

Agricultural Marketing Service (AMS) | National Organic Program (NOP)
National Organic Standards Board (NOSB) New Member Onboarding Training Agenda
Wednesday - Thursday, February 4-5, 2015
Location: USDA South Building - Room 0727-S, Washington DC

Wednesday February 4, 2015	Content
9:00 - 9:30 AM	AMS Welcome and Introductions Delivered by: Anne Alonzo, Miles McEvoy, and Team
9:30 - 10:15 AM	Organic Foods Production Act (OFPA) - Miles McEvoy
10:15 - 10:45 AM	Federal Advisory Committee Act (FACA) Overview - Jenny Tucker
10:45 - 11:00 AM	Break
11:00 - Noon	Overview of USDA Organic Regulations (Part 1) - Miles McEvoy
Noon - 1 PM	Lunch - (USDA Cafeteria). Meet and greet with AMS/NOP over lunch
1:00 - 1:30 PM	Overview of USDA Organic Regulations (Part 2) - Miles McEvoy
1:30 - 2:30 PM	NOP and NOSB Operational Guidelines (Charter, Nominations, Work agendas, Subcommittees, Public Meetings, FOIA Review). Emily Brown Rosen, Jenny Tucker (FOIA)
2:30 - 2:45 PM	Break
2:45 - 4:30 PM	Training: National List, and Sunset (Exercises/Hands-On Where Possible) <ul style="list-style-type: none"> • Review National List petition process - Lisa Brines • Review Sunset Process and Templates - Lisa Brines
4:30 - 5:00 PM	Q&A, Wrap-Up, day 2 Overview

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Thursday, February 5, 2015	Content
9:00 - 9:30 AM	Review/follow up questions from previous day
9:30 - 11:00 AM Break in middle	National Organic Program Overview: Overview of NOP and an introduction to the three Divisions and their key activities and priorities. Miles McEvoy, Cheri Courtney, Matthew Michael, and Jenny Tucker.
11:00 - 11:30 AM	USDA Organic Working Group (OWG) and Secretary's Organic Guidance - Betsy Rakola
11:30 - Noon	Guided Tour: NOP/NOSB Website - Michelle Arsenault, Emily Brown Rosen
Noon - 1 PM	Lunch (USDA Cafeteria)
1:00 - 3:00 PM Break Midway	Training: <ul style="list-style-type: none"> • Best practices for writing proposals and recommendations - Emily Brown Rosen/Standards • Best practices for evaluating technical reports - Emily Brown Rosen • Best practices for analyzing public comments - Emily Brown Rosen • Review key elements of rulemaking process; what information is needed to get a rule completed and through clearance (OGC and OBPA) - Shannon Nally Yanessa or Emily Brown Rosen (Back-Up)
3:00 - 4:00 PM	Ethics and Conflict of Interest (Teleconference/webcast with full NOSB) - Jenny Tucker
4:00 - 4:30 PM	Summary and Closing Discussion



National Organic Standards Board Training: Organic Foods Production Act (OFPA)

February 2015





- Main Provisions of the Organic Foods Production Act of 1990
- Establishment, Administration and Enforcement of the National Organic Program (NOP)
- The National Organic Standards Board— Creation, Membership, and Role of the Board in the NOP

OFPA: The Big Picture



- Organic Foods Production Act of 1990 (OFPA) (7 U.S.C. 6501 - 6522)
- Purpose:
 - To establish national standards governing the marketing of certain agricultural products as organically produced products
 - To assure consumers that organically produced products meet a consistent standard
 - To facilitate interstate commerce in fresh and processed food that is organically produced



- Definitions
 - Ag product
 - Handle
 - Handler
 - Livestock – includes fish, wild or domesticated, and nonplant life (e.g. mushrooms)
 - National List
 - Person
 - Synthetic



- National organic production program
 - State program
 - Consultation with the NOSB
 - USDA to implement through certifying agents
- National standards for organic production
 - Produced and handled without synthetic chemicals, except as provided
 - 3 years no prohibited substances prior to harvest
 - Produced and handled in compliance with Organic Plan



- Compliance requirements
 - May sell or label organic only in accordance with OFPA
 - No person may affix a label to, or provide other market information concerning, an ag product, if such label or information implies, directly or indirectly, that such product is produced and handled using organic methods, except in accordance with OFPA



- Compliance requirements
 - USDA seal
 - Imports
 - Exemptions for processed food (50% in OFPA)
 - Small farmer exemption



- General requirements
 - Be produced only on certified organic farms and handled only through certified organic handling operations
 - Organic Plan
 - Annual certification
 - On-site inspection
 - Periodic residue testing
 - Enforcement
 - Public access to certificates and lab analysis
 - Other terms determined to be necessary



- General requirements
 - Wild seafood
 - State program
- State organic certification program
 - May have additional requirements
- Prohibited crop production practices
- Animal production practices
 - Organic feed
 - No antibiotics or hormones
 - Dairy cows – 12 month transition



- Handling
 - No synthetics unless on National List
 - No sulfites except in wine
- Additional guidelines – testing and removal of organic label
- If production or handling not prohibited then shall be permitted (contrast with organic regulations)
- Organic Plan
- Accreditation



- Requirements of certifying agents
- Peer review of certifying agents



- Exemption for specific synthetics
 - The Secretary determine in consultation with HHS and EPA –
 - Would be harmful to human health or environment
 - Is necessary to production or handling because of unavailability of natural substitute
 - Is consistent with organic farming and handling
 - The substance contains active synthetic ingredients, or
 - Is used in production and contains synthetic inerts that are not classified by EPA as inerts of toxicological concern
- Prohibition of specific natural substances

Procedures for establishing NL



- National List must be based on NOSB recommendations
- Secretary may not add substances without NOSB recommendation
- NL must be established with notice and comment rulemaking
- Sunset – no NL listing is valid unless the NOSB reviews and the Secretary renews substance every 5 years

7 USC 6518:

National Organic Standards Board



OFPA, 7 U.S.C. 6518 (a) states that:

The Secretary shall establish a National Organic Standards Board:

- In accordance with 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

National Organic Standards Board Membership



- Four who own or operate an organic farming operation
- Two who own or operate an organic handling operation
- One who owns or operates a retail establishment with significant trade in organic products
- Three with expertise in areas of environmental protection and resource conservation
- Three who represent public interest or consumer interest groups
- One with expertise in the fields of toxicology, ecology, or biochemistry
- One who is a certifying agent

National Organic Standards Board Generally



- Secretary appoints Board members
- Five year terms; members cannot serve consecutive terms
- Secretary convenes meetings on a periodic basis
- Secretary shall authorize the Board to hire a staff director and shall detail staff of USDA or allow for the hiring of staff
- Secretary may, subject to appropriations, pay necessary expenses incurred by the Board in carrying out OFPA provisions

National Organic Standards Board Generally



- Members serve without compensation but may be paid for expenses while conducting the business of the Board
- Board selects a Chairperson
- At Board meetings, a quorum constitutes a majority of the members
- Decisive votes: 2/3 of votes cast at the meeting when a quorum is present
- No confidential business information obtained by the Board shall be released to the public

National Organic Standards Board Responsibilities



- Provide recommendations to the Secretary regarding implementation of OFPA
- Develop the proposed National List or proposed amendments to the National List for submission to the Secretary
- Convene technical advisory panels to provide scientific evaluation of materials
- Review botanical pesticides
- Advise the Secretary on product residue testing and emergency spray programs

National Organic Standards Board National List



- Requirements while establishing proposed amendments:
 - Review available information on potential adverse human and environmental effects
 - Obtain complete list of ingredients of considered substances from manufacturers to determine if it includes synthetic inert materials
 - Submit to the Secretary results of Board's evaluation and any technical advisory panel evaluation
- Use seven specified evaluation criteria
- Establish procedures for receiving petitions to evaluate substances for inclusion on the List
- Conduct Sunset review of each substance on the List within five years of it being adopted or renewed

Records, Compliance, Administration



- Recordkeeping
 - Records must be made available
 - Records of all inputs
 - confidentiality
- Investigations
 - Investigations, subpoena authority, take evidence
- Enforcement
 - Civil penalties - \$11,000 per violation
 - False statement, ineligibility
- Expedited appeals process



National Organic Standards Board Training: Federal Advisory Committee Act (FACA)

February 2015



Goal: Review Key Elements of FACA



- FACA Overview
- Agency Responsibilities
- Board Responsibilities
- NOP Authority in Setting Board Policy
- Shared Success Factors

Federal Advisory Committees



- OFPA: Secretary has responsibility to establish the NOSB **in accordance with the Federal Advisory Committee Act (FACA)**
- FACA Committees are established for the purpose of obtaining advice or recommendations on issues or policies **within the scope of an agency official's responsibilities**
- Like the NOSB, many FACA Boards are statutory: In 2012, 141 of the 169 USDA Boards were statutory
- **Federal advisory committees exist to advise and recommend, NOT to decide.**

FACA Committees Must Have....



- A **charter** with established mission and duties:
The USDA renews the NOSB Charter every two years.
- Fair and balanced **membership**: The Secretary appoints NOSB members based on OFPA categories.
- A **Designated Federal Official (DFO)** for advisory committee and its subcommittees. FACA assigns a number of activities to the DFO.
- Opportunity for reasonable participation by the public in advisory committee activities, subject to agency guidelines.

FACA Meeting Rules



- Open meetings with opportunity for public comment
 - Any member of the public is permitted to file a written statement with advisory committee.
 - Any member of the public may speak to or address advisory committee within appropriate guidelines.
- Feedback from previous CMO: “Only a few Boards have high comment rates, and of those, NOSB is 2nd highest.”
- Examples of public comment periods offered by others:
 - 2015 Dietary Guidelines Advisory Committee - 2 day meeting; 4 hours of oral comment.
 - USFS Committee: Forest Planning Rule Implementation. 1 day meeting; 1 hour of comment.

FACA Meeting Rules



- Reasonable time and accessible to the public; with sufficient space to accommodate committee, agency staff, and a reasonable number of the interested members of the public.
- Meetings must be announced 15 days in advance in Federal Register; Meeting minutes are required and are publicly available.

FACA Representatives



- FACA members may be regular government employees, special government employees, and/or representatives: NOSB members are **Representatives**
- NOSB members are classified as **representatives**.
 - Appointed based on ability to articulate and represent group's interests
 - In representing others, speak in “We” not “I” statements
 - Are not expected to provide independent expert advice.

Subcommittees Versus Committees



- Subcommittee's meetings must be conducted in accordance with FACA's openness requirements **IF**
 - Recommendations are made directly to the Federal agency, or
 - The parent advisory committee will adopt subcommittee recommendations without further deliberations
- NOSB subcommittee proposals do not come directly to USDA – they come through the NOSB Full Committee.
- This is why subcommittee calls are not currently open to the public. This is also why we call subcommittee products proposals rather than recommendations.

Agency Responsibilities



- Comply with FACA
- Issue administrative guidelines and management controls that apply to advisory committees
- Designate a Committee Management Officer (CMO) and Designate a Designated Federal Officer (DFO) for each advisory committee and its subcommittees
- Provide a written determination stating the reasons for closing any advisory committee meeting to the public
- Review, at least annually, the need to continue each existing advisory committee, consistent with the public interest and the purpose of each advisory committee

Agency Responsibilities



- Determine that ...staff, experts and consultants to advisory committees are justified and levels of agency support are adequate
- Develop procedures to assure that the committee's recommendations will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the committee's independent judgment
- Assure that the interests and affiliations of advisory committee members are reviewed for conformance with applicable conflict of interest statutes, regulations issued by Office of Government Ethics including any supplemental agency requirements, and other Federal ethics rules

NOP Responsibilities



- **NOP's Designated Federal Officer (DFO):**
 - Calls, attends, and adjourns committee meetings
 - Develops and approves agendas
 - Maintains required records and budgets
 - Ensures efficient operations and adherence to FACA and other laws
 - Develops committee reports for the Committee Management Officer: We must submit an annual report on Board activities, meetings, and expenses.

