

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

**August 13, 2013**

**Introduction**

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

**Background**

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

**Relevant Areas in the Rule**

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

**Discussion**

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

**Example #1: Original Introduction**

INTRODUCTION (page 4)

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

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

This manual is designed to assist the Board in its responsibilities. New Board members are encouraged to review this manual in depth as well as to become

familiar with the Organic Foods Production Act (OFPA), 7 CFR Part 205, and the NOSB New Member Guide. Existing members are advised to periodically review the contents to refresh their understanding of the Board's role and their duties. New policies and revisions to existing policies and procedures will be incorporated into the NOSB Policy and Procedures Manual from time to time, as determined by the Board.

### **Example #1: Revised Introduction**

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

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

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

This manual is designed to assist the Board in its responsibilities. New Board members are encouraged to review this manual in depth as well as to become familiar with the Organic Foods Production Act (OFPA), 7 CFR Part 205, and the NOSB New Member Guide. Existing members are advised to periodically review the contents to refresh their understanding of the Board's role and their duties.

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

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

### **Example # 2: Original text and formatting**

#### **OFFICER RESPONSIBILITIES**

##### **Chair**

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

- Schedule meetings of the Board and the Executive Subcommittee;
- Draft meeting agendas in consultation with Subcommittee chairs and NOP staff;
- Convene and preside at meetings;
- Review Subcommittee work plans;
- Review meeting minutes for accuracy, and
- Assist with the annual election of NOSB officers.

#### Vice Chair

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

### **Example # 2: New text and formatting**

#### Chair

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

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

#### Vice Chair

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

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

### **Example # 3: Reorganization of various topics/sections.**

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

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### Summary of recommendation

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

### Subcommittee Vote

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

Motion by: John Foster

Seconded by: Jay Feldman

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

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

# NATIONAL ORGANIC STANDARDS BOARD

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## POLICY AND PROCEDURES MANUAL

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Adopted October 19, 2002

\*DRAFT\* Revision August 13, 2013.

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

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

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

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## INTRODUCTION

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

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

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

This manual is designed to assist the Board in its responsibilities. New Board members are encouraged to review this manual in depth as well as to become familiar with the Organic Foods Production Act (OFPA), 7 CFR Part 205, and the NOSB New Member Guide. Existing members are advised to periodically review the contents to refresh their understanding of the Board's role and their duties.

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

## SECTION I

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### **NOSB VISION STATEMENT**

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

### **NOSB STATUTORY MISSION**

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

### **NOSB MISSION STATEMENT**

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

To carry out the mission, the Board will:

- Assist in the development and maintenance of organic standards and regulations
- Review petitioned materials for inclusion on, or deletion from, the National List of Approved and Prohibited Substances (National List)
- Recommend changes to the National List
- Communicate with the organic community to provide timely information concerning the NOP, making reasonable use of a variety of communication channels, including but not limited to conducting public meetings and soliciting and receiving public comments.
- Communicate and coordinate with, and provide support to, the NOP staff

### **DUTIES OF THE BOARD AND OFFICERS**

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

- (1) IN GENERAL -The Board shall provide recommendations to the Secretary regarding the implementation of this title.
- (2) NATIONAL LIST -The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 2118.
- (3) TECHNICAL ADVISORY PANELS -The Board shall convene technical advisory panels to provide scientific evaluation of the materials considered for inclusion on the National List. Such panels may include experts in agronomy, entomology, health sciences and other

relevant disciplines.

- (4) SPECIAL REVIEW OF BOTANICAL PESTICIDES -The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticide should be included in the list of prohibited natural substances.
- (5) PRODUCT RESIDUE TESTING -The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.
- (6) EMERGENCY SPRAY PROGRAMS -The Board shall advise the Secretary concerning rules for exemptions from specific requirements of this title (except the provisions of section 2112) with respect to agricultural products produced on certified organic farms if such farms are subject to a Federal or State emergency pest or disease treatment program.

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

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

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

To fulfill their responsibilities, Board members agree to adhere to the following Duties as described in this Manual--Duty of Care, Duty of Loyalty, and Duty of Obedience.

### **Duty of Care**

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

- Be reasonably informed - It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources.
- Participate in decisions - Board members are bound by responsibility to be active participants in decision making. Absence from a meeting is no protection from the responsibility for decisions made at the meeting.
- Make decisions with the care of an ordinary prudent person in a similar position - The law requires Board members to exercise the judgment of an ordinary prudent person who may be faced with a similar issue.

### **Duty of Loyalty**

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

- Address conflicts of interest - Board members bring to the NOSB particular areas of expertise based upon their personal and business interests in organic production and

marketing. Because Board members may have interests in conflict with those of the public they must be conscious of the potential for such conflicts and act with candor and care. Board members must abide by the NOSB conflict of interest policy.

- Recognize corporate opportunity - Before a Board member votes upon an issue in which they have a direct financial interest, that Board member must disclose the transaction to the Board in sufficient detail and adequate time to enable the Board to act, or decline to act, in regard to such transaction.

### **Duty of Obedience**

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

- Act within the requirements of the law - Board members must uphold all state and federal statutes, including the Federal Advisory Committee Act (FACA – 5 U.S.C. App. 2 et seq.)
- Adhere to the responsibilities of the Board as defined by the Organic Foods Production Act of 1990
- Adhere to the requirements specified in the NOSB Policy and Procedures Manual

### **Professional and Ethical Standards**

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

- **Professional Conduct**

NOSB members shall:

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

\*Nonpublic information is defined as information that a Board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should be expected to know, has not been made available to the general public. This includes information

that is “routinely exempt from disclosure in 5 U.S.C. 552 (Freedom of Information Act) or otherwise protected from disclosure by statute, Executive Order or regulation; is designated as confidential by the agency or program; or has not actually been disseminated to the general public and is not authorized to be made available to the public upon request.”

- Along with task force members shall keep confidential all information identified by petitioners as confidential business information.
- Speak with one voice to the maximum extent possible. Although there may be disagreements, NOSB members have the responsibility to support the integrity of the process, whether or not they agree with the final outcome. While NOSB members retain the right to express minority opinions, the public airing of dissension could strain interpersonal relationships and create distrust and conflict among NOSB members. Such stresses could undermine the NOSB’s ability to effectively carry out its role as a governmental advisory board
- Represent the segments of the population from which they were selected, while also representing the greater good of the population as a whole

- **Conflict of Interest**

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

*Be it resolved by the National Organic Standards Board:*

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

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

*A "direct financial gain" is defined as monetary consideration, contractual benefit or the expectation of future monetary gain to a Board member, including but not limited to, financial gain from parties who manufacture, distribute or hold exclusive title to a formula*

### **COMPOSITION OF THE BOARD 6518 (b)**

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

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

### **BOARD MEMBER STANDARDS**

- Participate in meetings - Members must make a commitment to attend meetings of the Board.
- Serve on Subcommittees, as assigned - Each member must be willing to serve on Subcommittees as assigned by the Chair, and to participate in the work of those Subcommittees.
- Be informed about Board business - Board members are expected to seek and study the information needed to make reasoned decisions and/or recommendations on all business brought before the Board.
- Fully disclose any conflicts of interest - Members having any commercial or immediate family interests that pose a potential or perceived conflict of interest must disclose that conflict to the Board and abide by any decision of the Board regarding the situation.

### **CONDUCTING BUSINESS**

- Quorum - As specified in OFPA, a majority of the members of the Board shall constitute a quorum for the purpose of conducting business. [§2119(h)] A majority of the members of a Subcommittee, including the Executive Subcommittee, shall constitute a quorum for the purpose of conducting business.
- Decisive votes - As specified in OFPA, two-thirds of the votes cast at a meeting of the Board at which a quorum is present shall be decisive of any motion [§2119(i)]. Following Robert's Rules of Order, all abstentions will be recorded as such and will not be included as

part of the total vote cast. Similarly, all Board members who recuse themselves due to conflicts of interest, or are absent, shall be recorded as such and their votes will not be counted towards the total number of votes cast. Both abstentions and recusals will be considered in order to establish a quorum.

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

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## SECTION III

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

The Designated Federal Officer assigned to the National Organic Standards Board and its Subcommittees, under the Federal Advisory Committee Act (U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10), is the National Organic Program's Advisory Board Specialist (ABS). The position of Advisory Board Specialist (ABS) (formerly the Executive Director) was added in 2005 to facilitate contact between the NOP and the NOSB.

Advisory Board Specialist duties include but are not limited to:

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

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

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

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

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

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

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

## **NOSB OFFICER RESPONSIBILITIES**

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

### **Chair**

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

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

### **Vice Chair**

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

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

### **Secretary**

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

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

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

### **Administrative Team**

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

## **ELECTION OF OFFICERS**

### **A. NOMINATIONS**

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

### **B. VOTING SCHEDULE**

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

### **C. ELIGIBILITY TO VOTE**

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

## **D. COUNTING OF VOTES**

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

## **EXECUTIVE SUBCOMMITTEE**

The Executive Subcommittee of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the chairs of each of the standing Subcommittees. The Executive Subcommittee, the DFO/ABS, and the NOP Deputy Administrator, shall meet monthly, as needed, or as called by the Chair, and shall conduct business on behalf of the Board. Only the full Board may take decisive action on guidance and other policy proposals from Subcommittees, including the status of materials proposed for addition or deletion on the National List. The Executive Subcommittee will provide guidance and feedback to the Subcommittees on their proposed work plans.

## **BOARD MEETINGS**

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

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

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

## SECTION IV

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### BOARD SUBCOMMITTEES

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

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

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

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

### STANDING SUBCOMMITTEES

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

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

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

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

**Materials Subcommittee (MS)** The Materials Subcommittee drafts proposals for consideration by the Board to provide guidance, clarification or proposed standards of the National List section of the organic regulations as contained in [7CFR Part 205] and OFPA. The MS works with the NOP and, other NOSB Subcommittees in managing the Materials Review Process, which includes tracking petitions, sufficiency reports, materials scheduled to sunset and the sunset review process. In addition to a Chair appointed by the Board Chair, the MS shall include in its membership a representative from each of the Livestock, Crops, and Handling Subcommittees. Other members may be appointed as needed. The MS occasionally works with other Subcommittees to develop joint proposals where materials are involved.

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

## **SUBCOMMITTEE MEETINGS**

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

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

## **TASK FORCES**

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

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

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

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

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

## AD HOC SUBCOMMITTEES

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

## SECTION V

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### **DUTIES OF SUBCOMMITTEE CHAIRS**

Subcommittee Chair duties:

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

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

### **DUTIES OF SUBCOMMITTEE VICE CHAIRS**

Subcommittee Vice Chair duties:

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

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

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

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

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

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

**After the election of NOSB Officers at the Fall Meeting:**

**Appointment of Subcommittee Chairs**

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

**Appointment of Subcommittee Vice Chairs**

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

**Time Frame for Appointments**

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

**Exchange of Subcommittee Files**

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

**Review of Subcommittee Files**

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

**Mentorship Period**

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

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

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

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

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

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

### **Between Board Appointments and Board Meetings:**

#### Changing Subcommittee Appointments

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

#### Filling a Subcommittee Chair and/or Vice Chair vacancy

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

### **PROCEDURES FOR COMPLETING SUBCOMMITTEE RECOMMENDATIONS**

Developing committee recommendations follows these broad steps:

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

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

### **PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS**

Subcommittee proposal and Discussion document process:

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

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

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

### **Guidelines for Writing Subcommittee Proposals and Discussion Documents**

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

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

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

### **Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings**

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

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

### **NOSB-NOP COLLABORATION**

The Organic Foods Production Act (6518 (a)) directed the Secretary of Agriculture to establish a National Organic Standards Board to assist in the development of standards for substances

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

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

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

The NOSB is a FACA advisory committee, and as such, must conduct business in the open, under the requirements of P.L. 94-409, also known as “Government in the Sunshine Act” (5 U.S.C.552b).

The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.

The NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, make NOP staffing decisions, or initiate policies of its own accord.

## **WORK PLANS**

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

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

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

E)

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

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

## SECTION VI

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### NOSB PROCEDURES

#### SUBCOMMITTEE WORKPLANS

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

##### Step 1: Identify all issues

The Subcommittee workplan will be based on:

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

Selection criteria for workplan items:

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

##### Step 2: Prioritize the issues

Workplan items should be prioritized according to the following criteria:

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

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

##### Step 3: Set a calendar for completing reviews

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

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

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

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

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## SECTION VII

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### MISCELLANEOUS PROCEDURES

#### Invited Speakers

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

### MISCELLANEOUS PROCEDURES

#### Invited Speakers

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

## Surveys Conducted on Behalf of NOSB Subcommittees

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

## Public Comment at NOSB Meetings:

- All persons wishing to comment at NOSB meetings during public comment periods must, in general, sign-up in advance per the instructions in the Federal Register Notice for the meeting. However, the NOSB will attempt to accommodate all persons requesting public comment time. Persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP working closely with the NOSB Chair and will depend on availability of time.
- All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. Advance submissions allow NOSB members the opportunity to read comments in advance electronically, and decreases the need for paper copies to be distributed during the meeting.
- Persons will be called upon to speak according to a posted schedule. However speakers should allow for some flexibility. Persons called upon who are absent from the room could potentially miss their opportunity for public comment.
- Time allotment for public comment per person will be four (4) minutes, with the options of reducing to a minimum of three (3) and extending to a maximum of five (5) minutes at the discretion of the NOP working closely with the NOSB Chair in advance of the meeting.
- Persons must give their names and affiliations for the record at the beginning of their public comment.
- Proxy speakers are not permitted.
- Public comment requests may be scheduled according to topic.
- Individuals providing public comment will refrain from any personal attacks and from remarks that otherwise impugn the character of any individual.
- Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.

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

**Policy for Public Communication between NOSB Meetings.**

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

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

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## SECTION VIII

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### NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

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

- ecologically, socially, and economically sustainable.
- 1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.
  - 1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.
  - 1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.
  - 1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.
  - 1.10 Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.
  - 1.11 Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (geo/gmo's) and products produced by or through the use of genetic engineering are prohibited.
  - 1.12 Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

Adopted October 17, 2001

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

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

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

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

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

## **MATERIALS REVIEW PROCESS**

**Evaluation procedures for substances petitioned for addition to, or removal from, the National List.** A petition to change the annotation to a listed material is in effect the addition or removal of one or more materials.

### **Definitions:**

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

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

### **Phase 1: Receipt of petition and examination of petition for completeness and eligibility**

During this phase the NOP will:

- Notify the petitioner via letter and/or email of receipt of the petition
- Determine whether the petition is complete.
- Determine whether the petitioned substance is eligible for petition under the Organic Foods Production Act (OFPA) and its implementing regulations; document this review using the NOP-OFPA checklist.
- Determine whether the petitioned use is approved under the statutory and regulatory authority of the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), or other appropriate federal agency if applicable
- Identify and secure any confidential business information (CBI) designated by the petitioner
- Notify, as applicable, the petitioner via letter and/or email of determination of completeness and eligibility, and acknowledge the designation of certain information as CBI.
- Upon determination by the NOP of completeness and eligibility, the following actions will be taken:
  - Publish the petition on the NOP website
  - Notify the National Organic Standards Board (NOSB) Materials Subcommittee chairperson and the chairperson of the Subcommittee that will review the substance (Crops, Livestock, Handling or other pertinent Subcommittees) that the petition is complete, provide to them the OFPA review and EPA/FDA determination checklist, and request that the Subcommittee review the petition for sufficiency, and submit a request for supplemental or clarifying information.

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

During this phase:

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

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

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

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

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

## **Phase 3: Evaluation by a Third Party Expert**

During this phase the NOP will:

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

During this phase the Third Party Expert will:

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

## **Phase 4: Sufficiency Determination**

During this phase the NOP will:

- Submit a copy of the draft TR for review to the NOSB Materials Subcommittee and the pertinent Subcommittee that will conduct the review (Crops, Livestock or Handling);
- Review the draft TR using the following performance criteria. The

report will be acceptable when it:

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

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

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

#### **Phase 5: Action by the Subcommittee conducting the review (Crops, Livestock or Handling)**

During this phase the Subcommittee conducting the review will:

- Discuss and recommend an action on the petitioned substance. The Subcommittee may convene as the TAP by email or conference call to provide complete evaluation of the petitioned substance, as provided by OFPA 6518(k)(3). The Subcommittee must convene and recommend an action on the petitioned substance no later than 60 days before a scheduled meeting of the full NOSB.

#### **Phase 6: Action by Full NOSB**

During this phase the NOP will:

- Publish the proposal on the NOP website and request a minimum of 30 days of written public comment on the proposal prior to the public NOSB business meeting.
- Include sufficient time on the agenda at the NOSB meeting for the Board to discuss the proposal and make a recommendation.

## TECHNICAL REVIEWS

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

Third party experts can consist of the following:

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

Steps to determine the need for a third party expert:

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

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

- A Subcommittee cannot proceed with a recommendation on a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
- The decision to request a third party expert needs to be made independent of the availability of funds. If there is a lack of funding to secure third party expert advice, the review of the material should be placed on hold.
- Although the Board has the final word on the approval or rejection of a petition, the decision to request a third party expert is the responsibility of the Subcommittee reviewing the material. In some cases the Materials Subcommittee can take the initiative to request a third party expert.
- Defining the required expertise is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee should strive to work with a range of technical experts (individuals, or institutions).

#### **WITHDRAWAL OF A PETITION BY THE PETITIONER**

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

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

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

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

#### **TECHNICAL ADVISORY PANEL (TAP) CONTRACT PROCEDURES**

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

## PRIORITY OF PETITIONS GUIDELINE

### Prioritization

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

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

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

#### 2. Priority 3: Petitions to add a material to the National List:

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

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

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

This prioritization guideline is only that, a guideline. When situations occur beyond the control of the reviewing Subcommittee, such as, but not limited to, Technical Report budgetary constraints, or a delay in the delivery of a Technical Review for a petitioned substance, the workplan may require adjustment by the NOSB and NOP.

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

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

### **BOARD PROCEDURES FOR THE MATERIALS' REVIEW PROCESS - Sunset**

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

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

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

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

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

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

### **Sunset Process (See Charts 1- 4 below)**

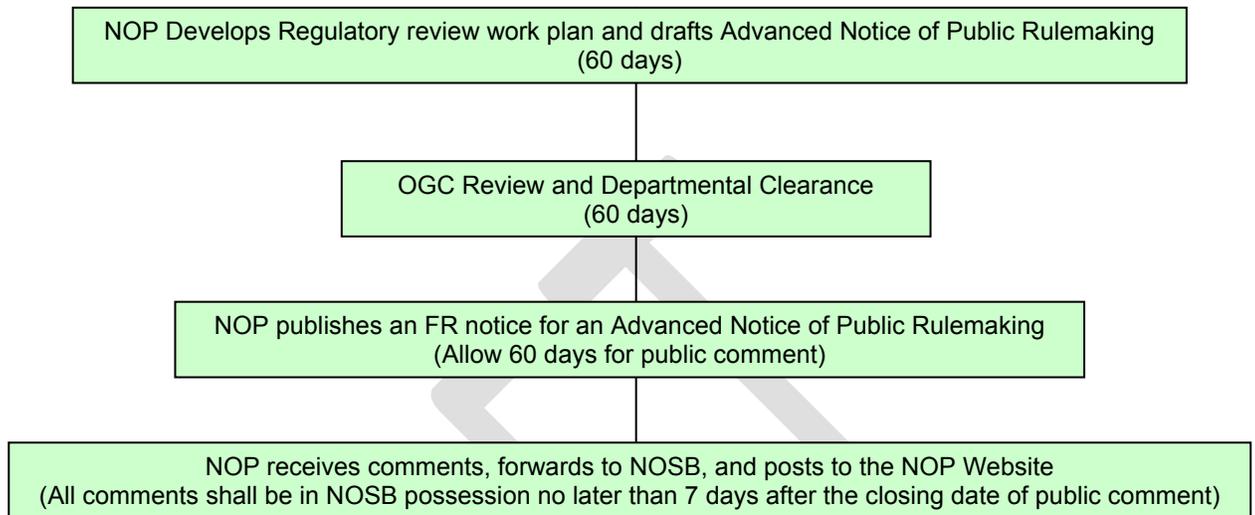
Although not all listed materials reach sunset status at the same time, the review process remains the same:

1. An Advance Notice of Proposed Rule Making (ANPR) is placed in the Federal Register (listing the pending sunset materials. The public has 60 days from the publication date to provide written comment. A Subcommittee may request a third party technical review in anticipation of any public comments or questions.
2. Public comments are collected and forwarded to the NOSB.
3. The appropriate NOSB Subcommittee begins review of the material with the intent of providing a proposal to the entire Board for the material's removal, renewal, *or renewal with the addition of an annotation*. The review is conducted based on “Force of Evidence” as presented by Board members, public comments, and scientific data from other sources This includes the original recommendation from the Board. The Subcommittee may request a third party technical review, if needed, to verify scientific evidence and claims made during public comment to the ANPR.
4. The reviewing NOSB Subcommittee provides its proposal to the full Board and the public no less than 60 days prior to the Board Meeting which would include the following:
  - A simple motion to remove, add or amend an annotation, resulting in the restriction or clarification of the use of a material (if applicable).
  - A simple motion to renew the existing listing.
5. At the public NOSB business meeting, the NOSB hears additional public comment, discusses the force of evidence, and votes on the Subcommittee's proposal.
6. The NOP reviews the NOSB recommendation and accompanying documentation and publishes a proposed rule to review the National List. The public has 90 days after the publication date to comment. All comments are made available on the NOP website.

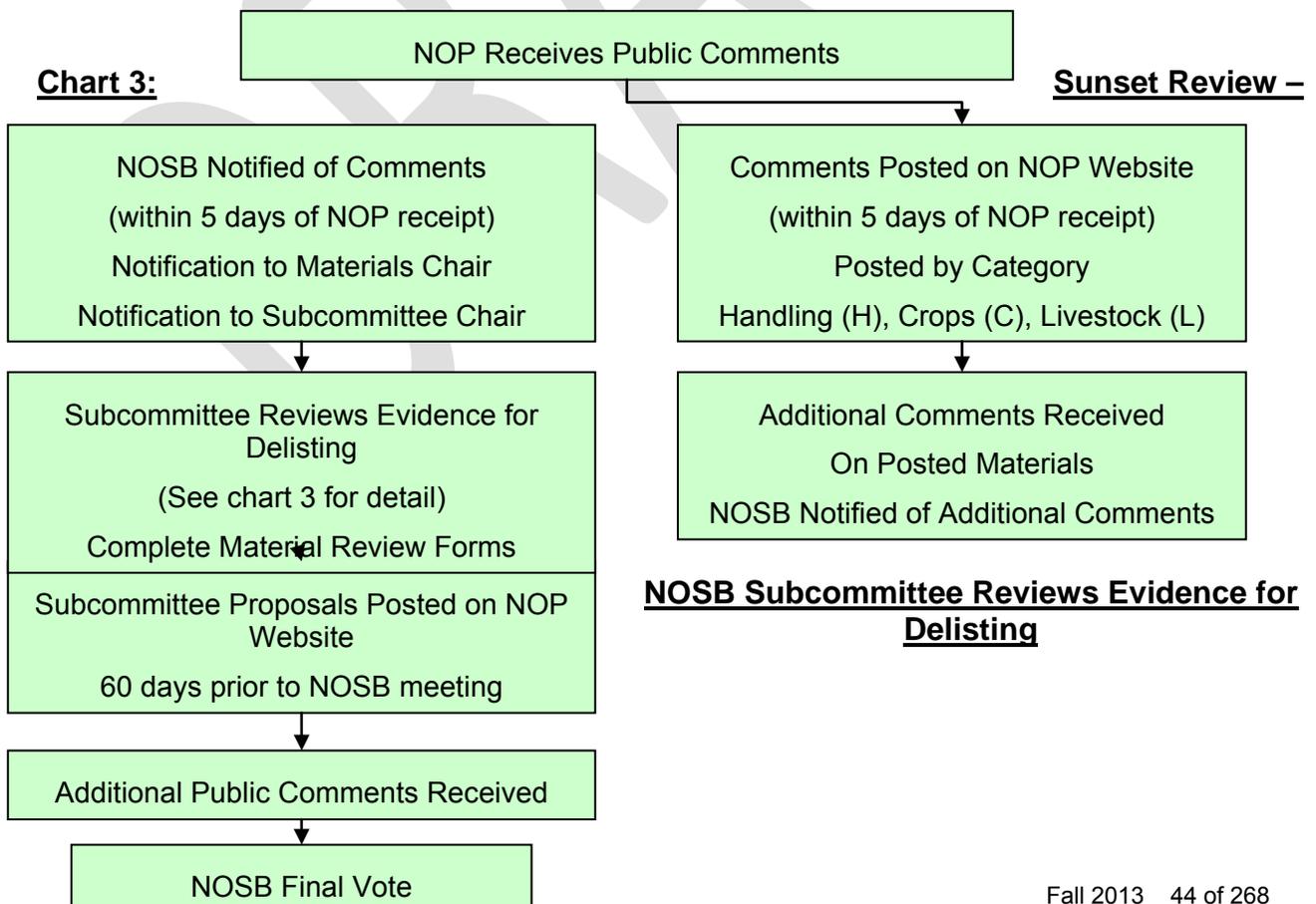
*The NOP will review public comment and draft the final rule. The final rule will proceed*

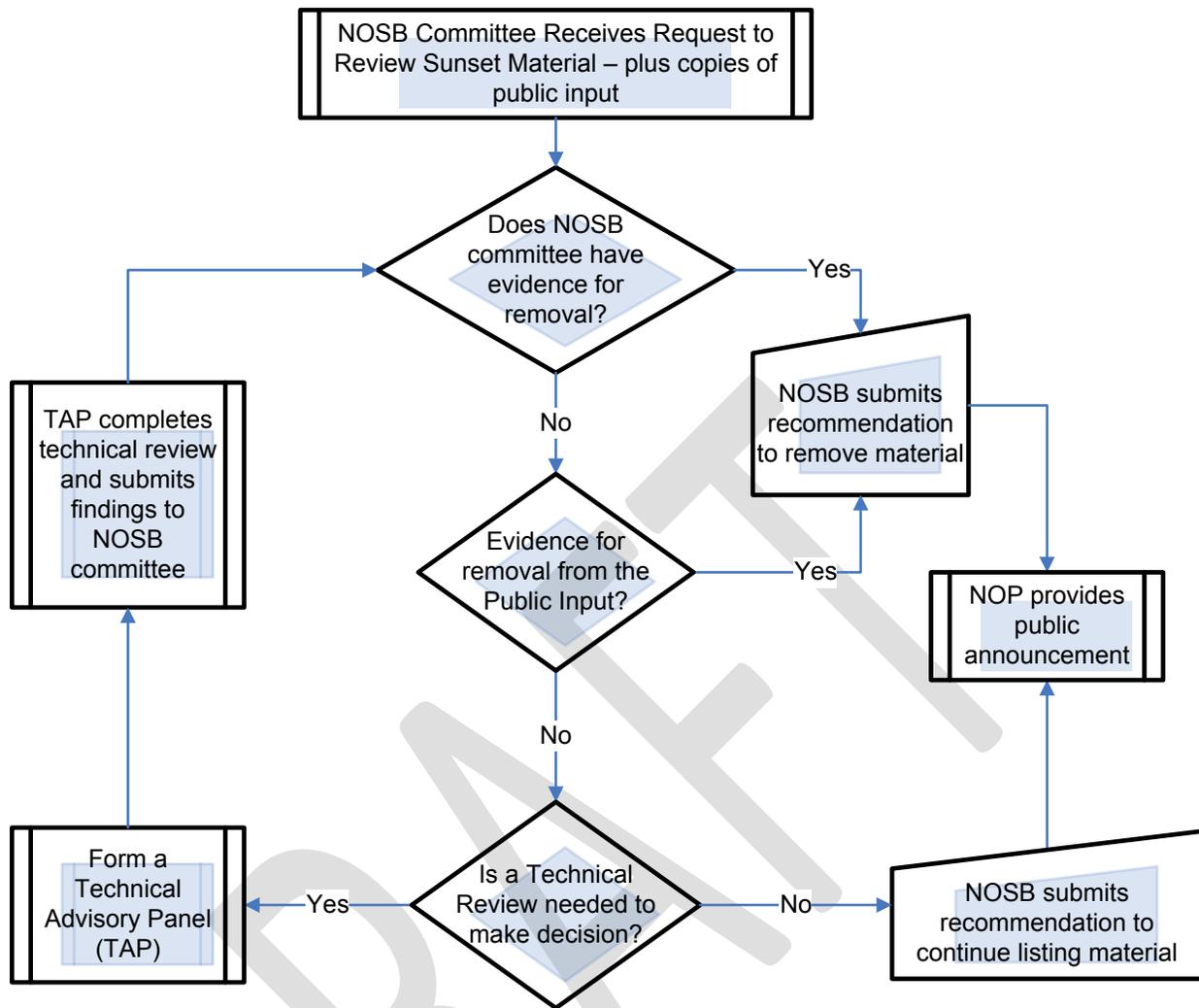
through interagency (i.e. OGC, OMB, and department) and congressional review, and upon clearance from the appropriate parties, the NOP will publish the final rule in the Federal Register. The final rule process is illustrated in Chart 4.

**Chart 1: Sunset Review – NOP Posts an ANPR**

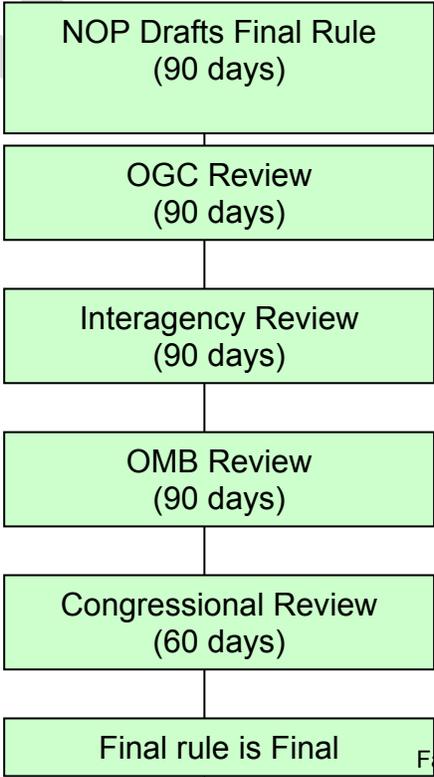


**Chart 2: Sunset Review – NOP Collects and Forwards Public Comment to the NOSB**





**Chart 4:**  
**Sunset**  
**Review**  
  
**Final Rule**  
**Process**



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

In order to minimize confusion in the organic community, the Board needs to monitor and correct any discrepancies that may occur between the time an item is voted on and subsequently published in the Federal Register. Examples include:

- Annotations that differ from the original NOSB recommendation. Annotations may be changed by the Program to accommodate the requirements of other federal regulatory bodies (ex: livestock medications withholding times).
- Annotations added to address any unforeseen consequences of an NOSB recommendation, to accommodate the requirements of the organic industry. For example, the absence of an explicit description of what methods of extraction are allowed for specific materials could result in the unwanted use of materials extracted using prohibited extraction processes.

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

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

## APPENDICES AND RESOURCES

### Appendix A - DECISION MAKING GUIDELINES FOR THE NOSB

- **Define the Problem**
  - What is the problem?
  - Identify where we are now.
    - State the present condition in no more than two sentences.
  - Identify where we want to be.
    - State the future objective in no more than two sentences.
  
- **Analyze the Problem**
  - Why is there a problem?
  - Is the evidence of the problem supported by credible and compelling facts or data?
    - What are the facts or data used to draw an affirmative conclusion?
  - Who does this problem affect?
  - What is the problem's effect?
  - In what time frame must the problem be resolved?
  - If the problem deserves immediate attention, what other priorities must be adjusted to accommodate this problem?
  - If the problem deserves immediate attention, what are the consequences of a delay?
  
- **Develop Possible Solutions**
  - Propose ideas for possible solutions
  - Evaluate ideas for possible solutions
    - List pros for each possible solution
    - List cons for each possible solution
  - Select a Solution
    - Is the recommended solution legal?
    - Is the recommended solution practical?
    - Is the recommended solution supported by credible and compelling facts or data?
      - What are the facts or data used to draw an affirmative conclusion?
    - How does the recommended solution solve the problem?
    - How does the recommended solution meet the time frame identified in 2(b)?
  - Review recommended solution for unintended consequences.
  
- **Develop Action Plan**
  - Develop Action Steps
    - Identify action steps to bridge the gap between present condition and future objective using the recommended solution.
  - Approve Action Plan
  - Implement Action Plan

## Appendix B - FACA FACTS

- The Federal Advisory Committee Act (FACA) (5 U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.
- Advisory committees must be chartered before they can meet or conduct any business. Charters must be renewed every two years or they will be terminated under the sunset provisions of Section 14 of the FACA, unless otherwise provided by law.
- Advisory committee meetings are required to be open to the public, with limited exceptions as provided for in Section 552b of title 5, United States Code. Meetings not subject to FACA include NOSB briefing meetings initiated by the USDA to exchange facts and information, member orientation and training, and NOSB Subcommittee meetings. Such meetings are not subject to FACA because they are not conducted for the purpose of providing the USDA with NOSB advice or recommendations.
- Designated Federal Officers must approve all meetings and agendas, and attend meetings. The Advisory Board Specialist is the NOSB's Designated Federal Officer.
- Meeting notices and agendas must be published in the Federal Register to accommodate public participation. Although not required by FACA, the NOP strives to:
  - Post a provisional agenda on its web site no later than 90 days before the meeting is scheduled to begin
  - Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin
  - Publish notice of the meeting in the Federal Register no later than 45 days before the meeting is scheduled to begin
- While meeting transcripts are not required under FACA, the NOP invests in transcripts to support the transparency of Board meetings and to support subsequent rulemaking activities. The NOP also issues a short meeting summary, which is required by FACA, after each biannual meeting that summarizes the key issues discussed, and the outcome of voting.
- Advisory committee documents must be available for public inspection and copying until the committee ceases to exist
- Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.
- Additional information may be found at the FACA homepage:  
<http://www.gsa.gov/Portal/gsa/ep/channelView.do?pageTypeld=8203&channelPage=/ep/channel/gsaOverview.jsp&channelId=-13170>

## Appendix C - PARLIAMENTARY PROCEDURE AT A GLANCE

TO DO THIS	YOU SAY THIS	May you interrupt speaker?	Must you be seconded ?	Is the motion debatable?	Vote required
Adjourn the meeting	I move that we adjourn	no	yes	no	majority
Recess the meeting	I move that we recess until...	no	yes	no	majority
Complain about noise, room temperature, etc.	Question of privilege	yes	no	no	no vote
Suspend further consideration of something	I move that the motion be laid on the table	no	yes	no	majority
End debate	I move the previous question	no	yes	no	2/3 vote
Postpone consideration of something	I move we postpone this matter until...	no	yes	yes	majority
Have something studied further	I move to refer the motion to the Subcommittee	no	yes	yes	majority
Amend a motion	I move to amend...	no	yes	yes	majority
Introduce business (a primary motion)	I move that...	no	yes	yes	majority
Object to procedure or to a personal affront	Point of order	yes	no	no	chair decides
Request information	Point of information	yes	no	no	no vote
Ask for a vote by actual count to verify a voice vote	I call for a division	no	no	no	no vote
Object to the consideration of some undiplomatic matter	I object to the consideration of the question	yes	no	no	2/3 vote
Take up a matter previously tabled	I move to take from the table	no	yes	no	majority
Reconsider something already disposed of	I move to reconsider...	yes	yes	yes	majority
Consider something vote out of its scheduled order	I move we suspend the rules and consider...	no	yes	no	2/3 vote
Vote on a ruling by the chair	I appeal the decision of the chair	yes	yes	yes	majority
Table a motion - take matter from table	I move to take from the table	No	Yes	No	majority
Rescind motions – Cancel previous action	I move to rescind	No	Yes	Yes	2/3 vote

Source: Robert's Rules of Order

## Appendix D - BASIC CHEMISTRY

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

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

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

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

## What is a substance?

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

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

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

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

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

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

**Salts:** a compound of a metal and nonmetal, or of a metal with a negative polyatomic group. Compounds that have an ammonium group ( $\text{NH}_4^+$ ) instead of a metal are also classified as salts. Some salts are  $\text{NaCl}$ ,  $\text{KCl}$ ,  $\text{KMnO}_4$  and  $\text{NH}_4\text{Cl}$ . A salt is an ionic solid at room temperature. Most have two ionic components (a) a cation, which can be a polyatomic group such as ammonium or a monoatomic metal such as  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Ca}^{2+}$  or  $\text{Mn}^{3+}$  and (b) an anion, which can be a negative polyatomic group or a monoatomic ion such as  $\text{Cl}^-$  or  $\text{NH}_3^-$ . A solid salt consists of ions in close association. When the salt dissolves in water, the ions are separated. Substances that exist as ions in solution are called electrolytes. When  $\text{NaCl}$  dissolves in water, the correct formula is  $\text{Na}^+ + \text{Cl}^-$ . This formula treats the component ions of the salts as independent entities, which is approximately how they behave in water solution. Salts are called strong electrolytes because they usually separate completely into ions in water. (Boyd text)

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

**Bases:** a compound that is a source of  $\text{OH}^-$  ions in water solution. A compound of a cation and the  $\text{OH}^-$  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  $\text{OH}^-$  are generally dissociate completely in water and are classified as strong bases. Some strong bases are  $\text{NaOH}$  (sodium hydroxide) and  $\text{KOH}$  (potassium hydroxide). Compounds that do not contain hydroxide ions are defined as bases if they produce  $\text{OH}^-$  ions by reaction with water. An example is ammonia ( $\text{NH}_3$ ) which reacts with water to produce hydroxide ions.

