

**Agricultural Marketing Service (AMS) | National Organic Program (NOP)
National Organic Standards Board (NOSB) New Member Training Agenda**

Monday, February 29, 2016

Location: USDA South Building - Washington DC - Cafeteria Room # 3

Time	Content	Notes: Slide presentation #/handout/weblinks
Online self-paced	Organic 101 and 201 (Can review either online with voiceover, or in pdf) http://www.ams.usda.gov/services/organic-certification/is-it-an-option	
Online self-paced	Sound & Sensible Organic Certification: <ul style="list-style-type: none"> http://www.ams.usda.gov/report-presentation/sound-sensible The Road to Organic Certification <ul style="list-style-type: none"> Interactive Video: "The Road to Organic Certification" 	
8:30 AM	Arrive at USDA South building - Cafeteria room #3. See instructions for getting into the USDA building	
9:00 - 9:30 AM	AMS Welcome and Introductions	Acting AMS Administrator Starmer ~4:00pm, AMS Deputy Administrator McEvoy ~5:00
9:30 - 10:00 AM	National Organic Program Overview: Brief overview of NOP and its divisions, and where NOSB fits in. Delivered by: Paul Lewis	PP_001 NOP Overview Handouts: 001a AMS Org Chart 001b NOP Org Chart 001c Program Handbook TOC
10:00 - 10:15 AM	Brief Overview of Organic Foods Production Act (OFPA) Delivered by: Mark Bradley	PP_002 OFPA Handouts: 002 OFPA (7 USC Ch 94 Organic)
10:15 - 10:45 AM	Overview of USDA Organic Regulations Delivered by: Mark Bradley	PP_003 USDA OrganicRegs Handouts: 003 Organic Regulations TOC only (Printed upon request 71 pages)
10:45 - 11:00 AM	Break	
11:15 - 11:30 AM	Brief Overview of Federal Advisory Committee Act (FACA): Delivered by: Paul Lewis	PP_004 FACA Link to FACA website
11:30 - 1:00 PM	National List Delivered by: Lisa Brines <ul style="list-style-type: none"> Review National List petition process 	PP_005 NL Petition Process Handouts: 005a_National List Petition Guidelines - 2007 005b_NOP 3005-1 OFPA Exemption Checklist 005c_NOP 3005-2 Petition Guidelines Checklist

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	Sunset Process Delivered by: Lisa Brines <ul style="list-style-type: none"> Review Sunset Process and Templates 	PP_006 Sunset Process Handouts: 006a_NOP 5611 SunsetDates - Pg. 1 only 006b_Sunset Process - 2013
1:00 PM	Lunch - (USDA Cafeteria). Meet and greet with AMS/NOP staff over lunch. USDA cafeteria has a good variety of food options. Credit cards accepted	
2:00 – 2:30 PM	Rulemaking Delivered by: Shannon Nally Yanessa <ul style="list-style-type: none"> Key elements of rulemaking process (Getting a rule completed and through clearance (OGC and OBPA). 	PP_007 Rulemaking Process
2:30 – 4:30 PM	Proposals, Technical Reports, Public Comments Delivered by: Emily Brown Rosen <ul style="list-style-type: none"> Best practices for writing proposals and recommendations Best practices for evaluating technical reports Best practices for analyzing public comments 	PP_008 BestPractices - Props Recs TRs PubComm Handouts: 008a_TR Samples Handout 008b_Crops Pet Mat Prop Template 2-24-16 008c_LS HS Pet Mat Prop Template 2-24-16
4:30 – 5:30 PM	NOP and NOSB Operational Guidelines (Charter, Nominations, Work agendas, Subcommittees, Public Meetings, FOIA Review, NOSB website). Delivered by: Emily Brown Rosen, Michelle Arsenault	PP_009 NOP NOSB OperatingGuides 009a_ NOSB Charter 2014 009b_2013 NOSB NewMmbrGuide 009c_Work Agenda example 009d_SC AssignCallsched Jan2016 009e_2016 Apr DRAFT Agenda_Internal
5:30 – 6:00	Summary and Closing Discussion	

Webinar Date: March 4	Content	
30 minutes (Entire NOSB)	USDA Organic Working Group (OWG) and Secretary's Organic Guidance - Betsy Rakola	
(1 hour) (Entire NOSB)	Ethics and Conflict of Interest Stuart Bender	



National Organic Standards Board Training: National Organic Program Overview

Agricultural Marketing Service | National Organic Program
February 2016





- 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?