FACA: Board Responsibilities



- **How should agencies consider the roles of advisory committee members and staff?**
- FACA does not assign any specific responsibilities to members of advisory committees and staff (other than DFO), although both perform critical roles
- **Agency heads, Committee Management Officers (CMOs), and Designated Federal Officers (DFOs)** should consider the distinctions between these roles and how they relate to each other in developing agency guidelines implementing FACA

NOP Authority in Setting Board Policy



- **Agency Guidelines for implementing FACA should reflect:**
 - Clear operating procedures should provide for the conduct of advisory committee meetings and other activities, and specify the relationship among the advisory committee members, the DFO, and staff;
 - In addition to complying with the Act, advisory committee members ...may be required to adhere to additional agency operating policies; and
 - Other agency-specific statutes and regulations may affect the agency's advisory committees directly or indirectly.

FACA and OFPA together



- OFPA doesn't direct the NOSB to decide.
- OFPA asks NOSB to:
 - **Assist** in development of Standards
 - **Provide recommendations**
 - **Evaluate** substances
 - **Develop proposed** National List and **proposed amendments** to the List for submission to the Secretary
- Secretary (authority delegated to AMS) retains decision-making and rulemaking authority

Criteria for Success Under FACA....



- Enhance accountability to public
- Control the undue influence of special interests by balancing committee membership
- Ensure that public access to committee deliberations is maximized.
- Monitor and reduce costs
- Eliminate unproductive and/or unnecessary committees
- Provide for an annual report of committee activities and accomplishments to Congress

NOP and NOSB Success Factors

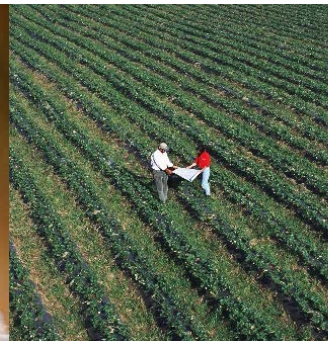


- NOP's success is measured in part by its success in managing the NOSB:
 - Are recommendations within the Committee's scope? (OFPA statute and agency responsibilities)
 - Are Board and program resources being used effectively and efficiently?
 - Is the NOP asking for advice that it can then act upon? (It wastes time and resources for the Board to work on items that the NOP cannot implement.)
 - Are appropriate management structures and processes in place and functioning?



Questions/Discussion

Agricultural Marketing Service | National Organic Program
February 2015





USDA Organic Regulations: Overview



NOP Definition of “organic”:

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



- Definitions
 - Commercially available
 - Excipients
 - Excluded methods
 - Handler
 - Labeling
 - Livestock – (excludes aquatic animals)
 - Prohibited substance
 - Unavoidable residual environmental contamination



- Applicability
 - What has to be certified
 - Exemptions and Exclusions
 - Recordkeeping
 - Allowed and prohibited substances, methods, and ingredients



Banned in Organic Production and Handling

- Use of genetic engineering (GMO)
- Use of ionizing radiation
- Sewage sludge



- Organic production and handling
 - Maintain or improve natural resources (soil and water quality)
 - Organic System Plan
 - Soil fertility
 - Seeds and planting stock
 - Crop rotation
 - Pest management practice standard



Natural Resources

NOP 205.200

Practices must *improve* or *maintain* the natural resources of the farming operation, including soil and water quality.



Organic Systems Plan

- Practices and procedures
- Substances to be used
- Monitoring practices to ensure plan works
- Recordkeeping system
- Preventing contact with prohibited substances
- Other info deemed necessary by certifier.





NOP Regulations: Crop Production

- No prohibited substances on land/fields for 3 years
- Establish buffer zones
- Maintain or improve soil condition
- Minimize soil erosion
- Rotations, cover crops, and application of plant and animal material
- No raw manure applications within 120/90 days before harvest.





Organic Seeds

NOP 205.204

- Organic seeds/planting stock required unless organic seeds/planting stock is not commercially available.
- If organic seeds not commercially available then untreated seeds may be used.
- Treated seeds are prohibited.



Pest Management

NOP 205.206

Bio-intensive pest management plans.

- Prevention first:
 - Crop rotations;
 - Resistant varieties;
 - Maintaining beneficial species habitat;
 - Sanitary cultural practices;
- Approved materials used only when crop rotation, biological control, and cultural practices are insufficient to control pests.



Wild Crop Harvest

- Sustainable harvest of defined area
- No prohibited substance exposure
- Protect the environment during harvest





NOP Organic Livestock



- Managed Organically from last 3rd of gestation
 - Poultry from second day of life.
 - Dairy animals may be converted in 1 year



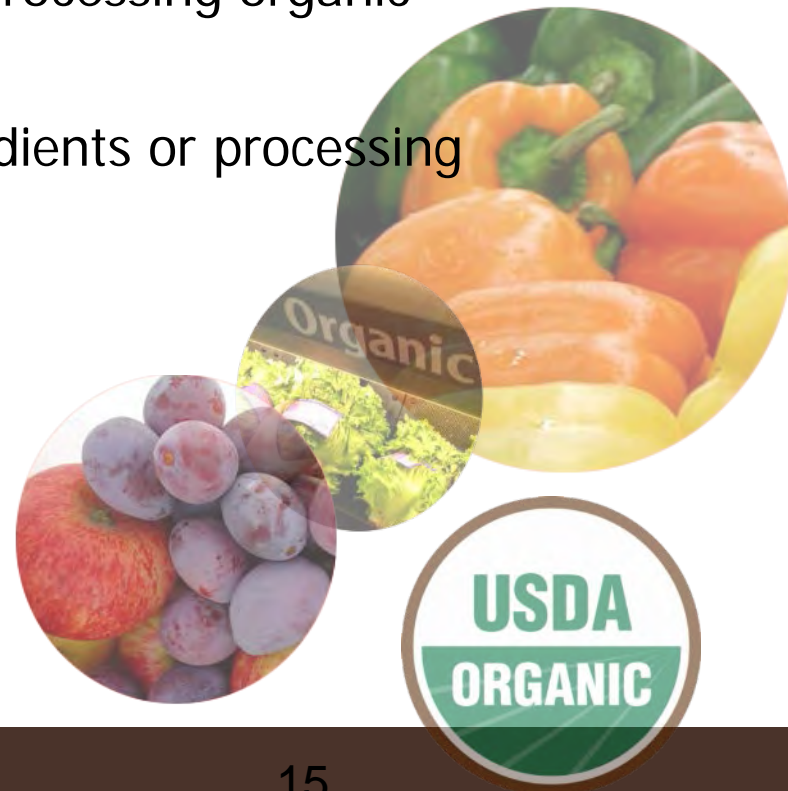
- 100% Organic Feed
 - Synthetic vitamins and trace minerals are Allowed
- Prohibited Substances
 - No Synthetic Hormones or Growth Promoters
 - No Antibiotics
- Animal Welfare – living conditions
 - Pasture requirement for ruminants
 - Outdoor access





HANDLING:

- Processing must be by certified operations
- Mechanical or biological methods for processing organic agricultural products
- "Organic" products: non-organic ingredients or processing aids must be on the National List
- Maintain organic integrity
- Preventive facility pest management





NOP Organic Handling-continued

- Avoid contact with prohibited substances
- Segregate from conventional product
- Label according to NOP regulations.

Croutons: Lightly Salted, Italian Herbs, and Onion Garlic.



606622

Ingredients: Organic Wheat Flour, Organic Non-Hydrogenated Palm Oil, Yeast, Salt, Organic Onion Powder, Organic Garlic Powder.

Dist. by Edward & Sons Trading Co., Inc.
P.O. Box 1326, Carpinteria, CA 93014 USA
www.edwardandsons.com

Certified organic by QAI, USA
Product of Israel

Understanding Organic Labeling



- 100% Organic
All ingredients & processing aids must be 100% certified organic.
- Organic
95% - 100% certified organic ingredients.
- Made with Organic ... (list up to three ingredients or food groups)
At least 70% organic ingredients.
- Less Than 70% Organic Ingredients
Claims are limited to ingredient statement.



100% Organic
Use of the USDA Organic Seal is optional.



Organic
(95% or more Organic Ingredients)
Use of the USDA Organic Seal is optional.



Made with Organic Ingredients
(At least 70% Organic Ingredients)



Less than 70% Organic Ingredients
(Organic Ingredients denoted in ingredient list only)



Subpart E - Certification

1. General requirements
2. Application
3. Review of application
4. Inspection
5. Certification
6. Denial of certification
7. Continuation of certification



Accreditation of Certifying Agents

7 CFR Subpart F 205.500-510

- The USDA Administrator of the Agricultural Marketing Service shall accredit a qualified applicant in the areas of crops, livestock, wild crops or handling or combination thereof to certify production or handling as a certified operation



General Requirements for Accreditation

- Have sufficient expertise to fully comply with and implement the terms and conditions of the organic certification program established under the Act and regulations
- Education
- Experience
- Training
- Administration
- Regulations
- Inspection/auditing
- Crops/livestock/processing/handling/wild crops



General Requirements

– Internal Audits

Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and **implement measures to correct any noncompliances identified in the evaluation**

- Internal Audits
 - Conducting by internal personnel or outside auditor
 - Evaluation of certification system and procedures
 - **Continuous Improvement**
 - Identify areas of strength and areas needing improvement
 - Better to find issues during an internal audit than during an external audit.



General Requirements – conflicts of interest

- Prevent conflicts of interest by:
Not certifying a production or handling operation if the certifying agent or a responsible connected party of such certifying agent has or has held a commercial interest in production or handling operation, including an immediate family interest or consulting within the 12 month period prior to the application of certification



General Requirements – accepting all certification decisions

- One rule to rule them all
- All certifiers must comply with the NOP regulations
- Certifiers cannot require any additional requirements beyond the NOP regulations

NOP accredited certifiers must accept certification decisions made by other NOP accredited certifiers.

Especially important for processed products utilizing ingredients certified by other certifiers.



Evidence of expertise – 205.504

- Policies and procedures for training, evaluating and supervising personnel
- Qualifications of staff
- Procedures used to evaluate applicants for certification
- Investigative procedures
- Residue testing procedures
- Procedures for handling violations
- Recordkeeping procedures
- Fees charged for certification
- Sample collection procedures



Public information

- Procedures for providing to the public the following information:
 - Organic certificates issued during the current and previous 3 years
 - List of all certified operations and products produced
 - Results of laboratory analyses for residues of pesticides and other prohibited substances.



- 205.509 - Peer review panel



Subpart G – Administrative

- 205.600 evaluation criteria
- 205.601 – Crops – allowed synthetics
- 205.602 – Crops – prohibited naturals
- 205.603 – Livestock – allowed synthetics
- 205.604 – Livestock – prohibited naturals
- 205.605 – Handling – allowed non-agricultural substances (natural and synthetic)
- 205.606 – Handling – allowed agricultural (commercially unavailable in organic form)



- 205.620-622 State organic programs
- 205.640-642 Fees
- 205.660-668 Compliance
- 205.670-672 Inspection and testing
- 205.680-681 Appeals



National Organic Standards Board Training: Operating Guidelines

Agricultural Marketing Service | National Organic Program
February 2015





- Nominations Process Overview
- Charter Renewal Overview
- Work Agenda Development
- Subcommittee Management
- Public Meeting Agenda
- Public Meeting Management
- FOIA Review

Nominations Process Overview



The Board nomination process takes about 1 year:

1. Prepare Federal Register call for nominations and outreach plan; complete clearance process
2. Announce call for nominations – we target having announcement open 2 months
3. Review applications for completeness and basic qualifications, i.e., fit in OFPA categories
4. Vet qualified candidates against exclusion criteria (examples: registered lobbyist; service on other Board)

Nominations Process Overview



The Board nomination process takes about 1 year:

6. Interview qualified and vetted candidates
7. Prepare slate and information summary about qualified and vetted candidates for Secretary consideration
8. Secretary selects appointee; appointee announced
9. Term begins in January

Nomination Process Criteria



A range of factors are considered in evaluating applicants:

- OFPA categories of seats to be filled – **mandatory**
- NOSB Recommendation on Criteria for Board Membership (1999) – More on this next slide!
- Ability to work collaboratively with other Board members and USDA
- Ability to represent all racial and ethnic groups, women and men, and persons with disabilities.

