1. Impact on humans and environment Yes No (see B below)							
2. Availability critoria	Voc. N	lo (soo P bolow)					
3. Compatibility & consistency	Yes	Yes No (see B below)					
2. 22p.2		. ,					
	C. Proposed Anno	C. Proposed Annotation:					
B. Substance fails criteria?							
Criteria category:	Basis for annotation	on:					
Comments:	To meet criteria al	bove: Criteria:					
	Other regulatory o	criteria: Citation:					
. Final Board Action & Vote: Motion by:	Second:						
Vote: Agricultural	Nonagricultural	Crops					
Yes: Synthetic	Not synthetic	Livestock					
No: Allowed ¹	Prohibited ²	Handling					
Abstain: No restriction	tain: No-restriction Deferred4 Rejected =						
Substance voted to be added as "allowed" Annotation:	on National List						
2) Substance to be added to "prohibited" par	agraph of National List						
Describe why a prohibited substance:							
3) Substance was rejected by vote for amend	ing National List						
Describe why material was rejected:							
4) Substance was recommended to be deferred	ed						
Describe why deferred; if any follow-up is nee	ded. If follow-up needed, who	o conducts follow-up					
E. Approved by NOSB Chair to transmit to NO	E. Approved by NOSB Chair to transmit to NOP:						
NOSR Chair	NOCE Chair Date						
, 22 2	, NOSB Chair Date F. NOP Action: Include in FR to amend National List: Pattern to NOSB, Pageon:						
, NOP Director	Date						

PROCEDURES FOR THE MATERIALS REVIEW PROCESS FOR NOSB MEMBERS

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

SUNSET REVIEW PROCESS

Sunset is a regulatory process for determining the continued listing of a material already approved or prohibited on the National List for use in organic agriculture production and handling. It is not used to petition to add a new substance (nor is it used to change an existing annotation) or new uses of a listed substance. If the review and renewal process is not concluded by the expiration date, the use of the material will become prohibited. (Since sunset is defined as the reviewing of regulations to ensure the continued relevance and not the creation of new regulation, all substance must be renewed as listed. If there is a need to consider changing an annotation or moving a material from one list to another, this may be accomplished through the existing procedures for petition.)

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

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

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

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

Steps followed in Sunset Process

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

- A public notice is placed in the Federal register (Advance Notice of Proposed Rule Making or ANPR
 of the pending sunset of the listed materials. The public has 60 days after the publication date to
 provide written comment (see Chart 1 below). The committee may request a third party technical
 review in anticipation of scientific evidence and claims likely to be made during public comment to
 the ANPR.
- 2. Public comments are collected and forward to the NOSB (see Chart 2).
- 3. The appropriate NOSB committee begins review of the material with the intent of providing a recommendation to the entire Board for the material's removal, renewal, or renewal with the addition of an annotation. The review is conducted based on "Force of Evidence" as presented by Board members, public comments, and scientific data from other sources (see Chart 3). This includes the original recommendation from the Board to list. The committee may request a third party technical review, if needed, to verify scientific evidence and claims made during public comment to the ANPR.
- The reviewing NOSB committee provides its recommendation to the full Board and the public no less than 60 days prior to the Board Meeting which would include the following:
 - (i). Simple motion to remove, add, or amend an annotation, resulting in the restriction or clarification of the use of a material (if applicable).
 - (ii). Simple motion to renew the existing listing.