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

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

### What constitutes a chemical change?

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

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

- Addition or combination reaction: Two substances combine to form one:
  - $2\text{Na} + \text{Cl}_2 \rightarrow 2\text{NaCl}$
- Decomposition reactions: One compound breaks into two or more compounds or elements.
  - $\text{CaCO}_3 \rightarrow \text{CaO} + \text{CO}_2$
- Displacement reactions: Substances exchange parts. There are many types of these reactions but one of the most important is called metathesis which is the exchange of ions by two ionic compounds, with the anion of one compound joining the cation of the other compound and vice versa.  $\text{AB} + \text{CD} \rightarrow \text{AD} + \text{CB}$ 
  - 1. Hydrolysis is a displacement reaction of a substance or ion with water. Water is a source of both  $\text{H}^+$  and  $\text{OH}^-$  ions. The  $\text{OH}^-$  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  $\text{H}^+$  cation combines with the negative portion of the compound, which may be an anion or an atom with a negative oxidation number.
  - Acid-base reaction: an acid is a substance that can donate a proton, and a base is a substance that can accept a proton.

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

Proteins are substances extracted from living organisms that maybe utilized in materials that are petitioned for use in organic production. Proteins are sensitive to relatively small changes in pH, temperature, or solvent composition may cause them to denature. Denaturation causes physical change, the most observable result is loss of biological activity. Except for cleavage of disulfide bonds, denaturation stems from changes in secondary, tertiary, or quaternary structures through disruption of noncovalent interactions, such as hydrogen bonds, salt linkages and hydrophobic reactions. Common denaturing agents include the following:

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

hydrogen bonding and hydrophobic interactions.

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

**References:**

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

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

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

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## Appendix E - FORMS

### NOSB Subcommittee proposal checklists (Handling, Crops/Livestock)

### Template for Subcommittee Proposal Narrative

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

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

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

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

**Subcommittee Vote:**

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

**Back-up motion:**

**Material Evaluation Checklist: (See appendix E)**

#### Proposals for policy or procedure changes should include the following:

**Introduction:**

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

**Background:**

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

## **Relevant areas in the (Regulation):**

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

## **Discussion:**

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

## **Proposal:**

The core idea of the proposal should be stated clearly.

## **Subcommittee Vote:**

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

## **Back-up motion:**

## **Minority opinion:**

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

## **Template for Subcommittee Discussion Document**

## **Cover sheet for Final NOSB recommendations**

## **Appendix F - INFORMATION TO BE INCLUDED IN A PETITION**

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

### **ITEM A**

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

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

### **ITEM B**

The petitioner must submit the following information:

- The substance's common name.
- The manufacturer's name, address, and telephone number.
- The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer, or disinfectant.
- A list of the crop, livestock, or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.
- The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.
- A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.
- Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.
- The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance.
- The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.
- Safety information about the substance including a Material Safety Data Sheet (MSDS)

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

- Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.
- A "Petition Justification Statement" which provides justification for one of the following actions requested in the petition:
  - *Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)*
    - Explain why the synthetic substance is necessary for the production or handling of an organic product.
    - Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural
  - methods that could be used in place of the petitioned synthetic substance.
    - Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (1) Region of production, including factors such as climate and number of regions;
  - (2) Number of suppliers and amount produced;
  - (3) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies;
  - (4) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies and;
  - (5) Any other issues which may present a challenge to a consistent supply.
- A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:
  - Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim.
  - "Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be
    - commercially valuable,
    - used in the applicant's business, and
    - maintained in secrecy.
  - Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."
  - The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy. (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy.
  - Each page with CBI-deletions should be marked "CBI-deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI- deleted."
  - If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBI-deleted.")
  - All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information usually cannot be claimed as confidential.

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

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

## **Appendix G - TECHNICAL ADVISORY PANEL (TAP) CONTRACT PROCEDURES**

### **Statement of Work**

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

### **Agency Need**

See Statement of Work, 1.0 Background.

- **Background**

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

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

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

- **Mission of USDA/AMS/NOP**

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

The NOSB reviews information from various sources in evaluating substances for inclusion on or removal from the National List. Sources include TAP evaluations, the Environmental Protection Agency, the Food and Drug Administration, the National Institute of Environmental Health Studies, and public comment. The NOSB submits its

recommendations, along with the results of the required evaluation and technical advisory panel evaluation for each substance, to the Secretary for consideration in accordance with the requirements of section 2118(d) of the OFPA (7 U.S.C. 6517(d)).

- **Specific Task**

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

For crop and livestock production substances, the contractor(s) shall use the criteria in Section 2119 of the OFPA (7 U.S.C. 6518 (m)(1-7)). The criteria are:

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

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

- Processing aid or adjuvant cannot be produced from a natural source and has no organic ingredients as substitutes;
- Manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA;
- The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations;
- The primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing, except in the latter case as required by law;
- It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances;
- Its use is compatible with the principles of organic handling; and,

- There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

### **Minimum Skills and Experience Requirements**

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

### **Place of Performance**

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

### **Government Furnished Equipment and Facility**

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

### **Compensation**

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

### **Period of Performance**

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

### **Scope of Performance**

#### **Phase 1: Data Gathering and Compilation (120 days)**

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

- Characterize [the] substance(s) and identify uses and applications;
- Determine whether [the] substance(s) are synthetic or non-synthetic (See 7.S.C. 6502 (21) for definition of synthetic);
- Determine [the] substance(s) chemical or biological composition and possible impact on human/animal health and the environment;
- Identify [the] substance(s) relevant toxicological studies, including ensuring substance does not contain residues of heavy metals or other environmental contaminants in

excess of Food and Drug Administration Action Level or Environmental Protection Agency tolerances;

- Determine [the] substance(s) persistence in the environment;
- Determine [the] substance(s) effect on soil structure and ecology;
- Identify alternatives to the use of the substance(s);
- Determine [the] substance(s) historical use in organic production, processing and handling; and
- Determine [the] substance(s) status under OFPA and with other government agencies.

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

### **Phase 2: Evaluation against Criteria (100 days)**

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

### **Phase 3: Recommendation (42 days)**

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

### **Evaluation Factors for Award**

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

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

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

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

### **Other Evaluation Factors**

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

Technical Factors:

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

Factor 2 Previous Demonstrated Experience and Past Performance

Factor 3 Quality Control

Factor 4 Capability and Experience of Key Personnel

Factor 5 Project Management and Support Capability

Factor 6 Reasonableness of Cost

### **Reporting Requirements**

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

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

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

Any deliverables required under the contract should be submitted upon completion and

addressed to: NOP Program Director, National Organic Program, USDA-AMS-TM-NOP, 1400 Independence Avenue, S.W., Room 4004-So., Ag Stop 0268, Washington, D.C. 20250-0268, Attention: Substance Evaluations.

## **Appendix H - Research Priorities Framework**

March 27, 2012

### **Introduction**

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

### **Background**

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

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

### **Relevant areas in the Rule**

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

"§ 205.2 Terms defined.

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

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

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

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

....."

### **Discussion**

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

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

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

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

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

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

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

### **Recommendation**

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

### **Criteria**

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

Criteria for research topics are:

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

### **Process Framework**

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

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

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

**August 13, 2013**

**Introduction**

The National Organic Standards Board (NOSB) Policy Development Subcommittee (PDS) proposes to update and revise various sections of the Policy and Procedures Manual (PPM), including the Advisory Board Specialist job duties, election of officers, task force appointments, procedures for completing Subcommittee proposals and miscellaneous procedures.

**Background**

The NOSB PPM is a guide meant to assist the Board members with operational procedures, roles, and responsibilities. The Policy Development Subcommittee revises the PPM as necessary to reflect changes in procedure and to provide clarification. During a comprehensive examination of the current PPM, several sections were identified as candidates for updating, and since the updates were not of a substantive nature, the PDS, in collaboration with the NOSB Vice Chair, chose to combine these revisions into one project.

**Relevant Areas in the Rule**

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

**Discussion**

The PPM contains guidance about the Board's standard operating procedures and policies, and the Policy Development Subcommittee in collaboration with the NOSB Vice Chair is charged with its ongoing review and maintenance. The PDS identified several sections in the PPM in need of revision based on minor changes in operating procedure, the need for clarity, or the need for copy editing. The PDS revised the following sections/topics in the July 25, 2013 version of the PPM:

**Section III, page 11 - Advisory Board Specialist job duties.** The Advisory Board Specialist job duties were clarified, and made distinct from those of the Designated Federal Officer, as these two positions are not necessarily staffed by the same person

**Section III, page 12 - Election of Officers.** The language regarding consecutive officer terms not being recommended was unclear, and was clarified by adding the term "historically". e.g. "Historically, more than two consecutive terms in any given officer position has not been recommended"

**Section IV, page 16 - Task force appointments.** The paragraph describing task forces was reworded slightly and reformatted with a bulleted list to make it easier to read. The original paragraph read as follows:

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.

The new paragraph reads as follows:

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

- Include at least one member of the NOSB
- Record and maintain meeting minutes
- Submit a final report to the Board
- Disband when its work has concluded or when the Board or NOP determines the task force is no longer necessary.

**Section V, page 20 - Procedures for completing Subcommittee proposals.** The procedures were clarified by adding language about who was responsible for what action. For example, instead of “The draft proposal or discussion document is posted for public comment”, the sentence now reads “The NOP will post the proposal or discussion document for public comment”

The original paragraph read as follows:

#### **PROCEDURES FOR COMPLETING SUBCOMMITTEE RECOMMENDATIONS**

Developing committee recommendations follows these broad steps:

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

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

The new paragraph reads as follows:

#### **PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS**

1. The Subcommittee drafts the proposal or discussion document based on workplan items (See Section V for detailed discussion about workplans)
2. The draft proposal or discussion document is voted upon by the Subcommittee members in order for it to pass from the Subcommittee to the full Board
3. The draft proposal or discussion document is posted for public comment
4. At any point in the process prior to the Board’s vote a Subcommittee may convene and, by simple majority, vote to withdraw its proposal.

5. During a subsequent Board meeting, the Subcommittee presents the proposals and discussion documents, as well as a summary of public comments, for discussion by the full Board.

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

**Section VII, page 26 - Misc procedures.** Several sentences in this section were rewritten for clarity and syntax. "Subcommittees identify the possible need for a presentation at the NOSB meeting. NOP may also identify needs for presentations and candidate speakers", was changed to "Subcommittees, the NOSB or the NOP may identify the need for presentations and candidate speakers regarding subjects of interest or concern to be addressed at NOSB meetings". The sentence "Invited speakers must provide objective information" was struck from this section as the NOP noted that there are situations in which speakers are invited because they hold a differing view.

### **Summary of Recommendation**

The Policy Development Subcommittee (PDS) proposes to update and revise the sections described above in the PPM to reflect minor changes in operating procedure, and improve clarity through formatting and copy editing: Advisory Board Specialist job duties, election of officers, task force appointments, procedures for completing Subcommittee proposals and miscellaneous procedures.

### **Committee Vote**

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

**Motion by:** John Foster

**Seconded by:** C Reuben Walker

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

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

# NATIONAL ORGANIC STANDARDS BOARD

## POLICY AND PROCEDURES MANUAL

Adopted October 19, 2002

\*DRAFT\* Revision August 13, 2013.

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

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

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

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## INTRODUCTION

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

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

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

This manual is designed to assist the Board in its responsibilities. New Board members are encouraged to review this manual in depth as well as to become familiar with the Organic Foods Production Act (OFPA), 7 CFR Part 205, and the NOSB New Member Guide. Existing members are advised to periodically review the contents to refresh their understanding of the Board's role and their duties.

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

## SECTION I

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### **NOSB VISION STATEMENT**

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

### **NOSB STATUTORY MISSION**

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

### **NOSB MISSION STATEMENT**

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

To carry out the mission, the Board will:

- Assist in the development and maintenance of organic standards and regulations
- Review petitioned materials for inclusion on, or deletion from, the National List of Approved and Prohibited Substances (National List)
- Recommend changes to the National List
- Communicate with the organic community to provide timely information concerning the NOP, making reasonable use of a variety of communication channels, including but not limited to conducting public meetings and soliciting and receiving public comments.
- Communicate and coordinate with, and provide support to, the NOP staff

### **DUTIES OF THE BOARD AND OFFICERS**

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

- (1) IN GENERAL -The Board shall provide recommendations to the Secretary regarding the implementation of this title.
- (2) NATIONAL LIST -The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 2118.
- (3) TECHNICAL ADVISORY PANELS -The Board shall convene technical advisory panels to provide scientific evaluation of the materials considered for inclusion on the National List. Such panels may include experts in agronomy, entomology, health sciences and other

relevant disciplines.

- (4) SPECIAL REVIEW OF BOTANICAL PESTICIDES -The Board shall, prior to the establishment of the National List, review all botanical pesticides used in agricultural production and consider whether any such botanical pesticide should be included in the list of prohibited natural substances.
- (5) PRODUCT RESIDUE TESTING -The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.
- (6) EMERGENCY SPRAY PROGRAMS -The Board shall advise the Secretary concerning rules for exemptions from specific requirements of this title (except the provisions of section 2112) with respect to agricultural products produced on certified organic farms if such farms are subject to a Federal or State emergency pest or disease treatment program.  
*(Additional Duties included in OFPA but not limited to):*  
6518(n) PETITIONS. The Board shall establish procedures under which persons may petition the Board for the purpose of evaluating substances for inclusion on the National List.  
6509(d) (2) STANDARDS. The National Organic Standards Board shall recommend to the Secretary standards in addition to those in paragraph (1) for the care of livestock to ensure that such livestock is organically produced.

To fulfill their responsibilities, Board members agree to adhere to the following Duties as described in this Manual--Duty of Care, Duty of Loyalty, and Duty of Obedience.

### **Duty of Care**

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

- Be reasonably informed - It is the duty of all Board members to seek and study the information needed to make a reasoned decision and/or recommendation on all business brought before the Board. The NOP will provide some of that information, but other information must be developed from independent sources.
- Participate in decisions - Board members are bound by responsibility to be active participants in decision making. Absence from a meeting is no protection from the responsibility for decisions made at the meeting.
- Make decisions with the care of an ordinary prudent person in a similar position - The law requires Board members to exercise the judgment of an ordinary prudent person who may be faced with a similar issue.

### **Duty of Loyalty**

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

- Address conflicts of interest - Board members bring to the NOSB particular areas of expertise based upon their personal and business interests in organic production and

marketing. Because Board members may have interests in conflict with those of the public they must be conscious of the potential for such conflicts and act with candor and care. Board members must abide by the NOSB conflict of interest policy.

- Recognize corporate opportunity - Before a Board member votes upon an issue in which they have a direct financial interest, that Board member must disclose the transaction to the Board in sufficient detail and adequate time to enable the Board to act, or decline to act, in regard to such transaction.

### **Duty of Obedience**

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

- Act within the requirements of the law - Board members must uphold all state and federal statutes, including the Federal Advisory Committee Act (FACA – 5 U.S.C. App. 2 et seq.)
- Adhere to the responsibilities of the Board as defined by the Organic Foods Production Act of 1990
- Adhere to the requirements specified in the NOSB Policy and Procedures Manual

### **Professional and Ethical Standards**

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

- **Professional Conduct**

NOSB members shall:

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

\*Nonpublic information is defined as information that a Board member gains by reason of participation in the NOSB and that he/she knows, or reasonably should be expected to know, has not been made available to the general public. This includes information

that is “routinely exempt from disclosure in 5 U.S.C. 552 (Freedom of Information Act) or otherwise protected from disclosure by statute, Executive Order or regulation; is designated as confidential by the agency or program; or has not actually been disseminated to the general public and is not authorized to be made available to the public upon request.”

- Along with task force members shall keep confidential all information identified by petitioners as confidential business information.
- Speak with one voice to the maximum extent possible. Although there may be disagreements, NOSB members have the responsibility to support the integrity of the process, whether or not they agree with the final outcome. While NOSB members retain the right to express minority opinions, the public airing of dissension could strain interpersonal relationships and create distrust and conflict among NOSB members. Such stresses could undermine the NOSB’s ability to effectively carry out its role as a governmental advisory board
- Represent the segments of the population from which they were selected, while also representing the greater good of the population as a whole

- **Conflict of Interest**

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

*Be it resolved by the National Organic Standards Board:*

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

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

*A "direct financial gain" is defined as monetary consideration, contractual benefit or the expectation of future monetary gain to a Board member, including but not limited to, financial gain from parties who manufacture, distribute or hold exclusive title to a formula*

### **COMPOSITION OF THE BOARD 6518 (b)**

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

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

### **BOARD MEMBER STANDARDS**

- Participate in meetings - Members must make a commitment to attend meetings of the Board.
- Serve on Subcommittees, as assigned - Each member must be willing to serve on Subcommittees as assigned by the Chair, and to participate in the work of those Subcommittees.
- Be informed about Board business - Board members are expected to seek and study the information needed to make reasoned decisions and/or recommendations on all business brought before the Board.
- Fully disclose any conflicts of interest - Members having any commercial or immediate family interests that pose a potential or perceived conflict of interest must disclose that conflict to the Board and abide by any decision of the Board regarding the situation.

### **CONDUCTING BUSINESS**

- Quorum - As specified in OFPA, a majority of the members of the Board shall constitute a quorum for the purpose of conducting business. [§2119(h)] A majority of the members of a Subcommittee, including the Executive Subcommittee, shall constitute a quorum for the purpose of conducting business.
- Decisive votes - As specified in OFPA, two-thirds of the votes cast at a meeting of the Board at which a quorum is present shall be decisive of any motion [§2119(i)]. Following Robert's Rules of Order, all abstentions will be recorded as such and will not be included as

part of the total vote cast. Similarly, all Board members who recuse themselves due to conflicts of interest, or are absent, shall be recorded as such and their votes will not be counted towards the total number of votes cast. Both abstentions and recusals will be considered in order to establish a quorum.

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

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## SECTION III

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

The Designated Federal Officer assigned to the National Organic Standards Board and its Subcommittees, under the Federal Advisory Committee Act (U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10), is the National Organic Program's Advisory Board Specialist (ABS). The position of Advisory Board Specialist (ABS) (formerly the Executive Director) was added in 2005 to facilitate contact between the NOP and the NOSB.

Advisory Board Specialist duties include but are not limited to:

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

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

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

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

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

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

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

## **NOSB OFFICER RESPONSIBILITIES**

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

### **Chair**

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

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

### **Vice Chair**

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

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

### **Secretary**

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

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

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

### **Administrative Team**

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

## **ELECTION OF OFFICERS**

### **A. NOMINATIONS**

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

### **B. VOTING SCHEDULE**

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

### **C. ELIGIBILITY TO VOTE**

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

## **D. COUNTING OF VOTES**

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

## **EXECUTIVE SUBCOMMITTEE**

The Executive Subcommittee of the NOSB shall be comprised of the Chair, Vice Chair, Secretary, and the chairs of each of the standing Subcommittees. The Executive Subcommittee, the DFO/ABS, and the NOP Deputy Administrator, shall meet monthly, as needed, or as called by the Chair, and shall conduct business on behalf of the Board. Only the full Board may take decisive action on guidance and other policy proposals from Subcommittees, including the status of materials proposed for addition or deletion on the National List. The Executive Subcommittee will provide guidance and feedback to the Subcommittees on their proposed work plans.

## **BOARD MEETINGS**

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

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

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

## SECTION IV

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### BOARD SUBCOMMITTEES

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

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

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

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

### STANDING SUBCOMMITTEES

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

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

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

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

**Materials Subcommittee (MS)** The Materials Subcommittee drafts proposals for consideration by the Board to provide guidance, clarification or proposed standards of the National List section of the organic regulations as contained in [7CFR Part 205] and OFPA. The MS works with the NOP and, other NOSB Subcommittees in managing the Materials Review Process, which includes tracking petitions, sufficiency reports, materials scheduled to sunset and the sunset review process. In addition to a Chair appointed by the Board Chair, the MS shall include in its membership a representative from each of the Livestock, Crops, and Handling Subcommittees. Other members may be appointed as needed. The MS occasionally works with other Subcommittees to develop joint proposals where materials are involved.

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

## **SUBCOMMITTEE MEETINGS**

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

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

## **TASK FORCES**

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

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

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

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

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

## AD HOC SUBCOMMITTEES

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

## SECTION V

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### **DUTIES OF SUBCOMMITTEE CHAIRS**

Subcommittee Chair duties:

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

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

### **DUTIES OF SUBCOMMITTEE VICE CHAIRS**

Subcommittee Vice Chair duties:

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

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

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

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

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

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

**After the election of NOSB Officers at the Fall Meeting:**

**Appointment of Subcommittee Chairs**

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

**Appointment of Subcommittee Vice Chairs**

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

**Time Frame for Appointments**

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

**Exchange of Subcommittee Files**

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

**Review of Subcommittee Files**

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

**Mentorship Period**

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

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

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

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

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

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

### **Between Board Appointments and Board Meetings:**

#### Changing Subcommittee Appointments

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

#### Filling a Subcommittee Chair and/or Vice Chair vacancy

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

### **PROCEDURES FOR COMPLETING SUBCOMMITTEE RECOMMENDATIONS**

Developing committee recommendations follows these broad steps:

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

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

### **PROCEDURES FOR COMPLETING SUBCOMMITTEE PROPOSALS AND DISCUSSION DOCUMENTS**

Subcommittee proposal and Discussion document process:

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

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

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

### **Guidelines for Writing Subcommittee Proposals and Discussion Documents**

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

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

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

### **Presenting Subcommittee Proposals and Discussion Documents at NOSB Meetings**

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

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

### **NOSB-NOP COLLABORATION**

The Organic Foods Production Act (6518 (a)) directed the Secretary of Agriculture to establish a National Organic Standards Board to assist in the development of standards for substances

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

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

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

The NOSB is a FACA advisory committee, and as such, must conduct business in the open, under the requirements of P.L. 94-409, also known as "Government in the Sunshine Act" (5 U.S.C.552b).

The USDA cannot delegate its authority as a regulatory body to private citizens, even when those private citizens are appointed by the Secretary to provide advice. However, the NOSB has unique statutory authority related to the recommendation of materials as approved or prohibited substances for inclusion on the National List.

The NOSB cannot direct USDA or bind the Secretary through its actions; for example, it cannot obligate funds, contract, make NOP staffing decisions, or initiate policies of its own accord.

## **WORK PLANS**

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

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

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

E)

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

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

## SECTION VI

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### NOSB PROCEDURES

#### SUBCOMMITTEE WORKPLANS

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

##### Step 1: Identify all issues

The Subcommittee workplan will be based on:

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

Selection criteria for workplan items:

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

##### Step 2: Prioritize the issues

Workplan items should be prioritized according to the following criteria:

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

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

##### Step 3: Set a calendar for completing reviews

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

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

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

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

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## SECTION VII

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### MISCELLANEOUS PROCEDURES

#### Invited Speakers

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

### MISCELLANEOUS PROCEDURES

#### Invited Speakers

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

## Surveys Conducted on Behalf of NOSB Subcommittees

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

## Public Comment at NOSB Meetings:

- All persons wishing to comment at NOSB meetings during public comment periods must, in general, sign-up in advance per the instructions in the Federal Register Notice for the meeting. However, the NOSB will attempt to accommodate all persons requesting public comment time. Persons requesting time after the closing date in the Meeting Notice, or during last minute sign-up at the meeting, will be placed on a waiting list and will be considered at the discretion of the NOP working closely with the NOSB Chair and will depend on availability of time.
- All presenters are encouraged to submit public comment in writing according to the Federal Register Notice. Advance submissions allow NOSB members the opportunity to read comments in advance electronically, and decreases the need for paper copies to be distributed during the meeting.
- Persons will be called upon to speak according to a posted schedule. However speakers should allow for some flexibility. Persons called upon who are absent from the room could potentially miss their opportunity for public comment.
- Time allotment for public comment per person will be four (4) minutes, with the options of reducing to a minimum of three (3) and extending to a maximum of five (5) minutes at the discretion of the NOP working closely with the NOSB Chair in advance of the meeting.
- Persons must give their names and affiliations for the record at the beginning of their public comment.
- Proxy speakers are not permitted.
- Public comment requests may be scheduled according to topic.
- Individuals providing public comment will refrain from any personal attacks and from remarks that otherwise impugn the character of any individual.
- Members of the public are asked to define clearly and succinctly the issues they wish to present before the Board. This will give NOSB members a comprehensible understanding of the speaker's concerns.

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

**Policy for Public Communication between NOSB Meetings.**

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

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

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## SECTION VIII

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### NOSB PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

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

- ecologically, socially, and economically sustainable.
- 1.6 Organic products are defined by specific production and handling standards that are intrinsic to the identification and labeling of such products.
  - 1.7 Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.
  - 1.8 Organic certification is a regulatory system which allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.
  - 1.9 Organic production and handling operations must comply with all applicable local, state, and federal laws and address food safety concerns adequately.
  - 1.10 Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.
  - 1.11 Genetic engineering (recombinant and technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (geo/gmo's) and products produced by or through the use of genetic engineering are prohibited.
  - 1.12 Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

Adopted October 17, 2001

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

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

In order to determine if a substance, its use, and manufacture are compatible with a system of sustainable agriculture and consistent with organic farming and handling, and in consideration of the NOSB Principles of Organic Production and Handling, the following factors are to be considered:

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

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

## **MATERIALS REVIEW PROCESS**

**Evaluation procedures for substances petitioned for addition to, or removal from, the National List.** A petition to change the annotation to a listed material is in effect the addition or removal of one or more materials.

### **Definitions:**

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

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

### **Phase 1: Receipt of petition and examination of petition for completeness and eligibility**

During this phase the NOP will:

- Notify the petitioner via letter and/or email of receipt of the petition
- Determine whether the petition is complete.
- Determine whether the petitioned substance is eligible for petition under the Organic Foods Production Act (OFPA) and its implementing regulations; document this review using the NOP-OFPA checklist.
- Determine whether the petitioned use is approved under the statutory and regulatory authority of the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), or other appropriate federal agency if applicable
- Identify and secure any confidential business information (CBI) designated by the petitioner
- Notify, as applicable, the petitioner via letter and/or email of determination of completeness and eligibility, and acknowledge the designation of certain information as CBI.
- Upon determination by the NOP of completeness and eligibility, the following actions will be taken:
  - Publish the petition on the NOP website
  - Notify the National Organic Standards Board (NOSB) Materials Subcommittee chairperson and the chairperson of the Subcommittee that will review the substance (Crops, Livestock, Handling or other pertinent Subcommittees) that the petition is complete, provide to them the OFPA review and EPA/FDA determination checklist, and request that the Subcommittee review the petition for sufficiency, and submit a request for supplemental or clarifying information.

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

During this phase:

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

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

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

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

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

## **Phase 3: Evaluation by a Third Party Expert**

During this phase the NOP will:

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

During this phase the Third Party Expert will:

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

## **Phase 4: Sufficiency Determination**

During this phase the NOP will:

- Submit a copy of the draft TR for review to the NOSB Materials Subcommittee and the pertinent Subcommittee that will conduct the review (Crops, Livestock or Handling);
- Review the draft TR using the following performance criteria. The

report will be acceptable when it:

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

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

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

#### **Phase 5: Action by the Subcommittee conducting the review (Crops, Livestock or Handling)**

During this phase the Subcommittee conducting the review will:

- Discuss and recommend an action on the petitioned substance. The Subcommittee may convene as the TAP by email or conference call to provide complete evaluation of the petitioned substance, as provided by OFPA 6518(k)(3). The Subcommittee must convene and recommend an action on the petitioned substance no later than 60 days before a scheduled meeting of the full NOSB.

#### **Phase 6: Action by Full NOSB**

During this phase the NOP will:

- Publish the proposal on the NOP website and request a minimum of 30 days of written public comment on the proposal prior to the public NOSB business meeting.
- Include sufficient time on the agenda at the NOSB meeting for the Board to discuss the proposal and make a recommendation.

## TECHNICAL REVIEWS

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

Third party experts can consist of the following:

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

Steps to determine the need for a third party expert:

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

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

- A Subcommittee cannot proceed with a recommendation on a material if it is determined that there is insufficient valid scientific information on that material's impact on the environment, human health and its compatibility with organic principles.
- The decision to request a third party expert needs to be made independent of the availability of funds. If there is a lack of funding to secure third party expert advice, the review of the material should be placed on hold.
- Although the Board has the final word on the approval or rejection of a petition, the decision to request a third party expert is the responsibility of the Subcommittee reviewing the material. In some cases the Materials Subcommittee can take the initiative to request a third party expert.
- Defining the required expertise is the responsibility of the Subcommittee reviewing the material or issue.
- To incorporate a diversity of opinions and to minimize the risk of bias, a Subcommittee should strive to work with a range of technical experts (individuals, or institutions).

#### **WITHDRAWAL OF A PETITION BY THE PETITIONER**

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

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

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

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

#### **TECHNICAL ADVISORY PANEL (TAP) CONTRACT PROCEDURES**

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

## PRIORITY OF PETITIONS GUIDELINE

### Prioritization

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

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

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

#### 2. Priority 3: Petitions to add a material to the National List:

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

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

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

This prioritization guideline is only that, a guideline. When situations occur beyond the control of the reviewing Subcommittee, such as, but not limited to, Technical Report budgetary constraints, or a delay in the delivery of a Technical Review for a petitioned substance, the workplan may require adjustment by the NOSB and NOP.

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

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

### **BOARD PROCEDURES FOR THE MATERIALS' REVIEW PROCESS - Sunset**

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

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

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

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

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

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

### **Sunset Process (See Charts 1- 4 below)**

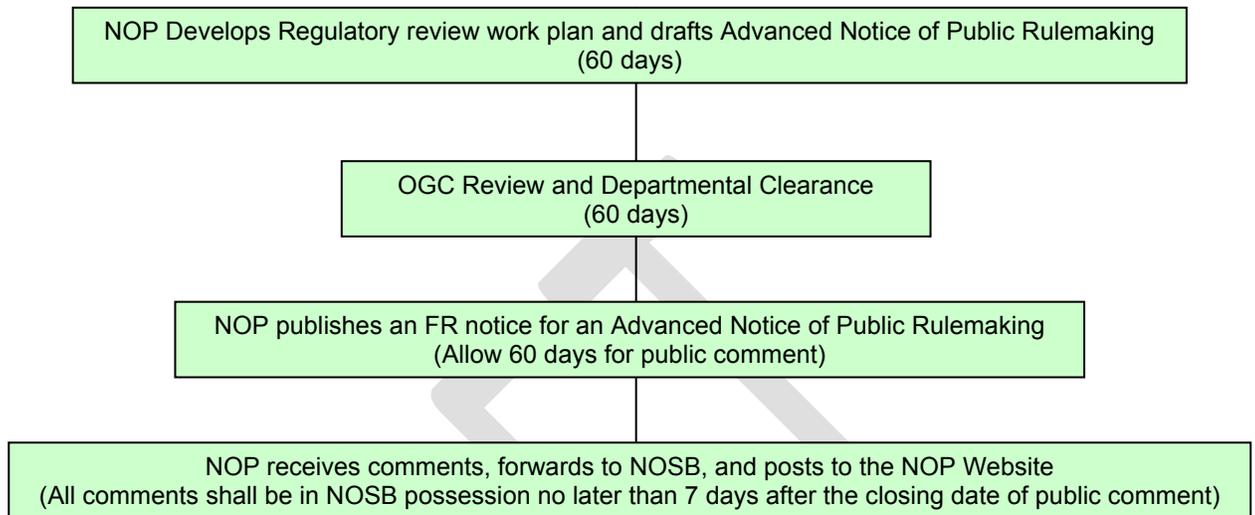
Although not all listed materials reach sunset status at the same time, the review process remains the same:

1. An Advance Notice of Proposed Rule Making (ANPR) is placed in the Federal Register (listing the pending sunset materials. The public has 60 days from the publication date to provide written comment. A Subcommittee may request a third party technical review in anticipation of any public comments or questions.
2. Public comments are collected and forwarded to the NOSB.
3. The appropriate NOSB Subcommittee begins review of the material with the intent of providing a proposal to the entire Board for the material's removal, renewal, *or renewal with the addition of an annotation*. The review is conducted based on “Force of Evidence” as presented by Board members, public comments, and scientific data from other sources This includes the original recommendation from the Board. The Subcommittee may request a third party technical review, if needed, to verify scientific evidence and claims made during public comment to the ANPR.
4. The reviewing NOSB Subcommittee provides its proposal to the full Board and the public no less than 60 days prior to the Board Meeting which would include the following:
  - A simple motion to remove, add or amend an annotation, resulting in the restriction or clarification of the use of a material (if applicable).
  - A simple motion to renew the existing listing.
5. At the public NOSB business meeting, the NOSB hears additional public comment, discusses the force of evidence, and votes on the Subcommittee's proposal.
6. The NOP reviews the NOSB recommendation and accompanying documentation and publishes a proposed rule to review the National List. The public has 90 days after the publication date to comment. All comments are made available on the NOP website.

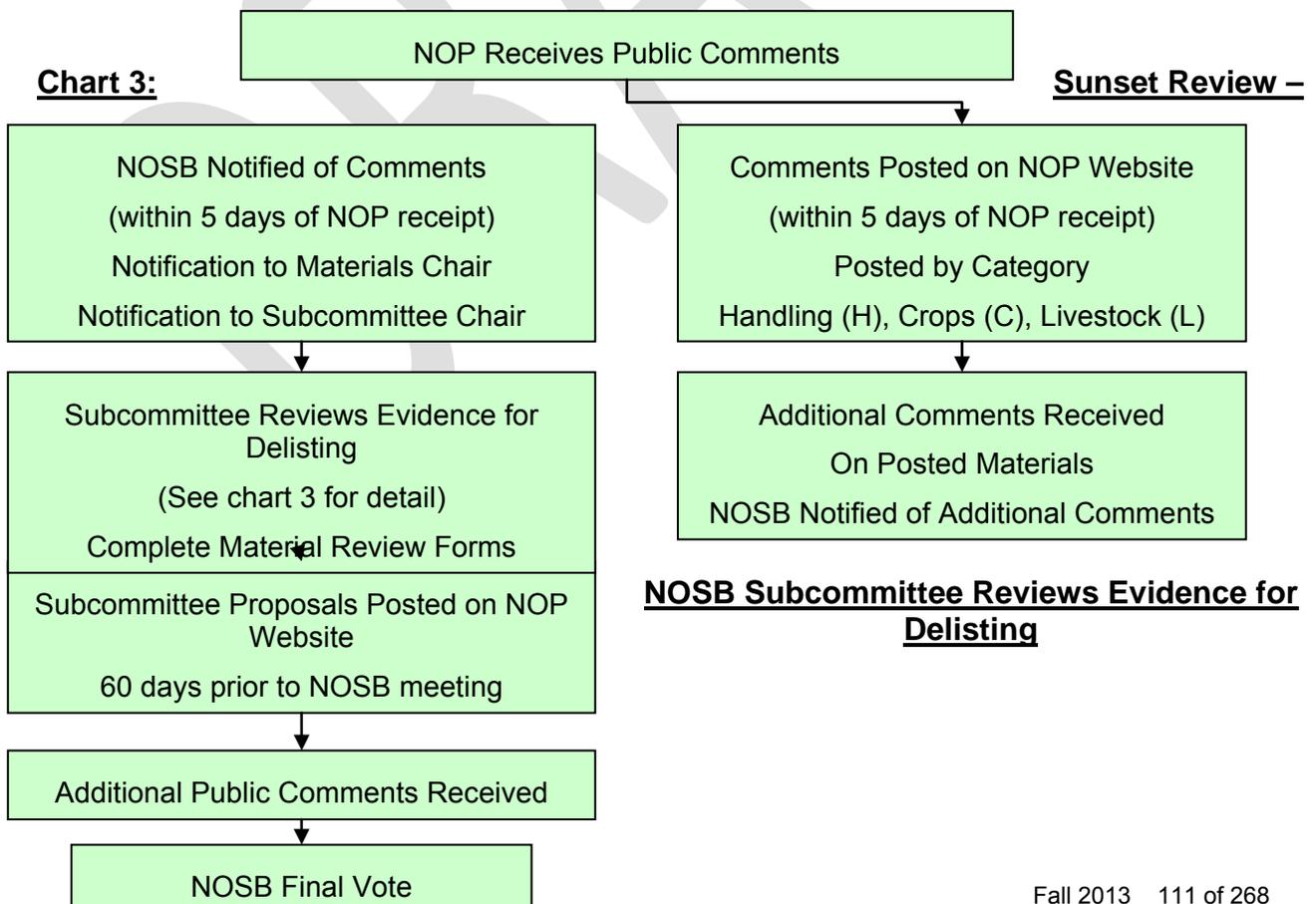
*The NOP will review public comment and draft the final rule. The final rule will proceed*

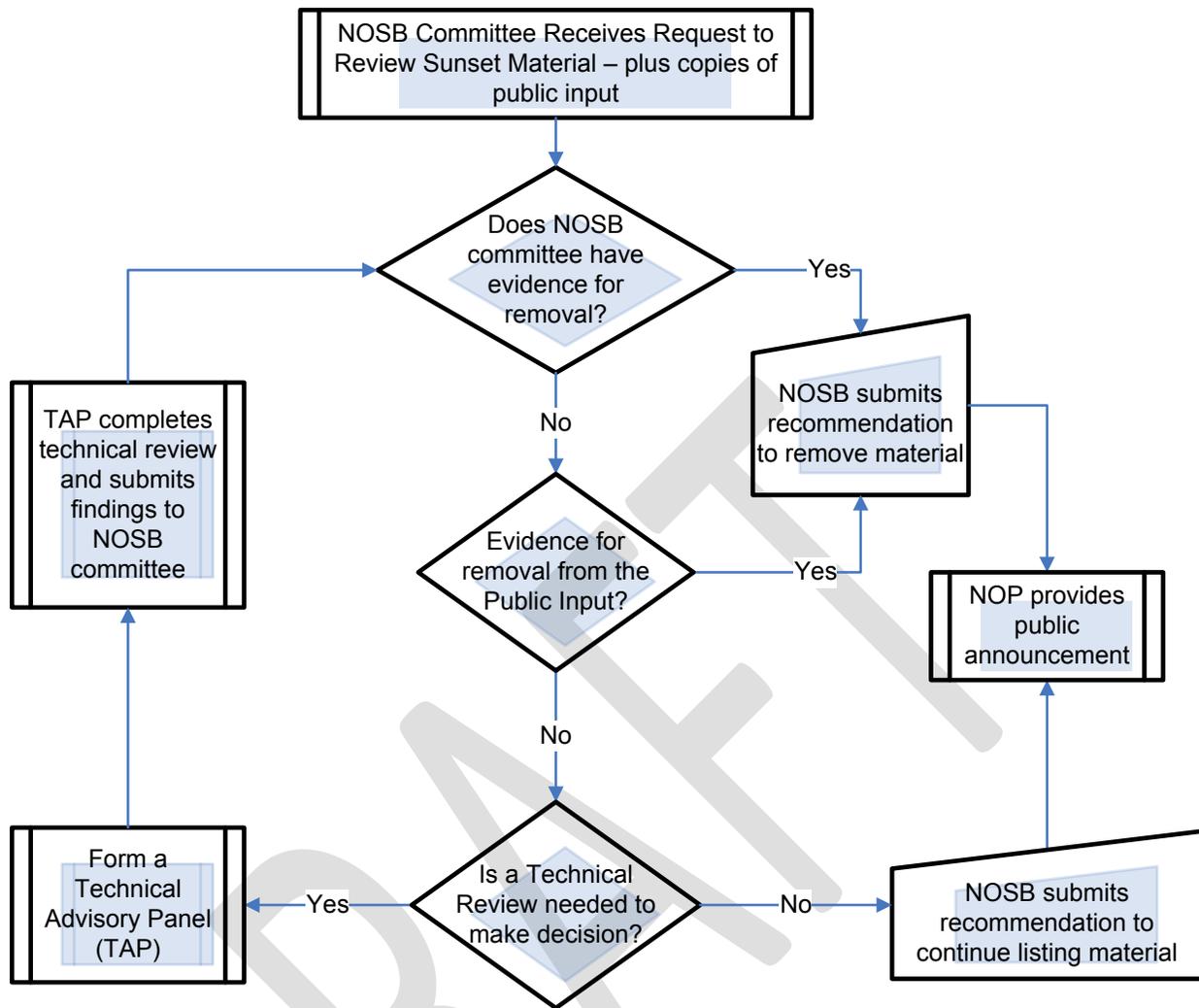
through interagency (i.e. OGC, OMB, and department) and congressional review, and upon clearance from the appropriate parties, the NOP will publish the final rule in the Federal Register. The final rule process is illustrated in Chart 4.