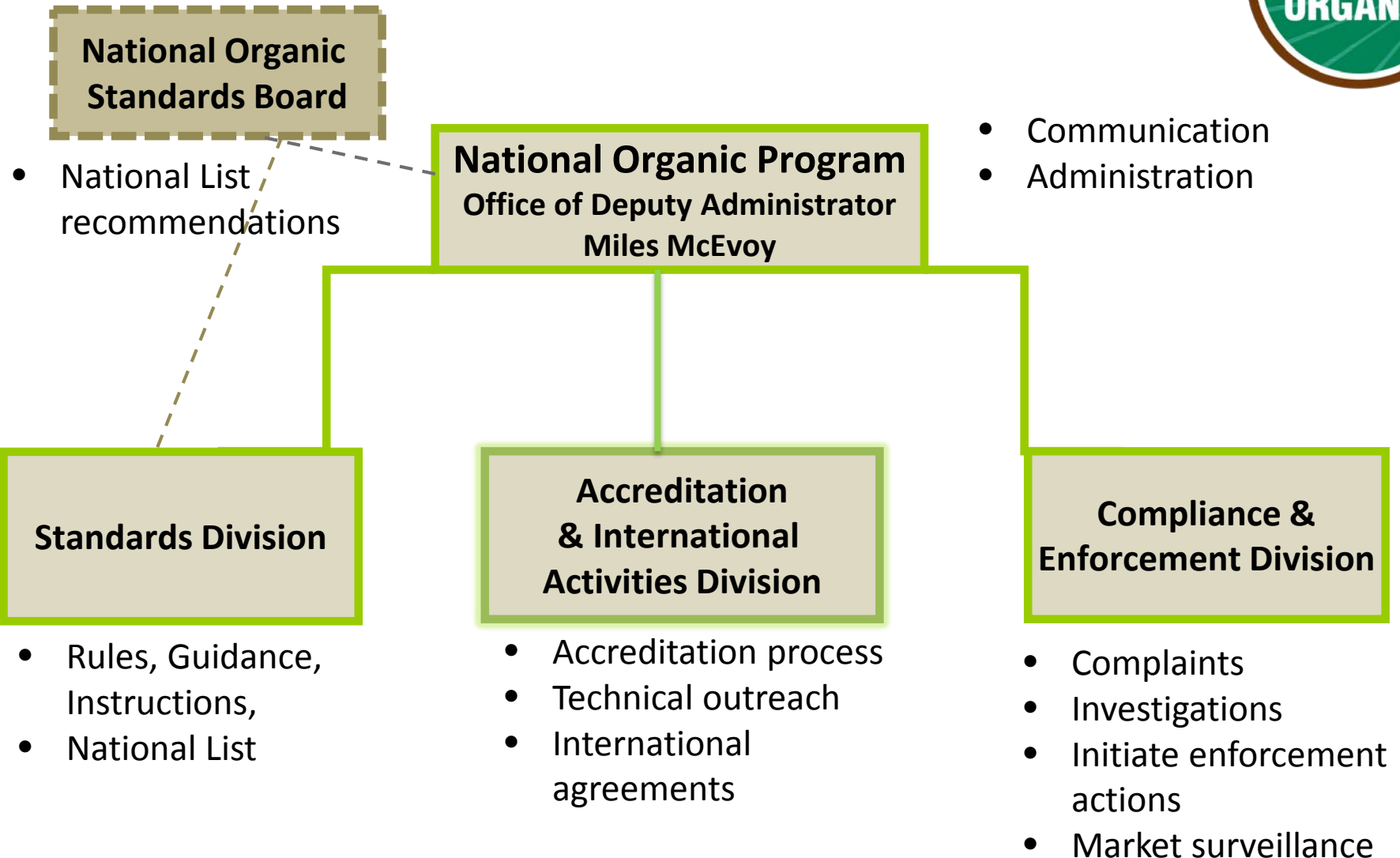
- Develop and maintain organic standards
- Accredite and oversee third party organic certifying agents, who review, inspect, and approve organic producers and handlers
- Implement international organic trade agreements
- Investigate complaints of violations (example: uncertified farmer selling food as organic, selling conventional food as organic)
- Manage the National Organic Standards Board
- **Oversight Responsibility:**
 - 79 certifying agents worldwide
 - 31,000 + certified organic operations
 - \$49 billion in U.S. organic sales (2015)

Quick Facts About NOP

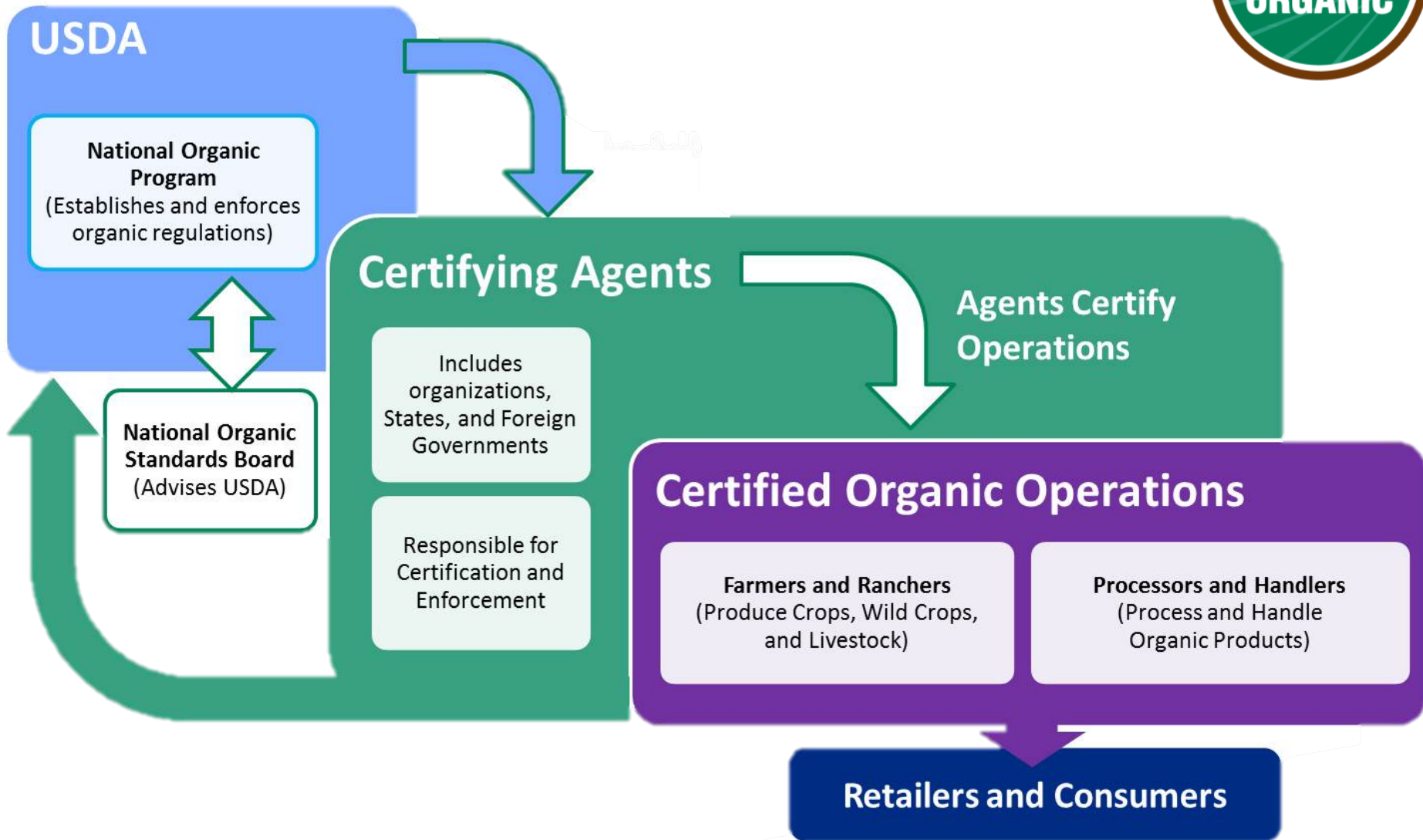


- **Staffing:** 45 employees in three Divisions and the Office of the Deputy Administrator
- **Budget:**
 - FY 2012: \$6.919 million
 - FY 2013: \$6.369 million
 - FY 2014 to 2016: \$9.04 million
- **NOP Leadership Team:**
 - Miles McEvoy – Deputy Administrator
 - Jennifer Tucker – Associate Deputy Administrator
 - Paul Lewis – Standards Division Director
 - Cheri Courtney – Accreditation and International Activities Div. Director
 - Matthew Michael – Compliance and Enforcement Division Director
- **MRP Leadership** – Betsy Rakola, USDA Organic Policy Advisor