NOSB Recommendations on Nominations Evaluation Criteria



- In 1999, NOSB recommended criteria for Board membership – these criteria are on NOP’s nominations webpage, are in Federal Register announcements, and are used during candidate evaluation.
- **Criteria include:**
 - Understanding of organic principles and practical experience in the organic community;
 - Experience in public policy;
 - Commitment to organic integrity;
 - Ability to evaluate technical information;
 - Willingness to commit time and energy needed;
 - Demonstrated experience and interest in organic production and certification

Charter Renewal Overview



- FACA requires that the NOSB charter be considered for renewal every two years.
- This involves review by USDA and the General Services Administration (GSA) (oversees FACA across agencies) in order to revalidate the need for the Board and its overarching governance.
- USDA releases Federal Register Notice announcing its intent to renew the Board's charter.
- This is a process that occurs between USDA and the GSA – the Board and public are not involved.



1. AMS establishes the work agenda with input from the NOSB.
2. Board may propose ideas, but should not start work on new topics without NOP approval
3. The public has a voice in this process:
 - Public may petition additions or deletions from the National List.
 - Public may also submit comments to the Board and write to the NOP.
4. FACA requires that agencies effectively use resources: we shouldn't ask for advice we can't act on.

Work Agendas: Criteria for Adding Items



- 1. Within Scope:** Item must be within the scope of OFPA and within agency authority.
- 2. USDA/NOP Priority:** Item must be a priority for the USDA/NOP; and something that the NOP is able to implement in a reasonable timeframe.
- 3. Clear Need:** Item must reflect a clear need for the NOP and/or organic community, for which information or advice is needed. (If it is a need, but NOP has enough information, it doesn't need to be on the work agenda.)
- 4. Clear Scope:** NOP must have a clear sense of the intent and scope of the work agenda item.



The Work Agenda establishes subcommittee scope for the upcoming semester or year. Process:

1. NOP develops list based on substance evaluations (e.g., petitions, sunset) and formal requests (via Memos) that NOP has provided NOSB.
2. NOP and Executive subcommittee review work agenda.
3. NOP approves final work agenda.

Subcommittee Management



- Subcommittees hold conference calls between public meetings to work on work plan items.
- Effective facilitation by the subcommittee chair elicits different questions and perspectives, while keeping the group focused and on task.
- Helping keep each other on point may help reduce time needed – regularly ask “what is our goal, and how does this discussion support the outcome we are trying to achieve?”
- Subcommittee notes maintained by NOP and posted on-line.

Discussion Documents/Proposals: Criteria for NOP Acceptance



- 1. Within NOSB Scope:** Item must have been within scope to be on work agenda; content of product must also be within scope of OFPA and agency authority.
- 2. Implementable:** Item must have been an NOP priority to be on work agenda; content of completed product must be something that NOP can actually implement if a recommendation is accepted.
- 3. Requests for Public Comment:** Public comment is vital in shaping advice; requests must be within NOP/OFPA authority and not conflict with current statute and rules.
- 4. Quality and Clarity:** Document must be clearly written. If two opinions or a minority opinion are included, the motion being voted on must be very clear.

Public Meeting Agenda



- Public meeting agenda prepared by NOP, driven by several factors:
 - Inclusion of work agenda items that have yielded discussion documents or proposals
 - Reasonable time for public comments
 - Time for presentations and expert panels
 - Cost

Substantive Changes at Public Meetings



- Only minor adjustments to discussion documents and proposals will be allowed before voting.
- **Consider the extent to which:**
 - A reasonable person affected by the recommendation would have understood that the published proposal affects his or her interests;
 - The recommendation's content is substantially different from the proposal's content; and
 - The effects of the recommendation differ from the effects of the proposal.
- The NOP Deputy Administrator or designee will determine if a proposed amendment is a substantive change. If public comments lead to substantive changes, the document goes back to subcommittee.

NOSB Meeting Ground Rules



Board members request of the audience:

- We ask commenters to focus on issues, not people.
- No questions or comments from the audience unless invited by the Board Chair.
- Commenters may not interrupt each other or step in for each other without the Chair's permission.
- Any sidebar conversations or commenter preparation activities must happen out in the hallway, to prevent disruption and the ability of others to hear what's going on.



FOIA/FACA Overview: Rules of the Road on Records Release

February 4, 2015

FOIA/Government in the Sunshine



- The Freedom of Information Act (**FOIA**) gives people the right to access information from the federal government.
- **FACA** notes: “The records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents **which were made available to or prepared for or by each advisory committee** shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports.”

Most of What You Write is OPEN



- NOSB records (your emails and your work) are subject to public inspection, following agency review.
- AMS will redact confidential business information, private email accounts, private phone numbers, and cell phone numbers. Work phone numbers, fax numbers and email addresses, are releasable.
- **Board member's opinions, exclamations, jokes, or other personal statements are likely to be released.**

AMS Review Essential:

Do Not Share NOSB Documents/Email



- NOSB communications (e.g., emails) and draft documents (e.g., draft proposals) must be available to the public: **through the agency that oversees the FACA Board.**
- NOP is the custodian of all Board records, so only AMS/NOP can make records available to requesting parties. AMS/NOP reviews all records before release, to determine whether any exemptions apply (e.g., personal information, confidential business information).
- Board members may speak with community members about the work being done by the Board, and ask for input.
- **No Board communications or documents are to be forwarded or shared with any individuals or constituencies outside the Board members and AMS/NOP.**

Best Practices



- Avoid sending full mail strings when responding or forwarding emails, unless relevant to discussion.
- Send only the information that is necessary to convey your message.
- Informality is natural, AND, watch what you state in your emails. Personal jokes and remarks usually cannot be redacted.
- Mark all drafts with watermarks or “DRAFT” in the header within the document.
- Do not circulate “drafts” outside of the NOSB.



Questions/Discussion

Agricultural Marketing Service | National Organic Program
February 2015



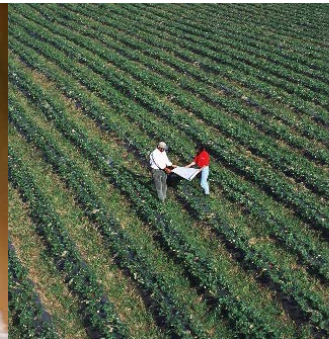


National List Petition Process

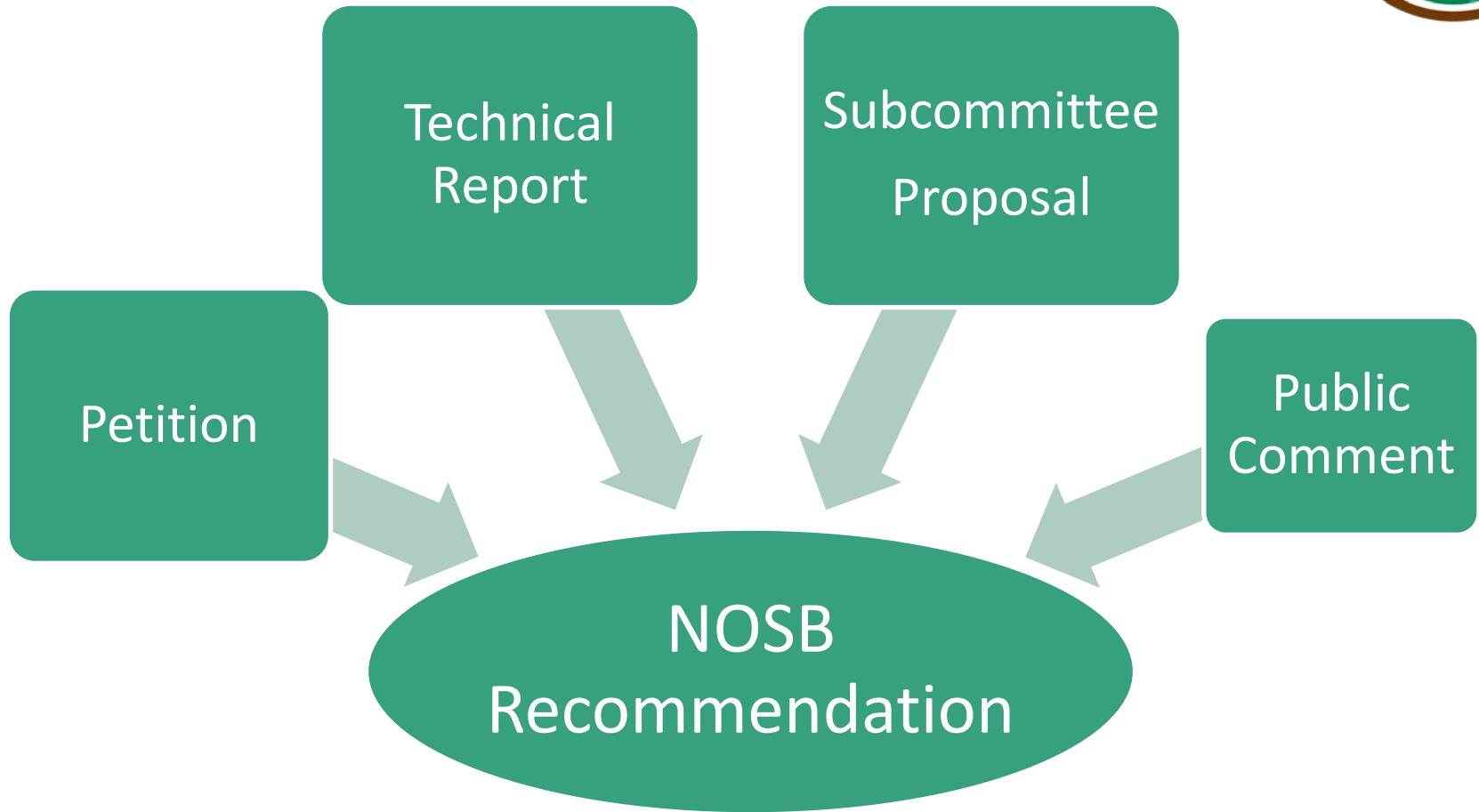
Lisa M. Brines, Ph.D.

Agricultural Marketing Service | National Organic Program

February 2015



Multiple inputs for NOSB Recommendations





NOSB has a Well-Developed Evaluation Process and Structure for Materials Review

- Evaluation Forms with Criteria linked to Organic Foods Production Act and USDA organic regulations.
- Boundaries for communicating with petitioners.
- Projected Timeline for review steps.



The Organic Foods Production Act:

Sec. 2119. [7 U.S.C. 6518] National Organic Standards Board.

(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.



USDA Organic Regulations, 7 CFR Part 205

§205.607 Amending the National List.

- (a) Any person may petition the National Organic Standards 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.
- (b) A person petitioning for amendment of the National List should request a copy of the petition procedures from the USDA at the address in §205.607(c).

Petition Process: Petition Guidelines



- Most recent version of petition guidelines were published in the Federal Register on January 18, 2007 [72 FR 2167]
- Guidelines explain what information must be included in a petition
- No specific template or form is required
- No fee or cost to petition
- Petitions may contain confidential business information (CBI). CBI is not available to NOSB or public.

NOP's Internal Process



- NOP confirms receipt of petition
- NOP reviews incoming petition for eligibility and sufficiency (generally within 30 days of submission)
- NOP is the primary point of contact for any correspondence between NOSB and petitioner

NOP's Internal Process



NOP's goal is to make sure that petitions are eligible and complete when they are distributed to the Subcommittee, so that revisions and supplementary petition information are infrequent

Two NOP checklists:

- OFPA Checklist, NOP 3005-1
- Petition Checklist, NOP 3005-2

Checklists are completed by NOP staff and provided to the NOSB Subcommittee, but are not posted for the public



- OFPA Checklist, NOP 3005-1
 - Used to determine eligibility of the substance for addition to the National List
 - Substances that are not eligible are not forwarded to the NOSB for review

Ineligible Petitions



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



Eligibility review of previously petitioned/rejected materials

- NOP reviews previous petition and technical report(s) for the substance
- NOP identifies why the substance was prohibited
- NOP reviews new petition for any information that was not submitted in an earlier petition or provided in the technical report
- No new information
 - Petitioner is notified that substance was previously reviewed and rejected and that no new information was provided
- New information
 - Petition proceeds to NOSB review. NOP does not determine whether the new information would be likely to warrant a change in decision

****Important that NOSB recommendations to reject petitions also contain sufficient justification****

NOP's Internal Process



- Petition Checklist, NOP 3005-2
 - Used to verify that the petition meets the submission guidelines
 - NOP does not fact check all of the data provided
 - NOP may identify areas where more information or references are needed for completeness
 - NOP's "sufficiency" determination does not mean NOP believes the substance should be added to the National List; only that it meets the eligibility requirements for NOSB review



- Examples of incomplete petitions:
 - Too much information identified as confidential business information
 - No description of alternatives
 - Labels not submitted
 - No reference list provided
 - Inadequate description of previous reviews (e.g., NOSB reviews)
 - Inadequate description of physical properties and chemical mode of action

NOP's Internal Review



- “...acceptance of the petition for NOSB review is an administrative matter and does not reflect a decision by NOP on the substantive merits of the petition.”
- “...the NOSB, during its evaluation of the petitioned substance, may have additional requests for information. A notice will be sent to you should the NOSB request additional information.”