**Chart 1: Sunset Review – NOP Posts an ANPR**

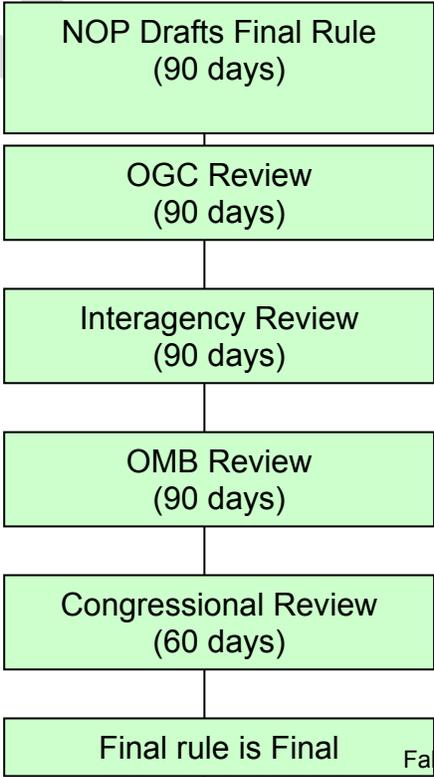


**Chart 2: Sunset Review – NOP Collects and Forwards Public Comment to the NOSB**





**Chart 4:**  
**Sunset Review**  
**Final Rule Process**



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

In order to minimize confusion in the organic community, the Board needs to monitor and correct any discrepancies that may occur between the time an item is voted on and subsequently published in the Federal Register. Examples include:

- Annotations that differ from the original NOSB recommendation. Annotations may be changed by the Program to accommodate the requirements of other federal regulatory bodies (ex: livestock medications withholding times).
- Annotations added to address any unforeseen consequences of an NOSB recommendation, to accommodate the requirements of the organic industry. For example, the absence of an explicit description of what methods of extraction are allowed for specific materials could result in the unwanted use of materials extracted using prohibited extraction processes.

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

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

## APPENDICES AND RESOURCES

### Appendix A - DECISION MAKING GUIDELINES FOR THE NOSB

- **Define the Problem**
  - What is the problem?
  - Identify where we are now.
    - State the present condition in no more than two sentences.
  - Identify where we want to be.
    - State the future objective in no more than two sentences.
  
- **Analyze the Problem**
  - Why is there a problem?
  - Is the evidence of the problem supported by credible and compelling facts or data?
    - What are the facts or data used to draw an affirmative conclusion?
  - Who does this problem affect?
  - What is the problem's effect?
  - In what time frame must the problem be resolved?
  - If the problem deserves immediate attention, what other priorities must be adjusted to accommodate this problem?
  - If the problem deserves immediate attention, what are the consequences of a delay?
  
- **Develop Possible Solutions**
  - Propose ideas for possible solutions
  - Evaluate ideas for possible solutions
    - List pros for each possible solution
    - List cons for each possible solution
  - Select a Solution
    - Is the recommended solution legal?
    - Is the recommended solution practical?
    - Is the recommended solution supported by credible and compelling facts or data?
      - What are the facts or data used to draw an affirmative conclusion?
    - How does the recommended solution solve the problem?
    - How does the recommended solution meet the time frame identified in 2(b)?
  - Review recommended solution for unintended consequences.
  
- **Develop Action Plan**
  - Develop Action Steps
    - Identify action steps to bridge the gap between present condition and future objective using the recommended solution.
  - Approve Action Plan
  - Implement Action Plan

## Appendix B - FACA FACTS

- The Federal Advisory Committee Act (FACA) (5 U.S.C. App.2) and its implementing regulations (41 CFR Part 101-6.10) govern the creation, operation, and termination of advisory committees in the Executive Branch of the Federal Government. The National Organic Standards Board (NOSB) is a Department of Agriculture (USDA) non-discretionary advisory committee required by the Organic Foods Production Act of 1990, as amended.
- Advisory committees must be chartered before they can meet or conduct any business. Charters must be renewed every two years or they will be terminated under the sunset provisions of Section 14 of the FACA, unless otherwise provided by law.
- Advisory committee meetings are required to be open to the public, with limited exceptions as provided for in Section 552b of title 5, United States Code. Meetings not subject to FACA include NOSB briefing meetings initiated by the USDA to exchange facts and information, member orientation and training, and NOSB Subcommittee meetings. Such meetings are not subject to FACA because they are not conducted for the purpose of providing the USDA with NOSB advice or recommendations.
- Designated Federal Officers must approve all meetings and agendas, and attend meetings. The Advisory Board Specialist is the NOSB's Designated Federal Officer.
- Meeting notices and agendas must be published in the Federal Register to accommodate public participation. Although not required by FACA, the NOP strives to:
  - Post a provisional agenda on its web site no later than 90 days before the meeting is scheduled to begin
  - Post a final agenda, on its web site, no later than 45 days before the meeting is scheduled to begin
  - Publish notice of the meeting in the Federal Register no later than 45 days before the meeting is scheduled to begin
- While meeting transcripts are not required under FACA, the NOP invests in transcripts to support the transparency of Board meetings and to support subsequent rulemaking activities. The NOP also issues a short meeting summary, which is required by FACA, after each biannual meeting that summarizes the key issues discussed, and the outcome of voting.
- Advisory committee documents must be available for public inspection and copying until the committee ceases to exist
- Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to reasonable rules or regulations.
- Additional information may be found at the FACA homepage:  
<http://www.gsa.gov/Portal/gsa/ep/channelView.do?pageTypeld=8203&channelPage=/ep/channel/gsaOverview.jsp&channelId=-13170>

## Appendix C - PARLIAMENTARY PROCEDURE AT A GLANCE

TO DO THIS	YOU SAY THIS	May you interrupt speaker?	Must you be seconded ?	Is the motion debatable?	Vote required
Adjourn the meeting	I move that we adjourn	no	yes	no	majority
Recess the meeting	I move that we recess until...	no	yes	no	majority
Complain about noise, room temperature, etc.	Question of privilege	yes	no	no	no vote
Suspend further consideration of something	I move that the motion be laid on the table	no	yes	no	majority
End debate	I move the previous question	no	yes	no	2/3 vote
Postpone consideration of something	I move we postpone this matter until...	no	yes	yes	majority
Have something studied further	I move to refer the motion to the Subcommittee	no	yes	yes	majority
Amend a motion	I move to amend...	no	yes	yes	majority
Introduce business (a primary motion)	I move that...	no	yes	yes	majority
Object to procedure or to a personal affront	Point of order	yes	no	no	chair decides
Request information	Point of information	yes	no	no	no vote
Ask for a vote by actual count to verify a voice vote	I call for a division	no	no	no	no vote
Object to the consideration of some undiplomatic matter	I object to the consideration of the question	yes	no	no	2/3 vote
Take up a matter previously tabled	I move to take from the table	no	yes	no	majority
Reconsider something already disposed of	I move to reconsider...	yes	yes	yes	majority
Consider something vote out of its scheduled order	I move we suspend the rules and consider...	no	yes	no	2/3 vote
Vote on a ruling by the chair	I appeal the decision of the chair	yes	yes	yes	majority
Table a motion - take matter from table	I move to take from the table	No	Yes	No	majority
Rescind motions – Cancel previous action	I move to rescind	No	Yes	Yes	2/3 vote

Source: Robert's Rules of Order

## Appendix D - BASIC CHEMISTRY

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

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

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

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

## What is a substance?

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

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

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

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

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

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

**Salts:** a compound of a metal and nonmetal, or of a metal with a negative polyatomic group. Compounds that have an ammonium group ( $\text{NH}_4^+$ ) instead of a metal are also classified as salts. Some salts are  $\text{NaCl}$ ,  $\text{KCl}$ ,  $\text{KMnO}_4$  and  $\text{NH}_4\text{Cl}$ . A salt is an ionic solid at room temperature. Most have two ionic components (a) a cation, which can be a polyatomic group such as ammonium or a monoatomic metal such as  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Ca}^{2+}$  or  $\text{Mn}^{3+}$  and (b) an anion, which can be a negative polyatomic group or a monoatomic ion such as  $\text{Cl}^-$  or  $\text{NH}_3^-$ . A solid salt consists of ions in close association. When the salt dissolves in water, the ions are separated. Substances that exist as ions in solution are called electrolytes. When  $\text{NaCl}$  dissolves in water, the correct formula is  $\text{Na}^+ + \text{Cl}^-$ . This formula treats the component ions of the salts as independent entities, which is approximately how they behave in water solution. Salts are called strong electrolytes because they usually separate completely into ions in water. (Boyd text)

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

**Bases:** a compound that is a source of  $\text{OH}^-$  ions in water solution. A compound of a cation and the  $\text{OH}^-$  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  $\text{OH}^-$  are generally dissociate completely in water and are classified as strong bases. Some strong bases are  $\text{NaOH}$  (sodium hydroxide) and  $\text{KOH}$  (potassium hydroxide). Compounds that do not contain hydroxide ions are defined as bases if they produce  $\text{OH}^-$  ions by reaction with water. An example is ammonia ( $\text{NH}_3$ ) which reacts with water to produce hydroxide ions.

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

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

### What constitutes a chemical change?

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

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

- Addition or combination reaction: Two substances combine to form one:
  - $2\text{Na} + \text{Cl}_2 \rightarrow 2\text{NaCl}$
- Decomposition reactions: One compound breaks into two or more compounds or elements.
  - $\text{CaCO}_3 \rightarrow \text{CaO} + \text{CO}_2$
- Displacement reactions: Substances exchange parts. There are many types of these reactions but one of the most important is called metathesis which is the exchange of ions by two ionic compounds, with the anion of one compound joining the cation of the other compound and vice versa.  $\text{AB} + \text{CD} \rightarrow \text{AD} + \text{CB}$ 
  - 1. Hydrolysis is a displacement reaction of a substance or ion with water. Water is a source of both  $\text{H}^+$  and  $\text{OH}^-$  ions. The  $\text{OH}^-$  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  $\text{H}^+$  cation combines with the negative portion of the compound, which may be an anion or an atom with a negative oxidation number.
  - Acid-base reaction: an acid is a substance that can donate a proton, and a base is a substance that can accept a proton.

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

Proteins are substances extracted from living organisms that maybe utilized in materials that are petitioned for use in organic production. Proteins are sensitive to relatively small changes in pH, temperature, or solvent composition may cause them to denature. Denaturation causes physical change, the most observable result is loss of biological activity. Except for cleavage of disulfide bonds, denaturation stems from changes in secondary, tertiary, or quaternary structures through disruption of noncovalent interactions, such as hydrogen bonds, salt linkages and hydrophobic reactions. Common denaturing agents include the following:

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

hydrogen bonding and hydrophobic interactions.

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

**References:**

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

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

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

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## Appendix E - FORMS

### NOSB Subcommittee proposal checklists (Handling, Crops/Livestock)

#### Template for Subcommittee Proposal Narrative

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

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

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

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

**Subcommittee Vote:**

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

**Back-up motion:**

**Material Evaluation Checklist: (See appendix E)**

#### Proposals for policy or procedure changes should include the following:

**Introduction:**

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

**Background:**

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

## **Relevant areas in the (Regulation):**

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

## **Discussion:**

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

## **Proposal:**

The core idea of the proposal should be stated clearly.

## **Subcommittee Vote:**

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

## **Back-up motion:**

## **Minority opinion:**

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

## **Template for Subcommittee Discussion Document**

### **Cover sheet for Final NOSB recommendations**

## **Appendix F - INFORMATION TO BE INCLUDED IN A PETITION**

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

### **ITEM A**

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

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

### **ITEM B**

The petitioner must submit the following information:

- The substance's common name.
- The manufacturer's name, address, and telephone number.
- The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer, or disinfectant.
- A list of the crop, livestock, or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.
- The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.
- A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.
- Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.
- The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance.
- The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.
- Safety information about the substance including a Material Safety Data Sheet (MSDS)

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

- Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.
- A "Petition Justification Statement" which provides justification for one of the following actions requested in the petition:
  - *Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)*
    - Explain why the synthetic substance is necessary for the production or handling of an organic product.
    - Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural
  - methods that could be used in place of the petitioned synthetic substance.
    - Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (1) Region of production, including factors such as climate and number of regions;
  - (2) Number of suppliers and amount produced;
  - (3) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies;
  - (4) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies and;
  - (5) Any other issues which may present a challenge to a consistent supply.
- A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:
  - Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim.
  - "Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be
    - commercially valuable,
    - used in the applicant's business, and
    - maintained in secrecy.
  - Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."
  - The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy. (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy.
  - Each page with CBI-deletions should be marked "CBI-deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI- deleted."
  - If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBI-deleted.")
  - All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information usually cannot be claimed as confidential.

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

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

## **Appendix G - TECHNICAL ADVISORY PANEL (TAP) CONTRACT PROCEDURES**

### **Statement of Work**

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

### **Agency Need**

See Statement of Work, 1.0 Background.

- **Background**

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

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

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

- **Mission of USDA/AMS/NOP**

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

The NOSB reviews information from various sources in evaluating substances for inclusion on or removal from the National List. Sources include TAP evaluations, the Environmental Protection Agency, the Food and Drug Administration, the National Institute of Environmental Health Studies, and public comment. The NOSB submits its

recommendations, along with the results of the required evaluation and technical advisory panel evaluation for each substance, to the Secretary for consideration in accordance with the requirements of section 2118(d) of the OFPA (7 U.S.C. 6517(d)).

- **Specific Task**

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

For crop and livestock production substances, the contractor(s) shall use the criteria in Section 2119 of the OFPA (7 U.S.C. 6518 (m)(1-7)). The criteria are:

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

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

- Processing aid or adjuvant cannot be produced from a natural source and has no organic ingredients as substitutes;
- Manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA;
- The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations;
- The primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing, except in the latter case as required by law;
- It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances;
- Its use is compatible with the principles of organic handling; and,

- There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

### **Minimum Skills and Experience Requirements**

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

### **Place of Performance**

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

### **Government Furnished Equipment and Facility**

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

### **Compensation**

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

### **Period of Performance**

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

### **Scope of Performance**

#### **Phase 1: Data Gathering and Compilation (120 days)**

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

- Characterize [the] substance(s) and identify uses and applications;
- Determine whether [the] substance(s) are synthetic or non-synthetic (See 7.S.C. 6502 (21) for definition of synthetic);
- Determine [the] substance(s) chemical or biological composition and possible impact on human/animal health and the environment;
- Identify [the] substance(s) relevant toxicological studies, including ensuring substance does not contain residues of heavy metals or other environmental contaminants in

excess of Food and Drug Administration Action Level or Environmental Protection Agency tolerances;

- Determine [the] substance(s) persistence in the environment;
- Determine [the] substance(s) effect on soil structure and ecology;
- Identify alternatives to the use of the substance(s);
- Determine [the] substance(s) historical use in organic production, processing and handling; and
- Determine [the] substance(s) status under OFPA and with other government agencies.

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

### **Phase 2: Evaluation against Criteria (100 days)**

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

### **Phase 3: Recommendation (42 days)**

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

### **Evaluation Factors for Award**

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

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

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

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

### **Other Evaluation Factors**

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

Technical Factors:

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

Factor 2 Previous Demonstrated Experience and Past Performance

Factor 3 Quality Control

Factor 4 Capability and Experience of Key Personnel

Factor 5 Project Management and Support Capability

Factor 6 Reasonableness of Cost

### **Reporting Requirements**

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

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

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

Any deliverables required under the contract should be submitted upon completion and

addressed to: NOP Program Director, National Organic Program, USDA-AMS-TM-NOP, 1400 Independence Avenue, S.W., Room 4004-So., Ag Stop 0268, Washington, D.C. 20250-0268, Attention: Substance Evaluations.

## **Appendix H - Research Priorities Framework**

March 27, 2012

### **Introduction**

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

### **Background**

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

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

### **Relevant areas in the Rule**

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

"§ 205.2 Terms defined.

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

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

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

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

....."

### **Discussion**

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

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

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

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

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

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

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

### **Recommendation**

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

### **Criteria**

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

Criteria for research topics are:

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

### **Process Framework**

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

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



**National Organic Standards Board  
Policy Development Subcommittee  
Disclosure of Interest (DOI) for a Determination of a Conflict of Interest (COI)**

**August 29, 2013**

**I. Introduction**

The current policy and practice in force for the disclosure of an interest (DOI) for a determination of a conflict of interest (COI) for the National Organic Standards Board (NOSB) are contained in a National Organic Program (NOP) memo entitled “Conflict of Interest Guidelines” dated March 29, 2013. The NOP issued these guidelines as NOSB policy based on its authority under section FACA §102-3.105. The NOP memo gives this reason for issuing its guidelines:

The NOSB’s Policy and Procedures Manual includes language about conflicts of interest. In the past year, however, the Board has worked on alternative language to further define conflict of interest and to outline procedures for managing conflicts as they are identified. The Board has not been successful in passing new language. As such, the National Organic Program (NOP) is issuing this memorandum to describe how the USDA views conflict of interest and appearance concerns, and to present the NOP’s expectations for how you are to evaluate and report these conflicts in the future.

The NOSB over the years has passed policy on COI, which is contained in the Policy and Procedures Manual (PPM). Nevertheless, this DOI proposal recommendation by the NOSB’s Policy Development Sub-Committee (PDS) is intended to correct the deficiencies mentioned above and align the NOSB’s PPM with NOP guidelines on COI.

**II. Background**

The NOSB recognizes that members have been specifically appointed to the NOSB to provide advice and counsel to the Secretary of Agriculture concerning policies related to the development of organic standards and the creation of amendments to the NOP’s National List. NOSB members have been appointed because they represent various interests involved in the organic community, enabling them to advise the Secretary of Agriculture on the implementation of the Organic Foods Production Act (OFPA).

NOP document entitled, “Conflict of Interest Guidelines,” dated March 29, 2013, states “Representatives are appointed to speak in “we” terms, serving as the voice of the group she/he represent (e.g., “we farmers/growers believe.....”). As such, each NOSB members are not expected to provide independent expert advice, BUT rather advice based on the interests of the group served. Therefore, the farmers/growers representatives must articulate the viewpoints and interests farmers/growers; the handlers representatives must articulate the viewpoints and interests of handlers; the certifier representative must articulate the viewpoints and interest of certifiers; the scientist representative must articulate the viewpoints and interests of scientists; the environmentalists/conservationists must articulate the viewpoints and interests of environmentalists/conservationists; the scientist representative must articulate the viewpoints and interest of scientists; the consumers/public interest representatives must articulate the viewpoints and interest of consumers/public stakeholders; and the retailer must articulate the viewpoints and interest of retailers.” The statutory composition of NOSB is composed of 15 members. OFPA describes the composition of the NOSB as follows:

- four (4) members who own or operate an organic farming operation;
- three (3) members with expertise in areas of environmental protection and resource conservation;

- three (3) members who represent the public interest or consumer interest groups;
- two (2) members who own or operate an organic handling operation;
- one (1) member who owns or operates a retail establishment with significant trade in organic products;
- one (1) member with expertise in the fields of toxicology, ecology, or biochemistry; and
- one (1) member who is a certifying agent.

NOSB members – like most federal advisory board members - are chosen specifically because of their professional expertise within a given area. Especially since NOSB members represent sectors of the industry directly impacted by the board’s decisions, it is necessary to maintain a clear and detailed NOSB COI policy. To prevent overt advocacy for direct financial gain and the appearance of self-interest or the appearance of wrongful activity, the NOSB has adopted a COI policy (NOSB, Policy & Procedures Manual 2011, pgs. 6-9). At this time, the PDS of the NOSB seeks to update the Board’s policy and procedures on COI to align with NOP’s policy and practice guidelines for dealing with a DOI and COI by NOSB.

The PDS considered three primary options in developing this proposal. The first option, called Option A, had a number of recommendations, including referencing the NOP Conflict of Interest Guidelines and placing it in the PPM as an appendix; inserting definitions and updating within the PPM; adding language related to Technical Report authorship disclosures; and outlining procedures for COI management that included the NOSB (in addition to the NOP) having a role in deciding whether another Board member’s interest warrants recusal.

Option A included many of the same recommendations as in the proposal voted on called Option B; the critical difference related to the procedure. Option A gave decision authority to the NOSB, whereas the voted-upon Option B acknowledges NOP as the sole decision-maker. Those who supported Option A felt that it provided clearer guidance to the COI process and left determinations less to the discretion of the NOP. They also supported a procedure that required disclosure of interests to the full board and the public, rather than only the NOP, in the belief that decision making of a board of representatives requires input from all perspectives, but also the recognition by other Board members of the perspectives from which differing opinions come. Option C had only one recommendation, which included a reference to the NOP Guidelines and a definition of conflict of interest.

Vetting of the options (A, B & C) resulted in the conclusion that the majority of PDS members preferred Option A, in complete form. One member felt that a subsection of Option A would suffice. Nonetheless, it was determined that since the NOP noted that the PDS would be precluded from putting forth option A for public consideration and NOSB determination (because of its conflict with the NOP memo) and since Option C was seen as much too simplistic for the PPM context, that Option B would be the considered option for moving ahead.

### **III. Relevant Areas of the Rule**

The OFPA establishes the NOSB at §2119 (7 U.S.C. 6518) (a). It reads, “The Secretary shall establish a NOSB (in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2 et seq.) 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.” The 2012 NOSB Revised Policy and Procedures Manual (PPM) dated April 11, 2012 on page 9 sets forth the current NOSB’s COI policy uses the terms potential or perceived COI without a clear definition. On page 7 of the PPM, the ability for NOSB to hear and make a determination on various types of COI is recognized beyond a direct financial gain. On page 11 of the PPM,

perceived COI is included in the concern. The wording “immediate family interests” is included on page 11 of the PPM.

The relevant statute is FACA § 102–3.105 “What are the responsibilities of an agency head? (h) Assure that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes, regulations issued by the U.S. Office of Government Ethics (OGE) including any supplemental agency requirements....” The NOP memo on COI, dated March 29, 2013 is guided by the USDA Office of Ethics ruling that fits within the “supplemental agency requirements” clause.

#### **IV. Discussion**

The benefits of the proposed recommendations include providing definition of COI and providing procedural steps for a DOI for a determination of a COI in the course of the NOSB’s business that align with NOP guidelines on COI policy and procedures for NOSB. The updated COI policy upon a DOI should provide greater transparency and confidence in Board decisions by the organic community.

The salient fact is that NOP guidelines are the current approach being used. As NOSB seeks to revise the PPM, the COI language needs to be updated to address current NOP policy and approach for managing a DOI for a determination of a COI. Presently, the PPM has at least eight (8) instances in three (3) sections that reference COI matters. Therefore, the alignment of the PPM with the current policy of the NOP and NOSB is vital and necessary. Despite current Board member concerns that may linger on whether NOSB or NOP should be the arbiter of DOI for a determination of a COI and the extent to which a DOI will be public, the fact remains that NOP guidelines on COI are presently and actively in force.

#### **V. Recommendation**

The Board references the NOP memo (Conflict of Interest Guidelines, Miles McEvoy, March 29, 2013) on conflict of interest (see appendix X) based on NOP’s position, citing NOP discretionary policy under the Federal Advisory Committee Act (FACA), that it is has the sole authority to define and manage the COI process.

NOP notes that previous public comments to the NOSB urged members to fully disclose the nature of their conflicts of interest to other NOSB members and the public. While NOSB members may share whatever information they wish with other Board members and the public, this level of disclosure is voluntary. For both legal and ethical reasons, the NOP respects the privacy of its volunteers, and does not require full disclosure of the nature of conflicts of interest to parties outside the NOP. Therefore, in an attempt to align NOSB’s COI policy and practices with the NOP guidelines on COI, the following recommendations are shown below.

##### **Recommendation #1**

If an NOSB member fails to disclose having a COI and votes on the item where a conflict exists, and COI is later revealed, it may lead to a reconsideration of the vote by the NOP. It could lead to a revote on said matter, if deemed so by NOP, at some point in the future.

##### **Recommendation #2**

Use COI as a general term rather than defining the terms of (1) perceived COI and (2) potential COI.

The term “conflict of interest” is defined as a situation in which there is an actual or potential COI of a Board member, which could impair the individual's objectivity or which has the potential to create an unfair competitive advantage. The following persons or entities specifically affected

are, (1) a member of your household, (2) a former employer or a prospective employer, (3) a client of yours or your spouse or partner, (4) a person or organization with which you have some kind of business or contract relationship, (5) your spouse or partner, or (6) a close family member.

### **Recommendation #3**

#### **Existing PPM Language**

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.

#### **Proposed Language Change**

The Duty of Loyalty requires Board members to exercise their power in the interest of the group she/he represents (e.g., "we farmers/growers believe.....") As such, each NOSB members are not expected to provide independent expert advice, BUT rather advice based on the interests of the group serves.

### **Recommendation #4**

#### **Sub-Committee Level**

As soon as a Board member discloses that she/he may have a COI with respect to a topic being worked on, she/he should inform the NOP. Said Board member may voluntarily share with or answer question(s) about the nature of the conflict from other subcommittee members. The NOP, working with the USDA Office of Ethics as needed, will validate whether a said disclosure is a COI and determine the level of said Board member participation (discussion and/or vote) on said matter wherein the disclosure is noted.

### **Recommendation #5**

#### **Full Board Meetings**

Approximately 2-4 weeks before the meeting, the NOP's DFO will provide a matrix of all NOSB members in advance of the meeting that lists the documents being voted on at the meeting. If a Board member identifies that a COI exists on any item(s) on the matrix, she/he must use the columns on the matrix to disclose having the COI and declare a recusal from voting on the item(s).

If a Board member is not sure whether a DOI interest is acceptable or poses problem, or is uncertain whether recusal is needed, then she/he must contact the NOP Associate Deputy Administrator to fully disclose the possible problem; the NOP will provide feedback verbally and via email to the member. The NOP determination is final. See NOP memo entitled, "Conflict of Interest Guidelines" dated March 29, 2013 for greater details. All DOI and COI must be recorded in the meeting minutes.

### **Recommendation #6**

#### **Technical Reviewers**

All technical reviews should disclose the names and address of all authors on the first page of the TR below the TR title.

### **Recommendation #7**

#### **Existing PPM Language, pg. 7**

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.

#### Suggested Language Change

Address conflicts of interest — Board members are expected to disclose interests that do not raise the level of being in conflict for the purpose of full disclosure for the public.

#### **Recommendation #8**

##### Existing PPM Language, pg. 8

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.

#### Suggested Language Change

Mandatory and Voluntary Disclosure of COI - A Board member must disclose any COI according to NOP guidelines and procedures. Failure to do so could result in a revote on a matter, shortly or long after the initial vote was taken. A Board member must mandatorily disclose her/his DOI to NOP in sufficient detail in writing and allow adequate time to enable the NOP to act — or decline to act — in regard to such matter. Said Board member may voluntarily share her/his DOI with NOSB.

#### **Recommendation #9**

##### Existing PPM Language, pg. 9

#### **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 perceived conflict of interest. To prevent overt advocacy for direct financial gain and the appearance of self-interest or the appearance of wrongful activity, the NOSB has adopted the following conflict of interest policy.

*Be it resolved by the National Organic Standards Board:*

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

*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*

Suggested Language Change

Delete this language since the NOP's March 29, 2013 COI guidelines broaden COI beyond a direct financial gain.

**Recommendation #10**

Existing PPM Language, pg. 11

Fully disclose any conflict of interest positions — Members having any commercial or immediate family interest that poses a potential or perceived conflict of interest must disclose that conflict to the Board and abide by any decision of the Board in dealing with the situation.

Suggested Language Change

Disclosure of and Interest — Members that provide a DOI may voluntarily disclose to NOSB and mandatorily disclose to NOP and abide by the final decision of NOP in said matter.

**Recommendation #11**

Existing PPM Language, pg. 38

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.

Suggested Language Change

None

**VI. Summary**

NOSB members with diverse backgrounds are recruited to provide balance to the NOSB. The recommendations put forth in this document are responsive to a number of requests by stakeholders and the NOP recent guidelines framework. The proposed recommendations help provide the essence of providing greater transparency of and expectations around NOSB members' work and technical reviewers on behalf of the organic community and the general public.

The current policy and practices in force for a DOI for a determination of a COI for the NOSB are entitled "Conflict of Interest Guidelines" dated March 29, 2013. The guidelines centers on recognizing and reporting COI and appearance concerns. The DOI proposal herein by the NOSB's PDS is intended to align with NOP guidelines on COI.

**VII. Committee Vote:**

Motion to accept the language as presented in Option A above.

Moved: C. Reuben Walker

Second: Jay Feldman

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

**Approved by Colehour Bondera, Subcommittee Chair, to transmit to NOSB August 29, 2013**

**National Organic Standards Board  
Materials Subcommittee  
Update of the Petition and Technical Review Process  
August 27, 2013**

## **Introduction**

The National Organic Program (NOP) has asked the NOSB for input on revising the procedures for petitions and technical review. These procedures are encompassed by a 2007 Federal Register notice, 72 FR 2167, and sections of the NOSB Policy and Procedures Manual (PPM) appearing on pages 34, 35, 37 and 38 of the current version.

This effort is aimed at making it clearer for petitioners to submit complete petitions and to know what to expect in the petition process, for the NOSB to have clear policies for reviewing petitions in a consistent way, and for the public to have transparency in how petitions are received, evaluated and reviewed.

Subjects covered in this proposal include petitioning to add or remove substances to the National List, how such petitions proceed once they are received, and how the NOSB determines which substances are on the National List. Also covered is the subject of adding, removing or changing and annotation placed on a listed substance.

Used throughout this proposal is the ~~strike through~~ for old language to be removed, and an underline for new language to be added.

## **Part 1. Procedures for Submitting National List Petitions**

Any person may submit a petition requesting a substance to be reviewed by the NOP and NOSB at any time. Each substance to be evaluated for the National List must be submitted in a separate petition. Only single substances may be petitioned for evaluation; formulated products cannot appear on the National List. When submitting petitions, an official petition contact should be designated for all correspondence and the petition should provide specific contact information including name, address, phone number, fax number and e-mail address.

To facilitate timely NOP review and NOSB consideration of petitions, petitioners must provide concise yet comprehensive responses to the required petition information items described under the guideline heading "Information to be included in a Petition." Upon receipt, the NOP will review the petition for completeness of the required petition information. If the required petition information is incomplete, the petition will be returned to the petitioner with a request for additional information.

Petitions for substance evaluations to add a substance onto, remove a substance from, or amend a substance presently on the National List involves a public and open process. Confidential Business Information (CBI) is no longer accepted in petitions. Petition information not categorized and accepted by USDA, pursuant to 7 CFR 1.27(d), as Confidential Business Information (CBI) will be considered available to the public for inspection. Published information usually cannot be claimed as confidential. When a petition is considered complete and forwarded for NOSB evaluation, ~~except for CBI~~, the petition will be made available for public inspection. Substance petitions that are complete and under evaluation by the NOSB will be posted on the NOP Web site at: <http://www.ams.usda.gov/nop>. Public comments may be submitted to either the NOSB or the NOP for any petitioned substance being evaluated by the NOSB. Comments also will be posted on the NOP Web site.

## Information To Be Included in a Petition

The guidelines for required information to be included in a petition are as follows:

**Item A**—Please indicate which section or sections the petitioned substance will be included on and/or removed from the National List. For petitions to change or add an annotation to an already listed substance, please indicate in which category of OFPA §6517 (c)(1)(B)(i) the substance is listed.

- Synthetic substances allowed for use in organic crop production, § 205.601.
- Non-synthetic substances prohibited for use in organic crop production, § 205.602.
- Synthetic substances allowed for use in organic livestock production, § 205.603.
- Non-synthetic substances prohibited for use in organic livestock production, § 205.604.
- Non-agricultural (non-organic) substances allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients),” § 205.605.
- Non-organic agricultural substances allowed in or on processed products labeled as “organic,” § 205.606.

**Item B**—Please provide concise and comprehensive responses in providing all of the following information items on the substance being petitioned (petitions to change annotations for an already listed substance need only complete #s 1, 2 (contact name), 3, 4, 12 (research backing up the change) & 13 (petition justification statement):

1. The substance’s chemical and/or material common name.
2. The petitioners name address and telephone number, the manufacturer’s or producer’s name, address and telephone number (if different) and other contact information of the manufacturer/producer of the substance listed in the petition.
3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (e.g., cereals, salad dressings) for which the substance will be used and a description of the substance’s function in the product(s) (e.g., ingredient, flavoring agent, emulsifier, processing aid).
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 may follow the guidelines in the Instructions for Submitting CBI listed in #13.~~
6. For Handling substances provide information about the ancillary substances (such as, but not limited to, carriers, emulsifiers or stabilizers) that may be included with the petitioned substance, including function, type of substance, and source if known.
7. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. If this information is not available, the petitioner should state so in the petition.
8. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. The information provided must confirm that the intended use of the substance is permitted under EPA or FDA regulations, as applicable. If this information does not exist or is not applicable, the petitioner should state so in the petition.
9. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, the petitioner should state so in the petition.
10. 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 and/ or manufacture;
- (d) effects on human health; and,
- (e) effects on soil organisms, crops, or livestock.

11. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. If this information does not exist, the petitioner should state so in the petition.

12. 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. For petitions to include substances onto the National List for organic handling, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. ~~Commercial availability does not depend upon geographic location or local market conditions.~~ If research information does not exist for the petitioned substance or for the contrasting position, the petitioner should state so in the petition.

13. A "Petition Justification Statement" which provides justification for any 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<sup>1</sup> 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, making sure to cover all uses of the listed substance.

. • 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, and their availability and applicability to all situations where the substance is used.

*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.

<sup>1</sup> Cultural methods. Methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

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, making sure to cover all uses.

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

- Provide a comparative description on why the non-organic form of the substance is necessary for use in organic handling.
- Provide current and historical industry information/research/evidence that explains how or why the substance cannot be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.
- Describe industry information on substance non-availability of organic sources including but not limited to the following guidance regarding commercial availability evaluation criteria: (1) Regions of production, including factors such as climate and number of regions; (2) Number of suppliers and amount produced; (3) Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies; (4) Trade related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies, and (5) Other issues which may present a challenge to a consistent supply.