NOP Organization and Activities



The Organic Stakeholder Community



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, origin of livestock

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: Conservation activity plan for organic system plans

4. Guidance Documents

Home: Program Handbook

- Provide options to satisfy regulatory requirements
- Support enforcement by referencing section of USDA organic regulations
- Example: substances in post-harvest handling



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: nanotechnology

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>

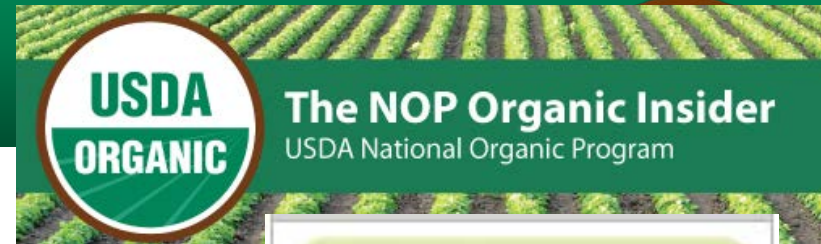
Training and Outreach



- 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 79 certifiers, which certify over 31,000 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 5 Accreditation Managers, and a Lead Auditor
 - Supplemented by audit team in AMS Quality Assurance Divisions, Livestock and Seed Program
- At the close of FY 2015, certifiers were in full compliance with 97% of the NOP's accreditation criteria, and have implemented corrective actions for all deficiencies.

Key Accreditation Activities



- Three accreditation renewal audits, 24 accreditation midterm audits, 3 satellite audits, initial accreditation audits and one peer review.
- Consider 41 reinstatement of certification requests
- Consider 5 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
 - Switzerland – Effective in July 2015
- **Recognition Agreements:**
 - India, Israel, Japan, 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 2016



- Publish updated list of certified operations
- ACA Certifier Training: Spring 2016
- New equivalency agreement activities
- Accreditation Audits and Follow-up
- Maintain existing recognition and equivalency arrangements – peer reviews, working groups
- Recruiting and onboarding new staff

Topics



- 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:

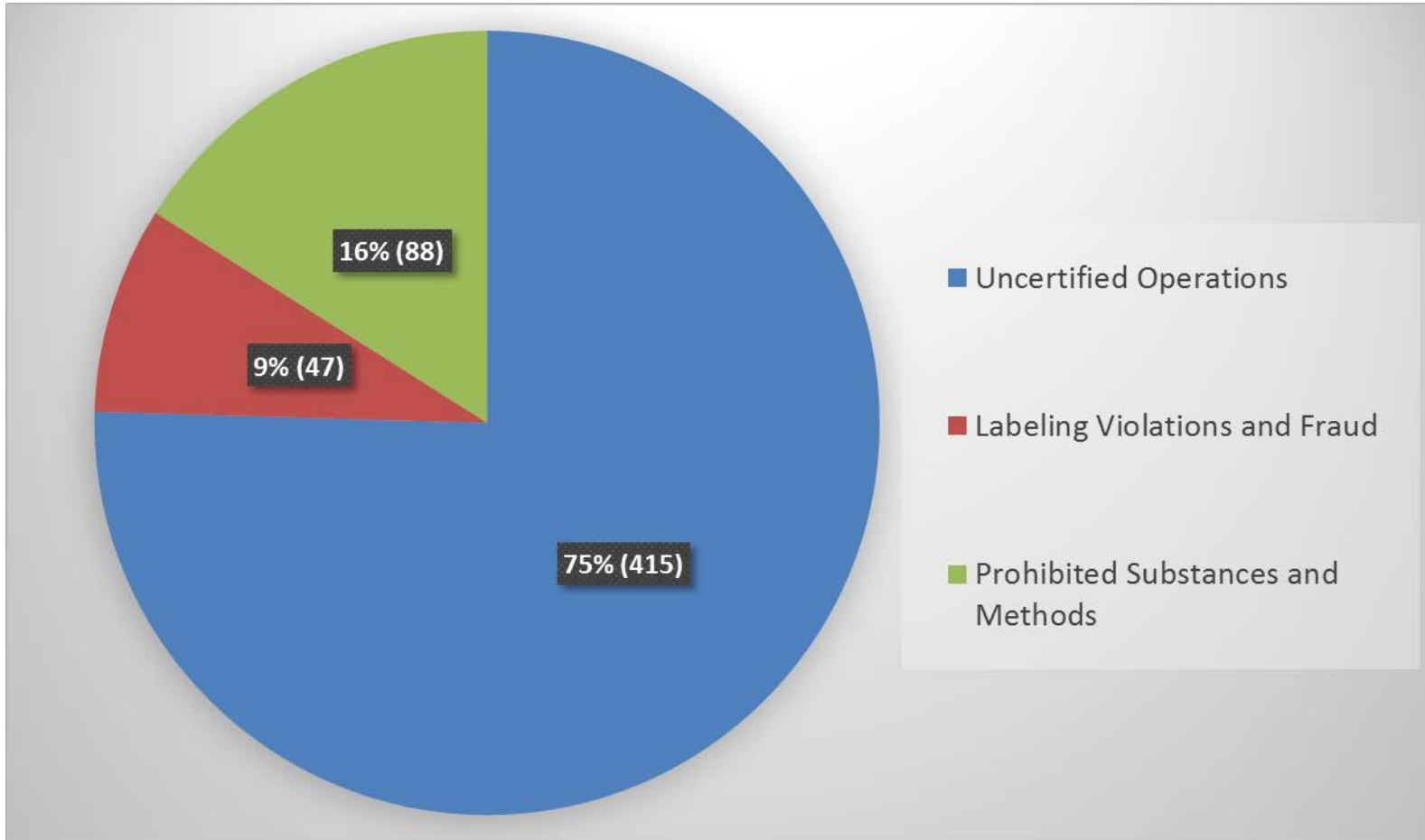
- Investigate complaints, work with operations to achieve compliance where possible and take enforcement actions as appropriate
- Represent the NOP in appeals of adverse actions
- Work with ACAs, State Programs and Federal partners on enforcement of the OFPA and the USDA organic regulations
- Lead enforcement-related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