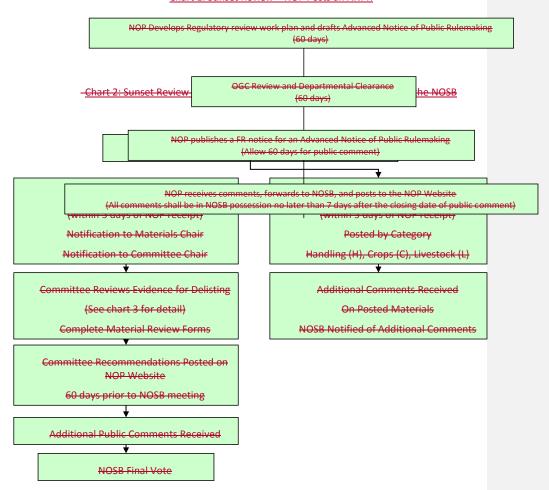
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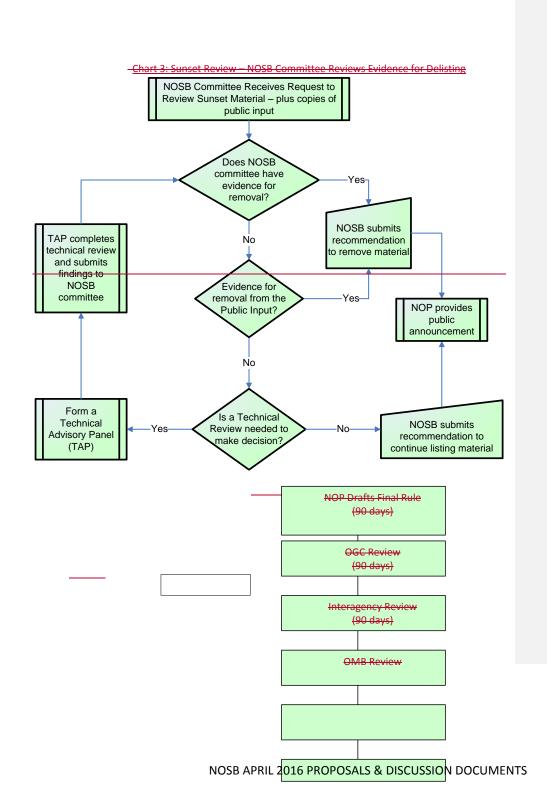
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- 5. At the public NOSB business meeting, the NOSB hears additional public comment, discusses the force of evidence, and votes on the committee's recommendation.
- The NOP reviews the NOSB recommendation and accompanying documentation and publishes a
 proposed rule to review the National List. The public has 90 days after the publication date to
 comment. All comments are made available on the NOP website.

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

-Chart 1: Sunset Review - NOP Posts an ANPR





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

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

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

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

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

- (1) The Secretary of the Board, with the assistance of the NOSB Executive Director, shall review all additions to the Federal Register and report to the Board any discrepancies between Board recommendation and those published in the Federal Register.
- (2) When the Program incorporates changes to a recommendation voted and presented by the Board, the Program is expected to communicate these changes prior to final action by the Program to the Board Chair, Vice Chair and Secretary. The Board Chair, Vice Chair and Secretary will report such activity to the Board and then work with the Program in order to assist the Program in stating the exact reasons for such deviations in the preamble to the Rule change posted.
- (3) In the cases of unintended consequences with a published recommendation, the Chair of the Board, with the approval of the Executive Committee, will assign committee to resolve the issue.

APPENDICES AND RESOURCES

-Appendix A - DECISION MAKING PROCEDURES FOR THE NOP

1.—Define the Problem

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

2.—Analyze the Problem

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a. Why is there a problem?

b. Is the evidence of the problem supported by credible and compelling facts or data?

i. What are the facts or data used to draw an affirmative conclusion?

c.—Who does this problem affect?

d. What is the problem's effect?

. In what time frame must the problem be resolved?

f. If the problem deserves immediate attention, what other priorities must be adjusted to accommodate this problem?

g. If the problem deserves immediate attention, what are the consequences of a delay?

3. Develop Possible Solutions

a. Propose ideas for possible solutions

b. Evaluate ideas for possible solutions

i. List pros for each possible solution

ii. List cons for each possible solution

c. Select a Solution

i. Is the recommended solution legal?

ii. Is the recommended solution practical?

iii. Is the recommended solution supported by credible and compelling facts or data?

1.—What are the facts or data used to draw an affirmative conclusion?

iv.—How does the recommended solution solve the problem?

v. How does the recommended solution meet the time frame identified in 2(b)?

d. Review recommended solution for unintended consequences.

4. Develop Action Plan

a. Develop Action Steps

i. Identify action steps to bridge the gap between present condition and future objective using the recommended solution.