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

- Provide a comparative description as to why the non-organic form of the substance is not necessary for use in organic handling.
- Provide current and historical industry information/research/evidence that explains how or why the substance can be obtained organically in the *appropriate form, appropriate quality, and appropriate quantity* to fulfill an essential function in a system of organic handling.
- Provide new industry information on substance availability of organic sources including but not limited to the following guidance commercial availability evaluation criteria:
  - (1) Region of production, including factors such as climate and number of regions;
  - (2) Number of suppliers and amount produced;
  - (3) Current and historical supplies related to weather events such as hurricanes, floods, or droughts that temporarily halt production or destroy crops or supplies;
  - (4) Trade related issues such as evidence of hoarding, war, trade barriers, and civil unrest that may temporarily restrict supplies and;
  - (5) Any other issues which may present a challenge to a consistent supply.

I. *Adding, amending, or removing an annotation for a listed substance in all sections*

- Provide evidence that the existing annotation is flawed, unnecessary, or outdated.

- Indicate why an annotation is needed or a change to existing one is needed.
- Explain what revision is needed to the annotation and why, with reference to the review criteria.

~~13. A Confidential Business 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. Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). Instructions for submitting CBI to the National List Petition process are presented in the instructions below.~~

~~.(a) Financial or commercial information the petitioner does not want disclosed for competitive reasons may be claimed as CBI. Applicants must submit a written justification to support each claim.~~

~~.(b) "Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the applicant's business, and (3) maintained in secrecy.~~

~~.(c) Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."~~

~~.(d) The CBI deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI deleted copy is paginated the same as the CBI copy (The CBI deleted copy of the application should be made from the same copy of the application which originally contained CBI). Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI deleted copy.~~

~~.(e) Each page with CBI deletions should be marked "CBI deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI deleted."~~

~~.(f) If several pages are CBI deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBI deleted.")~~

~~.(g) All published references that appear in the CBI copy should be included in the reference list of the CBI deleted copy. Published information cannot be claimed as confidential.~~

~~.(h) Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). If a determination is made to deny CBI treatment, the petitioner will be afforded an opportunity to withdraw the submission.~~

## **Part 2. NOSB Policy and Procedures Manual proposed revisions**

PPM, pp. 34-35:

### **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.**

The petition process is open to all, including members of the NOSB. The priority system for determining in which order petitions are reviewed will be applied to all petitions (Section VIII). These procedures also apply to petitions to add, remove, or change an annotation to an already listed substance.

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

P. 35

### **Phase 2: Determine whether a Third Party Technical Review is Required**

During this phase:

- ~~The NOSB materials committee, working with other~~ applicable NOSB committee 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) Whether the material is deemed appropriate for consideration on the National List (pending criteria). If the answer is no to this question, an explanation is required.
- 2) If the answer to question #1 is yes, the NOSB committee assigned for the review ~~(as identified by the Materials Committee Chair)~~ must decide whether
  - 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 appropriate sub ~~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 (*proceed to Phase 3: Evaluation by a Third Party Expert*)

pp. 37-38

## **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 subcommittee should follow these steps in deciding the need for third party expert:

1. Define whether the subcommittee 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 subcommittee does not have the expertise or resources (e.g., time), the Subcommittee 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 subcommittee must identify the main technical issues needed to be addressed including, but not limited to:

- a. All uses of the petitioned material beyond what the petitioner has requested
- b. All uses of the petitioned material in combination with other material(s) that have been already approved on the same section of the National List
- c. Interactions of the petitioned material, not addressed by the petitioner, and that may involve materials currently on the same section of the National List.
- d. All possible manufacturing methods for a petitioned material.
- e. Potential effects on public health and biodiversity
- f. Environmental risks and hazards including, but not limited to potential for developing pesticide resistance, or long-term effects on sustainability
- g. Ancillary substances that may be used in conjunction with handling materials, such as carriers, stabilizers or emulsifiers.

4. ~~If required~~, The Subcommittee should conduct a final review of the technical report and complete an assessment on the quality of work performed by the third party expert.

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

1. A Subcommittee cannot proceed with a recommendation on a material if it is determined that there is insufficient ~~limited~~ valid scientific information on that material's impact on the

environment, human health and its compatibility with organic principles.

2. The decision to request third party expert needs to be made independent of the availability of funds. If there is a lack of funding to secure third party expert advice, the review of the material should be placed on hold.

3. Although the Board has the final word on the approval or rejection of a petition, the decision to request a third party expert is the responsibility of the subcommittee reviewing the material.

4. The decision to define the expertise needed in the third party expert is the responsibility of the subcommittee reviewing the material or issue.

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

Once the Technical Reports are submitted to the requesting subcommittee, that committee determines if the issues have been addressed sufficiently. If there are remaining questions, the subcommittee can go back for further clarification and expansion of the technical report. Once the information is deemed sufficient, the report is acceptable for public posting.

### **Subcommittee Vote**

Motion to accept the proposal on Updating the petition and TR process as described above and voted on August 27

Motion by: Zea Sonnabend

Seconded by: Tracy Favre

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

**Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB August 27, 2013**

**National Organic Standards Board  
Materials Subcommittee  
Proposal - Confidential Business Information in Petitions**

**July 23, 2013**

**Introduction**

In preparation for the Spring 2013 NOSB meeting, the Materials Subcommittee submitted for Board review and public input a discussion document "Confidential Business Information in Petitions". That document discussed the procedures currently being used to address Confidential Business Information (CBI) as it relates to petitions for materials for inclusion on the National List, and the challenges associated with evaluation of petitioned materials without full and complete information, some of which could be classified as CBI. The document put forth two possible recommendations for modification of the current CBI policy, along with the request for feedback from the public.

***Possible Recommendation 1:***

CBI is not allowed in petitions. Petitioners must provide complete information about manufacturing processes and ingredients so that the NOSB and the public can fully evaluate each petitioned material. A modified version of this choice would be to not allow CBI for manufacturing processes or ingredients but to allow back up research and references to be submitted as CBI to assist the TR development.

***Possible Recommendation 2:***

CBI be allowed in petitions with the following stakeholder responsibilities:

For the National Organic Program

- A. The NOP will allow only information meeting the strict definition of CBI to be deleted from petitions considered by the board and posted for public viewing.
- B. The NOP must make it clear to petitioners what happens to the CBI submitted and who does and does not have access to it, preferably by revising the Petition Guidelines. It should be very clear to petitioners that the NOSB does not see the confidential information.
- C. The Technical Review contractor will have access to the CBI upon request. The contractor may then evaluate the CBI and conduct additional research to verify similar information.
- D. The TR contractor will indicate that they looked at CBI in the course of their review.

For Petitioners

- E. Petitioners are highly urged to provide complete information in their petitions, and keep CBI to the absolute minimum.
- F. Petitions Guideline B.13 requires a statement of reasons for the CBI. This statement needs to be clearly stated, and is part of the public petition that will be seen by the NOSB.
- G. Petitions will not be considered unless the rules in the Petitions Guidelines for CBI are followed completely.

- H. Petitioners need to be aware that petitions containing CBI are rarely approved by the NOSB and the board reserves the right to reject such a petition that does not give complete manufacturing information. The NOSB may also send back a petition as incomplete if there is simply not enough information to make a decision.

#### For the National Organic Standards Board

- I. The Policy and Procedures Manual will be updated to reflect any changes to CBI procedures based on this recommendation and the NOP revising the petition guidelines.
- J. Petitions that come in with CBI will be looked at in the usual way by the subcommittees and any that have withheld too much information to allow the Board to make an informed decision may be returned to the petitioner. Others will move forward for a Technical Review.
- K. If a petition is rejected because of CBI, the petitioner may re-petition and disclose the CBI, however, the NOSB will treat this at the lower level of priority with other re-petitioned substances.

#### **Summary of Public Comments**

Not surprisingly, there were differences of opinion regarding the need for allowances for CBI. Generally, public comments expressed the need for sufficient information for the NOSB to make determinations regarding the classification of materials – synthetic/non-synthetic and or agricultural/non-agricultural, and to determine the impact on human health and the environment. The majority of commenters expressed the opinion that a full list of ingredients should be disclosed. However, some commenters expressed the need for complete transparency regarding the full list of ingredients and manufacturing processes in the petitioned material. Others had concerns about protection of manufacturing processes and/or recipes of petitioned materials, and the potential for impact to participation in the National Organic Program, should CBI not be protected. The proposal for an affidavit process was generally either rejected outright or the opinion was expressed that the affidavit process would need more detail before it could be determined whether or not it would be effective.

Feedback pointed out the administrative difficulty in maintaining confidentiality of CBI provided to the NOSB and not the public and further stated that the transparency of the petition process and the relationship of the NOSB to the public could be adversely affected if such a procedure was implemented.

In order for the NOSB to discharge its responsibility for the proper evaluation of a petitioned material, the following information should be provided:

1. A complete list of ingredients included in the petitioned material. The exact recipes or formulations are not required; only sufficient information so that the NOSB can evaluate the impact on human health and the agro-ecosystem;
2. Sufficient information regarding the manufacturing process to allow for determining the classification of that material as either synthetic or non-synthetic and/or agricultural/non-agricultural and sufficient information regarding the manufacturing process to allow for an assessment of adverse health and environment effects that may be associated with the product's production. Detailed, proprietary information regarding the manufacturing process is not required, except as it relates to the statement above.

Petitioners are encouraged to review the Classification of Materials Draft Guidance (NOP 5033), the Synthetic/Non-Synthetic Decision Tree (NOP 5033-1), and the Agricultural/Non-Agricultural Decision Tree (NOP 5033-2) for draft guidance on what minimum information is necessary for determination of Classification of Petitioned Materials.

### **Conclusion and Recommendation**

The NOSB recognizes the investment and risk associated with development of proprietary materials and processes. The board's intention is not to place petitioners at economic risk through information provided as part of a petition process. However, the importance of transparency of the petition process, the right of the public to fully know the materials included in or on certified organic products, and the potential for an untenable administrative burden of management of CBI precludes the provision of CBI in materials petitions.

For this reason, the Materials Subcommittee is recommending a revision to the Material Petition process to eliminate the provision for Confidential Business Information.

### **Subcommittee Vote**

The Materials Subcommittee moves to accept this recommendation and present it for full Board discussion at the fall 2013 NOSB meeting.

Motion by: Tracy Favre

Second: Jay Feldman

Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

**Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB August 27, 2013**



**National Organic Standards Board  
Materials Subcommittee  
Proposal: Research Priorities for 2013**

**August 27, 2013**

**Introduction**

A Recommendation for a Framework to set Research Priorities was approved at the National Organic Standards Board (NOSB) meeting in May 2012. Part of that recommendation was that the priorities from the previous year of NOSB deliberations would be presented at each fall meeting. Therefore, we have collected suggested research topics from the NOSB subcommittees and from suggestions within the public comments and present the top research priorities for approval this fall.

After a recommendation is finalized by the NOSB each fall the Chair of the Board will make sure it is sent to the primary organic research funders such as NIFA, ARS, NRCS, and private foundations and other funders that may be identified. In addition all NOP staff, NOSB members and stakeholders can use the list for inspiring appropriate research.

**Background**

The reasons for encouraging research into organic production systems are well discussed in the previous two Materials Committee papers from fall 2011 and spring 2012.

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

Criteria for research topics are:

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

**Call for Researchers**

We hope that this information will be useful for researchers in many fields to defend and solicit funds for research that benefits organic production and handling. Therefore, we invite the public to comment on these topics, to circulate this widely, and to recommend that funders also prioritize these topics. Please submit comments on funders who might want to remain informed of research opportunities in organics.

**NOSB Research Priorities 2013:**

For 2013 the Subcommittee has re-emphasized four topics that were on the list last year, and has added several more pertinent topics. The top priorities are in this section without any ranking, with a description of some research questions and why each topic is important. The following section titled "Topics for future review" contains other subjects that the NOSB

subcommittees put forward but are secondary to the top priorities here. Research into these and interrelated issues is urgently needed.

### **Whole Farm Systems**

How can working with the natural world by including diversity of habitat, cropping systems, and biological life benefit an organic farm? Selected subjects within this heading include: Can crop species and varieties be specifically adapted to their site through plant breeding or cultural practices? How does biodiversity contribute to pest and disease resistance? What is the relationship between nutrient balancing fertilization practices and microbial life in the soil and susceptibility or resistance to pests? How can the need for a diverse ecological system be balanced with food safety concerns for a sustainable organic farming system?

### **Alternatives to Antibiotics (Tetracycline and Streptomycin) for Fire Blight**

With oxytetracycline and streptomycin due to expire from the National List in October of 2014, the organic apple and pear growers must find suitable alternatives to control the deadly fire blight disease. Since apples and pears are grown throughout the United States in many regions, these alternatives must work in a variety of climates and a variety of management systems. The following research issues are important to investigate: location, planting density, choice of varieties of cultivar and rootstock, soil improvement practices, pruning practices and general sanitation, groundcovers or intercrops, pollinator management, dormant copper sprays, bloom thinning/lime sulfur, early, full bloom, and late sprays with approved organic materials to prevent fire blight establishment, surveys for fire blight activity, and other cultural and preventative techniques.

### **Evaluation of Genetically Modified Vaccines (GMO)**

Prevention and avoidance of unintended GMO contamination are foundational to organic production and brand. It is of such importance that NOSB has a GMO Ad-Hoc Subcommittee. A need exists for research and/or outreach on easier ways to determine the types of vaccines. A better way of identifying the types of vaccines is critically important to our stakeholders, especially livestock producers. The testing of products that could be alternatives to GMO vaccines in livestock production is a top priority.

### **Methionine Alternative**

Methionine is an essential amino acid for poultry. Prior to the 1950's poultry and pigs were fed a plant and meat based diet without synthetic amino acids such as methionine. One former NOSB member stated, in §205.237(5) (b), "We have seemingly made vegetarians out of poultry and pigs". As the organic community moves toward reducing, removing, or providing additional annotations to synthetic methionine in the diets of poultry, a heightened need exists for the organic community to rally around omnivore producers to assist in marshaling our collective efforts in finding viable alternatives to synthetic methionine and help find approaches for making them more commercially available.

The key research areas are on alternatives such as herbal methionine, corn gluten meal, potato meal, management practices, pastures management, fish meals, animal by-products, and other non-plant materials. Additional research on the more promising alternatives related to bringing them into commercial production is also encouraged.

## **Organic Aquaculture**

Organically-labeled aquaculture products are increasing rapidly in markets around the world.

In the U.S., debate continues on appropriate use(s) of the organic label for aquaculture systems, and whether such use should be approved for open-water systems as well as closed systems such as ponds or tanks. Therefore, research efforts pertaining to both open and closed systems are needed.

Research needed includes:

- evaluating the environmental impacts of fish wastes from aquaculture systems on the environment;
- appropriateness of feed and other supplements such as trace minerals that may have synthetic sources;
- organic practices for fish health and management of diseases and parasites;
- and impacts and control of fish escapes in open water situations.

The subcommittee notes that application of organic agriculture principles (as described in OFPA) to aquaculture poses some definitional problems. OFPA refers to organic management principles and practices that were developed in the context of terrestrial plant and animal systems. Research approaches are needed which explore the extension of these principles to aquatic systems. (For example, see following discussion of “aquatic biodiversity”)

## **Aquatic Biodiversity**

Organic farmers promote biodiversity in cultivated and uncultivated areas through crop rotations and other practices. They are expected to maintain areas like hedgerows, woodlands, wetlands, and wildlife corridors to promote non-crop biodiversity on the farm. The conservation of biodiversity must be included in organic systems plans for aquaculture as well. NOSB materials recommendations need to be made with a goal of preserving and enhancing biodiversity. With the impending implementation of rules on organic aquaculture, it is important that decisions be made with a firm understanding of aquatic ecology and possible impacts of the Board’s decisions. Decisions concerning terrestrial inputs derived from aquatic environments also need to be based on an understanding of the impacts from such activities.

In particular, the NOSB needs to understand: nutrient and mineral cycling in various aquatic systems, the structure of aquatic food webs, the movement of pollutants in various aquatic systems, bioaccumulation and bioconcentration in aquatic organisms, and the status and impacts of overharvesting and other stresses on aquatic/marine plants and animals. Board members, certifiers, and aquaculture operators all need to know how biodiversity conservation measures should be implemented in aquaculture systems and materials decisions.

## **Herd Health**

The assessment of preventive organic practices to improve organic livestock health is critical and of high importance. These include general animal health as it relates to diseases prevention, uterine infections in peri-parturient animals, growth, and identification of vaccine types, nutrition, and production systems. Research that could lead practitioners to better prevention strategies, use of non-synthetic substances such as feed supplements that would improve health and management practices that minimize health issues are all important topics.

## **Pastured Poultry and Salmonella**

Raising poultry on pasture where the birds get a varied diet, are outdoors and have space to roam makes sense from an organic standpoint. But does pasturing of poultry lead to higher

rates of Salmonella infection? Some critics have claimed this but there is scant evidence to support or refute this opinion. Exploring where Salmonella infections can originate, whether the pasture system has some inherent buffering capacity against pathogens getting a foothold, and whether there truly is more risk involved in raising organic poultry on pasture are key research topics.

### **Commercial Availability Assessments**

The NOSB must make assessments of commercial availability of organic sources every time there is a petition or a sunset review for substances on §205.606 in particular (agricultural substances that may be used from non-organic sources). What are some resources for commercial availability information? Is it out there? If there is no information available, how could such information be developed?

### **Consumer Demand**

The NOSB get told often by commenters who are or claim to represent consumers that consumers have expectations about what organic means and what inputs and ingredients should be in organic food. Sometimes there is a wide difference between what consumer activist groups claim and sales of specific categories of organic products in the marketplace. How can the NOSB determine whether the consumers and groups who speak up are truly representing all consumers of organic, and if not, is there a better measure of consumer preference and expectations than sales figures for organic products? This has come up in the past year with particular regard to fortification by synthetic nutrients in infant formula and other processed food, as well as in the apple and pear marketplace with the discussion of oxytetracycline. Research into the relationship of consumer buying habits and their beliefs about them would be helpful.

### **Fate of Genetically Engineered Plant Material in Compost?**

What happens to transgenic DNA in the composting process? Materials such as cornstalks from GMO corn or manure from cows receiving rBGH are often composted yet there is little information on whether the genetically engineered material and traits break down in composting process. Do these materials affect the microbial ecology of a compost pile? Is there trait expression of Bt (*Bacillus thuringiensis*) after composting?

### **Reduction of Genetically Modified Content of Breeding Lines**

In grappling with the issue of a Seed Purity Standard, it came up in comment that breeding lines of corn and other crops had become polluted by GMO pollen entering their germplasm. This research question is posed to determine what techniques can be applied to reduce or eliminate contamination by unintended GMO presence in seed breeding materials. Can lines be "purified" so that there are non-detectable levels of GMOs after several selection cycles and how many generations would it take?

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### **Topics for Future Review**

This group of topics was submitted by the Crops and Livestock Subcommittees of the NOSB but did not make it into the Priorities for Research in 2013. They will remain in consideration for future year priorities.

- **Chlorine Alternatives**

Chlorine compounds are the most common equipment and food contact sanitizers used in the food processing and handling. They are also common disinfecting agents for farm equipment and tools. In its reactive forms –chlorine gas, hypochlorite, etc. – chlorine may react with organic matter to form organochlorines, which are generally persistent, toxic, carcinogenic, and often endocrine disruptors. Sometimes the reactions are purposeful, to create pesticides, solvents, pharmaceuticals, and other synthetic chemical products. Other times unintentional byproducts, such as chloroform or carbon tetrachloride, result from processes such as disinfection.

The fact that use of chlorine –as opposed to chloride– is so universally associated with the production of persistent toxic chemicals has led some environmental groups to seek a ban on chlorine-based chemicals. Since chlorine compounds have so many adverse impacts in the production-to-disposal life of the materials, we recommend that the NOSB support research to determine how organic production can move beyond reliance on chlorine-based materials.

- **Sulfuric Acid Alternatives**

Sulfuric acid is commonly used to lower the pH in the manufacture or processing of some agricultural inputs. The NOSB has received petitions for sulfuric acid itself and also for materials that have sulfuric acid as a processing aid in the manufacture. Recent examples include vinasse, magnesium oxide, and laminarin.

In 2006, the Crops Subcommittee voted unanimously to reject a petition to allow use of sulfuric acid in anaerobically digested livestock manure because “Sulfuric acid, when used in livestock manure, is changed to sulfate, which is in this case a synthetically derived plant nutrient. Additionally, it is an important air pollutant, e.g. acid rain. Other wholly natural materials can be used.” In 2012, the Crops Subcommittee took a similar position on a similar petition.

Unfortunately, the NOSB is not always able to identify alternatives, despite concerns about sulfate as a synthetic plant nutrient and environmental impacts. Research into natural acids or other substitutes that could be used in place of sulfuric acid to lower pH in the production of inputs for organic agriculture, as well as whether the pH lowering step is always required to purify, extract or stabilize raw inputs is important to the NOSB deliberations on materials.

- **Parasitism**

The control of internal and external parasites is important to animal welfare, growth, reproduction, and production. In organic production, the control of parasites is critical. The use of antibiotics is prohibited. A limited number of substances are available to control parasites. Antibiotics are not allowed in organic livestock production for growth, reproduction, and production. Antibiotics can be used on sick animals. However, these animals cannot be sold as organic. A critical need exists to explore ways to find materials for the control of internal and external parasites in organic livestock operations.

- **Mastitis**

Mastitis is a disease of the mammary gland. It is an inflammation in the mammary gland. It is generally associated with dairy cattle. It can be caused by bacteria, physical injury, etc. Mastitis is one of the most common and expensive diseases of dairy cattle. It can result in reduced milk production, discarded milk, treatment, and veterinary expenses. An urgent need exists for looking at ways to reduce mastitis in dairy herds. The research needs include the areas of herbal treatment of mastitis and management practices.

- **Pneumonia**

Pneumonia denotes a swelling of the lungs. Pneumonia is rare when animal populations and densities are low. In the winter, animals are housed or gather more closely together, increasing

the concentration of pathogens in their environment. Confinement and higher animal densities result in increased air temperatures, humidity, and condensation, which are beneficial conditions for pathogen survival and transmission. Pneumonia in a herd or flock means animals are not performing up to their maximum potential, production costs are higher, labor is increased, and food product quality is compromised. Responsible animal caretakers know it is their duty and responsibility to address animal welfare concerns and ensure a safe and healthy environment for their animals.

### **Subcommittee Vote**

Motion to adopt the proposed recommendation on NOSB Research Priorities for 2013.

Motion by: Zea Sonnabend

Second: Tracy Favre

Yes: 5 No: 0 Absent: 2 Abstain: 0 Recuse: 0

**Approved by Zea Sonnabend, Subcommittee Chair, to transmit to NOSB September 3, 2013**

**National Organic Standards Board  
Handling Subcommittee  
Petitioned Material Checklist  
Ammonium Hydroxide**

**February 19, 2013**

**Summary of Proposed Action:**

Ammonium Hydroxide is a powerful alkali petitioned for use as a boiler additive because it neutralizes carbonic acid in condensate to prevent corrosion. Ammonium hydroxide is produced by the addition of water to Ammonia. Ammonia is produced on a large scale worldwide and one of its largest uses by production volume is as an ingredient in non-organic fertilizer.

Ammonium hydroxide is a severe irritant which must be handled properly because exposure by humans and other mammals during production or use presents a serious toxicological concern. It is toxic by all routes, inhalation, dermal and ingestion and the toxicity is well documented. It is an air and water pollutant and contributes as a greenhouse gas. It is toxic to fish and other aquatic species. Spillage could cause considerable environmental damage.

Ammonium hydroxide is not essential to organic production. There are other boiler additives on the National List. There are also a number of alternative practices which can be used instead of boiler additives. The addition of ammonium hydroxide is not consistent with organic agriculture.

**Evaluation Criteria (see attached checklist for criteria in each category)**

	<b>Criteria Satisfied?</b>		
1. Impact on Humans and Environment	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> N/A

**Substance Fails Criteria Category: [3] Comments:**

Ammonium hydroxide has the potential to cause significant toxic damage to humans, mammals, aquatic systems and greenhouse gasses and is not essential or compatible with organic agriculture and handling.

**Subcommittee Action & Vote**, including classification proposal (state actual motion):

**Classification Motion:** Move to classify Ammonium hydroxide (CAS # 1336-21-6) as petitioned is synthetic

Motion by: Jean Richardson

Seconded by: Tracy Favre

Yes: 6 No: 0 Absent: 2 Abstain: 0 Recuse: 0

**Listing Motion:** Move to list Ammonium hydroxide (CAS # 1336-21-6) to the National List Section 205.605b]

Motion by: Jean Richardson

Seconded by: Colehour Bondera

Yes: 0 No: 6 Absent: 2 Abstain: 0 Recuse: 0

**Proposed Annotation (if any):** none

**Approved by John Foster, Subcommittee Chair, to transmit to NOSB February 19, 2013**

**NOSB Evaluation Criteria for Substances Added To the National List  
Handling**

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

**Ammonium hydroxide**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]	X			Toxic to environment if spilled or volatized to atmosphere ( <a href="#">TR (2001)</a> and <a href="#">petition</a> )
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]	X			Worker injury through breathing, ingestion or dermal contact and terrestrial damage with spills during manufacture. (Petition and TR).
3. Are there any adverse impacts on biodiversity? (§205.200)	X			Toxic damage will occur through spills in terrestrial or aquatic systems, and ammonia contributes to greenhouse gases (Petition pages 8-10) Fish are particularly at risk for toxic effects.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517(c)(1)(B)(ii)]		X		
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X			When released into air the gas contributes to Greenhouse gases.
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517(c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]	X			Yes toxic if inhaled, ingested or dermal contact
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	X			
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600(b)(5)]		X		

**NOSB Evaluation Criteria for Substances Added To the National List  
Handling**

**Category 2. Is the Substance Essential for Organic Production?      Ammonium hydroxide**

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments/Documentation. (TAP; petition; regulatory agency; other)</b>
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Ammonium hydroxide is manufactured from natural gas which is used to convert atmospheric nitrogen to ammonia and then water is added to produce the hydroxide form.
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		X		
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]		X		
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]		X		
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
9. Are there any alternative substances? [§6518(m)(6)]	X			There are non-organic alternatives on the NL
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]				There are a number of alternative practices which can be used (Petition page11) These include pre-treating water, replacing steam pipelines with stainless steel etc.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.		X		

**NOSB Evaluation Criteria for Substances Added To the National List  
Handling**

**Category 3. Is the substance compatible with organic handling practices? Ammonium hydroxide**

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments/Documentation. (TAP; petition; regulatory agency; other)</b>
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]		X		
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]		X		
4. Are the ancillary substances reviewed compatible with organic handling?			x	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]		X		
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]		X		

**NOSB Evaluation Criteria for Substances Added To the National List  
Handling**

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

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments/Documentation. (TAP; petition; regulatory agency; other)</b>
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?	X			The Petition describes in detail the reasons for petitioned use of this boiler additive
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 <b>form</b> to fulfill an essential function in a system of organic handling?	X			
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 <b>quality</b> to fulfill an essential function in a system of organic handling?			X	
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 <b>quantity</b> to fulfill an essential function in a system of organic handling?			X	
5. Does the industry information about unavailability include (but is not limited to) the following:			X	
a. Regions of production (including factors such as climate and number of regions);			X	
b. Number of suppliers and amount produced;			X	
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;			X	
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or			X	
e. Other issues which may present a challenge to a consistent supply?			X	



**National Organic Standards Board  
Handling Subcommittee  
Petitioned Material Checklist  
Glycerin CAS Number 56-81-5**

**August 20, 2013**

**Summary of Proposed Action:**

The petitioner has requested removal of Glycerin from 205.605(b) (synthetic materials for handling), stating that there is now sufficient quantity of organically produced glycerin and that synthetic glycerin is no longer required. The petitioner believes that the process of microbial fermentation that is used to produce organic glycerin is a superior method for the production of organic glycerin because it uses only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). Further, they state “An important reason that glycerin produced by hydrolysis of fats and oils should have been included at §205.606 is that items listed at §205.606 are subject to the restriction that they can be used “only when the product is not commercially available in organic form.” Certified organic glycerin is currently available, but there is no “commercial availability” requirement to incentivize processors to use it or certifiers to require it. This is why glycerin should be removed from the National List in order to encourage organic agricultural production.”

<http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5101924>

Because glycerin produced by hydrolysis of fats and oils is currently listed at 205.605(b), the NOSB seeks public comment regarding the potential impact to producers and industry should glycerin as is presently listed be removed from 205.605(b) of the National List. At present, the NOSB has not received a petition to add Glycerin produced by other methods to the National List.

**Background**

Glycerin is a viscous fluid that has a sweet taste. It is used in a wide variety of products including food, cosmetics, medical and industrial applications. As listed at 205.605(b), glycerin is formulated from hydrolysis of fats and oils. Per the Technical Review (line 122), there are a variety of methods for manufacture of glycerin from hydrolysis of fats and oils:

Table 2 Processes for producing glycerin by hydrolysis of fats and oils	
Lemmens Fryer's Process	Oil or fat is subjected in an autoclave to the conjoint action of heat and pressure (about 100 PSI) in the presence of an emulsifying and accelerating agent, e.g. zinc oxide or hydroxide (sodium hydroxide can be substituted) for about eight hours. The strong solution of glycerin formed is withdrawn and replaced by a quantity of hot, clean and preferably distilled water equal to about one third to one fourth of the weight of the original charge of oil or fat and treatment continued for an additional four hours. The dilute glycerin obtained from the latter part of the process is drawn off and used for the initial treatment of the further charge of oil or fat.
Budde and Robertson's Process	The oils or fats are heated and mechanically agitated with water and sulphuric acid gas, under pressure in a closed vessel or autoclave. The advantage claimed for the process are that the contents of the vessel are free from foreign matter introduced by reagents and need no purification; that the liberated glycerin is in the form of a pure and concentrated solution; that no permanent emulsion is formed and that the fatty acids are not discolored.
Ittner's Process	Coconut oil is kept in an autoclave in the presence of water at 70 atmospheres pressure and 225-245°C temperature and split into fatty acids and glycerin, both being soluble under these conditions in water. The glycerin solution separates in the bottom of the autoclave. The aqueous solution contains at the end of the splitting process more than 30 percent glycerin.

Continuous High Pressure Hydrolysis	In this process a constant flow of fat is maintained flowing upward through an autoclave column tower against a downward counter-flow of water at a pressure of 600 PSI maintained at temperature of 480-495°F. Under these conditions, the fat is almost completely miscible in water and the hydrolysis take place in a very short time. The liberated fatty acids, washed free of glycerin by the downward percolating water, leave the top of the column and pass through a flash tank while the liberated glycerin dissolves in the downward flow of water and is discharged from the bottom of the tower into the sweet-water storage tank.
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Additionally, per the petitioner “Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils.” Hydrolysis of fats and oils does change the chemical properties of the source material, and therefore it is considered a synthetic.

Per the petition: Four general methods of commercial glycerin production are or have been used:

1. Chemical synthesis by hydrogenolysis of carbohydrates (21 CFR 178.3500; 21CFR 172.866)) or by synthesis from propylene (mentioned in the 1995 Technical Advisory Panel report on glycerin). Neither chemical synthetic process has ever been deemed worthy of serious consideration for use in organic.
2. Biodiesel production comprises reaction of natural fats and oils – triglycerides – with methyl alcohol or ethyl alcohol to produce the methyl or ethyl esters of fatty acids. These synthetic fatty acid esters are the diesel fuel. Glycerin is a synthetic waste byproduct of this chemical process. The commercialization of the biodiesel process in the past few years has created an enormous supply of biodiesel glycerin that has largely displaced chemical synthesis from propylene. In fact, the low cost of biodiesel glycerin has resulted in commercialization of processes to use it as a raw material to produce epichlorohydrin, acrolein, propylene glycol, and other organic chemicals. There are safety concerns with biodiesel glycerin, discussed in Section B-11.
3. Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process are included in the National List. Glycerin produced by saponification was recommended by the NOSB in 1995 for inclusion on the National List with the annotation “produced by hydrolysis of fats and oils.” It is currently included on the National List as a synthetic nonagricultural substance at §205.605(b) [and also for livestock used at §205.603(a)(12)]. Certified organic glycerin is being produced by saponification of organic fats and oils.
4. Microbial fermentation of carbohydrate substances (analogous to citric acid currently included in the National List at §205.605(a)) to produce non-synthetic glycerin. This production method is briefly mentioned generically in the 1995 TAP Report and referred to in the Merck Index monograph on glycerol (glycerin), which cites a U.S. Patent No. 3,012,945 issued to Noda in 1961 for yeast fermentation to produce glycerin. Currently, microbial fermentation of organic cornstarch by the yeast *Candida krusei*1 is used commercially to produce certified organic glycerin as well as non-synthetic non-organic glycerin.

Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium

carbonate, sodium hydroxide, or potassium hydroxide) on the National List. Glycerin, produced organically by fermentation is an agricultural product as defined in 7 CFR 205.2, since it is a processed product produced from an agricultural commodity, e.g. cornstarch (TR lines 130 – 131). There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products. Specific supplier information (TR Table Line: 674).

**Evaluation Criteria (see attached checklist for criteria in each category)**

	<b>Criteria Satisfied?</b>		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
4. Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A

**Substance Fails Criteria Category:** [ ] **Comments:**

**Subcommittee Action & Vote**, including classification proposal (state actual motion):

**Classification Motion:** N/A

**Listing Motion:** Move to remove Glycerin produced by hydrolysis of fats and oils, CAS Number 56-81-5 from 205.605(b) of the National List.

Motion by: Tracy Favre

Seconded by: Harold Austin

Yes: 7 No: 0 Absent: 1 Abstain: 0 Recuse: 0

**Proposed Annotation (if any):** N/A

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

Notes:

**Approved by John Foster, Subcommittee Chair, to transmit to NOSB August 20, 2013**

**NOSB Evaluation Criteria for Substances Added To the National List Handling**

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

**Substance: Glycerin**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]		X		Wide variety of uses for food and industrial applications. Long-term history of safe use, TAP indicates no incidence of industrial poisoning. Glycerin should not come into contact with a strong oxidizing agent.
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]		X		For current listing: Manufactured from hydrolysis of fats and/or oils using steam splitting. Theoretically possible to have spill of oils, but unlikely. Fermentation methods: Unlikely
3. Are there any adverse impacts on biodiversity? (§205.200)			X	However, the petitioner claims that the residue from biodiesel production is used in the manufacture of glycerin, and one could argue that growing corn for biodiesel does have an impact on biodiversity.
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517(c)(1)(B)(ii)]		X		
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		Per Environmental Working Group (EWG), there seems to be no persistence in the environment. TR indicates it is readily biodegradable (line 568)..
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c)(1)(A)(i); 6517(c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]		X		Glycerin is considered GRAS and has a long history of safe use in a wide variety of food, cosmetic and medical applications. It is metabolized as a carbohydrate in the body.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]	X			See above comment.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600(b)(5)]		X		Manufactured from hydrolysis of fats and oils using steam splitting and then concentrated using distillation. Fermentation methods include isolation of cornstarch from organic corn.

**NOSB Evaluation Criteria for Substances Added To the National List Handling**

**Category 2. Is the Substance Essential for Organic Production? Substance: Glycerin**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X	X		As currently listed it is not considered agricultural. However, the petitioner makes the argument that it should have originally be listed at 205.606 since if it is manufactured using steam, then it should be considered agricultural. The fermentation method could be considered agricultural since it is manufactured using isolated cornstarch from organic corn.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			<p>Per the petition: "Saponification of natural fats and oils, a process of hydrolyzing the agricultural products fat or oil with water (steam) under pressure (high-pressure splitting) or with a solution of sodium carbonate, sodium hydroxide, or potassium hydroxide (traditional process) to produce synthetic glycerin and fatty acids. The steam process is described in the 1995 Technical Advisory Panel Report on glycerin. The alkali process is the traditional process used to saponify fats and oils. The three sources of alkali used in this process are included in the National List."</p> <p>Hydrolysis of fats and oils does change the chemical properties of the source material.</p> <p>Fermentation methods: The process for producing organic glycerin by microbial fermentation from carbohydrate substrates begins with organic corn from which cornstarch is isolated. The cornstarch is treated with enzymes to hydrolyze the starch and liberate glucose. The glucose is then fermented with an appropriate microorganism to produce glycerin. The glycerin is purified by passing through ion-exchange columns to remove inorganic elements required for growth of the microorganism and through activated charcoal to remove color and impurities.</p>
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			<p>Hydrolysis is the opposite to condensation. A large molecule is split into smaller sections by breaking a bond, adding -H to one section and -OH to the other.</p> <p>The products are simpler substances. Since it involves the <b>addition of water</b>, this explains why it is called hydrolysis, meaning <b>splitting by water</b>.</p> <p><b>A-B + H<sub>2</sub>O --&gt; A-H + B-OH</b>  <a href="http://www.biotopics.co.uk/as/condensation_and_hydrolysis.html">http://www.biotopics.co.uk/as/condensation_and_hydrolysis.html</a></p> <p>For fermentation method, see above.</p>

4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		<p>The process of hydrolysis is a naturally occurring process, but this material is manufacturing using high heat and pressure. Incidentally, all (food) digestion reactions are examples of hydrolysis, and the involvement of water is often not appreciated. Generally these reactions are controlled by enzymes such as carbohydrases, proteases, lipases, nucleases, more specific examples of which are fairly well known. (<a href="http://www.bitopics.co.uk/as/condensation_and_hydrolysis.html">http://www.bitopics.co.uk/as/condensation_and_hydrolysis.html</a>)</p> <p>For fermentation, see above.</p>
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		X		
6. Is there an organic substitute? [§205.600(b)(1)]	X			<p>Petitioner claims to have a fully organic version manufacturing using a fermentation process. See petition, (<a href="http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101924">http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101924</a>)</p> <p>Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.</p>
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]	X			<p>Glycerin is used in a wide variety of products including food, cosmetics, industrial and medical. It is a strong humectant. In organic food products it is used to improve texture, increase volume and is a major carrier for flavorings and colorings.</p>
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X	X		<p>Alcohols could be used a carriers for flavorings. And there are myriad other materials that could have a similar functional use in other formulations (such as softening and mouth feel in ice creams, keeping baked items soft, etc.) but glycerin is unique in that it can serve in all these functions.</p>
9. Are there any alternative substances? [§6518(m)(6)]	X			<p>Glycerin manufactured from petroleum products, glycerin from saponification of fats and oils and fermentation methods.</p>
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X	X		<p>Given the wide use of glycerin, it is likely that there are substitutes for particular uses, but it is unlikely that any one material would work in all the applications where glycerin is used.</p>
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed limitations.			X	

**NOSB Evaluation Criteria for Substances Added To the National List  
Handling**

**Category 3. Is the substance compatible with organic handling practices? Substance: Glycerin**

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments/Documentation. (TAP; petition; regulatory agency; other)</b>
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			TR says consistent when used with specific food products
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]		X		Current version on the National List is considered a synthetic, therefore it would not be preferred for organic handling. According to the petitioner, there is now sufficient capacity for organically produced glycerin to supply the organic market.
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]			X	Petition is to remove this substance from National List
4. Are the ancillary substances reviewed compatible with organic handling?			X	
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		One of the uses of glycerin is as a preservative but it has many more uses
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]	X			Glycerin is used as a flavor and/or color carrier, and is used to improve textures.