FY 2015 Successes



- Issued 13 civil penalties, totaling \$1.8 million, for willful violations of the USDA organic regulations
- Closed 390 complaint investigations, a new record, and important as we received a record high 550 complaints
- Issued 121 Notices of Warning, 36 Notices to Cease and Desist and 64 investigation referrals
- Published six fraudulent organic certificates on the NOP webpage
- Prevailed in an administrative hearing against Stoney-M Farm, seeking suspension of land to which prohibited substances had been applied
- Issued six subpoenas under new Farm Bill authority

FY16 Incoming Complaint Distribution by Type



2016 Priorities



- Maintain high closure rate of complaint reviews and investigations
- Work closely with OGC to pursue complaints for hearing against violators, as appropriate
- Contribute to policy, training and outreach development to improve compliance
- Expand cooperation with Federal and State partners regarding civil and criminal enforcement



- NOP: Overview, Cross-Cutting Activities
- Accreditation and International Activities
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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

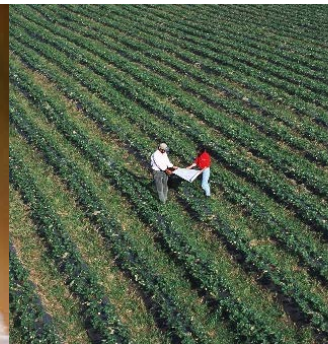


- Guidance
 - Classification of Materials
 - Treated Lumber
 - Calculation of Organic Ingredients
 - Crop and Livestock Materials
 - Pesticide spray drift
- Rulemaking
 - Final Rule: Origin of Livestock
 - Proposed Rule: Aquaculture
 - Proposed Rule: Pet Food
 - Proposed Rule: Animal Welfare
 - Proposed Rule: Apiculture



Questions/Discussion

Agricultural Marketing Service | National Organic Program
February 2016





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

February 2016





- 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

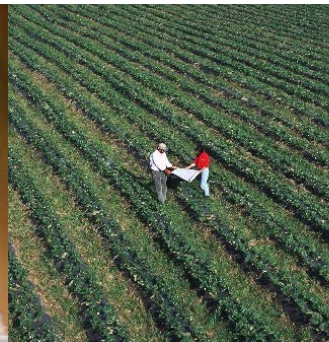


- Recordkeeping
 - Records must be made available
 - Records of all inputs
 - confidentiality
- Investigations
 - Investigations, subpoena authority, take evidence
- Enforcement
 - Civil penalties - \$11,000 per violation
 - False statement, ineligibility
- Expedited appeals process



Questions/Discussion

Agricultural Marketing Service | National Organic Program
February 2016





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: Federal Advisory Committee Act (FACA)

February 2016



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



- Subcommittees are considered part of the FACA, BUT, FACA's openness requirements do not apply.
- **This is because:**
 - NOSB subcommittee proposals do not come directly to USDA – they come through the NOSB Committee.
 - The full committee deliberates on Subcommittee work.
- 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

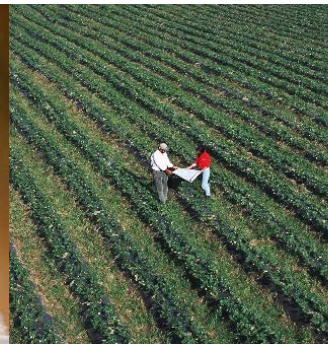


- NOP's success is measured in part by its success in managing the NOSB:
 - Are recommendations within the Committee's scope? (OFPA statute and agency responsibilities)
 - Are Board and program resources being used effectively and efficiently?
 - Is the NOP asking for advice that it can then act upon? (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

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February 2015



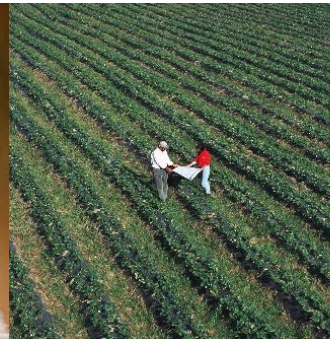


National List Petition Process

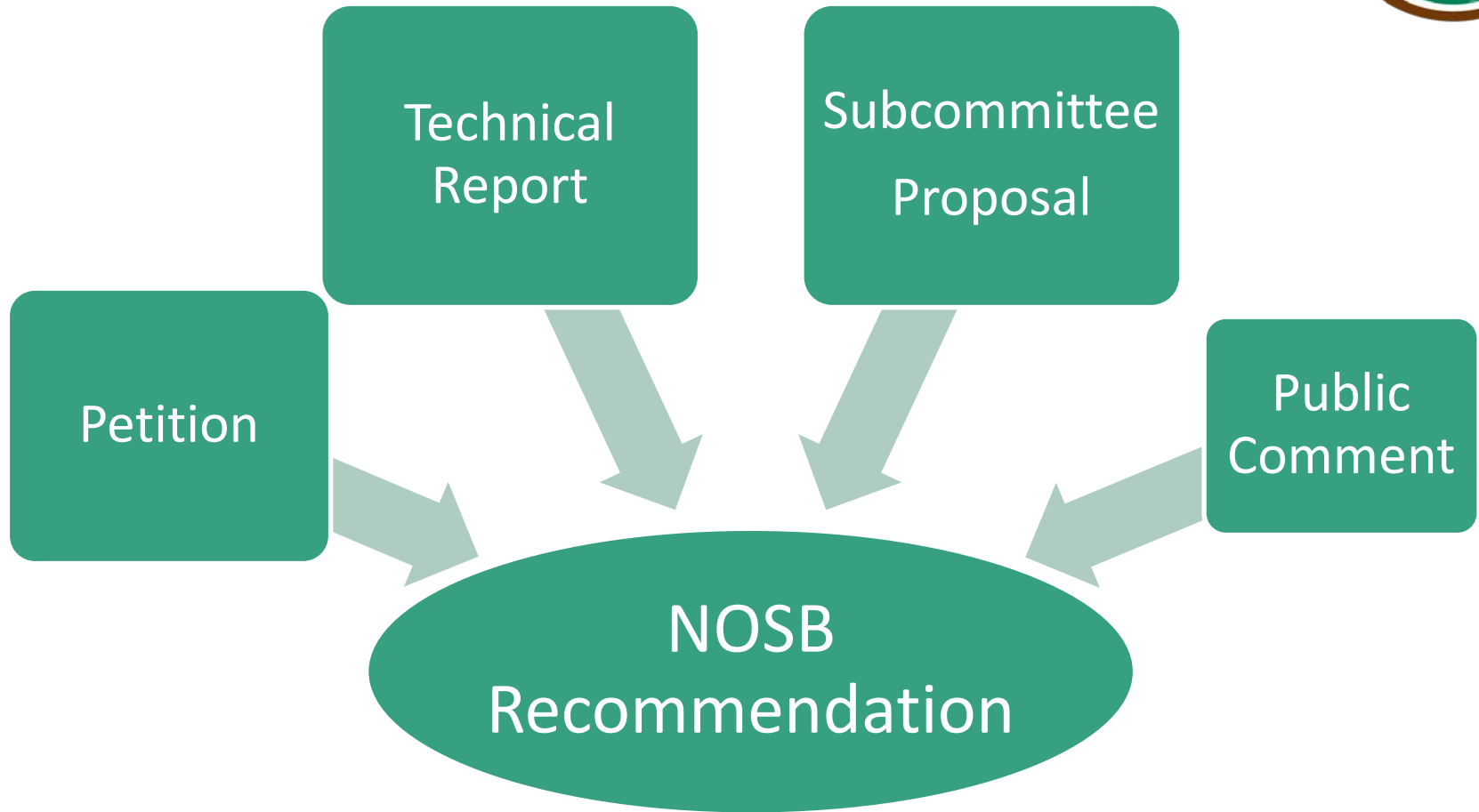
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Multiple inputs for NOSB Recommendations