b. Approve Action Plan

c. Implement Action Plan

Final - 5/9/2003

B. Appendix B -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,

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such as member orientation and training, and NOSB committee 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 Officials Officers must approve all meetings and agendas, and attend Formatted: Default, Indent: Left: 0.38", Tab stops: Not at meetings. The NOSB's Designated Federal OfficialOfficer. Formatted: Default, Indent: Left: 0.38", Tab stops: Not at 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 agenda₇ on its web site₇ no later than 90 days before the meeting is Formatted: Default scheduled to begino Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin, and Publish notice of the meeting in the Federal Register no later than 45 days before the meeting is scheduled to begin-Formatted: Default, Tab stops: Not at 0" Detailed minutes will be kept and must contain: Date and location of the meeting, A record of the persons present, A complete and accurate description of matters discussed and conclusions reached, and -Any advice or recommendations provided by the committee. • While meeting transcripts are not required under FACA, the NOP provides transcripts or meeting notes 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. Formatted: Default, Indent: Left: 0.38", Tab stops: Not at Advisory committee documents must be available for public inspection and copying until _the 4 committee ceases to exist. Interested persons shall be permitted to attend, appear before, or file statements with any Formatted: Default, Indent: Left: 0.38", Tab stops: Not at advisory committee, subject to reasonable rules or regulations. Formatted: Default, Indent: Left: 0.38", Tab stops: 0.38", • Additional information may be found at the FACA homepage: List tab + Not at 0" + 0.25" http://www.gsa.gov/Portal/gsa/ep/channelView.do?pageTypeId=8203&channel Page=/ep/channel/gsaOverview.jsp&channelId= 13170http://www.gsa.gov/portal/content/100916 Appendix C - DUTIES OF THE DESIGNATED FEDERAL OFFICER The Designated Federal Officer assigned to the National Organic Standards Board and its committees, under the Federal Advisory Committee Act (U.S.C. App.2) and its implementing

regulations (41 CFR Part 101-6.10), is the National Organic Program's Program Director. The Program Director:

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

Appendix D - PARLIAMENTARY PROCEDURE AT A GLANCE

TO DO THIS	YOU SAY THIS	May you interru pt speake r?	Must you be seconde d?	Is the motion debatabl e?	Vote requi red
Adjourn the meeting	I move that we adjourn	no	yes	no	majo rity
Recess the meeting	I move that we recess until	no	yes	no	majo rity
Complain about noise, room temperature, etc.	Question of privilege	yes	00	no	ote
Suspend further consideration of something	I move that the motion be laid on the table	00	yes	no	majo rity
End debate	I move the previous question	no	yes	no	2/3 vote
Postpone consideration of something	I move we post pone this matter until	no	yes	yes	majo rity
Have something studied further	I move to refer the motion to the committee	no	yes	yes	majo rity
Amend a motion	I move to amend	no	yes	yes	majo rity
Introduce business (a primary motion)	I move that	no	yes	yes	majo rity
Object to procedure or to a personal affront	Point of order	yes	no	no	chair decid es
Request information	Point of information	yes	no	no	no vote
Ask for a vote by actual count to	I call for a division	ne	no	no	no vote

verify a voice vote					
Object to the consideration of some undiplomatic matter	I object to the consideration of the question	yes	no	no	2/3 vote
Take up a matter previously tabled	I move to take from the table	10	yes	no	majo rity
Reconsider something already disposed of	l move to reconsider	yes	yes	yes	majo rity
Consider something vote out of its scheduled order	I move we suspend the rules and consider	no	yes	no	2/3 vote
Vote on a ruling by the chair	I appeal the decision of the chair	yes	yes	yes	majo rity
Table a motion take matter from table	I move to take from the table	No	Yes	No	majo rity
Rescind motions – Cancel previous action	I move to rescind	No	Yes	Yes	2/3 vote

Appendix E - BASIC CHEMISTRY

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

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

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

In a chemical reaction, the starting substance or substances, referred to as reactants, are changed into new substances or products. Chemists use an arrow as a shorthand form of the phrase "are changed into"; reactants—products (Matta and Wilbraham,1986). An example to distinguish between physical and chemical changes is illustrated when sulfur (a solid) is added to iron filings (a solid). They may be separated unchanged from a mixture of the two substances mixed together. This separation is an example of a physical change. If the mixture of these two substances is heated, a chemical change takes place and the sulfur and iron are changed into a nonmagnetic substance, iron sulfide: Iron + Sulfur Iron Sulfide (Matta and Wilbraham, 1986). A substances' composition and behavior in chemical reactions—its chemical reactivity—comprise its chemical properties.

What is a substance?

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

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

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

Mixtures consist of a physical blend or two or more substances in which the combined substances retain their identity. Most materials found in nature are mixtures. Mixtures can be either homogeneous (same composition throughout) or heterogeneous (has non-uniform composition). A solution is a type of a mixture where there is a homogeneous combination of different substances. The difference between a heterogeneous mixture and a solution is that any sample of a solution has the same composition, while the composition of a mixture is not the same throughout. Solutions may be gaseous, liquid or solid. Examples of mixtures on the National List are aquatic plants and fish emulsions. The various compounds and elements that make up these products are within the

plant, animal or mineral. When a particular component of the plant is desired for use in an agricultural input it typically has to be extracted and in many cases undergo additional chemical reactions to make it into a substance that is functional when combined with other substances.