- Updated Petition Information
 - Petitioner may submit updated (unsolicited) information after petition has been sent to NOSB
 - Petitioner may respond to additional information requested by NOSB
- Updates are posted alongside petition on NOP website

NOSB Subcommittee Process



Petition – NOSB subcommittee review

- Should be completed within 60 days of receipt of petition

The NOSB subcommittee may request:

- a) Additional information from petitioner
- b) Technical report

Adapted from NOSB Policy & Procedures Manual

Technical Reports



- Completed by third-party contractors
- TR templates include evaluation questions derived from OFPA criteria
- Minimum of 4 months for development
- Reports are posted on NOP website after acceptance by NOSB Subcommittee

NOSB Process: TR Requests



- Requests for technical reports (TRs) should be submitted within 60 days of receipt of petition
- TRs are always optional, but may be requested at the discretion of the Subcommittee
- Any additional information requested (beyond the scope of a standard technical report), must be aligned with the OFPA criteria
- If particular areas of focus are needed, please provide the details in the request.

NOSB Process: TR Requests



- For petitions to add new substances to the National List, we do not recommend limiting the scope of the technical report
- Limited scope / supplemental TRs may be appropriate in the following scenarios:
 - Crop or livestock petitions where classification is unclear
 - Petitions to amend an existing annotation
 - Petitions to remove an existing substance
 - Sunset substances

Technical Report Content



- Technical reports do not currently include:
 - Proprietary information
 - Economic impact information
- NOP accepts quality, accuracy and completeness of technical reports

Technical Reviews, cont.



- NOP reviews all TRs before they are distributed to the Subcommittee to ensure they meet the requirements of the contract
- NOP will ensure that TRs are sufficient and complete when they are distributed to the Subcommittee
- Occasionally, NOP will request that a subject matter expert from the Agricultural Research Service review a draft copy of the report. When this occurs, it will be noted when NOP distributes the report to the Subcommittee

Petition Process: Substance Evaluation Criteria



1. The potential of such substance for detrimental chemical interactions with other materials used in organic farming systems;
2. The toxicity and mode of action of the substance and of its breakdown products of any contaminants, and their persistence and areas of concentration in the environment;
3. The probability of environmental contamination during manufacture, use, misuse, or disposal of such substance;
4. The effect of the substance on human health;

OFPA, Sec. 2119(m)



5. The effect of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
6. The alternatives to using the substance in terms of practices or other available materials; and
7. Its compatibility with a system of sustainable agriculture.

Technical Advisory Panels (TAPs)



- **OFPA:** The NOSB shall convene technical advisory panels to provide scientific evaluation of materials considered for the National List.
- The NOSB has not convened independent Technical Advisory Panels since 2005. Currently the NOSB is relying on information within the Technical Reports provided by the NOP and public comment to make their final recommendations.
- TAPs previously included recommendations. Technical reports do not recommend actions to the NOSB.

Petition Process: 205.606 Evaluation Criteria



The NOSB shall determine whether agricultural substances petitioned for Section 205.606 are potentially commercially unavailable.

The NOSB will consider:

- Why the non-organic form of the substance is necessary for use in organic handling;
- The current and historical industry information/research/evidence that explains how or why the substance cannot be obtained organically in the appropriate form, quality, or quantity to fulfill an essential function in a system of organic handling.

Petition guidelines, 72 FR 2167



Industry information includes, but is not limited to the following:

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;

Petition guidelines, 72 FR 2167



Industry information includes, but is not limited to the following:

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.

NOSB Process - Checklists



- The NOSB checklists are a tool to facilitate and document evaluation of the petitioned substance against the OFPA criteria
- OFPA does not require checklists, but requires that Board shall consider seven different criteria

Example Substance:



- New Petition: Substance A for addition to National List, section 205.605(a)
- OFPA criteria:
 - the effect of the substance on human health
- Checklist question:
 - 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)]

Checklist Exercise:



Summary from TR:

- Substance A is considered nontoxic to humans and is not a carcinogen
- When used as petitioned, no adverse effects to human health have been reported
- Prolonged exposure to skin is known to cause tissue damage
- Ingestion of excessive quantities can produce non-life threatening side effects such as electrolyte imbalances or vomiting

Checklist exercise:



Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it?

Checklist exercise:



- In general, suggest limiting your answers to address the uses that are within the scope of the petition (although there may be exceptions, such as effects from misuse)
- Does recommendation demonstrate that NOSB met its obligation under OFPA to *consider* the effect of the substance on human health?
- Comments should be used to document the review and to provide clarity for stakeholders



- For substances that have a broad spectrum of utility, the NOP recommends that, to the extent possible, the NOSB review materials with a lens limited to the manner and amount that the substance would be used in organic production and handling



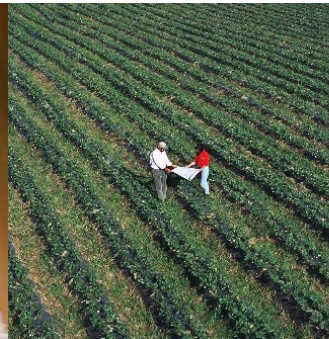
- Questions?

Review: Sunset Process

Lisa M. Brines, Ph.D.

Agricultural Marketing Service | National Organic Program

February 2015



Sunset Provision of OFPA



- No exemption or prohibition contained in the National List shall be valid unless the **NOSB has reviewed** such exemption or prohibition as provided in this section **within 5 years** of such exemption or prohibition being adopted or reviewed and the **Secretary has renewed** such exemption or prohibition

OFPA, Section 2118(e)

Sunset Dates



- Sunset dates are published in Program Handbook, NOP 5611
- 5 years is calculated from effective date of final rule or renewal
- For efficiency, sunset reviews are grouped by calendar year



Drawbacks to previous process:

- Each sunset year required 3 separate rulemaking documents (ANPR, PR, and FR)
- Substances were discussed in a single public meeting
- Removal could occur with 2/5 of votes cast (fewer than required of “decisive” actions)
- Annotation changes during sunset were problematic

Inconsistent decision making:



- Example #1: Substance A is petitioned for removal
 - Requires 2/3 votes to be recommended for removal (10 votes)
- Example #2: Substance A is subject to sunset
 - Previously needed 2/5 votes for non-renewal (6 votes)
- Even with identical data, same board members, and same public comments, could have conflicting recommendations!

Benefits to Updated Sunset Process



- **Thorough and transparent review process for all substances** - provides 2 public comment opportunities before the NOSB completes its review of each substance.
- Ensures that any change to the National List (petitioned or sunset) is supported by a 2/3 majority of the NOSB.
- Streamlines the administration of the National List by simplifying rulemaking.

What is the process?



- The Sunset Process is comprised of two components:
 - (1) The NOSB review (Steps 1-6) and
 - (2) USDA action (Steps 7-8) on substances within 5 years of their addition to or renewal on the National List.
- Key documents used for the review:
 - (1) Sunset List**
 - (2) Preliminary Review**
 - (3) NOSB Sunset Review**



- **Step 1** – Meeting announcement in Federal Register inviting comment on **Sunset List** (background may include requests for specific info from Subcommittees)
- **Step 2** – Written public comments submitted and analyzed by Subcommittees
- **Step 3 (Mtg #1)** – Subcommittees summarize background and public comment & receive oral comment

Process Mechanics Cont'd



- **Step 4** – Subcommittees analyze written and oral comments from Mtg #1 and prepare **Preliminary Review**.
 - Meeting announcement inviting comment on **Preliminary Review** published in Federal Register
- **Step 5** – Written public comments submitted and analyzed by Subcommittees

Process Mechanics Cont'd



- **Step 6 (Mtg #2)** – Subcommittees present **Preliminary Review**, receive oral comment, and discuss with the full Board.
 - Motions for removal from the **Preliminary Review** are voted on by the full Board.
 - After Mtg #2, NOSB completes **Sunset Review**.

Process Mechanics Cont'd



- **Step 7** – AMS reviews NOSB Sunset Review and considers rulemaking action for any recommended removals
- **Step 8** – AMS issues Federal Register Notice announcing renewal of applicable substances

Review New Documents



- Sunset list template
- Preliminary review template
- NOSB review template

Sunset 2015 Examples



- Sulfurous acid (Crops)
- Marsala – fortified cooking wine (Handling)

Spring 2014 Meeting

Sunset 2015 Summaries

Fall 2014 Meeting

Sunset 2015 Reviews



- Questions?



National Organic Standards Board Training: National Organic Program Overview

Agricultural Marketing Service | National Organic Program
February 2015





- NOP: Overview, Cross-Cutting Activities
- Accreditation and International Activities
- Compliance and Enforcement
- Standards

The National Organic Program (NOP)



- **Mission:**
Ensure the integrity of USDA organic products in the United States and throughout the world
- **Vision:**
Organic Integrity from Farm to Table,
Consumers Trust the Organic Label
- **Core Role:**
Implement the Organic Foods Production Act and the USDA organic regulations

What Does the Program Do?



- Develop and maintain organic standards
- Accredite and oversee third party organic certifying agents, who review, inspect, and approve organic producers and handlers
- Implement international organic trade agreements
- Investigate complaints of violations (example: uncertified farmer selling food as organic, selling conventional food as organic)
- Manage the National Organic Standards Board
- **Oversight Responsibility:**
 - 82 certifying agents worldwide
 - 25,000 certified organic operations
 - \$35 billion in U.S. organic sales (2013)

Quick Facts About NOP



- **Staffing:** 43 employees in three Divisions and the Office of the Deputy Administrator
- **Budget:**
 - FY 2012: \$6.919 million
 - FY 2013: \$6.369 million
 - FY 2014: \$9.04 million
- **NOP Leadership Team:**
 - Miles McEvoy – Deputy Administrator
 - Jennifer Tucker – Associate Deputy Administrator
 - VACANT (Recruiting) – Standards Division Director
 - Cheri Courtney – Accreditation and International Activities Division Director
 - Matthew Michael – Compliance and Enforcement Division Director
- **MRP Leadership** – Betsy Rakola, USDA Organics Specialist

10 Points of Organic Integrity



1. Clear/enforceable standards
2. Communication
3. Transparency
4. Certification
5. Complaints
6. Penalties
7. Market surveillance
8. Unannounced inspections
9. Periodic residue testing
10. Continuous improvement

Key Cross-Cutting Activities



- Policy Development
- Training and Outreach
- Communication
- Collaboration: Across USDA and with Other Agencies

Policy Development: NOP Document Matrix



- NOP publishes a range of different types of documents for policy and outreach purposes.
- The NOP Document Matrix is an internal tool that describes our different policy and outreach communication documents.
- **A brief overview of these document types follows. Often, NOSB recommendations will be considered against these options to determine best fit for implementation.**



1. Rules

Home: [USDA Organic Regulations](#)

- Amend the USDA organic regulations
- Allow enforcement actions
- If “significant” require additional clearance
- Example: pasture rule, aquaculture

2. Interpretive Rules

- Explain NOP’s interpretation of statutes/rules or clarifies existing rules
- Have not been used by NOP, but could be in the future

NOP Document Matrix



3. Instructions

Home: Program Handbook

- Instruct certifying agents how to apply certification and accreditation requirements per 205.501(a)(21)
- Aren't announced via the Federal Register
- Example: Organic System Plans, Reinstatements,