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 verify 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
- Technical report 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
- New forms with alternative format – in development

NOSB Review - Documentation



- 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 criteria (e.g., 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?

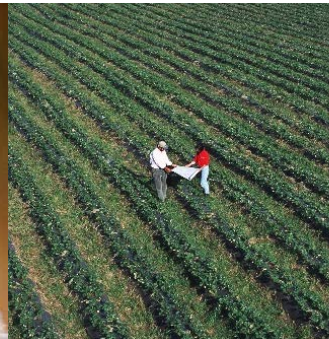


Sunset Process

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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



- Apply to National List substances
- 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



- **Thorough and transparent review process for all substances** - provides two 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



July 2015

- Subcommittees submitted Technical Reports requests

Spring 2016 Meeting

- Sunset 2018 Summaries
- Public comment

Fall 2016 Meeting

- Sunset 2018 Reviews
- Public comment
- Decisions to remove made here

Before Sunset Dates in 2018 (May 29/Nov 3)

- AMS renewal and removals, as applicable.

Review New Documents



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



- Questions?



Rulemaking

Shannon Nally Yanessa

Agricultural Marketing Service | National Organic Program
February 2016





- What happens when NOP receives an NOSB recommendation for rulemaking?
- How do we get from recommendation to a proposed or final rule?



Administrative Procedures Act

- Fosters transparency and public participation in the rulemaking process.

Basic requirements:

- Publish a proposed rule in the Federal Register.
- Invite and consider public comments.
- Issue final rule at least 30 days before effective date.

Rulemaking oversight



- Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB)
 - 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
- [Reginfo.gov dashboard](#)

How does NOP initiate a rulemaking?



- Submit a regulatory workplan
 - Summarizes objectives, possible alternatives, and effects of action to policy officials (non-technical)
 - Provides information needed for “designation” of significance
- Priority rulemaking actions appear on the Unified Agenda
 - Communicates to OMB and public about agencies regulatory plan

Significance designation



- **OMB reviews rules that may:**
 - **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;**
 - **Create serious inconsistency or interferes with an action of another agency;**
 - **Materially alter the budgetary impact of existing programs; or**
 - **Raise novel legal or policy issues.**

Significant vs Non-significant



What does this distinction mean in practice?

- Significant rules require additional analyses:
 - Regulatory Impact Analysis (cost-benefit) – E.O. 12866 & 13563
 - Regulatory Flexibility Act
 - Paperwork Reduction Act
 - Consultation & Coordination with Indian Tribal Governments
 - Civil Rights Impact Analysis

How does NOP draft a rule?



- Review all NOSB recommendations; technical information (e.g., TRs, petitions), overlapping regulations.
- Review and analyze public comments (final rule).
- Draft overview of the amendment(s), including justification for action and info on implementation;
- Draft amendatory instructions for Federal Register;
- Conduct necessary supplementary analyses.
- Facilitate NOP approval; engage other Divisions as needed.

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.

Clearance - review pathway



- Office of General Counsel & USDA General Counsel
- NOP Deputy Administrator
- AMS 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)

Red = needed
for significant
rules

Why does rulemaking take so long?



- Review of NOSB recommendation
- Draft Regulatory Workplan for OMB Designation
- 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



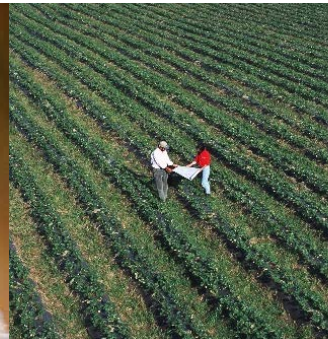
- [A Guide to the Rulemaking Process](#)
 - Office of Federal Register
- [The Office of Information and Regulatory Affairs: Myths and Realities](#)
 - Commentary By Cass R. Sunstein
- [The Regulatory Plan and Unified Agenda](#)
 - Office of Management & Budget