A distinction should be drawn between a mixture and a compound. The elements making up a compound cannot be recovered without a chemical change. The substances making up a mixture or solution can. Some mixtures can be separated into their various components by simple physical methods. An example is a gray colored mixture produced by stirring together powdered yellow sulfur and black iron filings. The individual particles of sulfur and iron can be readily distinguished from one another under a microscope. The mixture is easy to separate because the iron filings can be removed from the mixture with a magnet leaving sulfur behind. Both the sulfur and the iron are unchanged in composition (example from Matta and Wilbraham, 1986).

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

Salts: a compound of a metal and nonmetal, or of a metal with a negative polyatomic group. Compounds that have an ammonium group (NH4+) instead of a metal are also classified as salts. Some salts are NaCl, KCl, KMnO4 and NH4Cl. A salt is an ionic solid a room temperature. Most have two ionic components (a) a cation, which can be a polyatomic group such as ammonium or a monoatomic metal such as Na+, K+, Ca2+ or Mn3+ and (b) an anion, which can be a negative polyatomic group or a monoatomic ion such as Cl. or NH3. A solid salt consists of ions in close association. When the salt dissolves in water, the ions are separated. Substances that exist as ions in solution are called electrolytes. When NaCl dissolves in water, the correct formula is Na+ + Cl. This formula treats the component ions of the salts as independent entities, which is approximately how they behave in water solution. Salts are called strong electrolytes because they usually separate completely into ions in water. (Boyd text)

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

Bases: a compound that is a source of OH ions in water solution. A compound of a cation and the OH anion is a base. Bases resemble salts in many ways. They are ionic solids that dissociate into ions when dissolved in water. Bases that contain a cation and OH are generally dissociate completely in water and are classified as strong bases. Some strong bases are NaOH (sodium hydroxide) and KOH (potassium hydroxide). Compounds that do not contain hydroxide ions are defined as bases if they produce OH- ions by reaction with water. An example is ammonia (NH3) which reacts with water to produce hydroxide ions.

Nonelectrolytes: Compounds containing only nonmetals usually exist as discrete molecules, rather

than collections of ions. These compounds do not dissociate into ions when they dissolve in water. Many organic compounds are nonelectrolytes and they will not dissolve appreciably in water i.e. oil. Some will dissolve in water, although they will not dissociate into ions i.e. sugar, and ethyl alcohol.

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

What constitutes a chemical change?

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

The following are common types of chemical reactions that describe what is happening when different substances and compounds interact (Boikess and Edelson, 1978).

- 1. Addition or combination reaction: Two substances combine to form one: 2Na+Cl₂—2NaCl
- 3. Displacement reactions: Substances exchange parts. There are many types of these reactions but one of the most important is called metathesis which is the exchange of ions by two ionic compounds, with the anion of one compound joining the cation of the other compound and vice versa. AB+CD AD + CB
 - a. 1. Hydrolysis is a displacement reaction of a substance or ion with water. Water is a source of both H¹ and OH ions. The OH anion combines with the positive portion of the compound that is hydrolyzed. This positive portion may be a cation or an atom with a positive oxidation number. The H¹ cation combines with the negative portion of the compound, which may be an anion or an atom with a negative oxidation number.
 - b. Acid base reaction: an acid is a substance that can donate a proton, and a base is a substance that can accept a proton.

Since many materials used in organic agriculture are derived from plants and animals it is important to mention chemical reactions that occur in by products of these organisms. In living organisms, enzymes play the role in catalyzing a specific reaction or type of reactions.

Proteins are substances extracted from living organisms that maybe utilized in materials that are petitioned for use in organic production. Proteins are sensitive to relatively small changes in pH, temperature, or solvent composition may cause them to denature. Denaturation causes physical change, the most observable result is loss of biological activity. Except for cleavage of disulfide

bonds, denaturation stems from changes in secondary, tertiary, or quaternary structures through disruption of noncovalent interactions, such as hydrogen bonds, salt linkages and hydrophobic reactions. Common denaturing agents include the following:

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

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

References:

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

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

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

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