4. Guidance Documents

Home: Program Handbook

- Provide options to satisfy regulatory requirements
- Support enforcement by referencing section of USDA organic regulations
- Example: Unpackaged Commodities Guidance



5. Policy Memos

Home: Program Handbook

- Formally communicate NOP policy decisions, but less formally than instructions/rules
- Are generally directed at certifying agents
- Aren't announced via the Federal Register
- Example: GMO policy

6. Formal Letters

Home: Public Correspondence page

- Communicate non-policy information or requests
- Directed to certifying agents and NOSB
- Aren't announced via the Federal Register
- Example: response to NOSB recommendations



7. Federal Register Notices

Home: Rules/Notices Page

- Announce activities requiring legal notification
- Example: NOSB meeting announcement, NOSB Call for Nominations

8. Newsletter Articles

Home: About Us Page

- Highlight NOP announcements, provide status updates
- Aren't announced via the Federal Register
- Example: Origin of livestock update



9. NOP Organic Insider

Home: Insider archive

- Announces all NOP documents and activities
- Aren't announced via the Federal Register
- Examples: Recruiting announcements, new fact sheets, equivalency arrangement information, new policy documents and memos
- Subscribe to receive email updates:
<http://bit.ly/NOPOrganicInsider>

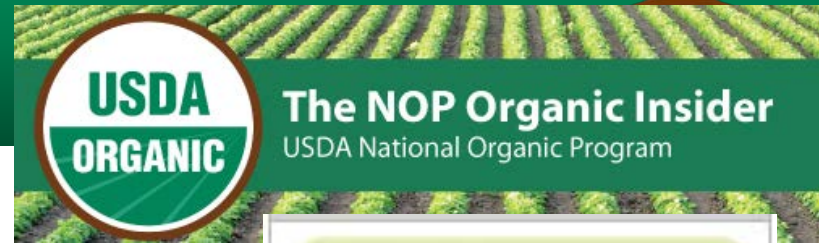
Training and Outreach



- Annual classroom training for NOP certifiers.
- Comprehensive webinar series for NOP auditors.
- Visits with certifiers across the country to launch and discuss the “sound and sensible” initiative.
- Conference Outreach: Expo East, MOSES, Others
- Publications: New fact sheets, talking points, questions and answers, blogs, and other educational resources to support candidate and existing certified operations.

NOP Communications

- Email notification service
- Quarterly Newsletter “Organic Integrity”
- “Hot Topics” Website Postings
- Fact Sheets, Questions and Answers
- Briefings, Talking Points
- Teleconferences and Webinars with Organic Community
- National Organic Standards Board Public Meetings
- Conference Presentations and Listening Sessions



Collaboration Across USDA and With Other Agencies



- AMS Livestock, Poultry, and Seed Program: Economic analyses, technical reports, appeals reviews, accreditation audits
- AMS Science and Technology Program: Residue Testing Program
- AMS Fruit and Vegetable Programs and Compliance and Analysis: Collaboration on investigations and enforcement actions; audits
- Food Safety Inspection Service and Natural Resources Conservation Service: Labelling coordination; streamline/reduce redundancies
- Economic Research Service, NASS/Census of Agriculture, and National Agricultural Library: New data usage agreements
- USDA Office of Chief Economist: Early review of NOP rules
- USDA Biotechnology Coordinating Group: NOP is AMS representative
- NOP works with OIG, Department of Justice, DHS Customs and Border Protection, the Food and Drug Administration, the Environmental Protection Agency, and the TTB on both enforcement and regulatory issues.
- Federal Trade Commission: Joint project to collect data on consumer perceptions of personal care products and textiles sold as organic.



- NOP: Overview, Cross-Cutting Activities
- Accreditation and International Activities
- Compliance and Enforcement
- Standards

Accreditation Activities



- NOP oversees the work of 82 certifiers, which certify over 25,000 certified organic operations.
 - Work includes audits, audit report reviews, notices of noncompliance, corrective action reviews, responding to questions, updating list of certified operations
 - This work is done by 3 Accreditation Managers, Lead Auditor, Program Analyst, and Program Specialist
 - Supplemented by audit team in AMS Quality Assurance Divisions, Livestock and Seed Program
- At the close of FY 2014, certifiers were in full compliance with 96% of the NOP's accreditation criteria, and have implemented corrective actions for all deficiencies.

Key Accreditation Activities



- Seven accreditation renewal audits, 42 accreditation midterm audits, and initial accreditation audit.
- Consider 34 reinstatement of certification requests
- Consider 7 requests for temporary variances to the USDA organic regulations
- Support training, policy development, and outreach activities (meetings, presentations, materials)
- Implement “sound and sensible” initiative to make the organic certification process affordable and attainable for organic operations.

International Trade



- The United States has trade arrangements with several nations to facilitate the exchange of organic products and provide market opportunities for organic producers.
- **Equivalency Agreements:**
 - U.S.-Canada – Launched in 2009
 - U.S.-European Union – Launched in June 2012
 - Japan – Effective in January 2014
 - Korea – Effective in July 2014
- **Recognition Agreements:**
 - India, Israel, New Zealand
- NOP works closely with the Foreign Agricultural Service (FAS) and the U.S. Trade Representative (USTR).

High Priority Certification Issues to Address



- Inconsistent certification process
- Recordkeeping focus and burden
- Expense of certification
- Burden of time that is involved in inspections and maintaining paperwork
- Some farms that comply with organic standards avoid certification.

The Sound and Sensible Initiative was established to start to address these issues.

'Sound + Sensible' Principles



1. **Efficient Processes:** Eliminate bureaucratic processes that do not contribute to organic integrity.
2. **Streamlined Recordkeeping:** Ensure that required records support organic integrity and are not a barrier to organic compliance.
3. **Practical Plans:** Support simple Organic System Plans that clearly capture organic practices.
4. **Fair, Focused Enforcement:** Focus enforcement on willful, egregious violators; handle minor violations in a way that leads to compliance; and publicize how enforcement protects the market.
5. **Integrity First:** Focus on factors that impact organic integrity the most, building consumer confidence.

Goal: Make Organic Certification:



Affordable, Accessible and Attainable for all operations

- **Affordable** – reasonable fees, reasonable compliance costs
- **Accessible** – certifiers and technical assistance available locally
- **Attainable** – Clear and understandable standards, plain language, reasonable record keeping requirements

AIA: Key Priorities in 2015



- Publish updated list of certified operations
- ACA Certifier Training: February 2015
- New equivalency agreement activities
- Accreditation Audits and Follow-up
- Maintain existing recognition and equivalency arrangements – peer reviews, working groups
- Recruiting and onboarding new staff



- NOP: Overview, Cross-Cutting Activities
- Accreditation and International Activities
- Compliance and Enforcement
- Standards

Purposes of Enforcement



Purpose: To protect the integrity of the organic standards so as to facilitate commerce

- Maintain consumer confidence
- Ensure a fair market for the great majority of organic operations that operate in compliance with the law



Key Activities:

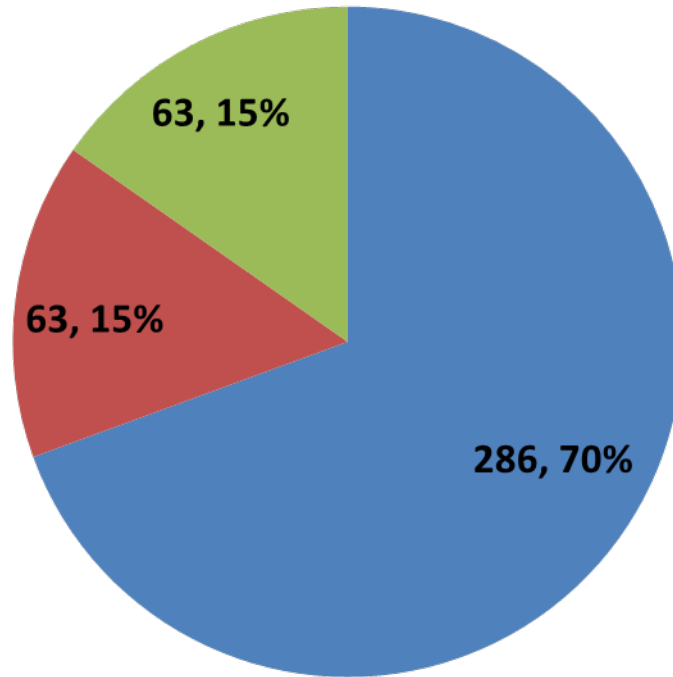
- Investigate complaints, work with operations to achieve compliance where possible and take enforcement actions as appropriate
- Represent the NOP in appeals of adverse actions
- Work with ACAs, State Programs and Federal partners on enforcement of the OFPA and the USDA organic regulations
- Lead enforcement-related policy development and outreach efforts

FY 2014 Successes



- Issued nine civil penalties, totaling \$81,500, for willful violations of the USDA organic regulations
- Closed 285 complaints, exceeding the record high number closed in FY12
- Initiated 162 initial enforcement actions, including 66 Notices of Warning, 29 Notices to Cease and Desist and 54 investigation referrals
- Published 13 fraudulent organic certificates on the NOP webpage
- Prevailed in an administrative hearing seeking revocation of a Pennsylvania operation.
- Issued first subpoena under new Farm Bill authority

FY14 Complaint Distribution by Type



■ Uncertified Operations

■ Labeling Violations and Fraud

■ Prohibited Substance and Methods

2015 Priorities



- Complaint investigations and closures - Reduce backlog and time to case closure
- Work closely with OGC to pursue complaints for hearing against violators, as appropriate
- Contribute to policy and training development to improve compliance
- Continue to implement Farm Bill provisions related to enforcement



- NOP: Overview, Cross-Cutting Activities
- Accreditation and International Activities
- Compliance and Enforcement
- Standards

Standards Division: Key Activities



- **Key Activities**

- Develop new rules and coordinate clearance
- Develop and maintain Regulatory Priorities Agenda
- Draft new and updated guidance and policy memos based on OIG feedback, certifier and community questions, and priority needs
- Develop materials to support rollout of new standards, respond to letters and questions about standards
- Maintain National List, including petition intake and response, and list management activities
- Support the National Organic Standards Board



- Origin of Livestock Draft Rule
- Aquaculture Draft Rule
- Pet Food Draft Rule
- Animal Welfare Rule
- Guidance: Substances in Post-Harvesting Handling, Drift Policy
- Material Clarifications for Certifiers
- National List Management, including Technical Report contract management
- Provide support for National Organic Standards Board subcommittees



Questions/Discussion

Agricultural Marketing Service | National Organic Program
February 2015





Organic Working Group and Secretary Vilsack's Guidance on Organic

Betsy Rakola, Organic Policy Advisor

NOSB Training 2015





- USDA Organic Policy Advisor & the Organic Working Group
- Training and Outreach
- Growing the Organic Sector
- Regulatory Reciprocity
- Data and Research
- Stakeholder engagement



USDA Organic Policy Advisor & Organic Working Group



The Organic Policy Advisor:

- Is a permanent staff position advising the Office of the Secretary
- Coordinates USDA Organic Working Group and develops annual action plan
- Implements Secretary Vilsack's 2013 Departmental Guidance on Organic Agriculture
- Works across USDA to ensure that programs work for organic
- Participates on other inter-agency USDA initiatives



Secretary Vilsack's May 2013 departmental guidance on organic agriculture outlined 5 priorities:

- Training and outreach
- Growing the sector
- Regulatory reciprocity (reducing paperwork)
- Research
- Data

The USDA's Organic Working Group defines annual projects for each of these priority areas.



Farm Bill program implementation update

- Organic Research and Extension Initiative - \$19 million
- Cost share increased - \$11 million available through states
- Organic data initiative restored - \$5 million for data collection
- Organic crop insurance expanding
- Research and promotion “checkoff” exemption
- Option for proposal of organic checkoff program



Training and Outreach



USDA Organic Working Group Training & Outreach Goals:

1. Update the Organic Literacy Initiative in early 2015
2. Work with external partners to distribute organic resources beyond the USDA



Organic Literacy Initiative



USDA ORGANIC

USDA Organic 101

What Does the Organic Label Mean?

Is Organic An Option For Me?