Best Practices: Proposals & Recommendations

Emily Brown Rosen

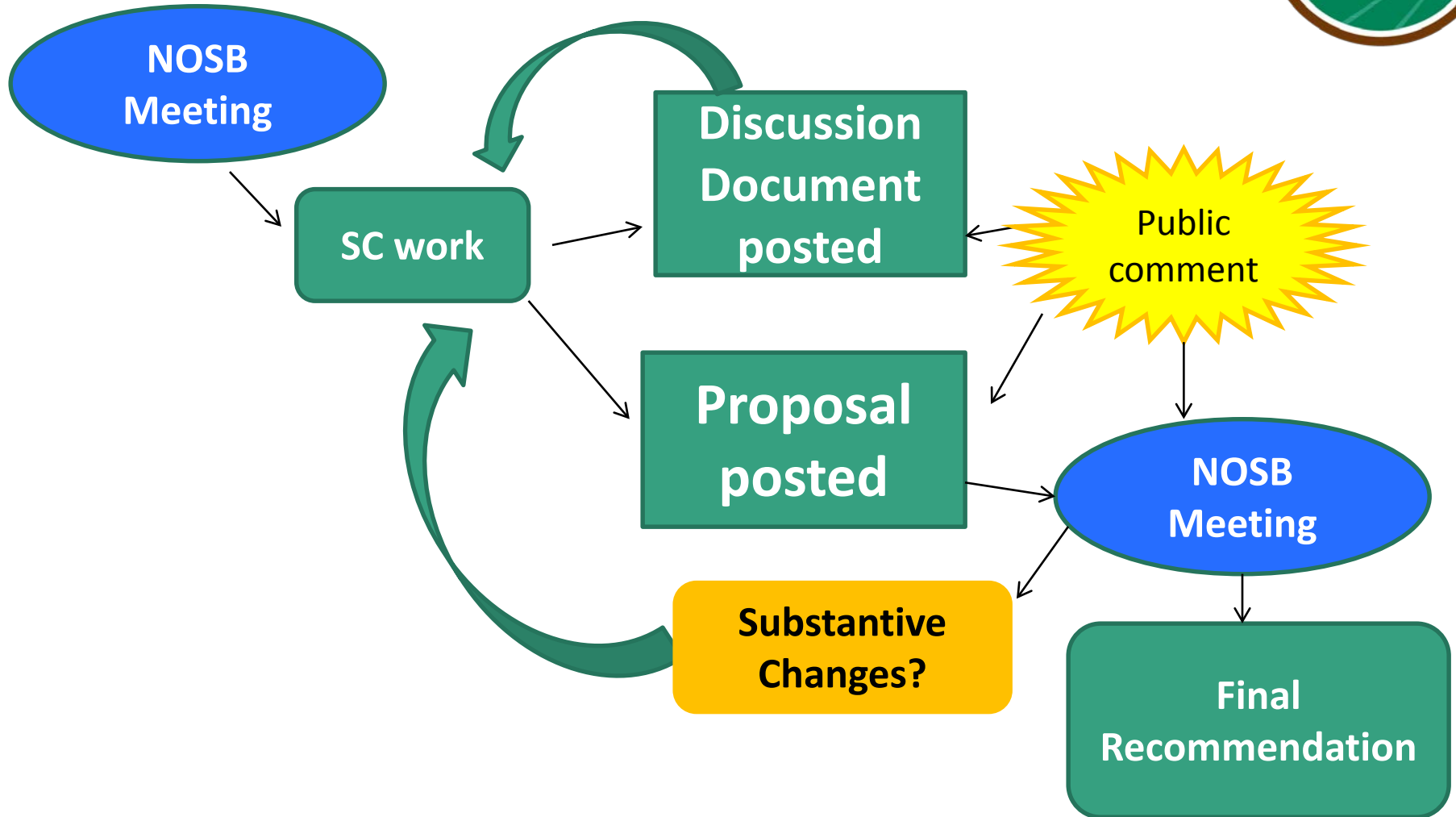
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- Review overall process and templates
- Example of a non-materials proposal
- Critical pieces of proposals & recommendations

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
 - Verbal update, discuss 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
 - Cover sheet is added to the SC proposal to summarize final action
 - 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

Forms used



- Materials Review Template for new petitions
 - Crops and livestock version
 - Handling version
- Other proposals - narrative
- 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, Developing Materials Proposals

Emily Brown Rosen

Agricultural Marketing Service | National Organic Program

February 2016





- Identifying key information
 - In petition
 - In Technical Review
- Filling out the Materials Review Template
- 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



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 Petition Review Template
 - Use Decision Tree
 - Classification of Materials Guidance



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 Review Template and answer questions.
- Discuss: does anyone have a different way to approach this?

Materials Review Template



- Provide reasoning
 - 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

Review Exercise - break into 2 groups



- Category 1 – Classification and Category 3 – Alternatives / Compatibility
- Category 2 – Adverse Impacts



- Once template complete fill out Summaries on page 1
- Summary of Proposed Action
 - Plainly describe what the proposed action is
 - Give brief justification for action, cite criteria met or not met



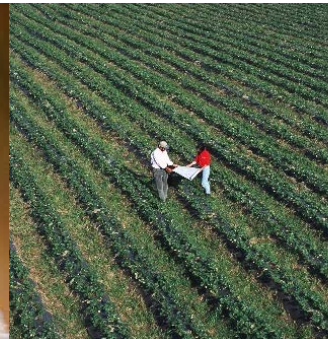
Questions?



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?



Sunset [Year] Review Summary Meeting 1 - Request for Public Comment [Crops/Livestock/Handling] Substances [Month Year]

Introduction

As part of the [Sunset Process](#), the National Organic Program (NOP) announces substances on the National List of Allowed and Prohibited Substances (National List) that are coming up for sunset review by the National Organic Standard Board (NOSB). The following list announces substances that are on the National List for use in organic crop production that must be reviewed by the NOSB and renewed by the USDA before their sunset dates in 2017. This list provides the substance's current status on the National List, use description, references to past technical reports, past NOSB actions, and regulatory history, as applicable. If a new technical report has been requested for a substance, this is noted in this list. To see if any new technical report is available, please check for updates under the substance name in the [Petitioned Substances Database](#).

Request for Comments

While the NOSB will not complete its review and any recommendations on these substances until the [spring/fall Year] public meeting, the NOP is requesting that the public provide comments about these substances to the NOSB as part of the [spring/fall Year] public meeting. These comments should be provided through www.regulations.gov by [Month, day, year] as explained in the meeting notice published in the [Federal Register](#).

These comments are necessary to guide the NOSB's review of each substance against the criteria in the Organic Foods Production Act (7 U.S.C. 6518(m)) and the USDA organic regulations (7 CFR 205.600). The current substances on the National List were originally recommended by the NOSB based on evidence available to the NOSB at the time of their last review which demonstrated that the substances were found to be: (1) not harmful to human health or the environment, (2) necessary because of the unavailability of wholly nonsynthetic alternatives, and (3) consistent and compatible with organic practices.