**NOSB Evaluation Criteria for Substances Added To the National List Handling**

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

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?			X	Petition is for removal of synthetic glycerin. Petitioner claims there is sufficient quantity of organic glycerin available. Per the TR: Glycerin can be produced organically by the process of microbial fermentation using only mechanical and biological processes as required in §205.270(a) without the use of allowed synthetics listed in §205.605(b). In addition, certified organic glycerin can be produced by hydrolysis of organic fats and oils using either steam splitting or traditional saponification with a catalytic amount of an alkali (sodium carbonate, sodium hydroxide, or potassium hydroxide) on the National List.
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 <b>form</b> to fulfill an essential function in a system of organic handling?			X	See above. Petitioner claims there is sufficient organic glycerin available and the synthetic non-organic version is no longer necessary.
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 <b>quality</b> to fulfill an essential function in a system of organic handling?	X			See petition at: <a href="http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101924">http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5101924</a>
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 <b>quantity</b> to fulfill an essential function in a system of organic handling?	X			When synthetic glycerin was recommended for inclusion on the National List, there was an insufficient supply of organic glycerin. According to the petitioner, that is no longer the case. Per the TR: There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products.
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);	X			
b. Number of suppliers and amount produced;	X			There are currently 21 USDA certified organic operations supplying glycerin for organic food or cosmetic products. Specific supplier information (TR Table Line: 674)

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;	X			
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or	X			
e. Other issues which may present a challenge to a consistent supply?	X			



**National Organic Standards Board  
Handling Subcommittee  
Polyalkylene Glycol Monobutyl Ether (PGME)  
Discussion Document  
August 20, 2013**

## **I INTRODUCTION**

The purpose of this document is to seek public comment on the proposal that the petition for PGME be removed from the NOSB workplan after the Fall 2013 meeting, and that the NOP should notify the petitioner that PGME is not eligible for petition to 205.605 (b) because it is not used in direct contact with organic products.

## **II BACKGROUND**

On December 27, 2012, the NOP received a petition requesting the addition of PGME to section 205.605 of the National List as a boiler water additive. Based on information in the petition, the NOP determined that the substance was eligible for petition to the National List. This decision was made based on the description of PGME as a processing aid that functions as a lubricant and surfactant within the pelleting process.

On January 28, 2013, the petition was sent to the NOSB Handling Subcommittee for review. The HS requested the development of a third-party technical report, which is posted on the NOP website.

The technical report, dated June 7, 2013, indicates that, since PGME is non-volatile, it remains in the boiler and does not come into direct contact with processed organic products.

The Handling Subcommittee prepared the Petitioned Material Checklist which was ready for final discussion and vote on August 20, 2013, at which time the Subcommittee determined that when used as a boiler additive, PGME is not required to be on the National List because it has no contact with organic products.

## **III RELEVANT AREAS OF THE RULE**

§ 205.607 Amending the National List.

“(a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated by the Board for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with the Act.”

The petition requests addition of PGME to 205.605 – “Non agricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

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

“(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

(1) The substance cannot be produced from a natural source and there are no organic substitutes;

(2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;

(3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;

(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;

(5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and

(6) The substance is essential for the handling of organically produced agricultural products.”

#### **IV DISCUSSION**

In reviewing PGME and developing the Materials Checklist the Handling Subcommittee found the following:

Polyalkylene Glycol Monobutyl Ether (PGME) polymeric fluid is a boiler steam additive petitioned for use in feed pellet mills. The petition is specifically for PGME with a minimum molecular weight of 1500 in accordance with conditions required by 21CFR Section 173.310.

PGME functions to reduce foaming during production of pelleted livestock feeds and also functions as a lubricant. PGME has the unique property of inverse solubility such that it dissolves easily in cold water, but at temperatures over 104F (cloud point) it is completely insoluble. Thus PGME is not delivered with the steam, but remains in the boiler as a precipitate until the boiler cools below cloud point and thus PGME does not contact the feed.

PGME has very low toxicity, is not considered harmful to the environment or humans, and presently has a range of uses approved through the FDA. Canadian, CODEX and Japanese standards do not address this additive. EEC standards require that processed feeds shall not have been processed with the aid of chemically synthesized solvents. IFOAM requires all additives to be declared. This material is regulated by FDA as a secondary direct food additive, and is not considered a GRAS substance.

There are no natural sources of PGME and there are not many natural anti-foam chemicals. Natural oils, such as cotton seed, lard, sunflower, safflower, palm oil, carnuba and peat waxes can be used, but none of them is as effective and none also provide lubricant properties during production. Some of the natural oils are available in organic form, but very little data is available on use of these oils.

When used as a boiler additive, the Handling subcommittee finds that PGME is not required to be on the National List because it has no direct contact with organic products.

#### **V REQUEST FOR PUBLIC COMMENT**

Based on the new information provided in the technical report, there are now questions about whether the original eligibility decision made by the NOP is still accurate. The original eligibility decision for this substance, which was based on the information contained in the petition only, may no longer be applicable.

This Discussion Document provides the opportunity for the petitioner to comment on the

accuracy of the technical description of PGME in the technical report and the opportunity for other members of the public to comment on the petition and technical report.

Subcommittee Vote:

Motion: To accept the Discussion Document as amended August 20, 2013.

Moved: Tracy Favre

Second: Harold Austin

Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1

**Approved by John Foster, Subcommittee Chair, to transmit to NOSB August 20, 2013**





## Sunset 2015 Review List - Request for Public Comment Handling Substances

September 5, 2013

### Introduction

As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic handling which must be reviewed by the NOSB and renewed by the NOP before their sunset dates in 2015. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

### Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Spring 2014 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Fall 2013 public meeting. These comments should be provided through [www.regulations.gov](http://www.regulations.gov) by October 1, 2013 as explained in the meeting notice published in the [Federal Register](#) on September 5, 2013.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance.

### Guidance on Submitting Your Comments

Comments should clearly indicate your position on continuing the allowance of substances on this list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

### ***For Comments That Support Substances Under Review:***

If you provide comments in support of an allowance of a substance on the National List, you should provide new information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic handling.

**For Comments That Do Not Support Substances Under Review:**

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with organic handling.

**For Comments Addressing the Availability of Alternatives:**

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- o Alternative management practices that would eliminate the need for the specific substance;
- o Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- o Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

**For Comments on Nonorganic Agricultural Substances at Section 205.606.**

For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

**Table 1. Guidance on submitting comments for alternatives to substances on the National List.**

If the currently listed substance is used in...	And is a...	Then the recommended alternative should be a (an)...
Handling	Nonsynthetic (non-agricultural) substance	<ul style="list-style-type: none"> <li>- Agricultural substance; or</li> <li>- Management practice.</li> </ul>
Handling	Synthetic substance	<ul style="list-style-type: none"> <li>- Another currently listed synthetic substance;</li> <li>- Nonsynthetic (non-agricultural) substance; or</li> <li>- Management practice.</li> </ul>



Written public comments will be accepted through Tuesday, October 1, 2013 via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.

## SUNSET 2015: HANDLING SUBSTANCES

### Gellan gum

*Nonsynthetic*

**Use** – As a nonagricultural (nonorganic) substance allowed as ingredient in or on processed products.

**Listing:** Gellan gum (CAS # 71010-52-1) – high acyl form only.

**Technical Report:** [2006](#)

**Petition(s):** [Gellan gum \(2004\)](#)

**Past NOSB Actions:** NOSB review and recommendation for addition to the National List – [04/22/08](#)

**Regulatory Background:** Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 ([75 FR 7751](#)).

**Sunset Date:** 12/14/2015

*Reference: 7 CFR 205.605(a)*

### Marsala

*Nonorganic Agricultural*

**Use** – As nonorganically produced agricultural product allowed as ingredient in or on processed products.

**Listing:** Fortified cooking wines. (1) Marsala

**Technical Report:** none

**Petition(s):** [Marsala](#), (2007).

**Past NOSB Actions:** NOSB review and recommendation for addition to the National List [11/30/07](#).

**Regulatory Background:** Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 ([75 FR 7751](#)).

**Sunset Date:** 12/14/2015

*Reference: 7 CFR 205.606(g)(1)*

### Sherry

*Nonorganic Agricultural*

**Use** – As nonorganically produced agricultural product allowed as ingredient in or on processed products.

**Listing:** Fortified cooking wines. (2) Sherry

**Technical Report:** none

**Original Petition:** [Sherry](#) (2007).

**Past NOSB Actions:** NOSB review and recommendation for addition to the National List, [05/08](#)

**Regulatory Background:** Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 ([75 FR 7751](#)).

**Sunset Date:** 12/14/2015

*Reference: 7 CFR 205.606(g)(2)*



## Tragacanth gum

*Nonorganic Agricultural*

**Use** – As nonorganically produced agricultural product allowed as ingredient in or on processed products.

**Listing:** Tragacanth gum (CAS #-9000-65-1).

**Technical Report:** none

**Original Petition:** [Tragacanth Gum \(PDF\)](#) (2007)

**Past NOSB Actions:** NOSB review and recommendation for addition to the National List [5/08](#)

**Regulatory Background:** Proposed rule (including justification) published 06/03/09 (74 FR 26591), Added to National List 12/13/2010 ([75 FR 7751](#)).

**Sunset Date:** 12/14/2015

*Reference: 7 CFR 205.606(x)*

**National Organic Standards Board  
Livestock Subcommittee  
Synthetic Methionine in Organic Poultry Feed Proposal**

**August 20, 2013**

### **Summary of Proposed Action**

The Livestock Subcommittee proposes to revise the current allowance of synthetic methionine (MET) to read:

DL–Methionine, DL–Methionine—hydroxy analog, and DL–Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum average pounds per ton of 100% synthetic methionine in the diet over the life of the flock: Laying and broiler chickens – 2 pounds; Turkeys and all other poultry – 3 pounds.

The Livestock Subcommittee would also like to propose NOP Guidance for Certifying Agents and Industry on how to calculate and verify the use and allowance of synthetic MET expressed as a maximum average pounds per ton of 100% synthetic methionine in the diet over the life of the bird.

### **Introduction**

The current organic standards allow for the use of synthetic MET for use only in organic poultry production at the following maximum levels of synthetic MET per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.

The allowed rates represent “step down” levels that were recommended by NOSB in April 2010, codified in a final rule on September 19, 2012, and went into effect on October 2, 2012.

NOSB recommended the step down rates in order to balance various interests including: (i) Providing for the basic maintenance requirements of organic poultry; (ii) satisfying consumer preference to reduce the use of synthetic MET in organic poultry production; and (iii) motivating the organic poultry industry to continue the pursuit of commercially sufficient sources of allowable natural sources of MET.

However, in the attempt to balance interests, the 2010 NOSB recommendation included an allowance for synthetic methionine expressed as a total maximum limit of pounds of MET per ton of feed, while the Methionine Task Force (MTF) July 2009 petition requested that methionine rates be expressed as an average over the life of the flock. The rates expressed as a maximum limit do not address MET demands when laying chicks first come into production.

In the NOP Proposed Rule published in the Federal Register on February 6, 2012, the NOP recognized that on April 8, 2011, the MTF submitted a new petition for revised maximum allowable levels of synthetic MET expressed as an average per ton of feed over the life of the bird as originally requested in the 2009 petition. As stated in the preamble to the Proposed Rule:

“The NOP anticipates that the NOSB will consider this petition at a future meeting. In the meantime, the NOP believes it is necessary to move forward issuing this proposed rule to address the April 2010 NOSB recommendation. This is necessary to prevent any gap in the

allowance of synthetic methionine in the diets of organic poultry due to the current expiration date of October 1, 2012.” – (Federal Register/Vol. 77, No. 24/Monday, February 6, 2012 pg. 5719).

This NOSB proposal addresses the petition submitted by the MTF on April 8, 2011.

## **Background**

MET is classified as an essential amino acid because it cannot be biologically produced by poultry and is necessary to maintain viability. MET is required for proper cell development and feathering in poultry. Natural feed sources with a high percentage of MET include blood meal, fish meal, crab meal, corn gluten meal, alfalfa meal, and sunflower seed meal. Synthetic MET is also used in poultry feed. This substance is a colorless or white crystalline powder that is soluble in water. It is regulated as an animal feed nutritional supplement by the Food and Drug Administration (21 CFR 582.5475).

The NOSB initiated a review of this substance in 1999, as a result of a petition requesting to add synthetic Met to the National List for poultry. In 2001, the NOSB evaluated a technical advisory panel analysis of MET against the criteria provided in the OFPA (7 U.S.C. 6517–6518), and determined that the use of synthetic MET feed supplementation is compatible with a system of organic poultry production. Consistent with the NOSB’s recommendation, the Secretary amended § 205.603 of the National List on October 31, 2003, to allow MET as a synthetic substance for use in organic poultry production until October 21, 2005 (68 FR 61987).

Based upon subsequent NOSB recommendations in March 2005 and May 2008, the Secretary amended the listing for MET to continue the use through October 21, 2008 (70 FR 61217), and again through October 1, 2010 (73 FR 54057). The 2005 and 2008 NOSB recommendations to continue the allowance for MET were informed by updates on the development of allowable natural alternatives, none of which had attained commercial viability. While expressing a strong preference for supplementation with allowable natural sources of MET, the NOSB concluded that terminating the allowance for synthetic MET would disrupt the well-established organic poultry market, and cause substantial economic harm to organic poultry producers. The NOSB and stakeholders agreed that the organic feed sector would continue to research and develop sufficient supplies of allowable organic and natural sources.

On July 31, 2009, the MTF, which is comprised of organic poultry producers, submitted a new petition requesting to extend the allowance for synthetic MET for five years until October 2014. In addition, the MTF proposed that the total amount of synthetic MET in the diet remain below the following levels, calculated as the average pounds per ton of 100% synthetic MET over the life of the bird:

Laying chickens—4 pounds; broiler chickens— 5 pounds; and, turkey and all other poultry—6 pounds.

In consideration of the July 2009 petition and public comments, the NOSB issued two recommendations on April 29, 2010. These recommendations acknowledged a need for the continued allowance of synthetic MET, and conveyed the intent to decrease the amount of synthetic MET allowed in organic poultry production and encourage development of natural alternatives. One recommendation proposed to allow synthetic MET in organic poultry production until October 1, 2012, at the following maximum levels per ton of feed:

Laying chickens—4 pounds; broiler chickens—5 pounds; and turkey and all other poultry—6 pounds.

The NOP codified this recommendation through a National List amendment published in the **Federal Register** on August 24, 2010 (75 FR 51919), and reaffirmed on March 14, 2011 (76 FR 13501).

The second NOSB recommendation from April 2010 proposed reduced maximum levels of synthetic MET after October 1, 2015. The NOSB recommended that the annotation or synthetic MET be revised to read:

For use only in organic poultry after October 1, 2012, at the following maximum levels per ton: laying and broiler chickens—2 pounds per ton; turkeys and all other poultry—3 pounds per ton.

The NOP issued a proposed rule in the Federal Register to amend the National List to reflect the 2010 recommendation on February 6, 2012 followed by a final rule published in the Federal Register on September 19, 2012:

DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds

The amended listing removed the expiration date of 2012 and subjected synthetic MET at rates listed above to review within five years in accordance with the OFPA provision for the sunset of National List substances (7 U.S.C 6517(e)). Synthetic MET is now subject to a sunset review by the NOSB by 2017.

### **Relevant areas in the Rule**

**7 CFR §205.603(d)(1)** - Synthetic substances allowed for use in organic livestock production. As feed additives.

### **Discussion**

Much is known about the nutritional needs of poultry and the feedstuffs available to poultry producers. The dietary demand for total MET declines with age for broilers and turkeys, while there is a decline during the early stages of pullet development, it increases just before laying begins and trails off as the birds age. The current proposal is somewhat of an estimate of the average demand for each class of birds based on the demand charts. Producers are feeding additional levels of protein, commonly soybean meal, to their birds in an attempt to meet the MET needs of the birds. This in effect is over feeding numerous amino acids in order to get enough MET into the birds. During the winter months, the birds would consume enough feed to meet their needs, but the additional protein in the feed was excreted into the barns causing ammonia levels to rise and blisters on the bird's feet. During the summer months, the birds naturally consume less feed as their nutritional maintenance requirement is lower, they cannot consume enough feed to meet the necessary level of MET. Producers and certifiers are seeing an increase in feather pecking which can lead to cannibalism, agitation and nervousness and other behavioral issues. This behavior change is an animal welfare issue and the organic

producers fail to understand why a logical solution cannot be adopted. If the rations could be tailored to the needs of the animal, why would the organic regulations prevent them from doing the right thing for the bird, especially if the overall intake would be at or below the allowed maximum over the course of its life.

Previous NOSB deliberations have discussed alternative sources for synthetic MET. The MTF has invested lots of time and money seeking viable alternatives for their industry in an effort to meet consumer expectations. High MET corn has production and yield issues. Corn variety trials are ongoing with the hopes this breeding work will be able to develop varieties that supply the appropriate amount of necessary amino acids. Pasture may provide some supplementation during the right conditions, but is certainly not a dependable solution. Other feed grains may have higher MET levels than corn, but have lower overall protein or may be limiting in other amino acids which makes them improbable solutions. The EU uses corn gluten meal to balance the MET demand since synthetic MET is not allowed, but 5% of their rations do not have to be organic. Organic corn gluten meal is not available to US producers. Fish meal and crab meal are used by some organic producers, while others are concerned about off flavors, and the availability is very low as most of these products are stabilized for transport with non-compliant stabilizers. Many organic consumers are looking for vegetarian based production systems as well. The NOSB Livestock Subcommittee put forth a discussion document on feeding animal byproducts to poultry as an alternative source of MET and while there was a minority that agreed with the proposal, the majority deemed that organic principles would be compromised. Because there is so much interest to find an alternative to synthetic MET for organic producers, numerous projects around the world are evaluating herbal and insect based sources. Because of the need for U.S. Food and Drug Administration (FDA) approval, these will be many years out if determined to be suitable alternatives.

Under this proposal, producers will have an increased liability to document feeding rates to document compliance with the regulation. Certifiers will have to develop tracking systems with producers and their feed mills to verify compliance. Larger poultry operations change the rations frequently to keep cost down by only feeding to meet the bird's needs. These operations will have detailed records on flock age, size, and feed rations fed on a daily basis. It will be somewhat complicated if a pullet flock is transferred to another farmer for egg production, who is with another certifier. All the feed documentation will have to follow as well. Smaller operations often feed the same ration throughout the life cycle of the bird and therefore would never feed more than the average. Certifiers have indicated that mechanisms can be developed with their clients, suitable to verify compliance with the regulation. They are in part motivated by the behavioral issues being reported by their inspectors during this first season under the new cap. The NOP may need to issue Guidance Documents or Instructions to certifiers to clarify how verification can be obtained. Certifiers affiliated with the Accredited Certifiers Association (ACA) often work together and help each other gain consistency in areas like this. This could also be a part of the annual training for certifiers conducted by the NOP and ACA.

The NOSB Livestock Subcommittee is unsure of how certifiers will handle a situation if the flock goes out of production prior to the average being below the regulatory cap. We are uncertain as to whether this would be a noncompliance that must not be repeated or a willful violation indicating civil penalties.

Calculating MET allowances average over the life of the flock, will result in the following:

- Feed rations can better adjust to the naturally changing demands of the bird. Poultry farmers will have more flexibility to appropriate adjust diets for stage of life, seasonality, breed, etc.;

- Overall usage of MET will be lowered. Producers can only add MET to the average cap, not consistently add MET at the maximum rate;
- Farmers and nutritionists will still be only marginally capable of meeting the bird's basic needs. The organic poultry industry will continue to have a tremendous incentive to actively evaluate novel sources of MET. With continued research and the development of effective alternatives proven to meet the demands of the organic poultry sector, the NOSB Livestock Subcommittee believes that MET can eventually be eliminated from organic production.

### **Current listing on the National List:**

DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.

The regulations currently express a total maximum limit of pounds of MET per ton of feed. Consistent with the petition from July 2009 and April 2011, this proposal requests that MET rates be expressed as an average per ton of feed over the life of the flock.

### **Recommended Committee Action & Vote**

Motion to accept the following amendment at §205.603(d): DL–Methionine, DL–Methionine—hydroxy analog, and DL–Methionine—hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9) -for use only in organic poultry production at the following maximum average pounds per ton of 100% synthetic methionine in the diet over the life of the flock: Laying and broiler chickens – 2 pounds; Turkeys and all other poultry – 3 pounds.

Motion by: Mac Stone

Seconded by: Francis Thicke

Yes: 7 No: 0 Abstain: 0 Absent: 2 Recuse: 0

### **Further Clarification of the Proposed Amendment**

Under this recommendation, producers would be able to exceed the above levels on a particular formulation, provided that there was an offsetting formulation below the level, such that the average inclusion rate of 100% synthetic MET over the entire life cycle of the flock was below the allowed maximum level.

Reference is specifically made to 100% synthetic MET, as some forms of synthetic MET (e.g. the liquid form Alimet) are not 100% MET. The maximum pounds as shown above is based on the 100% synthetic MET equivalent so that a consistent standard can be applied to all organic operations, irrespective of the form of MET they are using (e.g. wet vs. dry).

**Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB August 20, 2013**



**National Organic Standards Board  
Livestock Subcommittee  
Petitioned Material Checklist  
Acidified Sodium Chlorite (ASC) Proposal**

**August 20, 2013**

**Summary of Proposed Action:**

**Evaluation Criteria (see attached checklist for criteria in each category)**

	<b>Criteria Satisfied?</b>		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

**Substance Fails Criteria Category: 2**

**Comments:**

Acidified Sodium Chlorite (ASC) was petitioned for use as a pre and post teat dip treatment in organic livestock production. ASC is currently allowed on the national list as a disinfectant for direct food contact under 205.605(b). After carefully reviewing the petition, along with the Technical Evaluation Report prepared for the committee in 2013, we have found that this material generally satisfies the criteria related to impact on humans and the environment, along with general compatibility and consistency with organic principles. However, the TR notes that a number of functional alternative substances are available, and the committee's research and outreach to producers confirms that many substances are already used as mastitis-preventing teat dips. Accordingly, the essentiality criteria are not met, and the committee does not recommend the addition of ASC to the national list as a teat dip.

**Subcommittee Action & Vote**

**Classification Motion:** Motion to classify Acidified Sodium Chlorite (CAS # 7758-19-2 (sodium chlorite) and CAS # 14998-27-7 (chlorous acid)) as synthetic.

Motion by: Joe Dickson

Seconded by: Colehour Bondera

Yes: 8 No: 0 Absent: 1 Abstain: 0 Recuse: 0

**Listing Motion:** Motion to list Acidified Sodium Chlorite(CAS #s 13898-47-0 (Chlorous Acid), 7758-19-2 (Sodium Chlorite)) to section 205.603(a) and 205.603(b) of the National List annotated as follows: Acidified Sodium Chlorite, Allowed for use on organic livestock as a pre and post teat dip treatment, acidified with lactic acid or other GRAS acid.

Motion by: Joe Dickson

Seconded by: Colehour Bondera

Yes: 0 No: 8 Abstain: 0 Absent: 1 Recuse: 0

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

**Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB August 20, 2013**

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 1. Adverse impacts on humans or the environment? Acidified Sodium Chlorite**

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments/Documentation (TAP; petition; regulatory agency; other)</b>
1. Is there a probability of environmental contamination during use or misuse,? [§6518(m)(3)]		x		Risk is minimal. TR page 9, lines 359-369.
2. Is there a probability of environmental contamination during manufacture or disposal? [§6518(m)(3)]		x		TR page 9, lines 359-390.
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		x		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		x		Breakdown products are citric acid, salt and water (2009 handling recommendation).
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		x		When used as petitioned, SCA and its components exhibit minimal likelihood of persistence in the environment. TR page 7 lines 296-298.
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		x		"When used as petitioned, acidified sodium chlorite and its component chemicals exhibit minimal likelihood of persistence or accumulation in the environment." TR page 10, lines 436-428. The material is both GRAS and on the USDA National List for handling.
8. Are there adverse biological and chemical interactions in the agroecosystem, including biodiversity? [§6518(m)(5)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.
9. Are there detrimental physiological effects on soil organisms, crop- s, or livestock? [§6518(m)(5)]		x		As petitioned, substance does not interact with the agroecosystem. TR page 10 lines 410-411.

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 2. Is the Substance Essential for Organic Production: Acidified Sodium Chlorite**

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments/Documentation (TAP; petition; regulatory agency; other)</b>
1. Is the substance agricultural? [§6502(1)]		x		TR page 7, lines 280-293.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	x			TR page 6, lines 222-279
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]		x		The substance is synthetically produced. TR page 7, lines 280-293.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		x		The substance is synthetically produced. TR page 7, lines 280-293.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]		x		TR page 7.
6. Is there an organic substitute? [§205.600(b)(1)]		x		There are a limited number of organic or natural substances that are appropriate substitutes. Nisin, a natural material that may be a substitute, is not authorized for use as a teat dip due to earlier rejection by NOSB as an antibiotic . A number of essential oils and organic acids may also be used as teat dips. TR page 11, lines 542-547
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	x	x		See above.
8. Are there any alternative substances? [§6518(m)(6)]	x			The TR also suggests that a number of alternative substances, including iodine, alcohols, chlorine materials, hydrogen peroxide, chlorhexadine and certain essential oils may function as alternatives.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		x		Teat dips are critical in commercial dairy production to prevent mastitis. TR page 12.

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 3. Is the substance compatible with organic production practices? Acidified Sodium Chlorite**

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments/Documentation (TAP; petition; regulatory agency; other)</b>
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	x			TR, petition. Substance is already allowed for use in handling in direct food contact.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	x			
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			x	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			x	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			x	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);		x		TR page 6, lines 210-221
copper and sulfur compounds				
toxins derived from bacteria		x		TR page 6, lines 210-221
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		x		TR page 6, lines 210-221
livestock parasiticides and medicines		x		TR page 6, lines 210-221
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		x		TR page 6, lines 210-221

**National Organic Standards Board  
Livestock Subcommittee  
Petitioned Material Proposal  
Chlorine Materials in Aquatic Livestock Production**

**August 20, 2013**

**Summary of Proposed Action:**

Chlorine Materials are petitioned for use in aquatic livestock production, to be added to 205.611 - *Synthetic substances allowed for use in organic aquatic animal production* as follows:

(x) Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except*, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite)

- (i) Calcium hypochlorite.
- (ii) Chlorine dioxide
- (iii) Sodium hypochlorite

Chlorine materials are widely used for their disinfectant properties, and are currently approved for such uses in crop, livestock and processed organic product production. Annotations for each listing limit the use of chlorine materials to disinfection and sanitation, and require that residual chlorine levels be consistent with Safe Drinking Water Act levels. The Livestock Subcommittee has received a petition for the use of Chlorine Materials in aquatic livestock production. These materials are used in aquatic animal production for the disinfecting hard surfaces and culture water in nurseries, growout operations with tanks, harvest and slaughter equipment, and in processing facilities. Given that the materials' use in aquaculture applications is identical to existing uses in other production categories, the committee has not requested a new Technical Evaluation Report, but it is instead relying on recent TR's developed for Handling and Crops uses of this group of materials.

**Evaluation Criteria**

(Applicability noted for each category; Documentation attached)

1. Impact on Humans and Environment
2. Essential & Availability Criteria
3. Compatibility & Consistency  
as Organic (only for § 205.606)

**Criteria Satisfied?**

X Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
X Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
X Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

**Proposed Annotation (if any):** see listing motion below

**Basis for annotation:** X To meet criteria above  Other regulatory criteria  Citation

Notes: This annotation is consistent with other listings of Chlorine on the NL, and ensures that any environmental impact is effectively mitigated.

**Recommended Subcommittee Action & Vote**, including classification recommendation (state actual motion):

**Classification Motion:** Chlorine Materials (Calcium hypochlorite, chlorine dioxide, sodium hypochlorite) are synthetic.

Motion by: Joe Dickson

Seconded by: Jean Richardson

Yes: 9 No: 0 Absent: 0 Abstain: 0 Recuse: 0

**Listing Motion:** Motion to add chlorine materials (Calcium hypochlorite, chlorine dioxide, sodium hypochlorite) to §205.611 with the following annotation: Chlorine materials - Disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water in direct animal contact (for

example, culture water) shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.

Motion by: Joe Dickson

Seconded by: Tracy Favre

Yes: 5 No: 1 Abstain: 1 Absent: 2 Recuse: 0

**Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB August 20, 2013**

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

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

**Substance: Chlorine Materials**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]		X		2006 Crops TR lines 212-266. The TR identifies several areas of potential environmental impact, but notes that existing EPA regulations and the annotation restricting effluent to the levels of the Safe Drinking Water Act are sufficient to mitigate any environmental impact. The petitioner and a number of producers have confirmed that chlorine materials are not used in direct contact with the environment (e.g. ponds and net pens) and the restrictive annotation would prohibit such uses regardless. Should any doubt persist about this issue, we could consider including a targeted question in the recommendation to elicit technical responses from the sector.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		See Question 1
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517(c)(1)(B)(ii)]		X		No. [2006 Crops TR]
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		The annotation restricts use to levels no greater than those determined by the Safe Drinking Water Act, so the potential for detrimental chemical interaction is similar to that posed by municipal tap water.
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		The annotation restricts use to levels no greater than those determined by the Safe Drinking Water Act, so the potential for detrimental chemical interaction is similar to that posed by municipal tap water. Any presence of the substance in

			the overall agroecosystem would be required by the annotation to meet the requirements of the Safe Drinking Water Act, ensuring presence below 4 ppm.
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X	No. The substance degrades rapidly to naturally occurring compounds in the presence of air and sunlight [2006 Crops TR 417-432] This TR also confirms (in lines 384 –402) that these materials are not persistent in the environment in general, and that in water and soil, sodium and calcium hypochlorite separate into sodium, calcium and hypochlorite ions. Chlorine dioxide is also reactive and breaks down quickly. While the TER does not directly address its fate in aquatic environments, again, the annotation would limit the extent to which any chlorine material could be discharged into sea water or any other part of the environment.
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X	See Q # 1
8. Are there adverse biological and chemical interactions in the agroecosystem, including biodiversity? [§6518(m)(5)]		X	Any presence of the substance in the overall agroecosystem would be required by the annotation to meet the requirements of the Safe Drinking Water Act, ensuring presence below 4 ppm.
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X	The substance is not used in direct contact with soil or terrestrial livestock. It is only used in contact with hard surfaces and equipment, or culture water. [2006 Crops TR 322-327, petition]

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 2. Is the Substance Essential for Organic Production?      Substance: Chlorine Materials**

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments/Documentation (TAP; petition; regulatory agency; other)</b>
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Yes. 2006 TR Lines 149-171
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]			X	This process does not involve the chemical transformation of a natural substance; the starting materials are synthetic. 2006 TR Lines 177-178
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		2006 TR Lines 183-184
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	2006 TR Lines 183-184
6. Is there an organic substitute? [§205.600(b)(1)]			X	2006 TR Lines 183-184
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		Petition page 7-8 (notes the limitations on alternative materials) and 2011 Crops TER page 12.
8. Are there any alternative substances? [§6518(m)(6)]		X		
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 3. Is the substance compatible with organic production practices? Substance: Chlorine Materials**

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



**National Organic Standards Board  
Livestock Subcommittee  
Petitioned Material Proposal  
Tocopherols Aquaculture  
August 22, 2013**

**Summary of Proposed Action**

Tocopherols were petitioned in 2012 by the Aquaculture Working Group for use in aquaculture livestock production. Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species. Rich sources of naturally-occurring tocopherols include cereal grains, oilseeds, nuts, and vegetables (Burdock, 1997). The term “tocopherols” refers to structurally similar compounds that occur in nature in four forms: alpha-, beta-, gamma-, and delta-tocopherol (CIR, 2002). Tocopherols that are derived from plant products are often referred to as “mixed tocopherols” because the mixture contains all four forms of tocopherol (CIR, 2002). (TR lines 37-41) Per the petition, Tocopherols are intended to be used in organic aquaculture as an antioxidant added to aquatic animal feed (Aquaculture Working Group, 2012). Tocopherols are mixed with fish oil, fishmeal, and other feed ingredients to prevent oxidation of the polyunsaturated fatty acids present in the lipids and thereby protect the nutritional value of the feed. Polyunsaturated fatty acids are very susceptible to autoxidation when exposed to oxygen in the atmosphere (Tacon, 1992). During the process of lipid autoxidation, toxic degradation products are formed in the feed that may cause pathological changes in the fish (Hardy and Roley, 2000). Furthermore, oxidation destroys essential fatty acids in the feed, and consuming oxidized lipids may have deleterious effects on tissue levels of vitamins C and E. Finally, oxidation of the lipids in fish meal generates heat that is sometime sufficient to cause spontaneous combustion of feeds (Hardy and Roley, 2000).

Synthetic tocopherols are currently permitted for specific uses in organic livestock production and organic handling. Tocopherols are not specifically named in the National List as synthetic feed additives allowed for use in organic livestock production. However, mixed tocopherols are a source of vitamin E. Vitamins (used for enrichment or fortification when FDA approved) are included on the National List as synthetic ingredients allowed as feed additives in organic livestock production (7 CFR 205.603[d][3]). Tocopherols derived from vegetable oil are allowed for use as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group[s])” when rosemary extracts are not a suitable alternative (7 CFR 205.605[b])(TR lines 26-32).

Tocopherols are also affirmed as GRAS by the FDA when used as chemical preservatives (21 CFR 582.3890) and nutrients and/or dietary supplements (21 CFR 582.5890) in animal feeds in accordance with good manufacturing or feeding practice. No sources were identified that discuss any negative effects of tocopherols on biological or chemical interactions in the aquatic agro-ecosystem, including nontarget aquatic organisms, physical water conditions, endangered species, or biodiversity. TR lines 464-466. “Tocopherols are currently permitted by Canadian, European, and Japanese Organic Standards, IFOAM and CODEX, although they may not specifically be permitted as antioxidants in livestock feed production.

Since, at the time of this checklist there are no rules or policy standards for aquaculture, we believe that once the definitions for closed and open systems in organic aquaculture are defined, this material should be reviewed with an eye to whether it is appropriate for both open and closed systems. The Livestock Subcommittee wants to stress the importance of limiting the use of synthetic ingredients in organic aquaculture. We recognize that synthetic inputs may be needed to tweak the system or to respond to unusual situations. However, in order to be consistent with organic regulations, synthetic inputs cannot be the norm.

**Evaluation Criteria (see attached checklist for criteria in each category)**

1. Impact on Humans and Environment
2. Essential & Availability Criteria
3. Compatibility & Consistency

**Criteria Satisfied?**

X Yes  No  N/A  
X Yes  No  N/A  
X Yes  No  N/A

**Substance Fails Criteria Category:** None

**Subcommittee Action & Vote**

**Classification Motion:** Move to classify tocopherols, as petitioned, as synthetic.

Motion by: Tracy Favre

Seconded by: Colehour Bondera

Yes: 9 No: 0 Absent: 0 Abstain: 0 Recuse: 0

**Listing Motion:** Move to list tocopherols on section 205.611 of the National List for use in aquatic livestock production with the following annotation: Tocopherols derived from vegetable oils, not extracted using volatile synthetic solvents, are allowed as ingredients in aquatic livestock production when rosemary extracts are not a suitable alternative.