Information on Organic Agriculture for Farmers, Ranchers, and Businesses

This brochure provides an overview of the USDA organic regulations and how USDA supports organic agriculture. It includes information on getting certified, funding opportunities, and educational resources.

For more information, visit www.ams.usda.gov/organicinfo or, if viewing this brochure online, use the icons in each section.

USDA U.S. Department of Agriculture
USDA is an equal opportunity provider and employer
August 2012

USDA ORGANIC

USDA Organic 201

A Closer Look at the U.S. Department of Agriculture's Organic Programs

USDA Organic Resource Guide 2012

Your Guide to Organic and Organic-Related USDA Programs

USDA **USDA ORGANIC**



Where to find USDA resources on organic:

www.ams.usda.gov/OrganicInfo

usda.gov/organic



Growing the Sector

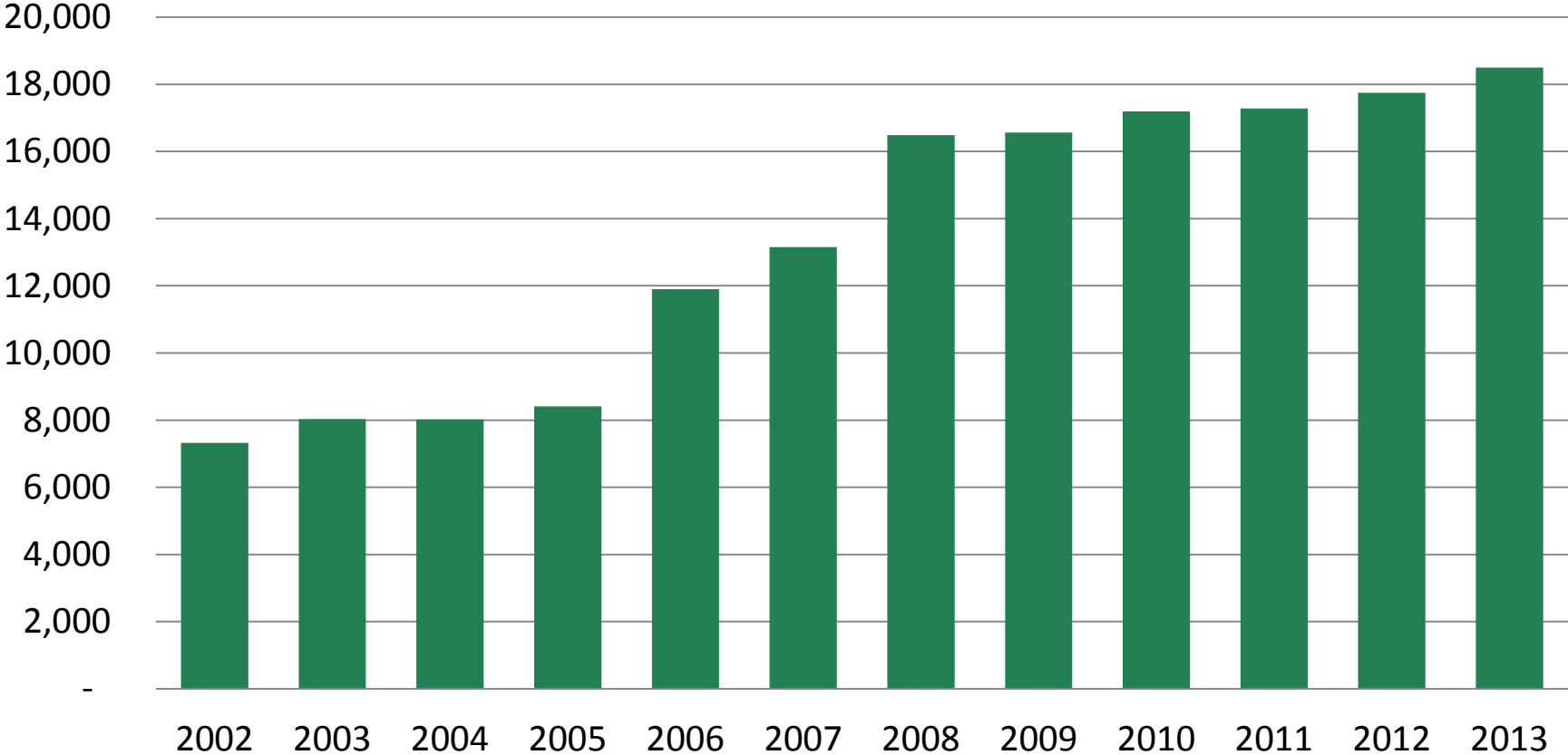


USDA Organic Working Group “Growing the Sector” Goals:

1. Identify Tools for Transition: how can existing USDA technical and financial assistance help producers transition to organic?
 - Conservation Reserve Program
 - Agroforestry technical assistance
2. Create web and print resources to help producers with financing, buffer zones, cover crops, etc.



USDA Certified Organic Operations, Domestic, 2002-2013



Note: Foreign operations may also be certified to the USDA organic standards.



Bridges to Opportunity: Partnership with the USDA Farm Service Agency

- FSA working to improve customer service, build knowledge of all USDA programs and sectors of agriculture
- Organic “pilot” launched in Minnesota in fiscal year 2015
- Connecting producers and handlers with the economic opportunities in the organic sector



Regulatory Reciprocity



Reciprocity team goals

1. Conservation - ongoing: Natural Resources Conservation Service and National Organic Program (NOP) are coordinating conservation program requirements and organic system plans.
2. Non-GE label claims – complete: Food Safety and Inspection Service streamlined procedures for certified organic meat and poultry processors
3. Crop insurance - new: Risk Management Agency and NOP will conduct a needs assessment for crop insurance documentation.



NRCS Conservation Activity Plans for Organic Producers

- USDA Natural Resources Conservation Service created a conservation activity plan that mirrors an OSP
- Important tool for transitioning producers: helps with paperwork *and* conservation implementation
- First step for EQIP: financial assistance **up to \$20,000 per year**



Organic System Plan

- Land Use History
- Affirmations
- Production practices
- Recordkeeping
- Commingling/contamination

The "plug-in" plan

Conservation Activity Plan

- Maps
- Natural resource assessment
- Planned practices
- Pest management
- Soil Fertility Management
- Crop rotation
- Inputs



We need more organic Technical Service Providers to implement the new organic conservation plans.

TSPs are individuals or businesses that have technical expertise in conservation planning and design.

Please help us recruit experts in organic agriculture!

Visit www.nrcs.usda.gov/wps/portal/nrcs/main/national/programs/technical/tsp/



Data



Crop insurance: USDA has new risk management tools for organic, small, and diversified producers

- Whole Farm insurance now available: certified farms may use organic prices, cover up to 85% of value
- Contract price elections available since spring 2014: insurance based on existing contract
- Price elections for organic crops: 26 organic crops now have insurance options
- Expansion continues through the Organic Data Initiative



Non-Insured Crop Disaster Assistance Program (NAP)

- 2015 interim rule: allows NAP to use organic and direct-to-consumer prices
- Coverage may vary by state, requires availability of good price data
- See your local Farm Service Agency office for more information: www.fsa.usda.gov



ORGANIC FARMING



Please respond! Learn more at www.agcensus.usda.gov

Responding to the 2014 Organic Survey is important!

Your agriculture operation and products are a valuable part of the ag industry and should be counted.

1. Total organic sales by farms in the U.S. increased by 83 percent between 2007 and 2012.
2. Sales from farms with certified or exempt organic product sales totaled more than \$3.1 billion in 2012.
3. Organic agriculture producers reported direct-to-consumers sales more often than conventional producers, with 42 percent of organic farmers selling directly to consumers in 2012.



U.S. Department of Agriculture
National Agricultural Statistics Service





Organic data: Who are organic producers?

- Organic special tabulation, 2012 agricultural census
 - Includes state-by-state data on organic producers
 - Shows that organic producers are more likely to have direct-to-consumer sales and participate in non-traditional markets, like CSAs
 - Organic farms were more likely to invest in on-farm renewable energy
 - Organic farmers are younger, on average, and more likely to be beginning farmers

**[www.agcensus.usda.gov/Publications/2012/
Online_Resources/Special_Organics_Tabulation/organictab.txt](http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Special_Organics_Tabulation/organictab.txt)**



Research



Research team goals

1. Review and respond to NOSB research priorities.
2. Conduct a stakeholder needs assessment of organic research priorities and develop a white paper on critical research needs.
3. *Possible new goal: collaborate with climate change team to identify organic practices which mitigate greenhouse gases*



Research Activities

- Organic-specific grant funding: \$25 million annually through organic set-aside programs
- Grants research solutions to common challenges: high-quality seed, nutrient management, controlling animal diseases with natural materials, cover cropping strategies
- Long-term organic studies at USDA research facilities examine performance, yields, climate change impacts, and more



Focus on stakeholder engagement through outreach and education

- 2015 webinar series will cover a broad range of topics, with time for discussion, questions and answers.
 - To receive email invitations, sign up at the USDA National Organic Program website: www.ams.usda.gov/nop
- USDA & NOP will participate in several conferences and annual meetings this fall/winter.



Betsy Rakola
USDA Organic Policy Advisor

www.usda.gov/organic

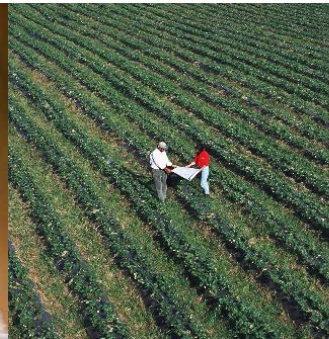
Betsy.Rakola@osec.usda.gov



Best Practices: Proposals & Recommendations

Emily Brown Rosen

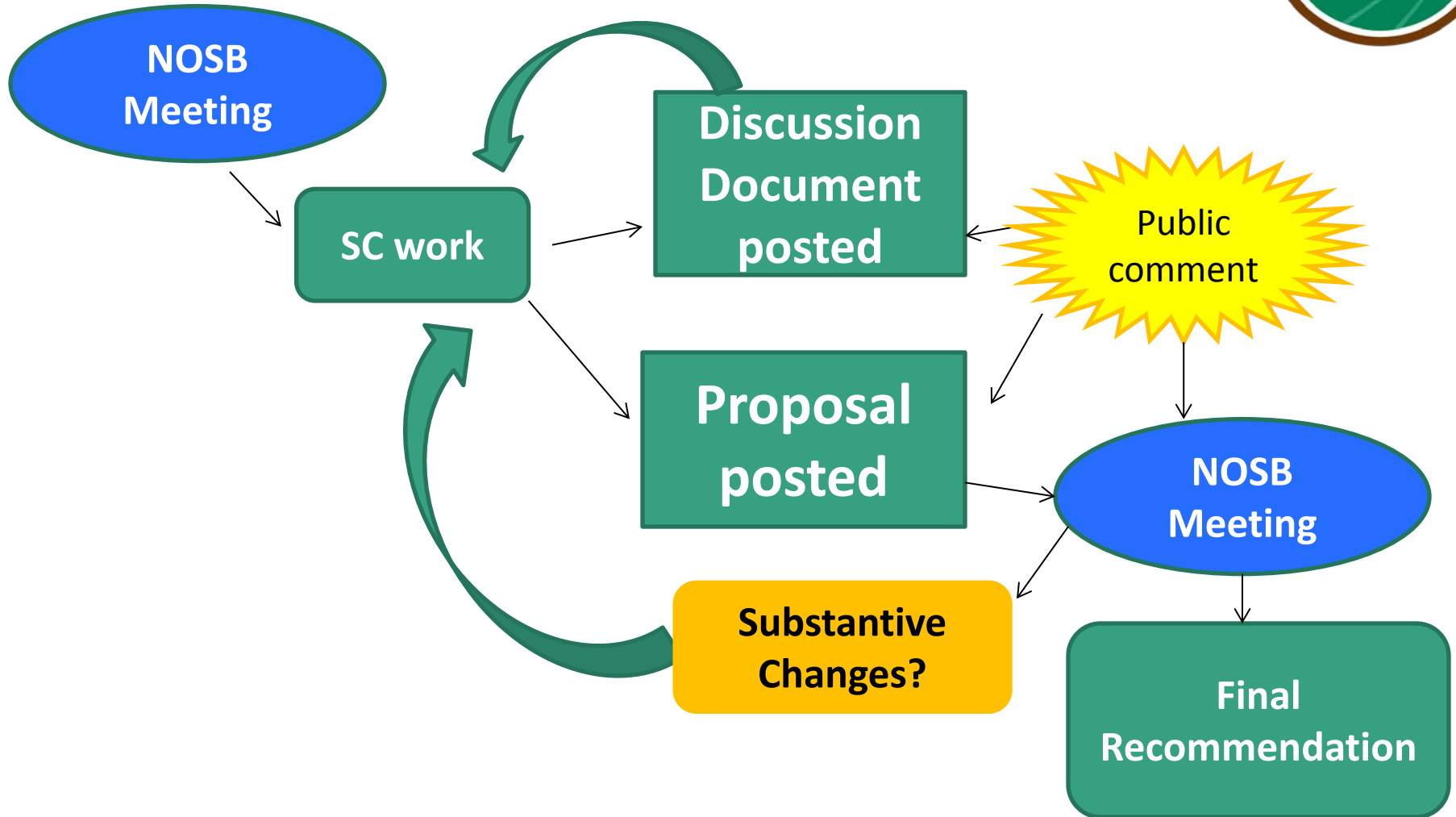
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- Review overall process and templates
- Example of a non-materials proposal
- Critical pieces of proposals & recommendations