Public comments should focus on providing new information about a substance since its last NOSB review. Such information could include research or data that may support a change in the NOSB's determination for a substance. Public comment should also address the continuing need for a substance or whether the substance is no longer needed or in demand.

Guidance on Submitting Your Comments

Comments should clearly indicate your position on the allowance or prohibition of substances on the list and explain the reasons for your position. You should include relevant information and data to support your position (e.g., scientific, environmental, manufacturing, industry impact information, etc.).

For Comments That Support Substances Under Review:

If you provide comments in support of an allowance of a substance on the National List, you should provide information demonstrating that the substance is:

- (1) not harmful to human health or the environment;
- (2) necessary to the production of the agricultural products because of the unavailability of wholly nonsynthetic substitute products; and
- (3) consistent with organic [crop production/livestock production/handling].

For Comments That Do Not Support Substances Under Review:

If you provide comments that do not support a substance on the National List, you should provide reasons why the use of the substance should no longer be allowed in organic production or handling. Specifically, comments that support the removal of a substance from the National List should provide new information since its last NOSB review to demonstrate that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with **[crop production/livestock production/handling]**.

For Comments Addressing the Availability of Alternatives:

Comments may present information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- o Alternative management practices that would eliminate the need for the specific substance;
- o Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- o Other organic or nonorganic agricultural substances.

Your comments should address whether any alternatives have a function and effect equivalent to or better than the allowed substance, and whether you want the substance to be allowed or removed from the National List. Assertions about alternative substances, except for those alternatives that already appear on the National List, should, if possible, include the name and address of the manufacturer of the alternative. Further, your comments should include a copy or the specific source of any supportive literature, which could include product or practice descriptions; performance and test data; reference standards; names and addresses of producers or handlers who have used the alternative under similar conditions and the date of use; and an itemized comparison of the function and effect of the proposed alternative(s) with substance under review. The following table can help you describe recommended alternatives in place of a current substance that you do not want to be continued.

[NOTE – ONLY include this paragraph on handling list] For Comments on Nonorganic Agricultural Substances at Section 205.606.

For nonorganic agricultural substances on section 205.606, the NOSB Handling Subcommittee requests current industry information regarding availability of and history of unavailability of an organic form of the substance in the appropriate form, quality, or quantity of the substance. The NOSB Handling Subcommittee would like to know if there is a change in supply of organic forms of the substance or demand for the substance (i.e. is an allowance for the nonorganic form still needed), as well as any new information about alternative substances that the NOSB did not previously consider.

Written public comments will be accepted through **[Month, day Year]** via www.regulations.gov. Comments received after that date may not be reviewed by the NOSB before the meeting.

Reference: 7 CFR §205.601 Synthetic substances allowed for use in organic crop production.

Reference: 7 CFR 205.603 Synthetic substances allowed for use in organic livestock production

Reference: 7 CFR 205.605 *Nonagricultural* (Nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

§205.605(a) Nonsynthetics allowed:

§205.605(b) Synthetics allowed:

Reference: 7 CFR §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

LIST of MATERIALS LINKED TO SUMMARY BELOW

EXAMPLES:

[Substance 1](#)

[Substance 2](#)

NAME OF SUBSTANCE 1

Reference: 205.60X1(X)(X)

Technical Report(s): 19XX TAP; XX/20XX TR; XX/20XX TR

Petition(s): 199X, 200X

Past NOSB Actions: XX/1995 NOSB minutes and vote; XX/20XX NOSB sunset recommendation; XX/20XX NOSB sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 0X/0X/200XX (XX FR XXXXX)

Sunset Date: XX/XX/20XX

Background from Subcommittee:

INSERT BACKGROUND TEXT/PRELIMINARY REVIEW

Supplemental Review Information

(LINK TO OPTIONAL CHECKLIST IF COMPLETED)

Additional information requested by NOSB

INSERT QUESTIONS FROM SUBCOMMITTEE OR “NONE”

NAME OF SUBSTANCE 2

Reference: 205.60X1(X)(X)

Technical Report(s): 19XX TAP; XX/20XX TR; XX/20XX TR

Petition(s): 199X, 200X

Past NOSB Actions: XX/1995 NOSB minutes and vote; XX/20XX NOSB sunset recommendation;
XX/20XX NOSB sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 0X/0X/200XX (XX FR XXXXX)

Sunset Date: XX/XX/20XX

Background from Subcommittee:

INSERT BACKGROUND TEXT/PRELIMINARY REVIEW

Supplemental Review Information

(LINK TO OPTIONAL CHECKLIST IF COMPLETED)

Additional information requested by NOSB

INSERT QUESTIONS FROM SUBCOMMITTEE OR "NONE"



Sunset [Year] Review Summary
Meeting 2 - Subcommittee Review
[Crops/Livestock/Handling] Substances
[Month Year]

As part of the National List Sunset Review process, the NOSB [Crops, Livestock, or Handling] Subcommittee has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic [crop production, livestock production, or handling].

If the Subcommittee has obtained **new** information since its last review that supports a motion to remove a substance from the National List, the Subcommittee will provide justification that demonstrates that the substance is:

- (1) harmful to human health or the environment;
- (2) unnecessary because of the availability of alternatives; and
- (3) inconsistent with organic production or handling.

Regarding the Availability of Alternatives:

Justification will include information about the viability of alternatives for a substance under sunset review. Viable alternatives include, but are not limited to:

- Alternative management practices that would eliminate the need for the specific substance;
- Other currently exempted substances that are on the National List, which could eliminate the need for this specific substance; and
- Other organic or nonorganic agricultural substances.

Justification should include reference to Technical Reports, petitions, public comments, or other relevant literature.

[LIST OF MATERIALS WITH LINKS TO MATERIAL BELOW]

EXAMPLES:

- [Substance 1](#)
- [Substance 2](#)

Links to additional references and supporting materials for each substance can be found on the NOP website: <http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

Commented [AM-A1]: Instructions for NOSB. Delete for posting

NAME OF SUBSTANCE 1

Reference: 205.60X1(X)(X)

Technical Report(s): 19XX TAP; XX/20XX TR; XX/20XX TR

Petition(s): 199X, 200X

Past NOSB Actions: XX/1995 NOSB minutes and vote; XX/20XX NOSB sunset recommendation; XX/20XX NOSB sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 0X/0X/200XX (XX FR XXXXX)

Sunset Date: XX/XX/20XX

Subcommittee Review

[INSERT REVIEW]

Motion to Remove:

This proposal to remove will be considered by the NOSB at its public meeting.