Motion by: Tracy Favre

Seconded by: Colehour Bondera

Yes: 9 No: 0 Absent: 0 Abstain: 0 Recuse: 0

**Proposed Annotation (if any):** See above

**Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB August 27, 2013**

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

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

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments/Documentation (TAP; petition; regulatory agency; other)</b>
1. Is there a probability of environmental contamination during, use or misuse? [§6518(m)(3)]	X	X		If solvents used in the manufacturing are released into the environment through waste streams, environmental contamination could occur. However, no sources were identified that discussed environmental contamination resulting from the manufacturing of tocopherols. (TR lines 498-501)
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X	X		The extraction of tocopherols from vegetable oil byproducts may include one or more of the following chemical processes: esterification, saponification, solvent extraction, and/or crystallization using a solvent (see the response to Evaluation Question #2). Physical separation methods may also be used during the extraction of tocopherols, and these include various distillation steps. Solvents used include: hexane, ethanol, isopropanol, acetone, isopentane, isohexane, and trichloroethylene (TR lines 282-284). Made from a byproduct of vegetable oil refining (oils of soybean, canola, sunflower, corn, and cottonseed, some of which are probably genetically engineered) (TR lines 289-292).
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]		X		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		TR lines 451-450.
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X			Excessive intake of tocopherols above the vitamin E requirement of fish could result in hypervitaminosis E, a condition of high storage levels of the vitamin in the fish which could result in toxic symptoms such as poor growth, toxic liver reaction, and death (De Silva et al., 2012; Halver, 2002) (TR lines 480-483).
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X			Tocopherols exert their antioxidant properties by reacting with free radicals, so they are unlikely to persist. Oxidized

				tocopherols can be recycled in the presence of other antioxidants, however, and some of the metabolites of tocopherols can be toxic. <sup>1</sup>
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		See TR lines 393-439. The tocopherol level found in the flesh of a fish is related to the fish's total dietary intake of tocopherols (Sargent et al., 2002). The use of tocopherols as an antioxidant or vitamin supplement in aquatic animal feed will possibly increase tocopherol levels in those fish that consume the feed, with unknown effects on the human consumer (TR lines 522-524).  No sources were identified that discuss adverse effects upon human health from the use of tocopherols as an antioxidant in aquatic or terrestrial animal feed. It is unlikely that the use of tocopherols as an antioxidant in aquatic animal feed would be harmful to human health. TR lines 509-511
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		X		No sources were identified that discuss any negative effects of tocopherols on biological or chemical interactions in the aquatic agro-ecosystem, including nontarget aquatic organisms, physical water conditions, endangered species, or biodiversity. TR lines 464-466.
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]			X	

<sup>1</sup> Aalt Bast and Guido R.M.M. Haenen, 2002. The toxicity of antioxidants and their metabolites. Environmental Toxicology and Pharmacology 11 (2002) 251-258.

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 2. Is the Substance Essential for Organic Production? Substance: Tocopherols**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			<p>TR lines 276-369.</p> <p>The 1995 Technical Advisory Panel (TAP) Report for Tocopherols, which reviewed the use of tocopherols as a food antioxidant, states that tocopherols are made via vacuum steam distillation of edible vegetable oil products (NOSB, 1995). TR lines 285-287</p>
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			<p>TR lines 276-369. Synthetics are added in extraction process.</p> <p>All of the methods found in the literature involve chemical processes. At the end of the process used to extract and purify tocopherols, the compounds remain in the same form as in the naturally occurring source materials. (TR lines 320-322)</p> <p>The petitioner provided a material safety data sheet (MSDS) for a product called Naturox® IPO Liquid (Kemin Industries, Inc.) which lists organic sunflower oil, lecithin, and rosemary extract as components of the mixed tocopherols formulation (Kemin Industries, Inc., 2008). The Joint Expert Committee on Food Additives (JECFA) specification for the food additive “mixed tocopherols concentrate” states that it may contain an edible vegetable oil added to adjust the required amount of total tocopherols (JECFA, 2006). Powdered forms of mixed tocopherols contain a carrier such as tapioca starch, gum acacia, and/or maltodextrin (Organic Technologies, 2009; NOSB, 1995). No additional sources were found that discuss possible additives to commercially-produced tocopherols for use as antioxidants in food or feed, including aquaculture feed products. (TR lines 55-63)</p>
4. Is the substance created by naturally	X	X		Naturally occurring tocopherols exist. But

occurring biological processes? [§6502(21)]				the petition is for synthetic tocopherols.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	Tocopherols are a group of lipophilic phenolic antioxidants that occur naturally in a variety of plant species. Rich sources of naturally-occurring tocopherols include cereal grains, oilseeds, nuts, and vegetables (Burdock, 1997). The term “tocopherols” refers to structurally similar compounds that occur in nature in four forms: alpha-, beta-, gamma-, and delta-tocopherol (CIR, 2002). Tocopherols that are derived from plant products are often referred to as “mixed tocopherols” because the mixture contains all four forms of tocopherol (CIR, 2002). (TR lines 37-41)
6. Is there an organic substitute? [§205.600(b)(1)]	X			Organic Rosemary oil may work in some applications.
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X			Rosemary extract, lecithin, vitamin C, natural sources of vitamin E (eg, wheat germ oil), and others (TR lines 531-583).
8. Are there any alternative substances? [§6518(m)(6)]	X			TR lines 575-583.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			Feeding live food, but whether or not this is practical is unknown.

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 3. Is the substance compatible with organic production practices? Substance:  
Tocopherols**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X	X		Synthetic tocopherols are currently permitted for specific uses in organic livestock production and organic handling. Tocopherols are not specifically named in the National List as synthetic feed additives allowed for use in organic livestock production. However, mixed tocopherols are a source of vitamin E. Vitamins (used for enrichment or fortification when FDA approved) are included on the National List as synthetic ingredients allowed as feed additives in organic livestock production (7 CFR 205.603[d][3]). Tocopherols derived from vegetable oil are allowed for use as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group[s])” when rosemary extracts are not a suitable alternative (7 CFR 205.605[b])(TR lines 26-32). Inconsistent with use of vitamins in terrestrial animals, where they are restricted to use for, “enrichment or fortification when FDA approved.” Synthetic preservative.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X	X		“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” (NOSB Principles of Organic Production and Handling).
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			Tocopherols are mixed with fish oil, fish meal, and other feed ingredients to prevent oxidation of the polyunsaturated fatty acids present in the lipids and thereby protect the nutritional value of the feed. Polyunsaturated fatty acids are very susceptible to autoxidation when exposed to oxygen in the atmosphere (Tacon, 1992). During the process of lipid autoxidation, toxic degradation products are formed in the feed that may cause pathological changes in the fish

				(Hardy and Roley, 2000). (TR lines 99-105) Furthermore, oxidation destroys essential fatty acids in the feed, and consuming oxidized lipids may have deleterious effects on tissue levels of vitamins C and E.
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]	X			Oxidation of the lipids in fish meal generates heat that is sometime sufficient to cause spontaneous combustion of feeds (Hardy and Roley, 2000). (TR lines 107-109) Tocopherols are used to stabilize fishmeal and are required under law if fishmeal is to be transported.
5. If used in livestock feed or pet food, is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]		X		See comments at Item 3 above.
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);		X		
copper and sulfur compounds				
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		

**National Organic Standards Board  
Livestock Subcommittee  
Petitioned Material Proposal  
Vitamins in Organic Aquatic Animals Production**

**June 17, 2013**

**Summary of Proposed Action:**

The use of synthetic vitamins in organic aquatic animal production was petitioned by the Aquaculture Working Group (AWG). The National Organic Program (NOP) allows the use of vitamins in organic livestock production as feed additives, under §205.603(d)(3) as "Vitamins, used for enrichment or fortification when FDA approved."

Vitamins are essential for animals raised on land or in water. Natural vitamins are found in sources that include fish, fish oils, green leafy vegetables, soybean, and many livestock by-products. The commercial availability is a major impediment and concern. Synthetic vitamins can be processed via chemical and fermentation methods.

The use of synthetic vitamins should help reduce the harvesting of our fish populations worldwide. As our fish population declines, its can have a negative impact on individuals of various communities, countries, and cultures.

Most of the major standards for organic aquaculture allow the use of synthetic vitamins. These included the Canadian General Standards Board, European Economic Community Council (EEC), United Kingdom Soil Association Standards, Codex Alimentarius, International Federation of Organic Agricultural Movements (IFOAM). In the United States, synthetic vitamins are NOP approved for use in land-based livestock production. For consistency, the allowance for synthetic vitamins is fair and balance approach for meeting the essential nutrient demand of vitamins in aquatic animal diets, until viable non-synthetic vitamins sources are in the market place.

The Livestock Subcommittee has received a petition for the use of synthetic vitamins in aquatic animals feed on January 6, 2012. A Technical Report (TR) was requested by the subcommittee. The TR provided new and helpful information for the LSC and full NOSB to consider in the evaluation of synthetic vitamins in aquatic animals diets.

**Evaluation Criteria (see attached checklist for criteria in each category)**

	<b>Criteria Satisfied?</b>		
1. Impact on Humans and Environment	X Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	X Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	X Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

**Substance Fails Criteria Category:** None      **Comments:** No criteria category failed.

**Subcommittee Action & Vote**

**Classification Motion:** Move to classify vitamins as petitioned for aquatic animals as synthetic

Motion by: Jean Richardson

Seconded by: C. Reuben Walker

Yes: 9 No: 0 Absent: 0 Abstain: 0 Recuse: 0

**Listing Motion:** Move to list vitamins as petitioned for aquatic animals on section 205.611 of the National List

Motion by: C. Reuben Walker

Seconded by: Mac Stone

Yes: 9 No: 0 Absent: 0 Abstain: 0 Recuse: 0

Proposed Annotation (if any): None

Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB June 17, 2013

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 1. Adverse impacts on humans or the environment? Substance: Vitamins for Aquatic Animals**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]	X	X		Environmental contamination could possibly occur; however, the risks are low when manufacturers exercise good standard operating procedures for vitamins production, use, and disposal.  [See 2013 Vitamins for Aquatic Animals TR, pgs. 19-24]
2. Is there a probability of environmental contamination during manufacture or disposal? [§6518(m)(3)]	X	X		The environmental risks are low when manufacturers exercise good standard operating procedures.  [See 2013 Vitamins for Aquatic Animals TR, pgs. 19-24]
3. Does the substance contain inerts classified by EPA as “inerts of toxicological concern?” [§6517(c)(1)(B)(ii)]		X		According to the 2013 Vitamins for Aquatic Animals TR, pg. 24) it is unlikely that any of the petitioned vitamins would cause bioaccumulation in aquatic life. Practicing good aquatic animal husbandry practices for feeding intervals and volumes are approaches to mitigate potential harm to the environment and biodiversity.  [See 2013 Vitamins for Aquatic Animals TR, pg. 24]
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		Most of the chemical interactions of vitamins occur inside the aquatic animal body. The proper incorporation of the various vitamins in aquatic animals feed should bring about good health and negate or minimize any detrimental chemical interactions with other materials used.  [See 2013 Vitamins for Aquatic Animals TR, pgs. 22-23]
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]	X	X		See #3
6. Is there persistence or concentration of	X	X		

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
the material or breakdown products in the environment? [§6518(m)(2)]				See #3
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		No harmful effect is expected to result from the petitioned used (i.e. aquatic vitamin feed supplement).  [See 2013 Vitamins for Aquatic Animals TR, pgs. 24-25]
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		X		It is unlikely that adverse biological and chemical interactions in the agro-ecosystem environment would occur.  [See 2013 Vitamins for Aquatic Animals TR, pg. 23]
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		See #8

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 2. Is the Substance Essential for Organic Production? Substance: Vitamins for Aquatic Animals**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Vitamins can be produced using chemicals, fermentation, excluded method, or extraction from natural materials sources. [See 2013 Aquatic Animals TR, pgs. 13-19]. (7 CFR 205.105) prohibits certain excluded methods, including use of genetically modified organisms (GMO)  2008 NOSB aquaculture recommendation - 205.252(j) (6) prohibits the use of any GMO or any organism produced by any other excluded method
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			See #1
4. Is the substance created by naturally occurring biological processes?		X		See #1

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
[§6502(21)]				
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X	X		<p>There are natural sources such as forage fish, wild caught fish, shrimp, zooplankton and a combination plant-based and animal based feeds. The best source is fish meal. However, the availability and fragile commercial supply make is a major impediment in formulating fish diets.</p> <p>See 2013 Aquatic Animals TR, pgs. 28-29].</p>
6. Is there an organic substitute? [§205.600(b)(1)]	X	X		See #5
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X	X		See #5
8. Are there any alternative substances? [§6518(m)(6)]	X	X		<p>Vitamins are essential. Forage fish, wild caught fish, shrimp, zooplankton and a combination plant-based and animal based feeds.</p> <p>[See 2013 vitamins for Aquatic Animals TR, pgs. 28-29].</p>
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X	X		<p>See #8. However, the issue of commercially availability and viable alternatives are major impediments.</p> <p>[See 2013 Vitamins for Aquatic Animals TR, pgs. 28-29].</p>

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 3. Is the substance compatible with organic production practices? Substance: Vitamins for Aquatic Animals**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Synthetic vitamins are consistent with organic farming principles of several organic entities to include (1) European Union, (2) Canadian General Standards Board, (3) United Kingdom (UK) Soil Association, (4) IFOAM, and (5) Naturland Organics. [See 2013 Vitamins for Aquatic Animals TR, pgs. 11-13].
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			See #1.
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			
4. If used in livestock feed or pet food, is the primary use as a preservative? [§205.600(b)(4)]		X		
5. If used in livestock feed or pet food, is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]		X		
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i); copper and sulfur compounds		X		
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		



**National Organic Standards Board  
Livestock Subcommittee  
Petitioned Material Checklist  
Trace Minerals for Aquatic Animals Proposal**

**August 6, 2013**

**Summary of Proposed Action:**

The use of synthetic minerals in organic aquatic animal production was petitioned by the Aquaculture Working Group (AWG). The National Organic Program (NOP) allows the use of minerals in organic livestock production as feed additives, under §205.603(d)(2) as “Trace minerals, for enrichment or fortification when FDA approved.” The Technical Review (TR) was compiled by the Pesticide Research Institute for the USDA National Organic Program. The Livestock subcommittee determined that the TR is sufficient according to NOSB review criteria for TR’s.

Minerals are essential for animals raised on land or in water. Minerals, like carbohydrates, proteins, fats, and vitamins are foundational to good humane animal health. Natural minerals are found in sources that include fish, fish oils, green leafy vegetables, soybean, and many livestock by-products. The commercial availability is a major impediment and concern. Synthetic minerals are mainly produced by chemical methods.

Minerals are petitioned for enrichment and fortification, if FDA approved. The use petitioned is the same use currently used in organic livestock production. The use of petitioned minerals should help reduce the harvesting of our fish populations worldwide. As our fish population declines, its can have a negative impact on individuals of various communities, countries, and cultures.

All of the major standards for organic aquaculture or aquaculture allow the use of synthetic minerals. In the United States, synthetic minerals are NOP approved for use in land-based livestock production. For consistency, the allowance for synthetic minerals is a fair and balanced approach for meeting the essential nutrient demand of minerals in aquatic animal diets, until viable non-synthetic minerals sources are in the market place.

The Livestock Subcommittee has received a petition for the use of synthetic minerals in aquatic animals feed on January 6, 2012. A TR was requested by the LSC- Chair in early January, 2013. The TR was received on June 24, 2013. The TR provided helpful information for the LSC and NOSB to consider in the subcommittee and Board to evaluate as it pertains to synthetic minerals in aquatic animal production.

**Evaluation Criteria (see attached checklist for criteria in each category)**

	<b>Criteria Satisfied?</b>		
1. Impact on Humans and Environment	X Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	X Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	X Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

**Substance Fails Criteria Category: NA**

**Subcommittee Action & Vote**, including classification proposal (state actual motion):

**Classification Motion:** Move to classify trace minerals as petitioned for aquatic animals as synthetic

Motion by: C. Reuben Walker

Seconded by: Francis Thicke

Yes: 7 No: 0 Absent: 2 Abstain: 0 Recuse: 0

**Listing Motion:** Move to list trace minerals as petitioned for aquatic animals on section 205.611 of the National List

Motion by: Francis Thicke

Seconded by: C. Reuben Walker

Yes: 7 No: 0 Absent: 2 Abstain: 0 Recuse: 0

**Proposed Annotation (if any):** None

**Approved by Tracy Favre, Subcommittee Chair, to transmit to NOSB August 6, 2013**

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 1. Adverse impacts on humans or the environment? Substance: Trace Minerals for Aquatic Animals**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]	X	X		<p>“When used as petitioned, trace minerals from unconsumed feed pellets have the potential to persist in treated bodies of water, ground water, sediments and bioaccumulate in animal tissues.” But, “Overall, the risk of lethal effects from bioconcentration of the petitioned trace elements is considered to be low.”</p> <p>[See 2013 Trace Minerals TR, pgs. 15-16]</p>
2. Is there a probability of environmental contamination during manufacture or disposal? [§6518(m)(3)]	X	X		<p>Environmental contamination could possibly occur; however, the risks are low when manufacturers exercise good standard operating procedures for minerals production, use, and disposal.</p> <p>[See 2013 Trace Minerals TR, pgs. 18-19]</p>
3. Does the substance contain inerts classified by EPA as “inerts of toxicological concern?” [§6517 (c)(1)(B)(ii)]		X		<p>The petitioned minerals are not requested for use as a pesticide, thus by definition, trace minerals are not inerts.</p> <p>[See 2013 Trace Minerals TR, pg. 13]</p>
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		<p>No direct interaction between trace minerals and other aquatic animal feed additives were identified. The petitioned trace minerals are chemically equivalent to trace minerals that are used for fortification of organic livestock feed under 7 CFR 206.603.</p> <p>[See 2013 Trace Minerals TR, pgs. 19-20]</p>
5. Is there a toxic or other adverse action of				There is a wide range of potential toxicities

the material or its breakdown products? [§6518(m)(2)]	X	X	associated with the various trace minerals. However, comparison of (aquaculture) effluent concentrations to the aquatic toxicity ... and drinking water quality standards for each mineral points to a negligible potential for toxicity under the prescribed use of the substance.”  [See 2013 Trace Minerals TR, pgs. 16-17]
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]	X	X	According to the 2013 Aquatic Animal TR, pgs. 20-21) the potential may occur. The risk of lethal effects from bioconcentration of the petitioned trace elements is considered low.  [See 2013 Trace Minerals TR, pgs. 21-22]
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X	Environmental concentrations of trace minerals are unlikely to cause adverse health effects in humans.  [See 2013 Trace Minerals TR, pgs. 21-22]
8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		X	No reported toxicity has been observed in non-target wildlife or livestock. The authors believe that minerals are unlikely to exhibit toxicity toward the agro-system. Accidental release during production may lead to ecological impairment.  [See 2013 Trace Minerals TR, pg. 20]
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X	Trace elements are required by soil organisms, crops and livestock, so if the usage rates are kept within the requirements for aquatic animals, there should be no detrimental effects.

**NOSB Evaluation Criteria for Substances Added To the National List  
Livestock**

**Category 2. Is the Substance Essential for Organic Production? Substance: Trace Minerals for Aquatic Animals**

<b>Question</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Comments/Documentation (TAP; petition; regulatory agency; other)</b>
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			Minerals are primarily produced using chemical synthesis and extraction from either natural or reclaimed sources.  [2013 Trace Minerals TR, pgs. 13-15].
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			See #2
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		See #2
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X	X		There are natural sources -- fish meal being the best source -- but availability of those sources and the resource demands required to use them widely make them unrealistic sources of trace minerals.  [2013 Trace Minerals TR, pgs. 24-25].
6. Is there an organic substitute? [§205.600(b)(1)]	X	X		See #5
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X	X		See #5
8. Are there any alternative substances? [§6518(m)(6)]		X		Trace minerals are essential. Forage fish, wild caught fish, and shrimp are leading alternatives.  [See 2013 Trace Minerals TR, pgs. 24-25].
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]		X		Trace minerals are essential. The issue of commercially availability and viable alternatives are major impediments. [See 2013 Trace Minerals TR, pgs. 24-25].

## NOSB Evaluation Criteria for Substances Added To the National List

### Livestock

#### Category 3. Is the substance compatible with organic production practices? Substance: Trace Minerals for Aquatic Animals

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			Synthetic minerals are consistent with organic farming principles of several organic entities to include (1) European Union, (2) Canadian General Standards Board, (3) Codex Alimentarius, (4) Japan Ministry of Agriculture, Forestry, and Fisheries, (5) International Federation of Organic Agricultural Movements, and (6) NOP. [See 2013 Trace Mineral Aquatic Animals TR, pgs. 11-12].
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			See #1.
3. If used in livestock feed or pet food, is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			
4. If used in livestock feed or pet food, is the primary use as a preservative? [§205.600(b)(4)]		X		
5. If used in livestock feed or pet food, is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]		X		
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i); copper and sulfur compounds		X		
toxins derived from bacteria		X		
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals	X			
livestock parasiticides and medicines		X		
production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		



**National Organic Standards Board  
Compliance, Accreditation, and Certification Sub-Committee  
Discussion Document  
Voluntary Retail Certification Requirement Clarification and Guidance**

**August 13, 2013**

## **1. Introduction**

While the National Organic Standards and various National Organic Program (NOP) guidance resources are clear on the compliance expectations for growers, handlers, and livestock operators, the NOP's expectations are less clear for retail operators. Retail stores function not only as handlers of organic products, but also as purchasers, verifiers, and marketers of specific products and organic agriculture in general. In many cases, retail operations are exempt from the requirement for certification for handlers (7 CFR 205.101(a)(2)) and excluded from the certification requirement (205.101(b)(2)). However, this exclusion and exemption are not completely clear regarding the extent to which a retailer may handle and process products while still qualifying for the exemption and/or exclusion. Numerous retailers have become voluntarily certified as handlers, yet there are many areas where handling organic system plans (OSP) and operational expectations do not apply directly to retail operations, and the retail sector would benefit from clearer NOP guidance on its expectations for compliance for certified and non-certified retail operations. Finally, retailers who sell both organic and non-organic products, market their certification to consumers, often using the USDA seal. Retailers (along with other producers) need clear guidance on the use of the USDA Organic Seal and the "organic" claim in general, in the marketing of split operations.

The CAC Sub-Committee through this new discussion document is reaching out to the various organic stakeholders that are impacted by the 2009 NOSB guidance recommendation "Clarification of Marketing for Voluntary Retail Certification" and asking for their input as to what specific issues need more clarity to help with understanding and compliance. We would also like to solicit detailed information about any existing inconsistencies that could use more clarity to enable a more consistent process of review and accreditation by the various accredited certifying agents (ACAs), NOP, and ultimately the retailers themselves.

This is a very complex issue and it is the intent of the CAC Sub-Committee that after receiving feedback from the various stakeholders impacted by this discussion document, it can then move forward with an additional guidance recommendation for the National Organic Program. The intent is to attempt to accomplish this through education and outreach, in a way that can provide better clarification to assist the retailers and certifiers with a more clear and concise understanding of what is required of an organic retailer by the regulation.

## **2. Background**

In 2009, the NOSB approved a CACS Guidance Recommendation entitled "Clarification of Marketing for Voluntary Retail Certification." This recommendation presented general background on the exemptions allowed for retailers, and described a need for clearer guidance around the use of the USDA seal and the "organic" claim in the marketing of organic retail stores. The recommendation acknowledged that the phrase "Certified Organic Retailer" may be challenging to a consumer, and identified a need for clearer guidance around the use of this term.

The 2009 recommendation then identifies a number of specific certification areas where the NOP should provide clearer guidance in order to facilitate consistency and clarity among retail operators:

- Guidance on the use of the USDA seal in marketing certified retail operations.
- Clear and consistent guidelines for deli and bakery operations, identifying precisely under what conditions certification is required. Additional guidance on the ACAs' role in managing voluntary retail certification programs. Clarity on retailers' role in improving the marketing of voluntary retailer organic certification.

A number of the 2009 NOSB's recommendations remain unaddressed by the NOP. Given that the issues described in the earlier recommendation remain critical, we have updated that recommendation to include a number of additional concerns and requests.

### **3. Relevant Areas of the Rule**

#### **§ 205.100 What has to be certified.**

(a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

(b) Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation's next anniversary date of certification. Such recognition shall only be available to those operations certified by a certifying agent that receives its accreditation within 18 months from February 20, 2001.

(c) Any operation that:

(1) Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than 3.91(b)(1)(xxxvii) of this title per violation.

(2) Makes a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

#### **§ 205.101 Exemptions and exclusions from certification.**

(a) *Exemptions.*

(1) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of § 205.310. The products from such operations shall not be used as ingredients identified as organic in processed products produced by another handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from the requirements in this part.

(3) A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in this part, except:

- (i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;
- (ii) The labeling provisions of §§ 205.305 and 205.310; and
- (iii) The recordkeeping provisions in paragraph (c) of this section.

(4) A handling operation or portion of a handling operation that only identifies organic ingredients on the information panel is exempt from the requirements in this part, except:

- (i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;
- (ii) The labeling provisions of §§ 205.305 and 205.310; and
- (iii) The recordkeeping provisions in paragraph (c) of this section.

(b) *Exclusions.*

(1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272 with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:

- (i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and

(ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.

(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” is excluded from the requirements in this part, except:

(i) The requirements for the prevention of contact with prohibited substances as set forth in § 205.272; and

(ii) The labeling provisions of § 205.310.

(c) *Records to be maintained by exempt operations.* (1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

(i) Prove that ingredients identified as organic were organically produced and handled; and

(ii) Verify quantities produced from such ingredients.

(2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

#### **§ 205.270 Organic handling requirements.**

(a) Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

(b) Nonagricultural substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used:

(1) In or on a processed agricultural product intended to be sold, labeled, or represented as “organic,” pursuant to § 205.301(b), if not commercially available in organic form.

(2) In or on a processed agricultural product intended to be sold, labeled, or represented as “made with organic (specified ingredients or food group(s)),” pursuant to § 205.301(c).

(c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or in or on any ingredients labeled as organic:

(1) Practices prohibited under paragraphs (e) and (f) of § 205.105.

(2) A volatile synthetic solvent or other synthetic processing aid not allowed under § 205.605: *Except*, that, nonorganic ingredients in products labeled “made with organic (specified ingredients or food group(s))” are not subject to this requirement.

#### **§ 205.310 Agricultural products produced on an exempt or excluded operation.**

(a) An agricultural product organically produced or handled on an exempt or excluded operation must not:

(1) Display the USDA seal or any certifying agent's seal or other identifying mark which represents the exempt or excluded operation as a certified organic operation, or

(2) Be represented as a certified organic product or certified organic ingredient to any buyer.

(b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multi-ingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as “organic” in a product processed by others.

(c) Such product is subject to requirements specified in paragraph (a) of § 205.300, and paragraphs (f)(1) through (f)(7) of § 205.301.

#### **§ 205.311 USDA Seal.**

(a) The USDA seal described in paragraphs (b) and (c) of this section may be used only for raw or processed agricultural products described in paragraphs (a), (b), (e)(1), and (e)(2) of § 205.301.

(b) The USDA seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:

(1) On a white background with a brown outer circle and with the term, “USDA,” in green overlaying a white upper semicircle and with the term, “organic,” in white overlaying the green lower half circle; or

(2) On a white or transparent background with black outer circle and black “USDA” on a white or transparent upper half of the circle with a contrasting white or transparent “organic” on the black lower half circle.

(3) The green or black lower half circle may have four light lines running from left to right and disappearing at the point on the right horizon to resemble a cultivated field.



**Figure 1**

**§ 205.400 General requirements for certification.**

A person seeking to receive or maintain organic certification under the regulations in this part must:

- (a) Comply with the Act and applicable organic production and handling regulations of this part;
- (b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in § 205.200;
- (c) Permit on-site inspections with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices by the certifying agent as provided for in § 205.403;
- (d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State organic program's governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.104;
- (e) Submit the applicable fees charged by the certifying agent; and
- (f) Immediately notify the certifying agent concerning any:
  - (1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and
  - (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

**Questions and/or Concerns requiring additional clarification:**

The following questions and concerns should be reviewed in the context of the consumer and the integrity of the USDA organic seal. Consumers expect to be able to track every ingredient

listed on a product back to the organic certificate. Whether purchasing from a Farmers' Market or large store the consumer expects clear proof of certification. What mechanisms need to be in place to show proof of who certified the cut of meat, or the granola scooped out of a bulk bin at a large store?

### **Issue 1 – Who does 205.101(a)(2) apply to? What is a retailer who "handles but does not process?"**

Section 205.101(a)(2) exempts retail food establishments or portions thereof that handle organic agriculture products but do not process them:

A handling operation that is a retail food establishment or portion of a retail food establishment that **handles** organically produced agricultural products **but does not process** them is exempt from the requirements in this part.

Section 205.2 defines "handle:"

Handle. To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

And "processing:"

Processing. Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

By these definitions, all processing constitutes handling, but not all handling is processing. What are these instances of handling that are not processing? The very broad definition of "processing" includes any act of packaging or "enclosing food in a container." It appears that the only retail activity that could be considered handling but not processing is merchandising and stacking produce. What about filling bulk grocery bins, or displaying cuts of meat to be wrapped and labeled for the customer?

### **Issue 2 – Who does the 205.101(b)(2) exclusion apply to?**

Section 205.101(b)(2) excludes retail food establishments or portions thereof that process on-premises raw and ready-to-eat food from certified organic products:

205.101(b)(2) (exclusions): A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, **raw and ready-to-eat food from agricultural products** that were previously labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" is excluded from the requirements of this part, except:

- (i) the requirements for the prevention of contact with prohibited substances as set forth in 205.272; and
- (ii) the labeling provisions of 205.310.

What is "raw and ready to eat?" Does this group of products include all fresh meat, bulk groceries, etc.?

Does this exemption apply to brick and mortar retailers who package products under the exemption, then sell them on websites and mail them to offsite customers? Does it apply to retailers who only operate online?

Does this exemption apply to farms that may process and/or package products on farm, then sell them at a farmer's market? What about selling such products at the farm gate?

Does this exemption apply to farms that may process and /or package products on the farm and then sell these goods via web-based sales?

**Issue 3 - Under what conditions is a retailer exempt from certification?** The following scenario is presented to help illustrate the confusion around exempt retail operations: A retailer purchases certified organic bulk olive oil and transfers it to a bulk delivery bin (fusti) as well as bottles it. The handling operations and the retail front are all in the same building. They "handle" and sell direct to customers through retail (store and website) sales. The fusti and the bottle have their own company label. No references to any certification or any use of the USDA organic seal are used. They also sell bottled olive oil on their website, as well as at their brick and mortar location. Would this operation be considered exempt? What are the ACAs hearing about these types of situations? What actions are being taken by the ACAs, if any? With the increase in web-based retail sales who is collecting or monitoring this newest form of retail sales? How is this going?

**Issue 4 -** To what extent can a retailer process foods without certification? Does all repackaging constitute processing? What about simple repackaging, such as placing figs in plastic containers and affixing stickers to them? Is there a way the "on premise" exclusions in section 205.101(b)(2) can be defined and made easier to understand so that more there can be more consistency for retailers?

**Issue 5 -** May non-certified exempt retailers make a "certified organic" claim for products processed in store? For an example: Is simply stacking and merchandizing produce such as vegetables or fruit, considered to be "handling" or can this be considered to be "processing"? Is this exempt?

**Issue 6 -** What are the guidelines for making a "Certified Organic Retailer" claim?

Note that some retailers are certified for a specific department, and some for many departments and product categories. Can a store that only has a single department certified claim to be a "certified organic retailer?"

While the regulations are clear as to the use of the USDA seal and the organic claim with individual food *products*, there are no guidelines for the use of the seal in marketing an entire store, portion of a store or product line which contains both organic and non-organic products. The same issue applies to split agricultural operations (e.g. a farm that grows both organic and

non-organic produce), and clear marketing guidance would be beneficial for these operations as well.

**Issue 7** – How can we help to foster consistency between “all” retail operations, certified or not? How can we ensure consistency between how ACA’s and the NOP look at retail operations to ensure that they are in compliance?

**Issue 8** – How can we communicate in a consistent and easy to understand manner what the NOP’s expectations are to the various retail operations, whether they are brick and mortar, sell at farmers markets, farm stands, or sell using on-line sales methods, to ensure that they are better informed. Thus, helping to ensure that they each have been properly communicated with and have been made aware of what is expected of them, as an organic retail operation.

**Issue 9** – Is there anything else we could/or should look at? What are the inconsistencies that are currently aiding in creating confusion amongst retailers, ACA’s, or with the consumer? Suggestions on how these can be brought into a more balanced base for consistency purposes?

The CAC Subcommittee would like to solicit stakeholder feedback and input about areas of the rule that are unclear. The feedback will then be included in a recommendation to the NOP requesting the development of Education and Outreach guidance to clarify the existing rule. This clarification will provide retailers with a clearer more concise understanding of how the rule applies to a retail operation (certified or non-certified), so each retailer can ensure that they are in full compliance thus, helping to protect and maintain consumer confidence and organic integrity.

**Motion:** To approve the Retail Certification document as presented

Motion: Jean Richardson

Seconded: John Foster

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Joe Dickson, Subcommittee Chair, to transmit to NOSB August 13, 2013**



**National Organic Standards Board  
Compliance, Accreditation, and Certification Subcommittee  
Discussion Document  
Toward Clarifying Accredited Certifying Agents' Application of § 205.206(e)**

**August 20, 2013**

**Introduction:**

Organic crop production has passed its first decade of existence under full implementation of the National Organic Program (NOP). While many positive features of this program stand out as contributing to a more sustainable, healthy environment as a function of the legislation and regulations we as an industry and community operate under, from time to time we identify areas for possible improvement.

One of the legacy features found in the National Organic Standards (NOS) that is a derivative of many organic standards in existence prior to the NOP (e.g. CCOF, Oregon Tilth) was a codified preference for softer, less invasive, and less disruptive methods of pest control over their harder, more invasive, and more disruptive counterparts. The Compliance, Accreditation, and Certification Subcommittee (CACS) supports this preference without reservation while recognizing that pest control and management is one of the most challenging aspects of organic crop production, and that the very existence of a section on pest control in the NOS is a formal recognition of the essentiality of such activities to protect crops from the myriad of daunting and potentially devastating pests such as insects, mites and other invertebrates, weeds, plant pathogens, rodents, deer and other vertebrates.

**Regulatory Citations Background:**

§ 205.206 Crop pest, weed, and disease management practice standard, provides for the following:

(a) The producer must use management practices to prevent crop pests, weeds, and diseases including but not limited to:

(1) Crop rotation and soil and crop nutrient management practices, as provided for in §§205.203 and 205.205;

(2) Sanitation measures to remove disease vectors, weed seeds, and habitat for pest organisms; and

(3) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.

(b) Pest problems may be controlled through mechanical or physical methods including but not limited to:

(1) Augmentation or introduction of predators or parasites of the pest species;

(2) Development of habitat for natural enemies of pests;

(3) Nonsynthetic controls such as lures, traps, and repellents.

(c) Weed problems may be controlled through:

(1) Mulching with fully biodegradable materials;

(2) Mowing;

(3) Livestock grazing;

(4) Hand weeding and mechanical cultivation;

(5) Flame, heat, or electrical means; or

(6) Plastic or other synthetic mulches: Provided that, they are removed from the field at the end of the growing or harvest season.

(d) Disease problems may be controlled through:

(1) Management practices which suppress the spread of disease organisms; or

(2) Application of nonsynthetic biological, botanical, or mineral inputs.

(e) When the practices provided for in paragraphs (a) through (d) of this section are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic crop production may be applied to prevent, suppress, or control pests, weeds, or diseases: Provided, That, the conditions for using the substance are documented in the organic system plan.

### **Discussion:**

The Crops, Accreditation, and Certification Subcommittee has determined that there is uncertainty and variability in the understanding and application of the mandates and nuances of § 205.206(e). Additionally there appears to be insufficient understanding in how substances reviewed and recommended by the NOSB, added to that National List by the Secretary of Agriculture, and allowed as listed on § 205.601 are utilized responsibly in the context of the cascading requirements found in § 205.206(e).

The underlying principle guiding this section of the regulation is that only when other, less disruptive, less harmful, less toxic methods, strategies, and tactics have been employed and found wanting may synthetic substances found on the National List be used as part of an Organic System Plan. It was never the intention of the regulation to allow the application of any synthetic crop input unless other, less toxic and persistent means had been tried without adequate success. This feature is unique in that it is the only federally-regulated mandate for Integrated Pest Management while also being a centerpiece of the crop production standards of which the organic community can be proud.

It is the Subcommittee's contention that a comprehensive and clear understanding of § 205.206(e) across all sectors of the organic community and industry is essential in the continued fair appraisal of substances on the National List and their alternatives, whether that appraisal occurs in the sunset process or in consideration of petitions. Only when the process is fair and equitable by which alternatives to pesticides—referenced in § 205.206(a)-(d)—are assessed as essential and viable can the essentiality and viability of pesticides—referenced in § 205.206(e)—be assessed fairly and equitably.

The Subcommittee also contends that the public is generally unaware of the rigors placed on organic operations and organic certifiers by § 205.206(e) and therefore undervalues the efforts of each in assuring compliance with the applicable regulation. This lack of awareness can allow for undeserved skepticism and second-guessing that impedes effective and efficient management of crop pests. Clarity about these rigors would serve the community well in allowing organic operations to focus on crop production and compliant activities instead of defending those actions.

Toward clarifying the collective understanding and unifying collective application of § 205.206(e), the Subcommittee is seeking comments on this subject and in particular would like to ask the following questions of the certification community.

1. What activities or practices do you require of applicants and certified operators in their Organic System Plans (OSP) with respect to their compliance with §205.206(e)?

2. What form of verification or records from the operator do you require in support of their compliance with § 205.206(e), either during review of the OSP, during the inspection, or upon the inspection review?

3. What information do you require when an operator needs to amend their OSP on short notice when pest pressure unpredictably or unexpectedly rises beyond their decision threshold?