NOSB Process





- Proposal
 - Come from Subcommittees
 - Propose an action, include a SC vote
 - Examples:
 - Motion to List, Remove, or Change a substance
 - Motion that calls for policy clarification or guidance
 - Motion to change the regulation elsewhere

Discussion document



- Provided by Subcommittee
 - Used to collect information
 - Posted for comment
- No vote taken at first meeting
 - Discussion of comments
- Returns to subcommittee for further development
- May be turned into a Proposal at next meeting

Recommendation



- Product of full board
- SC proposal is voted on at meeting
 - Final product is considered the recommendation to NOP
 - If substantive changes are considered during a meeting, must get sent back to SC for revision and re-posting

Other types of documents



- Reports or Updates
 - Subcommittee does not expect public comment, but wants to provide update to public
 - No votes or action expected by NOP in response



- Materials Checklists for new petitions
 - Crops and livestock version
 - Handling version
- Narrative format for other proposals
- Sunset templates
 - Initial Meeting 1 Summary
 - Meeting 2 Subcommittee Prelim Review
 - NOSB Final Sunset Review

Example of narrative format recommendation



Calculation of Organic Percent, April 2013

Compliance Certification and
Accreditation Subcommittee

What are the critical pieces?



- **Assessment of Existing Rule**

- Did you check if other parts of the regulations may be impacted by your proposed action?
 - E.g., sulfites in fortified wines, colors
- If other parts are impacted, what is your advice?

- **Accuracy**

- Did you use the correct citations to OFPA and the USDA organic regulations?
 - E.g., Tetracycline

What are the critical pieces?



- **Clear Use of Technical Information**
 - Did you ensure that accurate citations for any technical information is included?
 - Did you clearly articulate why the technical information is relevant and supports any justification?
 - E.g., Carrageenan

What are the critical pieces?



- **Clear Explanation of “Limits”**
 - If there is some quantitative limit proposed, did you articulate the basis for the limit?
 - E.g., Methionine
 - E.g., Stocking Density

What are the critical pieces?



- **Use of Criteria**

- Did you clearly explain your evaluation of the OFPA criteria and how it connects to your proposal?
 - E.g., Why a natural material is not effective
- For 606 materials, did you discuss evidence of commercial availability?
 - E.g., hops

What are the critical pieces?



- **Responsive**
 - Did you address the petitioner's request?
 - Did you explain why you chose an alternative to or rejected the petitioned use?
 - E.g., pet food amino acids

What are the critical pieces?



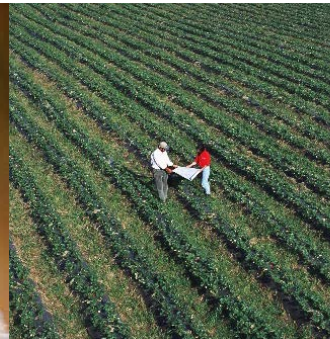
- **Impacts on Organic Market**
 - To the extent that data or public comment is available, did you summarize information on expected impacts on...?
 - Organic producers and handlers
 - Organic consumers
 - Certifying agents



Best Practices: Evaluating Technical Reports and Petitions

Emily Brown Rosen

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- Identifying key information
 - In petition
 - In Technical Review
- Filling out the Checklist
- Providing a summary narrative

Finding the Key Information



- You have just received an email with a large TR linked, and request for review



Where to start?

- Identity
- Classification
- What is it used for

Finding the Key Information



1. Identity of the Substance

- Is it obvious?
- Are there various forms?
- What was the petitioned form?

Example: formic acid

Finding the Key Information



- Identity
 - Is there one CAS number?
 - Are there variations in form?
 - Are there discrepancies between petitioned name and TR name?

Example of Identity Problem



- Petition was for “cellulose fibers”
 - For use in hot dog casings, also anticaking and filtering
- TR says: Chemical name = Cellulose, β -1-4-D-glucan
 - Other names include:
 - powdered cellulose; alpha-cellulose, flour cellulose; cellulose fibers.
 - Microcrystalline cellulose, MCC, (derived from cellulose) is also called cellulose gel.
 - Cellulose casing, regenerated cellulose

Example of Identity problem



From TAP

- Cellulose
 - CAS Number: 9004-34-6- alpha cellulose

- **Other Codes:**

INS numbers:

- 460 cellulose
- 460(i) microcrystalline cellulose
- 460(ii) powdered cellulose

Example of Identity problem



- Best to identify the exact identity in final recommendation:
 - CAS number, INS number or other
 - Will help in future reviews

Finding the Key Information



2. How should the substance be classified?
 - Synthetic
 - Nonsynthetic
 - Agricultural
- Find this in the TR
- Does the petition also support this finding?
 - If not, explain reasoning for a different determination
 - Cite support for decision on Checklist , Category 2

Finding the Key Information



3. What is the petitioned use?
 - Is it clear from petition?
 - Are there other uses mentioned in TR?

 - Review Example: formic acid

Read the Documents !



- Once oriented – read carefully the entire TR
- Revisit petition for comparison
 - Petition Justification statement- does it seem valid?
- Then go through checklist and answer questions.
- Discuss: does anyone have a different way to approach this?

Checklist use



- Yes vs No – sometimes could be both
 - Provide reasoning in comments section
 - Overall use is to balance overall evaluation, one factor might offset another
 - No one criterion is determining
- Sometimes there is no answer, can indicate that information is lacking

Checklist Exercise - break into 3 groups



- Category 1 – Adverse Impacts on humans and environment
 - Questions 2, 3, 10
- Category 2 – Is the substance Essential?
 - Questions 7, 8, 9
- Category 3- Is the substance Compatible?
 - Questions 1, 2

Summary



- Once checklist complete fill out first page , based on SC discussion
- List motions and votes
- Summary of Proposed Action
 - Plainly describe what the proposed action is
 - Give brief justification for action, cite criteria met or not met



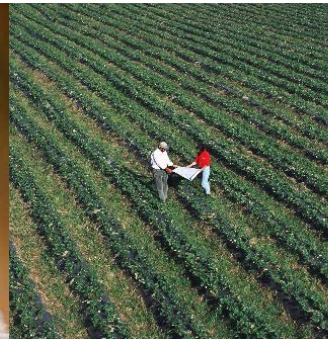
Questions?



Best Practices: Comment Evaluation

Emily Brown Rosen

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Role of Public Comment



- Enables stakeholder feedback and participation
- Provides input on current needs and uses
- Provides input on public concerns
- Improves the final NOSB recommendation
- Helps support the final NOP action



- Large number of comments on some topics
- Limited time to review
- Not always specific or helpful

- Useful to have a system for review
 - Start with a table
 - Count numbers
 - Summarize significant ideas

Weighing the comments



- NOSB should treat comments similarly as USDA does in rulemaking
 - It is not a ballot initiative or an up-or-down vote
 - Total numbers for or against are not determinative alone
 - NOSB recommendations should have justification based on comments, scientific data, expert opinions, and facts accumulated during the NOSB process.
 - If the comments contains persuasive new data or sound policy arguments, the SC could defer a final recommendation, or re-propose with changes.



Total comments: 25 - Bulk Handling Draft Guidance (Internal NOP review)

	Suggested changes	Likes	other
Certifiers Assoc. – 43 signers	<ul style="list-style-type: none"> - Transporters optionally may be certified, thinks “handle” does not include transport - provide definition of broker: does not physically handle? - Sealed containers – should mean tamper proof,& impermeable 	Supports in general	Supported by (mkt coop)
XYZ certifier	<ul style="list-style-type: none"> handlers, not always reqd to be certified. -Certifiers may not be able to inspect railroad cars and trucks -have not been requiring hay brokers to be certified 		
organic farmer, MN	<ul style="list-style-type: none"> -Undue burden on smaller growers using custom haulers -will be a lack of transporters if all have to be certified 		Also filed as assoc, 144 members



Crops Subcommittee Presentation

Total in favor of adding Biodegradable Mulch Film: 163

- Farmers: 38
- Consumers: 114
- Organizations: 11

(Including, among others: BPI; Beyond Pesticides; CCOF; Driscoll's; NOFA; NatureWorks; Novamont; OTA; Oregon Tilth; Proteima; USDA BioPreferred Program)

Total opposed to listing Biodegradable Mulch Film: 4

- Farmers: 0
- Consumers: 1
- Organizations: 3

(CFS; Organically Grown Company; PCO)

Total requesting clarification, annotation changes or further research: 3

- Organizations: 3

(CROPP Cooperative; OMRI; QAI)

Examples – NOSB meeting Oct 2012



Crops Subcommittee Presentation

205.601(b)(2)

(A)(2) showing at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, tested according to ISO 17556 or ASTM 5988

- **BPI**: Although sometimes used as synonyms, the terms “biodegradation” and “mineralization” are different. The 90% threshold value required by the petition and ASTM test methods refer to mineralization. A complete biodegradation is inferred when a mineralization level of 90% is reached.
- **CFS**: Concerned whether the tests have been adequately field verified; the TR did not address these questions. 10% of the mulch is allowed to remain in the microbial biomass or as an undegraded or partially degraded residue in soil; concerns for persistence in farm environment.
- **OMRI**: This language can serve as an appropriate and adequate review without A(1). 5988 is a testing method, rather than a standard to which certification can be obtained; concerned about certifier expertise to determine if materials meet the annotation. A(2) & (E) conflict over the 2 year &/or end of each growing season biodegradation timeframe.
- **PCO**: there are too many standards referenced in the annotation.

Examples - NOSB meeting Oct 2012

Crops Subcommittee Presentation



Concern	Response
Short and long-term impact of pigments on ecosystem	<i>Only titanium dioxide and carbon black are being petitioned. Titanium dioxide is non-synthetic and would be allowed anyway, and carbon black is pure carbon and in effect already allowed as the main component of the ink in newspaper mulch</i>
Can metal catalysts build up in the soil and with what impacts?	<i>An important part of meeting the ASTM 6400 standard above is to verify that any substances such as catalysts break down completely along with the other ingredients. All additives will be tested for by the MRO or the manufacturer.</i>
Are there other additives or processing aids that have potential negative impacts?	<i>Same comment as above. Additionally, one of the makers of PLA bioplastic stated that the TR was inaccurate about the solvents used to produce PLA. No solvents are used for PLA.</i>



Nov. 2009 Handling Committee *Sunset Review of Octadecylamine*

Since the original recommendation dated September 1, 2009 was posted, the NOSB has received 9 comments related to the Handling Committee's original recommendation. Comments were received from organic manufacturers, certifiers, trade associations, and consultants to the organic industry. All comments disagree with the September 1, 2009 recommendation, stating that this substance is still a necessary additive to boiler feed water of some organic operations to minimize corrosion of boilers and steam lines, especially for manufacturers who run predominantly organic products, and whose facilities are located in areas where water quality is exceptionally poor. There were no comments posted that agreed with the Handling Committee's original decision.