4. Other than through records, how do you verify that approved substances are applied only when other, less toxic or aggressive means have been tried and found wanting?

**Recommended Motion:**

To approve and forward to the NOSB the discussion document "Toward Clarifying Accredited Certifying Agents' Application of § 205.206(e)".

**Subcommittee Vote:**

Motion: John Foster  
Second: Joe Dickson

Yes: 7 No: 0 Abstain: 0 Absent: 1 Recuse: 0

**Approved by Joe Dickson, Subcommittee Chair, to transmit to NOSB August 20, 2013**



**National Organic Standards Board**  
**Compliance, Accreditation and Certification Subcommittee**  
**Discussion Document**  
**Sound & Sensible Initiative**  
**August 27, 2013**

## **Introduction**

Each year every organic producer and handler is inspected and certified through an independent third party process. Over the decade since the National Organic Program (NOP) was established this inspection process through Accredited Certifying Agencies (ACAs) has resulted in strong consumer confidence in the integrity of the organic seal and an increase in the organic sector of agriculture. Today there are 84 (49 domestic) ACAs and over 25,000 (17,500 domestic) organic producer/handlers. Organic standards were intended to be consistent throughout the country while allowing for regional diversity.

Moving forward, it is imperative that we maintain an incontestable process of compliance with the regulation. ACAs require rigorous documentation from their clients on all aspects of an operation as well as having to meet their own accreditation standards established with the NOP. The Organic System Plan (OSP) is the primary tool used to convey the necessary information about a given operation. Over time, the amount and degree of required documentation has increased to a point that it is seen as a barrier to entry for some farmers and handlers, and a frustration to existing operations.

Some direct marketers have become frustrated by the amount of paperwork and choose not to seek renewal of their certification. Some farm families have indicated that completing the OSP for submission is more stressful than filing their federal income taxes with the IRS. For some, the fear of using the wrong material input will wipe out years of transition and understanding of organic principles. Still others feel the stress of inspection day to have every minute detail up to date is overly daunting, especially during the growing season. Because of these and now, lack of cost-share funds, many growers are disenfranchised with the system and opt out. This leads to greenwashing the organic term. Signage like “better than organic”, “organik”, “naturally grown”, or “unsprayed” are terms direct marketers are using. Many consumers equate local with organic. Why should they go through all of this, if the other guy can claim the same thing?

The increase in enforcement by the NOP to reduce the abuse is a key element in helping certified growers stay with the program. The consumer educational efforts of the NOP are very helpful as well. ACAs have increased their efforts in systematic unannounced inspections and residue testing with guidance from the NOP, which helps compliant farmers feel proud of following all the rules.

The goal of this discussion document is to inform the organic community of steps being taken by the NOP and ACAs to streamline the entire inspection process and to seek additional input from the community. For the ACA, it must be sound. For the farmer and handler, it must be sensible.

## **Background**

At the farm (and facility) level, the owners prepare their OSP by evaluating the previous year’s performance and speculate what changes will be made in the coming year. Compiling all the receipts, logs, seed lists,

and field history documents is time consuming, albeit a good business practice anyway. Other factors such as new neighbors may create new buffer issues, early weather prediction for rotation decisions, market demand or contraction all must be factored in while completing the OSP. Often this new plan is well under way before the ACA is able to verify all points are accurate or complete. The OSP reviewer will submit a list of questions for the inspector to verify when on-site.

At the ACA level, the ACAs prepare an Accreditation Manual when seeking authority from the USDA-NOP to certify operations as organic. Each ACA is allowed by the NOP to interpret the regulation and develop its own policies and process's to verify an operation's compliance with the regulation. Each ACA is somewhat different, meeting the regional, cultural, and agronomic needs of their clients. The Accreditation branch of the NOP periodically audits the ACA to ensure that they are meeting their self-proclaimed protocols which verify their client's compliance with the USDA organic regulations. Many farmers perceive the present verification process as "document chasing and data collection" rather than visual inspection of compliance. In recent years, ACAs have begun to look at how the information exchange with their clients can be simplified to lighten the paperwork burden while maintaining the integrity that consumers expect.

At the NOP level, they conducted "re-calibration training" for their auditors early in 2013, based on feedback from ACAs on how the process is being overworked and inconsistent between audit teams. The NOP also enlisted consultants to evaluate their internal processes to advise them on simplification steps that could be made. The NOP accreditation staff also conducts regular meetings to ensure that consistency of interpretations of the rule and policies are conveyed to all ACAs uniformly as they arise. The NOP conducts annual training for ACAs with the goal of consistency in the implementation of the certification process. The NOP has been challenged by the Secretary of Agriculture to evaluate barriers to entry into the organic sector and reduce the challenges for existing operations.

This paperwork burden is seen as more of a farm issue, as most handlers must maintain adequate records for food safety traceability purposes that often meet the needs of the ACA.

## **Relevant areas of the Rule**

**The Organic Foods Production Act (OFPA) of 1990** and the USDA organic regulations, (The Rule).

### **Discussion**

Farmers attend educational conferences during the winter meeting season to learn about successful organically compliant growing and managing strategies from other growers. This is also an opportunity for the ACAs to educate farmers about compliant materials use and the certification process in general. It can seem rather daunting to decide what logs and record keeping systems must be in place. The questions on the ACA(?) forms may feel redundant and out of touch with how the operation works. Many have the appropriate records on hand but they do not fit the format of the forms. The fear of finding out the Insecto 2.1 was not compliant when you have been using Insecto 2.0 for years, weighs heavy on farmer's minds.

In the spring of 2013 leaders from the Accredited Certifiers Association, Independent Organic Inspectors Association, the NOSB, the NOP, and the broader community met to discuss the best way to reduce the paperwork burden without relaxing integrity standards. The following topics have been identified as the focus for this initiative: A) Re-tooling the Organic System Plan, B) noncompliances and reminders, C) materials review, D) on-site Inspection, E) Oversight Systems, and F) other considerations. The following discussion reflects the comments provided by participants at these and ensuing meetings:

## **A. Re-tooling the Organic System Plan (OSP) to streamline flow of information**

The Organic System Plan may be the largest cultural barrier to paperwork reduction in the organic certification process. It has historically been a paper based, lengthy and annually updated document that has been interpreted as needing to capture all elements of a compliance plan accurately and in real time.

The USDA Organic regulation (Section 205.406(a) – Continuation of certification) outlines the necessary requirements for an operation to update their certification annually. Within this section a certified operation must do the following annually: pay certification fees; and submit an updated organic production or handling plan which includes:

- Changes from the previous year;
- Changes in the coming year;
- Outline any additions to or deletions of contact, business name and/or address;
- Provide an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and,
- Any other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.

These are examples where organic integrity is not in question. The trigger of a noncompliance carries with it a string of communications and documentation of verification that the action was corrected, taking staff time away from more pertinent issues.

ACAs typically try to communicate with their farm clients in the winter and early spring, before the OSP is put in place. Many ACAs are under the impression they must have their clients submit a complete OSP, versus an update that indicates any notable changes or deviations from the previous plan in place. The ACAs need the flexibility to develop better mechanisms of communicating with their clients, without fear of retribution from the auditors. Some ACAs that have implemented abbreviated update reporting methods can see the benefit of time savings and lessened frustration by their farmer clients.

Farmers and handlers need the flexibility to notify their ACA of changes by phone or other electronic means. This is capturing the activities in real time, as an OSP is a working document, not a file server. The ACA and the client have the joint responsibility to annually verify the ACA has the most complete version on hand. Verification of acceptance of the information should only be necessary when the compliance of the action is in question.

Additionally, updates to the OSP should not only be allowed, but encouraged at the time of inspection. Also, inspectors should be encouraged to clarify the regulation for the client at inspection so the operator can better inform the ACA of their activities and demonstrate compliance. Growers can easily not realize the need to notify the ACA of a minor change to the plan they submitted back in the winter, until the inspector recognizes the deviation. Inspectors are often the only face of certification for an operator. Relaxing the tone of information exchange at the time of inspection will greatly improve customer service and encourage compliance by the client.

## **B. Use of Noncompliances and Reminders to Motivate Clients toward Compliance**

Often the first communication a farmer gets after an inspection is a letter with an attached “Notice of Noncompliance” with or without an updated certificate. The noncompliances must be addressed in some given time frame, depending on the severity of the violation. Often these are minor technical errors where organic integrity is not in question. This letter has an impersonal feel and the farmers prefer the ACA simply advise them of the corrections that must be made.

In 2012 the ACAs were given NOP 2612 Instruction Document, *Recommended Penalties for Violations of Specific Regulatory Requirements* and the *Penalty Matrix by Category of Violation* in an effort to provide consistency to compliance decisions. It was widely believed that the Instruction Document and Penalty Matrix rely too heavily on the use of noncompliances to address issues that do not affect organic integrity. The overreliance on noncompliance notices creates an adversarial relationship between certifiers and operators, and hampers beneficial collaboration that can better achieve desired continual improvement of organic systems.

Several ACAs submitted comments and suggested revisions to the Penalty Matrix and to NOP 2612, *Recommended Penalties for Violations of Specific Regulatory Requirements*. This document has since been retrieved by the NOP for further evaluation with intention to employ sound and sensible principles within, as a result of this discussion.

ACAs need to have the ability to communicate with their clients in various methods with the goal of gaining or verifying compliance in the most time effective manner. Often the information can be conveyed with a simple email or phone conversation. Again, the issuance of a noncompliance causes a cascade of documentation of verification that a corrective action was performed, often consuming more of the clients and ACA staff time than the corrective action itself. Improving customer service is one of the simplest ways to encourage new growers into organics, and preventing ill will between growers and their ACA. ACAs know which of their clients need more attention and firm, deliberate communication to protect organic integrity. Any time organic integrity is in question, the ACA has tools to enforce the regulations, and document it for future reference. Overuse of noncompliances dilutes their effectiveness.

Revisions to the Penalty Matrix relative to required actions by the ACA for noncompliances and major noncompliances should be evaluated by the NOP in conjunction with leadership of the Accredited Certifiers Association. This revision can then be put forth at annual trainings and posted on the NOP website.

## **C. Input Materials Review and Clarity of Use by Certified Operations**

Lack of clarity about what materials can/cannot be used in an organic system is a leading barrier to entry for many direct marketing operations. Growers participating as a supplier to distributors or handlers are often given guidelines on material use by the buyer. ACAs can provide a list of materials to their clients that are allowed in an organic production system, but cannot inform the client on the effectiveness of any particular one. On occasion, ACAs may reach a different conclusion about a particular materials acceptance for use by a farmer or handler. This causes concern to the operator and can also lead to certifier shopping by a farmer. Fear of making a mistake, jeopardizing years of learning and work along

with the inability to get real time answers, is a hindrance to farmers' comfort level with being certified organic.

Although information on materials is necessary to complete multiple parts of the organic certification cycle, current materials evaluation systems are recognized as a weakness. There is no industry standard that provides criteria or procedures for review of brand name materials—OFPA and the NOP regulations only address review of generic materials. As a result, certifiers have implemented materials review systems that differ widely in both methodology and rigor and sometimes produce inconsistent results such as different rulings on the same brand name product.

Materials review systems require personnel with specialized training and skills and the pool of workers with such training is limited. Many certifiers do not have staff that is appropriately trained to perform materials reviews, which is a significant factor that can affect the soundness of decisions about materials.

Certifiers also report an inability to perform materials reviews in a timely fashion. Typically, there is an influx of applications for certification and continuation of certification that are processed over a span of months. During this period, operators are using the materials that they have reported on the OSPs, including those that may not yet have been approved by their certifier. Problems arise if the certifier's review of the material eventually determines that an operator has used a material that does not meet NOP standards. A critically important reason that concerns about materials review are so widespread is that NOP's oversight of materials review systems through accreditation assessments is not rigorous. For example, NOP's Accreditation Assessment Checklist (Revision Date: May, 15, 2013) addresses materials review in a cursory fashion. Rather than a checklist of questions about the specific methods used in materials evaluation, NOP's document contains only a single question about materials evaluation: "Are the materials and inputs used in compliance with the NL and annotations?"

Although the Organic Materials Review Institute (OMRI) provides high-quality materials review services, there are still many brand name materials that are not submitted to OMRI and therefore must be reviewed by ACAs when these products appear on operators' OSPs. As reported during the ACA trainings, the need to review materials requires each ACA to devote resources to maintaining its own review system. To do so, certifiers must recruit and retain staff members who are competent to review materials and they must implement information systems to ensure that inspectors and reviewers have adequate information on each material.

Unfortunately, after doing the work to evaluate materials, most ACAs lack mechanisms for sharing the results of their evaluations, resulting in certifiers duplicating efforts to review the same materials. Some certifiers stated that they have not yet implemented effective procedures for sharing information about reviewed materials internally, among their own reviewers and inspectors. Clearly, it would be more sensible to have one review by a well-trained staffer, with the results shared.

Another problem is that maintaining review materials systems creates a financial burden on each ACA. And if every certifier evaluates many of the same materials these duplicate costs are passed on to the farmer and consumer.

Materials review makes its way into the Sound and Sensible discussion because of the duplicative efforts of the ACAs.

There is a need for training that is specific to materials review. Perhaps OMRI and the International Organic Inspectors Association (IOIA) could work together to offer trainings on development and implementation of certifier-based materials review programs.

Standardizing the materials review systems through NOP issuing guidance on the criteria needed for such systems. One mechanism for such guidance could be in the form of increased detail on assessment of materials review systems in the NOP's accreditation checklist. Thus moving toward a centralized review system through policies that encourage materials suppliers to submit their materials to OMRI, operators to use OMRI-approved materials, and requiring all certifiers and other Material Review Organizations (MROs) to make public their lists of approved materials. This would provide more transparency to operators, certifiers, and the public (Sound), reduce duplicative reviews of the same material (Sensible), and reduce the amount of time all certifiers would need to spend on evaluating materials (Sensible).

It was acknowledged that publishing lists of approved (and prohibited) materials has inherent risks and liability for the ACA. It was noted that the higher level of oversight and a standard material review process, would likely lead to more confidence among certifiers regarding accepting other lists and publishing their own list. Publication of the lists would also serve as a precursor to establishment of a body to analyze the results of different certifiers' evaluations and resolve any points of disagreement. The farming community would like to see one list for brand name materials, managed by the NOP.

- Moving towards materials review systems that incorporate inspections of materials suppliers based on random selection as well as risk factors such as concerns about individual suppliers, problems specific to certain types or classes of materials.
- Expanding the scope of the NOP's accreditation program to include MROs that are not ACAs as discussed by the NOSB in 2012 would be both Sound and Sensible.

#### **D. Inspections and the Exit interview Process**

Inspection day can be very stressful for farmers. The inspection is a snapshot view of every detail of everything on that farm. Good organic farmers are very proud of their operations, but worry that some document may be missing, causing the inspector to wonder what else might be wrong. The division between regulation and education must be maintained, but certifiers and inspectors are compelled to assist in the understanding of the regulation and it need not be adversarial in nature.

As stated before, the farm or facility inspection is the only real face to face transaction in the certification process. Certifiers often have very rigid inspection report forms (often 20 or more pages long) that inspectors must complete while on-site or after leaving the operation. In most cases, the inspection report body could be much shorter if the Exit Interview process and document included OSP updates, follow-up to certifier's requests, follow-up to last year's non-compliances, scope of inspection, as well as issues of concern and further information needed. The focus of the body of the inspection report could be reporting things that could not be verified, things that were inconsistent with the OSP, or that were unusual.

The Exit Interview document is critical because it is the one document that is co-signed by the operator and the inspector. While ACAs generally require specific discussion of and documentation of noncompliances during the Exit Interview, the Exit Interview is neither well-enough used nor understood. Properly used, it ties together updates, reports, and reviewers. In general terms, everyone understands what is to be covered in the Exit Interview (issues of concern and further information needed).

Currently, the Exit Interview formats used by different certifiers vary widely. They are often free-form, relying on the knowledge of the inspector on how to structure and report audit findings and nonconformities. Potential non-compliances are often buried in the body of the report and not re-iterated on the Exit Interview document. Industry-wide, there is much less focus on structure of the Exit Interview (both process and document) than the inspection report, when the exit interview is actually more important. Great inconsistency in what certifiers expect and what inspectors are doing has resulted. The exit interview should summarize updates to the OSP. As described above, updates at inspection are still often the best way to update minor changes.

In addition, the NOP should take steps toward implementation of the NOSB Inspector Qualifications Recommendation of December 2011. The recommendation includes good steps to increase inspector performance, including continuous education requirements and witness audits. Witness audits are valuable, but are currently vastly under-utilized.

## **E. Oversight Systems**

Both OFPA and the early NOSB recommendations envisioned a multi-level oversight system (inspection, certification, accreditation, and oversight of accreditation) managed with rigor and accountability. USDA and NOP address requirements for quality assurance of inspection and certification through the accreditation system; however, a mechanism for continuous oversight of the NOP accreditation system itself has not been institutionalized. This type of review is performed when equivalency agreements are being considered with other programs like the EU or Canada. This committee can not only evaluate accreditation protocols and consistency between the Standards, accreditation, and enforcement divisions, but information systems and internal processes, much like the USDA auditors evaluate the ACA to their own accreditation manual.

Continuous oversight of the NOP would not only ensure that noncompliances in the accreditation system are identified through procedures such as internal and external audits, but also that corrective actions are taken by the accreditation body (NOP), reviewed by USDA management, and reported to the oversight body (Peer Review Panel) within a time frame set by the oversight body.

It has also been pointed out in the preliminary discussions; there is no feedback mechanism for farmers, handlers, ACAs, inspectors, or auditors to provide information on how well the process works. There is actually a disincentive to do so for fear of retribution. This need not be only for complaints, but a positive place for suggestions and ideas on how to make the process more Sound and Sensible. The NOP oversight committee could be a forum for such information exchange. This committee could mine the data looking for common threads that show up in audit reports.

## **Conclusion**

The CACS welcomes thoughts and ideas on what steps can be taken to streamline the accreditation and certification process to encourage new farmers and handlers to transition to organic practices and to maintain existing organic operations in the program.

**For the ACA, it must be sound. For the farmer and handler, it must be sensible.**

## **Discussion Questions**

1. How can the OSP/information exchange mechanism be altered verify compliance in a more user friendly manner?
2. How could a feedback loop for operators and ACAs be developed for complaints and suggested changes without fear of retribution?
3. How can new technologies be employed to verify compliance and reduce document deluge?
4. How can ACAs create a functional information exchange with operators and inspectors to verify all information is current and accurate?
5. What forms of communication should be available for ACAs to encourage and document compliance, other than Notices of Noncompliance?
6. When is visual verification satisfactory and when must documents be sent to the ACA?
7. How can the ACAs and inspectors develop a more user friendly process to verify compliance with the regulation?
8. What are examples of USDA Food Safety and Inspection Service (FSIS), Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA) inspection protocols that are less burdensome but effective to consider here?
9. How should a peer review process for the NOP itself function? Who should be on that committee?
10. How should approved materials lists be shared among certifiers and to the operators themselves?

**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material checklist  
Streptomycin**

**August 6, 2013**

**Discussion Summary:**

The NOSB has been petitioned to remove the existing expiration date of October 21, 2014 for Streptomycin and replace it with a new one of Oct 21, 2017, for both apples and pears. The petitioner states that this would allow adequate time for the transition from strep over to non-antibiotic, biological alternatives for fire blight control.

There are two different positions on this subject: those that support the petition request for an extension and those that oppose an extension.

Both sides agree that it is time for a phase out for the allowed use of strep. The supporters believe that three additional years until October 2017 is reasonable, and opponents believe that yet another extension offers no assurance of phase out.

Proponents of an extension feel that:

- ~Because of the investment involved to establish an orchard (as well as the businesses established to handle this produce) in both time, money, and the need for completion of existing research of materials, that a slowdown (or extension) of the expiration date is needed, especially for pear growers.
- ~This slow down would benefit growers, processors, producers, handlers, and consumers alike.
- ~Alternative materials are still not readily showing consistent control and one material's registration (Previsto copper) has been delayed by EPA. Thus, the farmers still need some additional time in order to prepare for the transition to a non-antibiotic fire blight control period in time.

•Opponents feel that:

- ~Fire blight resistance to streptomycin is widespread in the U.S.
- ~Raise the question of essentiality, based on the significant percentage of growers selling to markets that do not allow antibiotic treatments.
- ~Organic integrity and sales are threatened because of consumer expectation that antibiotics are not used in organic production.

•Both sides agree that the “core” issue here is whether or not there is a risk of enhancing antibiotic resistance in human pathogens. There is science that supports both sides of this argument and the level of concerns that are raised by this particular use pattern. Supporters cite issues of use patterns and limits of residues as indicative of no evidence of harm. Opponents cite resistant human pathogens in strep treated orchards and horizontal gene transfer identified as leading to antibiotic resistance.

•While there has been a direct linkage shown to exist between infection and colonization of humans by antibiotic resistant bacteria in animals (Larsen et al 2010), supporters cite no direct linkage has been demonstrated between antibiotic resistant bacteria in humans and antibiotic sprays applied to plants (Stockwell and Duffy, 2012), such as the current use of strep in apples and pears for fire blight control. Lab results vary in their conclusions. Opponents cite evidence that bacteria, including *Erwinia amylovora* and human pathogens, share a common genetic basis for resistance, transmitted by plasmids, to streptomycin in particular. (McGhee et al, 2010; Sundin, 2000; Sundin and Bender, 1996; Pezzella et al, 2004; Scherer et al, 2013; Foster et al, 2004.)

•Proponents state: there is no evidence that applications of antibiotics to orchards during bloom contributes to antibiotic resistance in human pathogens. The amount and timing of the use of strep in orchards and environment

does not contribute to any human health concerns, especially in light of streptomycin being ineffective in humans when ingested orally.

- Opponents state: there is evidence that an application of strep leads to an increase in resistance to streptomycin in orchard bacteria, that human pathogens and fire blight bacteria share the same gene pool of genes resistant to streptomycin (i.e. that the same genes responsible for resistance in *Erwinia amylovora* are also responsible for resistance in human pathogens), that human pathogens do not need to be present in the orchard to obtain resistance genes acquired by and augmented in orchard bacteria, that strep residues are sometimes present in treated fruit, and that strep is still a critically important antimicrobial for use against human pathogens.

- The primary point of discussion here is whether to grant an extension or not to the current expiration date for streptomycin in October 2014. The points proponents say should be considered are: What impact does an extension/or non-extension have on the stakeholders that either use this material or have built their businesses around expanded crop availability; How will a decision impact the supply chain, How will a decision impact the consumer (all consumers, not just a select group(s)), What are the risks/if any for granting an extension or not, and would granting a short extension for allowed use knowing what the use patterns are pose any significant increases in human health concerns from resistance than currently exist today?

- The points opponents say should be considered are: What impact does yet another extension, which was first called for by the NOSB in 1995, have on the integrity of the organic label? What are the public health hazards of using antibiotics for nontherapeutic uses and why are infectious disease doctors concerned? What is the threat of low-level environmental exposure to antibiotics? What are the alternative strategies that are used to manage or prevent fire blight?

- Remember, according to proponents, this is not a new material, but one that has been on the National List of Approved Materials for a number of years as being allowed for use by organic growers to use on their organically grown and certified crops. Opponents point to long-standing NOSB attempts to phase out the use of antibiotics in organic apple and pear production, with votes by previous boards to phase-out, only to have subsequent boards issue extensions.

- One other point of discussion, proponents state, would be how to ensure a full expiration of strep from the National List, if an extension for use were to happen. They ask, how could we ensure all stakeholders that there would be an absolute point when this usage would truly expire? Opponents, who would like the 2014 antibiotic expiration date to take effect, believe that the debate on antibiotics and votes to phase them out by previous boards have resulted in only extended deadlines for too long, and organic should not in any way contribute to the worldwide crisis in antibiotic resistance, while ultimately threatening consumer confidence in the organic label.

### **Summary of Proposed Action:**

The Crops Subcommittee proposes to:

Remove the existing expiration date of October 21, 2014 for streptomycin and replace that with a new expiration date of October 21, 2017. This would be for use in both apples and pears for control of fire blight.

The Crops Subcommittee puts forward this resolution:

**Resolution:** The National Organic Standards Board is committed to the phase out of this material. Between now and the expiration date the Board urges growers and certifiers to include in organic systems plans an annual increase in the extent and/or number of alternative practices and materials that are trialed for controlling fire blight. In addition, the board strongly advocates to USDA a high priority for increased support for research into these alternative practices and materials.

## **Introduction**

A Petition to the National Organic Standards Board (NOSB) was received for the Removal of the Expiration Date (October 21, 2014) for streptomycin and the establishment of October 21, 2017 as its sunset date, in order to allow for adequate time for the transition to proven effective non-antibiotic, i.e. biological alternatives for fire blight control in apples and pears.

Because this subject is complex and there are two different positions to be represented, this recommendation is organized to present two separate positions - those for and those against an extension. These are designed to supplement the points raised in the checklist. Most of the same background presented in the Spring 2013 Recommendation for Oxytetracycline is relevant to Streptomycin, except for the 2007 and 2008 actions.

The subcommittee acknowledges the concerns of consumers and previous NOSB members who feel that it is time to phase this material out from organic agriculture. The two positions represented in the discussion section of this document differ on the timing of the phase-out. Additional concerns are being put forward in a separate resolution on the subject.

## **Points of Agreement and Disagreement**

This section focusses on how the material is used in the context of both plant and human health. Because much of the general information was covered in the proposal for Oxytetracycline, this review focusses on the differences and similarities between the two materials. Specific portions address Checklist categories as noted.

### **1. Fire blight control**

Proponents of both positions agree that orchard establishment requires a large investment of time and money, that apples and pears are grown in a variety of locations that require different management plans, and that more research is needed into systems for preventing fire blight damage.

#### **Proponents of extending the expiration date of streptomycin say:**

- Because of the very large investment of time and money that establishing an orchard entails, the variety of locations that apples and pears are grown, and the very rudimentary state of research on alternatives to this material in that variety of locations, we are supporting slowing down the removal of streptomycin from the National List.
- Since the organic pear industry is more at risk to fire blight than apples there is concern that pear research and control measures are lagging behind and that an expanded time frame will be needed. Streptomycin is still fairly widely used in pears, especially those grown in areas with high humidity and warm springs.
- A slightly extended date of 2017 will benefit consumers and growers alike. The few more seasons of research will enable new products to be tested in both apples and pears in a variety of weather conditions.
- In 2009, about 15% of the total apple area and 40% of the pears (organic and conventional) were treated with streptomycin or oxytetracycline for control of Fireblight, the disease caused by the bacteria *Erwinia amylovora*.<sup>1</sup>
- Experience of pear growers especially in the 2013 season has shown that Blossom Protect has not worked well in the Pacific Northwest or California. It was an unusually warm spring. The copper material that is very promising has been delayed in registration until at least 2014 nationwide and 2015 in California.

### **Opponents to extending the expiration date of streptomycin say:**

- Like most challenges in organic production systems, with fire blight there is no one material and no one practice that will eliminate the problem. Fire blight must be met with a truly organic systems approach that is sensitive to the potential adverse health and environmental effects of inputs and consumer expectations.<sup>2</sup>
- Fire blight resistance to streptomycin is widespread in the United States. Streptomycin-resistant strains of fire blight have been found in California, Oregon, Washington, Michigan, New York,<sup>3</sup> Missouri,<sup>4</sup> and Utah.<sup>5</sup> Plasmid-borne genes have been found to confer resistance in California, Michigan,<sup>6</sup> and New York.<sup>7</sup>
- With regard to the “essentiality” of streptomycin, not all organic apple and pear growers depend on antibiotics. In fact, there is a sizeable proportion of growers of both apples and pears who do not use antibiotics.
- As of March 10, 2011, there were 96 businesses certified as EU-compliant organic producers of apples and/or pears in the state of Washington alone, representing about one third of the state’s organic apple and one fourth of the state’s organic pear production. EU-compliant organic apple and pear growers cannot use antibiotics, and face a three-year ban from selling in the EU if they do.<sup>8</sup> In addition, cultural changes in the orchard environment have contributed to epidemics of fire blight.<sup>9</sup>

### **2. Need for phase out of streptomycin**

The sub-committee acknowledges the concerns of consumers and previous NOSB members who feel that it is time to phase this material out from organic agriculture. The two positions represented in the discussion section of this document differ on the timing of the phase-out.

### **Proponents of an extension for streptomycin say:**

Because of the need to make sure that this material is phased out, a resolution motion has been added to affirm the commitment by the NOSB to all organic stakeholders. The NOSB must ensure that the decisions made reflect due consideration of the various needs and concerns of the vast array of all our organic stakeholders, especially when dealing with complicated issues, such as this one.

Additionally, in spite of the claims below about the threat of spreading resistance to streptomycin, most of the research on this subject has been conducted with antibiotics used in livestock and very little in orchard environments. Some very recent research specifically for an orchard situation noted that more streptomycin-resistant isolates were cultured from non-sprayed orchards compared to sprayed orchards.<sup>10</sup>

### **Opponents of an extension for streptomycin say:**

Streptomycin is an antibiotic considered by the World Health Organization to be of critical importance to human medicine.<sup>11</sup> Streptomycin is used in a way that exposes bacteria in the orchard to the antibiotic.<sup>12</sup> Current science shows that environmental exposure to antibiotic use in the environment is the major cause of development and spread of antibiotic resistance in human pathogens.<sup>13</sup> The spread of antibiotic resistance does not require contact between the antibiotic and human pathogens because the major means of spreading antibiotic resistance is through the transfer of genes between different bacteria. Uses resulting in low residues (subtherapeutic or subinhibitory levels) can create a high health risk.<sup>14</sup> Streptomycin resistance is evident and expected to grow if urgent use precaution is not exercised.<sup>15</sup> Organic production should not be contributing to the problem of antibiotic resistance.

### **3. Antibiotic Resistance**

Proponents and opponents of extending the expiration date of streptomycin agree that the core issue here is whether there is a risk of enhancing antibiotic resistance in human pathogens. The most astute and experienced scientists in this area realize that science and medicine have to find a way to co-exist with resistance, including managing reservoirs of resistance in the environment and preventing development of new forms of resistance. (Am. Academy of Microbiology, 2009).

### Proponents of extending the expiration date of streptomycin say:

- Antibiotic-resistant bacteria that are competent phyllosphere colonisers can persist in the environment, evidently independent of antibiotic use, as shown by Yashiro and McManus (2012). They demonstrated that long-term applications of streptomycin alone did not alter the bacterial communities on apple leaves. They sampled leaves from four orchards that were treated with spring-time applications of streptomycin over 10 years and from four orchards that were not sprayed with antibiotics. The bacterial genera *Massilia*, *Methylobacterium*, *Pantoea*, *Pseudomonas*, and *Sphingomonas* were detected from all orchards, regardless of spray history. More streptomycin-resistant isolates (65%) were cultured from non-sprayed orchards compared to sprayed orchards (50%). They concluded that factors other than streptomycin influence both the proportion of streptomycin-resistant bacteria and phylogenetic makeup of bacterial communities on apple leaves (Yashiro and McManus, 2012).
- There are numerous reports that the use of antibiotics in animal production is associated with increase of antibiotic-resistant bacteria in animals, waste-water, and manure (for some examples see Larsen 2010, Wright 2010). A direct linkage was reported between infection and colonization of humans by antibiotic resistant bacteria from farm animals (Larsen et al 2010). No direct linkage has been demonstrated between antibiotic resistant bacteria in humans and antibiotic sprays on plants (Stockwell and Duffy, 2012).

### Opponents of extending the expiration date of streptomycin say:

- Application of streptomycin leads to an increase of streptomycin resistance in the fireblight organism and other bacteria in the orchard.

Selection of bacteria resistant to streptomycin occurs at extremely low antibiotic concentrations.<sup>16</sup> It is accepted that reliance on streptomycin for fireblight control resulted in the development and spread of resistance to streptomycin in *E. amylovora*.<sup>17</sup> Resistance genes are prevalent in treated soils,<sup>18</sup> and researchers have concluded that resistance is often acquired through gene transfer.<sup>19</sup> Some researchers found the highest concentration of streptomycin-resistant bacteria in the phylloplane of treated crops,<sup>20</sup> but Yashiro and McManus (2012)<sup>21</sup> found a higher percentage of cultured phyllosphere bacteria resistant to streptomycin at non-sprayed orchards than at sprayed orchards. But they stated,

However, our conclusion does not absolve streptomycin of all risk associated with its use. For example, it is possible that streptomycin could select for novel resistance genes in apple orchards, even if the overall frequency of resistant bacteria is not increased. A greater diversity of mobile resistance genes in apple orchards could lead to horizontal transfer of resistance among a greater range of bacteria, which in turn could be consumed on fresh produce.

- Streptomycin resistance genes from the orchard are transferable to other bacteria. Streptomycin resistance in *E. amylovora* may come from a chromosomal or two known streptomycin resistance genes carried on plasmids.<sup>22</sup> “The carriage of *strA-strB* within an integron, a transposon, and on broad-host-range plasmids has facilitated the world-wide dissemination of this determinant among at least 21 bacterial genera.”<sup>23</sup> The streptomycin resistance genes (*strA-strB*) are known to be carried on transposons and spread by horizontal gene transfer, but are unlikely to have been transferred directly –it is more likely that they are spread through intermediate bacteria. “The distribution of the *strA-strB* genes in the environment clearly illustrates the expansiveness of a common microbial gene pool and the rapid dissemination of Ab<sup>f</sup> determinants in bacterial populations.”<sup>24</sup> This has been confirmed by a several researchers.<sup>25</sup>

- Streptomycin is a critically important antimicrobial. Streptomycin is classified as a critically important antimicrobial by the World Health Organization. It is a limited therapy as part of treatment of enterococcal endocarditis and Multi-Drug Resistant (MDR) tuberculosis.<sup>26</sup> It is also effective in treating *Brucella* (brucellosis), *Calymmatobacterium granulomatis* (donovanosis, granuloma inguinale), *Escherichia coli*, *Proteus* spp., *Aerobacter aerogenes*, *Klebsiella pneumoniae*, and *Enterococcus faecalis* in urinary tract infections, *Francisella tularensis*, *Haemophilus ducreyi* (chancroid), *Haemophilus influenzae* (in respiratory, endocardial, and meningeal infections - concomitantly with another antibacterial agent), *Klebsiella pneumoniae pneumonia* (concomitantly with another antibacterial agent), *Mycobacterium*

tuberculosis, *Pasteurella pestis*, *Streptococcus viridans*, *Enterococcus faecalis* (in endocardial infections - concomitantly with penicillin).<sup>27</sup>

#### 4. Ecological Impacts

Opponents of extending the use of streptomycin say:

- Streptomycin use may have unforeseen ecological impacts.

Since resistance to antibiotics is more prevalent in some groups of microorganisms than others, the dispersal of streptomycin in the environment can disrupt the microbial ecology. For instance, blue-green algae, which are important in sequestering carbon dioxide and releasing oxygen gas, are as a group susceptible to antibiotics.<sup>28</sup>

#### Differences between Streptomycin and Oxytetracycline

- Use: While tetracycline is only used during bloom and will only be present on fruit that set early in the bloom period while the late blooms are being sprayed, streptomycin is registered for use from early bloom until 45 days before harvest.
- Mode of Action: Streptomycin binds irreversibly to bacterial ribosomes and block synthesis of proteins (51). Oxytetracycline binds reversibly to these proteins (McManus et al., 2002). (Category 1, Question 9)
- Mechanism of Resistance: There are 2 mechanisms of resistance to streptomycin in fire blight bacteria: spontaneous mutation of a chromosomal gene which encodes production of ribosomal protein, thus strep cannot bind to ribosome and bacteria becomes immune to antibiotic. This is most common in the US. Acquired resistance has been detected occasionally in MI and CA. The pathogen acquired plasmids that contained genes encoding an enzyme that inactivates strep. These resistant isolates of fire blight were detected in an orchard ten years after applications were stopped (34). The fire blight bacteria has not been known to develop resistance to tetracycline in the laboratory, and little is known about the mechanisms for resistance to tetracycline in that bacteria.
- \*\* Genetics of Resistance: The genes for resistance to streptomycin that are transferred by plasmid are the same genes known to confer resistance to streptomycin in human pathogens.<sup>29</sup> This is a step in the chain of causation that is not known for tetracycline.
- Residue on Fruit: While there were not specific studies besides EPA data that set ADI limits that showed residue of tetracycline on fruit, one study in Austrian orchards showed detection of streptomycin residues (33) in apples, with the highest concentrations in the apple core. Apple fruit were collected about three months after bloom and tested for streptomycin. The level of detection was 2 µg/kg (0.002 ppm or 2 ppb) and the limit of quantification was identified as 7 µg/kg (0.007 ppm or 7 ppb). They reported that the highest concentration of streptomycin detected was 18 µg/kg (0.018 ppm), well below the EPA tolerance of 250 µg/kg (0.25 ppm). The Austrian ADI for streptomycin is 0.03 mg per kg of body mass per day (0.03 ppm). The study did not report on exactly what spray practices led to this result.)(Category 1, Question 9)
- Use in medicine: Both tetracycline and streptomycin are classified as critically important antimicrobials by the World Health Organization. Tetracycline is one of a limited number of therapies for infections due to *Brucella*, *Chlamydia* spp. and *Rickettsia* spp. Streptomycin is a Limited therapy as part of treatment of enterococcal endocarditis and Multi-Drug Resistant (MDR) tuberculosis. Tetracycline has a higher priority because it is used more frequently for specific uses, which could lead to faster spread of resistance. Tetracycline is administered orally, while streptomycin is administered by injection.<sup>30</sup> It is unclear what link there may be between oral ingestion and the build-up of resistance to injected streptomycin.

#### Conclusions

##### **Those supporting an extension of streptomycin use say:**

There is no evidence that applications of antibiotics to orchards during bloom contributes to antibiotic-resistance in human pathogens. Human pathogens have not been found in orchards and would have to be present for the resistance genes to transfer. Naturally occurring streptomycin resistant bacteria may be a minor

components of the overall bacterial communities found on apple flowers and in soils, but their presence is independent of the antibiotic application. The amount and timing of the use of this material in an orchard environment does not contribute to any human health concerns, especially in light of streptomycin being ineffective in humans when ingested orally.

**Those opposing an extension of streptomycin use say:**

There is evidence that application of streptomycin leads to increase resistance to streptomycin in orchard bacteria, that human pathogens and the fire blight bacteria share the same gene pool of genes resistant to streptomycin (i.e., that the same genes responsible for resistance in *Erwinia amylovora* are also responsible for resistance in human pathogens), that human pathogens do not need to be present in the orchard to obtain resistance genes acquired by and augmented in orchard bacteria, that streptomycin residues are sometimes present in treated fruit, and that streptomycin is still a critically important antimicrobial for use against human pathogens. In light of the crisis of antibiotic resistance, we cannot allow streptomycin use to be extended in organic production.

**Evaluation Criteria (see attached checklist for criteria in each category)**

- 1. Impact on Humans and Environment
- 2. Essential & Availability Criteria
- 3. Compatibility & Consistency

Criteria Satisfied?

- Yes    No    N/A
- Yes    No    N/A
- Yes    No    N/A

**Substance Fails Criteria Category:** NA

**Recommended Subcommittee Action & Vote**, including classification recommendation (state actual motion):

**Classification Motion:** Streptomycin is synthetic and is already classified as such on the National List so there was no need to make a motion to that effect.

**Listing Motion:** To remove existing expiration date of October 21, 2014 for streptomycin on §205.601(i)(11), and replace it with an expiration date of October 21, 2017,” so that the listing reads: (11) Streptomycin, for fire blight control in apples and pears only until October 21, 2017.

Motion by: Harold Austin

Seconded by: Zea Sonnabend

Yes: 5   No: 3   Absent: 0   Abstain: 0   Recuse: 0

**Additional Motion: Resolution:** The National Organic Standards Board is committed to the phase out of this material. Between now and the expiration date the Board urges growers and certifiers to include in organic systems plans an annual increase in the extent and/or number of alternative practices and materials that are trialed for controlling fire blight. In addition, the board strongly advocates to USDA a high priority for increased support for research into these alternative practices and materials.

Motion by: Harold Austin

Seconded by: Zea Sonnabend

Yes: 8   No: 0   Absent: 0   Abstain: 0   Recuse: 0

**Approved by Jay Feldman, Subcommittee Chair, to transmit to NOSB August 6, 2013**

**NOSB Evaluation Criteria for Substances Added To the National List  
Crops or Livestock**

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

**Substance: Streptomycin**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during use or misuse? [§6518(m)(3)]	X	X		The petition claims the manufacturing process as CBI. However, the 2011 TR (lines 314-315) states, "Dzhedzhev et al. (1975) reported that the manufacture of streptomycin resulted in high atmospheric concentrations of the solvents butyl alcohol and butyl acetate in the workplace." The TR also says (lines 315-332) Streptomycin is produced using fermentation, a process that usually involves the use of solvents and gases that may be discharged into water or air, subject to EPA permits. The TR concludes (lines 326-328) that assuming streptomycin manufacturers comply with applicable water and air regulations; it is unlikely that environmental contamination will result from the fermentation process. (March 8, 2011 TR – lines 326-328) also in that same TR, lines 334-341 states that no surface residue can be found on pear or apple trees after four to six weeks following a spray application(Gardan and Manceau (1984)). Also in this same section the EPA (1988) states streptomycin residues are non-detectable (<0.5ppm) on crops when treated according to label use rates and directions. TR lines 414-415 states that the RED for streptomycin concluded that agricultural streptomycin products, labeled and used according to EPA regulations, will not pose unreasonable risks or adverse effects to the environment (EPA 1992). There is an EPA registration review of streptomycin underway that is scheduled to be completed in 2014.
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]	X	X		See above for detailed explanation
3. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517(c)(1)(B)(ii)]		X		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]	X			Streptomycin should not be applied following an application of a Bordeaux mixture and it is incompatible with lime sulfur (according to the 2002 HSDB) (March 8, 2011 TR lines 357 & 358). Fall 2013 250 of 268

<p>5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]</p>	<p>X</p>	<p>X</p>	<p>March 8, 2011 TR (lines 338) states that strep breakdowns into products that include methylamine, carbon dioxide, and urea, all of which occur naturally in the environment. (EPA 1988, 1992) EPA cited data that showed that streptomycin biodegrades relatively quickly in soil and water.</p> <p>Streptomycin can be phytotoxic to plants; therefore it is sprayed on the surface of plants rather than injected (McManus and Stockwell, 2000). Most apple and pear producers are prudent in their use of streptomycin sprays to reduce costs and to prevent the development of streptomycin-resistant strains of <i>Erwinia amylovora</i>. Disease risk models help producers optimize the timing of antibiotic sprays and reduce the total number of applications. These measures can help reduce the development of antibiotic resistance. (March 8, 2011 TR lines 111-115)</p> <p>There is a high probability that streptomycin resistant bacteria are present in the environment as a consequence of pesticidal use of streptomycin (EPA, 2006a). (TR lines 429-431) The HED Chapter of the TRED states that there have been reports of adverse effects resulting from use of streptomycin as a pesticide (EPA, 2006a). (TR lines 449-450) Because of the risk to workers, personal protective equipment is advised to prevent skin contact with streptomycin, and workers are not permitted re-entry into treated areas for at least 12 hours. (TR lines 454-456)</p>
<p>6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]</p>	<p>X</p>	<p>X</p>	<p>A certain background level of streptomycin is expected in soil due to the natural presence of the bacterium <i>Streptomyces griseus</i> (Brosche, 2010). EPA (1988, 1992) cited data that show that streptomycin biodegrades relatively quickly in soil and water. (TR lines 207-210). The breakdown products include methylamine, carbon dioxide, and urea, all of which occur naturally in the environment. Therefore, the application of streptomycin for control of fire blight in apples and in pears in accordance with labeled instructions is unlikely to contaminate the environment. (TR lines 337-341).</p> <p>According to EPA, streptomycin is moderately persistent in aerobic soil (a single value of <math>t_{1/2}</math> = 17.5 days was determined). EPI Suite estimated a shorter aerobic soil half-life (<math>t_{1/2}</math> = 25 days) and a longer sediment half-life (<math>t_{1/2}</math> = 100 days). Given the moderate persistence/high mobility and solubility of streptomycin, the chemical is expected to dissipate relatively slowly and at the same time be vulnerable to leaching/run-off. (TR lines 217-225) Gardan and Manceau (1984) reported that no surface residue of streptomycin was detectable on pear or apple trees after four to six weeks following spray application. However, Mayerhofer et al. (2009) showed that the use of streptomycin sprays can lead to detectable concentrations of streptomycin in apples. Streptomycin was detected</p>

			<p>in 20 of 41 samples from orchards that were treated one to three times with streptomycin sprays. The concentration of streptomycin was highest in the apple cores and skin and ranged from 1.9 to 18.4 µg/kg (equivalent to 0.0019 to 0.0184 ppm, well below the EPA's established tolerance of 0.25 ppm). (TR lines 238-244)</p>
<p>7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]</p>	<p>X</p>	<p>X</p>	<p>The TRED for streptomycin concluded that “there is reasonable certainty that no harm to any population subgroup will result from exposure to streptomycin (EPA, 2006b). (March 8, 2011 TR lines 438 – 439) Also, in the TR lines 441-444 states that “Current tolerances (maximum residue limits) for streptomycin on or in apples and pears is 0.25ppm. Assuming that the maximum amount of streptomycin residues are present in all types of food which may contain residues, EPA determined that chronic aggregate dietary exposure from streptomycin residues in food and water is not considered to be a human health concern (EPA, 2006a).</p> <p>Bacterial resistance to streptomycin as a result of pesticidal use has the potential to cause adverse public health consequences if human bacterial pathogens are present in orchards and develop resistance or if non-pathogenic bacteria in orchards develop resistance and later transfer the resistance to human bacterial pathogens. EPA's assessment concluded that “the possibility of antibiotic resistance resulting in adverse human health consequences was of medium concern following occupational application and was of high concern following application by residential users” (EPA, 2006a, pg. 3). (TR lines 645-650)</p> <p>Streptomycin remains important in modern medicine, and an increase in streptomycin-resistant bacteria in the environment and in humans may lead to adverse human health consequences. Streptomycin is used today in medicine in combination therapy to treat tuberculosis (due to increasing resistance to other anti-tubercular drugs) and enterococcal endocarditis (when there is resistance to gentamicin). It is also used to treat the plague and tularemia. (TR lines 634-638)</p> <p>See also question #5.</p> <p>Streptomycin is toxic to algae (Qian <i>et al.</i>, 2012) and therefore the EPA requires a warning on any streptomycin label include a warning not to apply directly to water or in areas where surface water is present, and to not contaminate water during cleaning of equipment or disposal of wastes. TR lines 414-415 states that the RED for streptomycin concluded that agricultural streptomycin products, labeled and used according to EPA regulations, will not pose unreasonable risks or adverse effects to the environment (EPA 1992). There is an EPA registration review of streptomycin underway that is scheduled to be completed in 2014.</p>

<p>8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]</p>	<p>X</p>		<p>Toxic to bacteria and algae. See question #7. The ammonium-Nitrogen concentration was significantly increased following application of streptomycin, possibly indicating that nitrifying bacteria were susceptible to this bactericide. This study also found that application of streptomycin at a rate of 3 mg/g soil caused a continuing reduction in the total bacterial population which lasted longer than the study (22 days). Streptomycin applied at 3 mg/g soil also reduced active hyphae only on the first day following application. A broad-spectrum antibiotic like streptomycin would be expected to inhibit the nitrification process in soil. The presence of streptomycin in three different types of soils affected the ecological balance in the soil, causing the elimination of some bacterial populations. The eliminated species were described as beneficial bacteria involved in various metabolic processes, mineralization of organic compounds, degradation of toxic compounds, or creating soil structure. This study also isolated from the soils many strains of bacteria demonstrating resistance to streptomycin, including opportunistic pathogens of humans and/or animals. (2011 TR lines 377-378, 379-382, 386-387, 389-391, 395-398) Based on the limited data available, it is still unclear if the use of streptomycin for control of fire blight has significant negative effects on interactions in the agro-ecosystem, including soil organisms. There are no studies available in the field and the studies in the laboratory with soil bacterial populations appear to be contradictory. (TR lines 404-407)</p>
<p>9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]</p>	<p>X</p>		<p>Toxic to algae. (TR line 347) Algae are present in most of the soils where moisture and sunlight are available, mostly blue-green (Cyanophyta) and green (Chlorophyta). Soil algae are important in maintaining fertility, building soil organic matter, building soil structure, increasing water holding capacity, and aerating soils.<sup>31</sup></p>

**NOSB Evaluation Criteria for Substances Added To the National List  
Crops or Livestock**

**Category 2. Is the Substance Essential for Organic Production?      Substance: Streptomycin**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]	X			
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]		X		
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			Streptomycin is a naturally occurring compound which is produced by the soil bacterium <i>Streptomyces griseus</i> . Agricultural streptomycin is produced on a large scale by aerobic fermentation of <i>Streptomyces griseus</i> followed by isolation and purification by ion exchange (HSDB, 2002; EPA, 1992) March 8, 2011 TR lines 172-174. Also, TR lines 199-200 states that Streptomycin is produced through a naturally occurring process (aerobic fermentation), but the processes used to isolate and purify the substance are not naturally occurring. The forms of streptomycin currently on the National List as approved are listed as synthetic substances.
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	X	X		Streptomycin is a naturally occurring compound which is produced by the soil bacterium <i>Streptomyces griseus</i> . Commercially, streptomycin is produced through a naturally occurring process (aerobic fermentation), but the processes used to isolate and purify the substance are not naturally occurring. (TR lines 199-201)
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	
6. Is there an organic substitute? [§205.600(b)(1)]			X	
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]	X	X		There are several biological control agents (such as bacteria or yeast) that are used to try to outcompete the fire blight pathogen where it occurs on the blossom. These materials are used for fire blight suppression. Two strains of beneficial bacterium, <i>Pantoea agglomerans</i> , are: Bloomtime Biological and Blight Ban C9-1. The bacterium <i>Pseudomonas fluorescens</i> A506 is marketed as Blight Ban A506. There are two strains of yeast <i>Aureobasidium</i>

		<p><i>pullulans</i> that are used to make up the product Blossom Protect (Bio-ferm, Germany) which has recently been introduced into the market to help in controlling fire blight. TR 2011 lines 468-486. In this same TR, Blight Ban A506 is rated as being poor to fair for effectiveness, lines 493-505 (Johnson et al.,2009) in inoculated trials and slightly better in field trials (Johnson 2010). Johnson further states that Bloomtime and Blight Ban C9-1 both performed slightly better with about 50% reduction in disease incidence observed in the inoculated field tests. He rates Bloomtime Biological as poor to good and the effectiveness of Serenade Max and Blossom Protect as fair to good for effectiveness for fire blight suppression. By comparison, the antibiotic treatment oxytetracycline is described as fair to very good, and treatment with streptomycin is poor to excellent (the poor rating is due to widespread pathogen resistance to streptomycin within the western states). (TR lines 493-507) Disease control was more consistent in field trials conducted with compatible mixtures of antagonistic organisms than with single strains –up to 68 and 71% disease reduction on average, compared to 39% and 81% on average, for oxytetracycline and streptomycin, respectively. (TR lines 517-532) In Germany, treatment with Blossom Protect resulted in an average efficiency of 82% reduction in fire blight incidence (results from six different trials). (TR lines 547-548) Johnson (2010) reports that he and his colleagues evaluated Blossom Protect in an inoculated fire blight trial in 2008 (also using four applications during bloom). They found this product to be nearly as effective as streptomycin (Agri-Mycin) in an orchard with high disease pressure. (TR lines 552-555) A large amount of public comment received in written form to FR Docket AMS-NOP-12-0070 and verbally at the Spring 2013 meeting indicated that the above "substitute products" did not work well in certain regions or agricultural systems and therefore were not true substitutes.</p>
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8. Are there any alternative substances? [§6518(m)(6)]	X		Besides the biologicals, there are alternative substances that are listed as having some control of fire blight and of these oxytetracycline is by far the best alternative substance. Other materials listed are various copper mixtures (a couple of new products currently being looked at by researchers), lime-sulfur, and Peracetic acid (which is as a disinfectant and not as a spray replacement material).
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X	X	No one practice can eliminate fire blight, including the use of antibiotics. There are practices that can help in reducing fire blight potential in an orchard as part of a systems approach. Some of these would include using fire blight prediction models to assist in proper timing of materials applications, monitoring and removal of infected plant tissue, planting of resistant root stocks (this would only protect the root system and not the fruit producing portion of the tree), ground cover and water management to help reduce humidity levels within an orchard, and also planting of more fire blight resistant cultivars. (TR lines 601-617, 671-701)

**NOSB Evaluation Criteria for Substances Added To the National List  
Crops or Livestock**

**Category 3. Is the substance compatible with organic production practices? Substance:  
Streptomycin**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic farming and handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X	X		It is currently included on the National List of Allowed and Prohibited Substances, as a synthetic substance allowed in organic crop production for fire blight control in apples and pears only [7 CFR 205.601 (i)(11)] as previously /currently approved by the NOSB and implemented into policy by the NOP. Contrary to consumer expectations. Inconsistent with prohibition on antibiotics in livestock. Inconsistent with European requirements.
2. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X	X		If it is used as part of an organic systems plan in a rotational manner, to enhance resistance management in an effort to minimize the potential for resistance to fire blight to develop. Increases likelihood of antibiotic resistance in pathogenic organisms. It is not sustainable because the fire blight organism will develop resistance.
3. If used in livestock feed or pet food, Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]			X	
4. If used in livestock feed or pet food, Is the primary use as a preservative? [§205.600(b)(4)]			X	
5. If used in livestock feed or pet food, Is the primary use to recreate or improve flavors, colors, textures, or nutritive value lost in processing (except when required by law)? [§205.600(b)(4)]			X	
6. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories: [§6517(c)(1)(B)(i);  copper and sulfur compounds		X		
toxins derived from bacteria	X			
pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals		X		
livestock parasiticides and medicines		X		

production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers		X		
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<sup>1</sup> Stockwell, V.O., and Duffy, B., 2012. Use of antibiotics in plant agriculture. Rev. Sci. Tech. Off. Int. Epiz., 31:199-210.

<sup>2</sup> As reported in Ostenson, H.T. 2010. Organic pome and cherry production and marketing issues: Past, present and future. Acta Hort. (ISHS) 873:137-144, and presented to IFOAM, "Over the last ten years, the Hartman Group (Bellevue, Washington, USA) has studied changes in consumer attitudes, backgrounds, and buying characteristics related to the organic market. The Hartman Group surveyed about two thousand household consumers across four regions of the USA. They found that the 'traditional' properties suggested by 'organic' were no longer the same properties held by the new organic consumer. The survey indicated that traditional properties such as 'locally-grown,' Fair Trade, 'tastes better,' and sustainable production ranked at the bottom. The new organic consumers made it clear that they want, plain and simple, a product centered around the 'absence of all health concerns,' and the absence of pesticides, growth hormones, GMO's, antibiotics, and BSE."

<sup>3</sup> McGhee, G. C., Guasco, J., Bellomo, L. M., Blumer-Schuette, S. E., Shane, W. W., Irish-Brown, A., and Sundin, G. W., 2011. Genetic analysis of streptomycin-resistant (SmR) strains of *Erwinia amylovora* suggests that dissemination of two genotypes is responsible for the current distribution of SmR *E. amylovora* in Michigan. Phytopathology 101:182- 191.

<sup>4</sup> Russo, N. L., Burr, T. J., Breth, D. I., and Aldwinckle, H. S., 2008. Isolation of streptomycin resistant isolates of *Erwinia amylovora* in New York. Plant Dis. 92:714-718.

<sup>5</sup> Claudia Nischwitz, Christine Dhiman, 2012. Streptomycin resistance of *Erwinia amylovora*, causal agent of fire blight. Utah State University Extension and Utah Plant Pest Diagnostic Laboratory, PLP-018.

<sup>6</sup> McGhee, G. C., Guasco, J., Bellomo, L. M., Blumer-Schuette, S. E., Shane, W. W., Irish-Brown, A., and Sundin, G. W. 2011. Genetic analysis of streptomycin-resistant (SmR) strains of *Erwinia amylovora* suggests that dissemination of two genotypes is responsible for the current distribution of SmR *E. amylovora* in Michigan. Phytopathology 101:182- 191.

<sup>7</sup> Russo, N. L., Burr, T. J., Breth, D. I., and Aldwinckle, H. S., 2008. Isolation of streptomycin resistant isolates of *Erwinia amylovora* in New York. Plant Dis. 92:714-718.

<sup>8</sup> Instead, these growers rely on a number of other practices, allowing them to avoid fire blight damage to susceptible varieties. Balancing nutrients and avoiding over-application of nitrogen fertilizers, especially on susceptible varieties of apples or pears; avoidance of over-pruning in the dormant season; use of pre-bloom foliar nutrient sprays even though there is no foliage; use of copper materials on the trees between delayed dormant and tight cluster stages as preventive measures against overwintering FB; use of lime sulfur during bloom to thin apples; and, use of Serenade MAX (in the future, perhaps Blossom Protect) post-bloom and at petal-fall, with good spray coverage. (With some differences for pears.)

<sup>9</sup> In response, the following is suggested: Increase species diversity; decrease tree density; use resistant cultivars and rootstocks; plant a variety of cultivars on a variety of rootstocks.

<sup>10</sup> Yashiro, E & McManus, P. 2012 Effect of streptomycin treatment on bacterial community structure in the apple phyllosphere. PLoS ONE 7(5): e37131. doi:10.1371/journal.pone.0037131

<sup>11</sup> WHO, 2009. Critically Important Antimicrobials for Human Medicine, [http://www.who.int/foodsafety/foodborne\\_disease/CIA\\_2nd\\_rev\\_2009.pdf](http://www.who.int/foodsafety/foodborne_disease/CIA_2nd_rev_2009.pdf) See Table 1.

<sup>12</sup> Streptomycin TR, 2011. Lines 423-431.

<sup>13</sup> American Academy of Microbiology, 2009. Antibiotic Resistance: An Ecological Perspective on an Old Problem. <http://academy.asm.org/images/stories/documents/antibioticresistance.pdf> (pp.1-5, 10.)

<sup>14</sup> American Academy of Microbiology, 2009. (p.8.)

<sup>15</sup> Streptomycin TR, 2011. Lines 632-633. American Academy of Microbiology, 2009. (p.2.)

<sup>16</sup> Gullberg E, Cao S, Berg OG, Ilbäck C, Sandegren L, et al., 2011. Selection of Resistant Bacteria at Very Low Antibiotic Concentrations. PLoS Pathog 7(7): 1-9.

<sup>17</sup> McGhee, G. C., Guasco, J., Bellomo, L. M., Blumer-Schuette, S. E., Shane, W. W., Irish-Brown, A., and Sundin, G. W. 2011. Genetic analysis of streptomycin-resistant (SmR) strains of *Erwinia amylovora* suggests that dissemination of two genotypes is responsible for the current distribution of SmR *E. amylovora* in Michigan. Phytopathology 101:182-191. Alan L. Jones and Elise L. Schnabel, 2000. The Development of Streptomycin-resistant Strains of *Erwinia amylovora*, in J.L. Vanneste (ed.), *Fire Blight The Disease and its Causative Agent, Erwinia amylovora*, CAB International, UK. Pp. 235-254.

<sup>18</sup> S. Tolba et al., 2002. Distribution of streptomycin resistance and biosynthesis genes in streptomycetes recovered from different soil sites. FEMS Microbiology Ecology 42: 269-276

<sup>19</sup> Egan, S., Wiener, P., Kallio, D., and Wellington, E.M.H. (2001) Phylogeny of Streptomyces species and evidence of horizontal transfer of entire and partial antibiotic gene clusters. Antonie Van Leeuwenhoek 79, 127-133. Wiener, P.,

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<sup>20</sup> George W. Sundin, Dave E. Monks, Carol L. Bender, 1995. Distribution of the streptomycin-resistance transposon Tn5393 among phylloplane and soil bacteria from managed agricultural habitats. *Canadian Journal of Microbiology*, 41(9): 792-799.

<sup>21</sup> Yashiro E, McManus PS, 2012. Effect of Streptomycin Treatment on Bacterial Community Structure in the Apple Phyllosphere. *PLoS ONE* 7(5): e37131

<sup>22</sup> McGhee, G. C., Guasco, J., Bellomo, L. M., Blumer-Schuetz, S. E., Shane, W. W., Irish-Brown, A., and Sundin, G. W. 2011. Genetic analysis of streptomycin-resistant (SmR) strains of *Erwinia amylovora* suggests that dissemination of two genotypes is responsible for the current distribution of SmR *E. amylovora* in Michigan. *Phytopathology* 101:182- 191.

<sup>23</sup> Sundin, G. W. 2002. Distinct recent lineages of the *strA-strB* streptomycin-resistance genes in clinical and environmental bacteria. *Curr. Microbiol.* 45:63-69.

<sup>24</sup> GW Sundin and CL Bender, 1996. Dissemination of the *strA-strB* streptomycin-resistance genes among commensal and pathogenic bacteria from humans, animals, and plants, *Molecular Ecology* 5, 133-143

<sup>25</sup> See for example, Cristina Pezzella, Antonia Ricci, Elisabetta DiGiannatale, Ida Luzzi, and Alessandra Carattoli, 2004. Tetracycline and Streptomycin Resistance Genes, Transposons, and Plasmids in *Salmonella enterica* Isolates from Animals in Italy. *Antimicrobial Agents and Chemotherapy*, 48 (3): 903–908. Alexandre Scherer, Hans-Rudolf Vogt, Edy M. Vilei, Joachim Frey, and Vincent Perreten, 2013. Enhanced antibiotic multi-resistance in nasal and faecal bacteria after agricultural use of streptomycin, *Environmental Microbiology* 15(1), 297–304. (“This study shows that the application of low concentrations of streptomycin on grass, as occurs during the spraying of orchards, selects for multidrug-resistant nasal and enteric bacterial flora, including extended-spectrum beta-lactamase-producing *E. coli*.”) Foster, G. C., McGhee, G. C., Jones, A. L., and Sundin, G. W. 2004. Nucleotide sequences, genetic organization, and distribution of pEU30 and pEL60 from *Erwinia amylovora*. *Appl. Environ. Microbiol.* 70:7539-7544.

<sup>26</sup> WHO, 2009. Critically Important Antimicrobials for Human Medicine, [http://www.who.int/foodsafety/foodborne\\_disease/CIA\\_2nd\\_rev\\_2009.pdf](http://www.who.int/foodsafety/foodborne_disease/CIA_2nd_rev_2009.pdf) See Table 1. Tuberculosis is rapidly developing resistance to all known antimicrobials. Phillip Trollip, 2013. Emergence and Spread of Extensively and Totally Drug-Resistant Tuberculosis, South Africa. *Emerging Infectious Diseases*, 19 (3): 449-455 [www.cdc.gov/eid](http://www.cdc.gov/eid)

<sup>27</sup> <http://www.drugs.com/pro/streptomycin.html>

<sup>28</sup> Jose Luis Martinez, 2009. Environmental pollution by antibiotics and by antibiotic resistance determinants. *Environmental Pollution* 157: 2893–2902.

<sup>29</sup> See, for example, the following articles. C.-S. Chiou and A. L. Jones, 1993. Nucleotide Sequence Analysis of a Transposon (Tn5393) Carrying Streptomycin Resistance Genes in *Erwinia amylovora* and Other Gram-Negative Bacteria. *Journal of Bacteriology*, Vol. 175, (3): 732-740. GW Sundin and CL Bender, 1996. Dissemination of the *strA-strB* streptomycin-resistance genes among commensal and pathogenic bacteria from humans, animals, and plants, *Molecular Ecology* 5, 133-143. McGhee, G. C., and Sundin, G. W. 2011. Evaluation of kasugamycin for fire blight management, effect on nontarget bacteria, and assessment of kasugamycin resistance potential in *Erwinia amylovora*. *Phytopathology* 101:192-204. Cristina Pezzella, Antonia Ricci, Elisabetta DiGiannatale, Ida Luzzi, and Alessandra Carattoli, 2004. Tetracycline and Streptomycin Resistance Genes, Transposons, and Plasmids in *Salmonella enterica* Isolates from Animals in Italy. *Antimicrobial Agents and Chemotherapy*, 48 (3): 903–908. Alexandre Scherer, Hans-Rudolf Vogt, Edy M. Vilei, Joachim Frey, and Vincent Perreten, 2013. Enhanced antibiotic multi-resistance in nasal and faecal bacteria after agricultural use of streptomycin, *Environmental Microbiology* 15(1), 297–304.

<sup>30</sup> WHO, 2009. Critically Important Antimicrobials for Human Medicine, [http://www.who.int/foodsafety/foodborne\\_disease/CIA\\_2nd\\_rev\\_2009.pdf](http://www.who.int/foodsafety/foodborne_disease/CIA_2nd_rev_2009.pdf) See Table 1.

<sup>31</sup> “Soil microorganism—algae” My Agriculture Information Bank <http://agriinfo.in/?page=topic&superid=5&topicid=150> Zancan, S., Trevisan, R., & Paoletti, M. G. (2006). Soil algae composition under different agro-ecosystems in North-Eastern Italy. *Agriculture, ecosystems & environment*, 112(1), 1-12.



**National Organic Standards Board  
Crops Subcommittee  
Petitioned Material Checklist  
Magnesium Oxide**

**August 6, 2013**

**Summary of Proposed Action:**

Magnesium Oxide (MgO) has been petitioned for use under §205.601 Synthetic substances allowed for use in organic crop production. Specifically, the petition states “Magnesium oxide is intended to be used to control the viscosity of a clay suspension agent to prevent settling of materials suspended in water or other liquids.” The petitioner indicates they wish to use MgO for the application of finely ground humates, but the petition is written more broadly: “The substance is intended to be used in combination with other organic inputs applied as a liquid foliar on a wide variety of different agricultural, vegetable, fruit, and horticultural crops.”

The petitioner indicates they would use MgO at a very low level: at 0.074% of the humate suspension being applied, which would equate to 0.0007 to 0.0014 pounds of MgO applied per acre.

Magnesium oxide occurs as the mineral magnesite, and in its hydrated form – magnesium hydroxide -- is the naturally occurring mineral periclase. Magnesium oxide appears to be a fairly benign compound that has a wide range of uses, including as an antacid and laxative (milk of magnesia), and in lots of industrial processes such as in producing cement, abrasive materials and furnace linings.

There are several manufacturing processes used to produce MgO. It is commonly made from sea water or salt brines, but can also be made by heating MgCO<sub>3</sub> limestone to drive off CO<sub>2</sub> and produce MgO. (To produce MgO from sea water or salt brine uses the following procedure: The raw materials are lime and salt water -- either sea water or brine from salty wells. The lime is heated to produce calcium oxide. Fresh water is then added to the calcium oxide to produce calcium hydroxide. Sea water or salt brine from a well -- treated with a small amount of sulfuric or hydrochloric acid -- is then added to the calcium hydroxide, causing the magnesium chloride in the salt water to react with calcium hydroxide to produce magnesium hydroxide and calcium chloride. The magnesium hydroxide is then heated to produce magnesium oxide.)

The MgO manufactured using sea water or salt brine (and some acid) produces a purer and more refined form of MgO than that produced by heating magnesium carbonate limestone, and so is preferred by the petitioner.

**Evaluation Criteria (see attached checklist for criteria in each category)**

	<b>Criteria Satisfied?</b>		
1. Impact on Humans and Environment	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2. Essential & Availability Criteria	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
3. Compatibility & Consistency	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

**Subcommittee Action & Vote:**

**Classification Motion:** Move to classify Magnesium Oxide as petitioned as synthetic.

Motion by: Francis Thicke

Seconded by: Colehour Bondera

Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

**Listing Motion:** Move to list Magnesium Oxide to §205.601 with the following annotation: For use only to control the viscosity of a clay suspension agent for humates.”

Motion by: Francis Thicke

Seconded by: Zea Sonnabend

Yes: 8 No: 0 Absent: 0 Abstain: 0 Recuse: 0

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

Notes:

**Approved by Jay Feldman, Subcommittee Chair, to transmit to NOSB August 6, 2013**

**NOSB Evaluation Criteria for Substances Added To the National List  
Crops**

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

**Substance: Magnesium Oxide**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is there a probability of environmental contamination during, use or misuse? [§6518(m)(3)]		X		
2. Is there a probability of environmental contamination during, manufacture or disposal? [§6518(m)(3)]		X		When MgO is produced using sea water or salt brine, a small amount of acid is used to lower the pH of the salt solution to prevent the formation of carbonates.  When MgO is produced using magnesium carbonate limestone, carbon dioxide is released into the atmosphere. Additional carbon dioxide is produced through the burning of fossil fuels used to achieve the high heat required to decompose the limestone.
3. Does the substance contain inerts classified by EPA as ‘inerts of toxicological concern’? [§6517 (c)(1)(B)(ii)]		X		
4. Is there potential for detrimental chemical interaction with other materials used in organic farming systems? [§6518(m)(1)]		X		
5. Is there a toxic or other adverse action of the material or its breakdown products? [§6518(m)(2)]		X		
6. Is there persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		X		
7. Would the use of the substance be harmful to human health or the environment? [§6517 (c)(1)(A)(i); §6517 (c)(2)(A)(i); §6518(m)(4)]		X		

8. Are there adverse biological and chemical interactions in the agro-ecosystem, including biodiversity? [§6518(m)(5)]		X		
9. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518(m)(5)]		X		

**NOSB Evaluation Criteria for Substances Added To the National List  
Crops**

**Category 2. Is the Substance Essential for Organic Production? Substance: Magnesium Oxide**

Question	Yes	No	N/A	Comments/Documentation (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]	X			
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			
4. Is the substance created by naturally occurring biological processes? [§6502(21)]		X		
5. Is there a natural source of the substance? [§ 205.600(b)(1)]			X	
6. Is there an organic substitute? [§205.600(b)(1)]			X	
7. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]		X		
8. Are there any alternative substances? [§6518(m)(6)]		X		None that have the desired functional properties, according to the petitioner.
9. Are there other practices that would make the substance unnecessary? [§6518(m)(6)]	X			MgO is not absolutely essential for the materials application it is petitioned for, but it makes application easier, and perhaps safer for the person applying the materials (reduces dust).

**NOSB Evaluation Criteria for Substances Added To the National List  
Crops**

**Category 3. Is the substance compatible with organic production practices? Substance: MgO**

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



## Sunset 2015 Review List - Request for Public Comment Crops Substances

September 5, 2013

### Introduction

As part of the Sunset Process, the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production which must be reviewed by the NOSB and renewed by the NOP before their sunset dates in 2015. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

### Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the Spring 2014 public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the Fall 2013 public meeting. These comments should be provided through [www.regulations.gov](http://www.regulations.gov) by October 1, 2013 as explained in the meeting notice published in the [Federal Register](#) on September 5, 2013.

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance.

### Guidance on Submitting Your Comments

Comments should clearly indicate your position on continuing the allowance of substances on this list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

### ***For Comments That Support Substances Under Review:***

If you provide comments in support of an allowance of a substance on the National List, you should provide new information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic production.

***For Comments That Do Not Support Substances Under Review:***

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with organic production.

***For Comments Addressing the Availability of Alternatives:***

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- o Alternative management practices that would eliminate the need for the specific substance;
- o Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- o Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

**Table 1. Guidance on submitting comments for alternatives to substances on the National List.**

If the currently listed substance is used in...	And is a...	Then the recommended alternative should be a (an)...
Crop Production	Synthetic substance	<ul style="list-style-type: none"> <li>- Another currently listed synthetic substance;</li> <li>- Nonsynthetic substance; or</li> <li>- Management practice.</li> </ul>

Written public comments will be accepted through Tuesday, October 1, 2013 via [www.regulations.gov](http://www.regulations.gov). Comments received after that date may not be reviewed by the NOSB before the meeting.



## SUNSET 2015: CROPS SUBSTANCES

### Aqueous potassium silicate (Listing 1 of 2 – 205.601(e))

*Synthetic*

**Use** – As an insecticide (including acaricides or mite control).

**Listing:** Aqueous potassium silicate (CAS # 1312-76-1)—The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

**Technical Report:** [2003, New report requested 4/2013.](#)

**Petition(s):** [Potassium Silicate \(PDF\)](#) (2004), [Potassium Silicate Supplemental \(PDF\)](#) (2006)

**Past NOSB Actions:** NOSB review and recommendation for addition to the National List - [11/30/07.](#)

**Regulatory Background:** Proposed rule (including justification) published 6/3/2009 (74 FR 26591). Added to National List 12/13/2010 (75 FR 77521).

**Sunset Date:** 12/14/2015

*Reference: 7 CFR 205.601(e)*

### Aqueous potassium silicate (Listing 2 of 2 – 205.601(i))

*Synthetic*

**Use** – As plant disease control.

**Listing:** Aqueous potassium silicate (CAS # 1312-76-1)—The silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.

**Technical Report:** [2003, New report requested 4/2013.](#)

**Petition(s):** [Potassium Silicate \(PDF\)](#) (2004), [Potassium Silicate Supplemental \(PDF\)](#) (2006)

**Past NOSB Actions:** Approval for addition to the National List on [11/30/07.](#)

**Regulatory Background:** Proposed rule (including justification) published 6/3/2009 (74 FR 26591). Added to National List 12/13/2010 (75 FR 77521).

**Sunset Date:** 12/14/2015

*Reference: 7 CFR 205.601(i)*

### Sodium carbonate peroxyhydrate

*Synthetic*

**Use** – As an algaecide.

**Listing:** Sodium carbonate peroxyhydrate (CAS # 15630-89-4)—Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.

**Technical Report:** [2006, New report requested 4/2013.](#)

**Original Petition:** [Sodium Carbonate Peroxyhydrate \(PDF\)](#) (2005)

**Past NOSB Actions:** Approval for addition to the National List on [11/30/07.](#)

**Regulatory Background:** Proposed rule (including justification) published 6/3/2009 (74 FR 26591). Added to National List 12/13/2010 (75 FR 77521).

**Sunset Date:** 12/14/2015

*Reference: 7 CFR 205.601(a)*



## Sulfurous acid

*Synthetic*

**Use** – As plant or soil amendment.

**Listing:** Sulfurous acid (CAS # 7782-99-2)—for on-farm generation of substance utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.

**Technical Report:** [2010, New report requested 4/2013.](#)

**Original Petition:** [Sulfurous Acid \(PDF\)](#) (2008)

**Past NOSB Actions:** Approval for addition to the National List on [5/09](#)

**Regulatory Background:** Proposed rule (including justification) published 1/12/2010 (75 FR 1555).  
Added to National List 7/6/2010 (75 FR 38693).

**Sunset Date:** 7/7/2015

*Reference: 7 CFR 205.601(j)*