- Importance of Acknowledging Comments
 - There will always be disagreements
 - Public can accept they will not always get their desired outcome
 - If they are not ignored
 - If the reasons are explained
 - Results in more consensus, and stronger program in the long run

Evaluation of Comments



- Questions?
- Other ideas or tips?
- What works for you?

NOSB Training



Rulemaking

Shannon Nally Yanessa

Agricultural Marketing Service | National Organic Program
February 2014



What is a Rule?



- A rule is a “an agency statement of general applicability and future effect designed to implement, interpret or prescribe law or policy or describing the organization, procedure or practice requirements of an agency...”
- Must be issued in accordance with the **Administrative Procedure Act.**

The Simplified Rulemaking Process



- Publish Proposed Rule in the Federal Register.
- Provide interested parties an opportunity to submit written data, views, or opinions about the proposed rule.
- Publish a Final Rule in the Federal Register.

How does NOP initiate a rulemaking?



- We are required to prepare, submit and receive approval on a regulatory **workplan** for **every stage** of rulemaking.
 - Summarizes objectives, possible alternatives, and effects of action to policy officials (non-technical)
 - Provides information needed for “designation” of significance
 - Communicates to OMB and public about agencies regulatory plan



- Office of Information and Regulatory Affairs (OIRA)
 - Operates as an “information aggregator” across government
 - Facilitates interagency coordination & communication
 - Considers costs and benefits of regulations
 - Ensures public engagement in process
 - Ensures compliance with relevant statutes
- Career staff: ~45.



- **OMB reviews rules that are:**
 - Likely to have an annual effect on the economy of over \$100 million or more, or adversely affect the economy, a sector of the economy, jobs, or competition;
 - Creates serious inconsistency or interferes with an action of another agency;
 - Materially alter the budgetary impact of existing programs; or
 - Raises novel legal or policy issues.

*Rules that have an effect of \$100M or more on the economy are Economically Significant rules, often considered “major” and triggers Congressional Review Act.

How do stakeholders know what rules agencies are working on?



- Once OMB approves a workplan, this information is published:
 - In the fall in a “Regulatory Plan”; and
 - Every spring and fall an “Agenda of Regulatory and Deregulatory Actions”.
- This “Unified Agenda” is how agencies announce future rulemaking activities update the public on pending and completed regulatory actions.

How does NOP draft a rule?



- Review and summarize all NOSB recommendations;
- Summarize technical information (e.g. CAS, use/availability/function, production system details);
- Review overlapping regulations and coordinate with those agencies (e.g., FDA, EPA);
- Draft overview of the amendment(s), including justification for action and info on implementation;
- Draft amendatory instructions for Federal Register; and
- Conduct necessary supplementary analyses.
- Facilitate NOP approval; engage other Divisions as needed.

How are rules structured?



- Required front sections!
 - Summary
 - Dates
 - Addresses
 - Agency Contact
 - Comment Instructions
- Supplementary Information
 - Background, Overview of Amendment, Impact Analyses, EOs
- Must have legal authority and instructions for Federal Register

Executive Orders 12866 & 13563

Regulatory Planning & Review



- Agencies must assess both costs and benefits of regulation.
- Agencies should propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.
- Agencies should consider alternatives and select an approach that maximizes net benefits.

Cost/Benefit Estimates



Costs (range)	Benefits
<p>\$500 million - \$4.2 billion</p> <p>The upper limit is the upper limit for sales of product categories that would be impacted by this action. The lower bound is based on industry data summarizing annual commodity ingredient sales and retail sales of organic products.</p>	<p>Establishes a clear, finite list of essential and required vitamins and mineral for use in organic food, including infant formula.</p>
	<p>Facilitates the use of essential or required vitamins and minerals in organic food, including infant formula.</p>
	<p>Fosters certainty in determining whether a specific ingredient can be used in an organic product.</p>
	<p>Facilitates enforcement of organic product composition standards.</p>

The Regulatory Flexibility Act (RFA)



- Requires agencies to assess the potential economic effects of rules on small U.S. businesses, non-profit organizations, and small governmental jurisdictions.
- “Small” using Small Business Administration criteria.
- For purposes of NOP rules, most affected entities are considered “small” by SBA.



- The agency must consider following:
 - Does the RFA apply to this rule?
 - Will this rule have a significant economic impact on a substantial number of small entities?
 - What is the potential economic impact of the rule on small entities?
 - What has been/can be done to minimize the adverse economic impact of the rule on small entities? Are there alternatives?

Paperwork Reduction Act



- Goal is to minimize federal paperwork for individuals, small businesses, and State and local governments.
- The agency must show that:
 - Paperwork is least burdensome;
 - Not duplicative of other federal collections; and
 - Information has practical use.

Additional Analyses



- **EO 13175** - Consultation & Coordination with Indian Tribal Governments
 - Requires agencies to consider the compliance costs imposed on tribal governments by regulations.
 - Requires agencies to consult with tribal governments if the regulation would have tribal implications and preempt tribal law.
- **Civil Rights Impact Analysis** - Requires agencies to assess any disproportionate impact on protected groups.

Great! Whew. We finished a draft. How do we clear rules for publication?



- Not Significant
 - Office of General Counsel
 - Deputy Administrator
 - Administrator
 - Undersecretary
 - Secretary

Clearance for significant actions?



- Office of General Counsel & USDA General Counsel
- Deputy Administrator
- Administrator
- Office of Budget and Program Analysis
- Office of Risk Assessment and Cost Benefit Analysis
- Assistant Secretary, Civil Rights
- Office of Chief Economist
- Office of Chief of Information
- Office of Tribal Relations
- Undersecretary
- Secretary
- OMB – includes interagency review.
 - 90-day review; can be extended.
- (Congressional Review Act)

Why does rulemaking take so long?



- Review of NOSB recommendation
- Draft Regulatory Workplan for OMB Designation
- Conduct and Draft Required Analyses
- Draft Proposed Rule
- Clearance & Federal Register Publication
- Comment Period
- Comment Analysis
- Workplan Addendum for OMB Designation
- Revise Required Analyses
- Draft Final Rule
- Clearance & Federal Register Publication
- Effective Date of Final Rule

Proposed
Rule
Stage

Final Rule
Stage

How can public comments affect the final rule?



- The notice-and-comment process enables anyone to submit a comment on any part of a proposed rule.
- An agency is not permitted to base its final rule on the number of comments in support of the rule over those in opposition to it.
- The agency must base its reasoning and conclusions on the rulemaking record, consisting of the comments, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages.
- If the rulemaking record contains persuasive new data or sound policy arguments, the agency may decide to terminate the rulemaking.
- Or, the agency may decide to continue the rulemaking but change aspects of the rule to reflect these new issues.

Ex Parte Communication



- A private communication between agency decision makers and other persons regarding substance of the rule.
- It is USDA policy to avoid ex parte communications during rulemaking.
- Once proposed rule is published, we can:
 - Answer factual questions
 - Accept written comment
 - Accept oral comment during public hearing
- If it does occur, we draft memo about the communication and post as part of rulemaking record.

How are rules incorporated into the regulations?



- The Code of Federal Regulations (CFR) contains all of the generally applicable rules of the Federal government with current or future effect.
- On the day a final rule is published in the Federal Register, Federal Register staff process the material for codification into the CFR.
 - Rules that are immediately effective are integrated into the “Electronic Code of Federal Regulations” (e-CFR) database (ecfr.gpoaccess.gov).
 - Rules with delayed effective dates are placed in amendment files and linked from the main e-CFR database.



- [A Guide to the Rulemaking Process](#)
 - Office of Federal Register
- [The Office of Information and Regulatory Affairs: Myths and Realities](#)
 - Commentary By Cass R. Sunstein
- [The Regulatory Plan and Unified Agenda](#)
 - Office of Management & Budget



National Organic Standards Board Refresher Training: Ethics and Conflict of Interest Training

February 2015





- **Ethics: Challenges and Strategies**
- **Managing Interests and Conflicts of Interest**

Challenges



- **NOSB-Developed Mission Statement:** Provide effective and constructive advice, clarification and guidance to the Secretary of Agriculture concerning the National Organic Program and the consensus of the organic community.
- **Realistic challenges in making this mission real:**
 - Making recommendations that are defensible and hold up under legal and public scrutiny.
 - Getting sufficient and pertinent information and facts.
 - Consistent and transparent analysis of facts.
 - Interacting with the public, receiving and evaluating input.
 - Balancing stakeholder interests.



As a Board member representing an interested and engaged community, and making recommendations that will have wide-reaching regulatory impacts, your decisions and actions are carefully scrutinized.

Perceptions matter.

Optics and Ethics: Common Concerns



- Absence of Transparency: When relevant facts are hidden from one or more parties involved in making a decision.
- Unwarranted Gain: Seeking an improper or unearned benefit for yourself or others (“disproportionate gain”)
- Lack of Impartiality: Allowing friendships, family relationships, personal, financial, or other biases to influence you improperly. You must represent collective interests.
- Nonperformance of Obligation: Failing to meet the obligations of your position: NOT voting, NOT contributing your input, or NOT gathering and weighing facts from all stakeholders to the best of your ability.

Optics – How things appear to others - is important!

Strategies for Ethical Decision Making



- Gathering Information: Information about alternatives may come from multiple sources. Failing to gather sufficient information can lead to poor decision making.
- Identifying Stakeholders: All of the people who have an interest in the outcome of a decision are the stakeholders. To choose the most ethical alternative, identify all the parties who will be affected. Is it appropriate or even possible to assess which stakeholders are significantly more affected than others? What is your criteria for assessing impact?
- Analysis: Find the Right Balance between: Utility, Rights, Fairness, and Relationships – Personal, organizational, and cultural values underlie most decisions



- **Ethics: Challenges and Strategies**

- **Managing Interests and Conflicts of Interest**

USDA Policy for Board Representatives



- “Representatives” are appointed based on ability to share the viewpoints and perspectives of the community or sector you represent.
- Even if there is no financial conflict of interest, your outside relationships may raise questions in the public’s mind about how fair you can be while working on a particular committee matter.
- You should avoid participating in those particular matters in which you could **reasonably be viewed by others as engaging in “self-dealing” to benefit yourself or someone close to you.**
- Be alert for situations when one of the following persons or entities will be specifically affected by your committee’s activities:
 - a member of your household;
 - a former employer or a prospective employer;
 - a client of yours or your spouse;
 - a person or organization with which you have some kind of business or contract relationship; or your spouse’s employer.

Key: Disproportionate Impact



- Board members are appointed in part because of their interests. As such, finding the line between an **acceptable interest** and a **conflict of interest** is important.
- Definition of Conflict of Interest: A situation in which there is an actual or potential direct financial interest of a Board member, or a person or entity associated with a Board member, which could **impair the individual's objectivity** or which **has the potential to create an unfair competitive advantage**.
- **Acceptable Interest:** An interest carried by an NOSB member in the interest of a represented group.
- **Conflict of Interest:** Interest that directly and disproportionately benefits the NOSB member (or a person associated with that member).

Disclosure of Interests



- Conflict of Interest is as much about the appearance of a personal conflict and loss of impartiality as it is about actual direct interest.
- Board members need to review proposals and research any actual and potential conflicts of interest.
- If a Board member discloses having a conflict of interest and offers to recuse him or herself, NOP will accept that, with no questions asked. You do not need to give the details of the conflict – just state that a conflict exists.
- If the Board member discloses a potential Conflict of Interest and is uncertain as to whether he or she should recuse him or herself, then the NOP will make the determination about whether a conflict exists, and will instruct the member accordingly as to whether to vote or not.

Process Used at the NOSB Meetings



- The Designated Federal Officer (DFO) will provide a matrix in advance of the meeting that lists proposals being voted on at the meeting. Review the list and:
 - Decide on your own to recuse yourself and notify the DFO which proposals you will not be voting on OR
 - If you are unsure, contact the NOP Associate Deputy Administrator to discuss your possible conflict to determine whether you should recuse or not.
- NOP will compile a list of all recusals for the meeting.
- At the beginning of each Subcommittee session, DFO will identify NOSB members that have a COI and will not be voting.
- When it is time to vote, the Board member recusing will simply state “Recuse” when it is his or her time to vote.



Questions/Discussion

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