The Subcommittee proposes removal of this substance from the National List based on the following criteria in the Organic Foods Production Act (OFPA) and/or 7 CFR 205.600(b): [INSERT CRITERIA]

Motion to remove [SUBSTANCE 1] (CAS # XX-XX-X) from 205.60X(X)

Motion by:

Seconded by:

Yes: 0 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by XXX XXX, Subcommittee Chair, to transmit to NOSB MONTH DATE, YEAR



Sunset [Year]
NOSB Final Review
[Crops/Livestock/Handling] Substances
[Month Year]

As part of the National List Sunset Review process, the NOSB has evaluated the need for the continued allowance for or prohibition of the following substances for use in organic crop production.

[LIST OF MATERIALS WITH LINKS TO MATERIAL BELOW]

EXAMPLES:

[Substance 1](#)

[Substance 2](#)

Links to additional references and supporting materials for each substance can be found on the NOP website: <http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned>

NAME OF SUBSTANCE 1

Reference: 205.60X1(X)(X)

Technical Report(s): 19XX TAP; XX/20XX TR; XX/20XX TR

Petition(s): 199X, 200X

Past NOSB Actions: XX/1995 NOSB minutes and vote; XX/20XX NOSB sunset recommendation; XX/20XX NOSB sunset recommendation

Recent Regulatory Background: Sunset renewal notice published 0X/0X/200XX (XX FR XXXXX)

Sunset Date: XX/XX/20XX

Subcommittee Review [INSERT LINK TO PROPOSAL/REVIEW]

NOSB Review

Vote

Motion to remove [SUBSTANCE 1] (CAS # XX-XX-X) from 205.60X(X)

Motion by:

Seconded by:

Yes: 0 No: 0 Abstain: 0 Recuse: 0 Absent: 0

Outcome: Motion failed. NOSB completed its sunset review. OR

Outcome: Motion passed. NOSB completed its sunset review and recommended removal of [substance X]

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date:

Subject:

Chair:

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other:

Statement of Recommendation: (Motion # 1)

Motion to accept the Calculating Percentage Organic in Multi-Ingredient Products, as amended April 11, 2013.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

1. Proposed Regulatory Change at 205.302(a) brings language into line with actual practice to make calculations based on "all ingredients", not "finished product", which is consistent with OFPA and NOP
2. Recommendations for development of self-calculating forms, exclusion of salt, processed single ingredients with specification sheets, multi-ingredient ingredients calculations, and organic labeling versus organic content, provide guidance language for clarification of the Rule consistent with OFPA and NOP.
3. The organic community requires easily accessible, web based, detailed Guidance, with examples from the NOP, on the items listed above, and especially in calculation of excluded water.

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

**National Organic Standards Board
Compliance, Accreditation and Certification
Proposal
Calculating Percentage of Organic Ingredients in Multi-ingredient Products**

Amended April 11, 2013

I. INTRODUCTION:

The purpose of this document is to propose recommendations on determination of percentage organic ingredients in multi-ingredient products in order to assist the NOP in development of guidance for handlers and certifiers.

Consumers expect that labels on multi-ingredient products sold as “100% organic” or “organic” or “made with organic” reflect an accurate determination of percentage organic ingredients, and that all certifiers have uniformly calculated such percentages.

The integrity of USDA organic products in the USA and throughout the world depends on assurances of consistency and uniformity in interpretation and application of the Rule and associated Regulations, especially when calculating percentage organic ingredients.

II. BACKGROUND:

The Regulation at 205.302(c), under “Calculating the percentage of organically produced ingredients” states:

“ The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage”.

Thus, when an ingredient has been certified to the “organic” category, the supplier of that ingredient must provide information to the handler making the finished product regarding the actual percentage of organic content of that ingredient.

Over the years this has resulted in a wide variety of mechanisms for determining percentage of organic ingredients, and a wide variety of ways of establishing systems which allow verification by auditors and inspectors.

For example, if the supplier does not provide positive information, verified by the certifier, that the organic ingredient contains more than 95% organic content, then many, BUT NOT ALL certifiers will only allow that ingredient to be calculated at 95% organic content.

With limited guidance, a lack of uniformity in procedures has developed. For example some certifiers may permit handlers to include 100% of the weight/volume of certified ingredients as organic, even if the ingredient is a formulated product and includes other permitted substances and may be in fact be anywhere from 95-100% organic. Chocolate chips for example may be certified organic, and contain 96% organic ingredients, plus 4% permitted substances on 205.605/606. A cookie manufacturer may be considering that the entire weight of the chips counts as organic in the final cookie product.

Many certificates list raw agricultural ingredients as “organic” when in fact they should be listed as “100% organic.” This can have a serious impact in calculating percentage organic in a multi-

ingredient product if the handler must, by default, list those raw agricultural ingredients as 95%. Further, some handlers and certifiers may not be accurately examining the water and salt content for exclusion from the percentage calculation.

There is also a wide array of mechanisms in place amongst handlers as to how processing aids as opposed to additives are recorded or, if necessary calculated as part of the ingredient list. Sub-ingredients are often added to multi-ingredient products, such as spice, oil, sugar, flavor or sauce mixes. Such sub-ingredients may be entirely or partially organic in ingredient make up, and the producer of such sub-ingredient mix may provide a Specification sheet listing ingredients and their organic percentages. In other instances no details are provided on sub-ingredients.

When the percentage of organic ingredients as a percentage of all ingredients is calculated to be close to 95% or close to 70% then the issue of correct labeling of that product becomes difficult for the handler and those who must approve or verify. Standard practice is to calculate ingredients as a percentage *of all ingredients*, although the relevant area of the Rule, as cited below, still states the calculation should be as a percentage *of finished product*.

In October, 2001 the NOSB, recommended¹ to change the regulations at § 205.302(a), to replace the phrase “finished product” with “of all ingredients”. The rationale was: Most products lose weight during processing. Dividing the total weight of all combined organic ingredients by the weight of the finished products could easily show that a product contains over 100% organic ingredients. Current practice is to divide the total weight of all combined organic ingredients by the total weight of all ingredients (excluding salt and water). This calculation establishes the total percentage of organic ingredients. The Rule should be changed to correctly calculate the percentage of organic ingredients”.

This regulation change has not yet taken place.

III. RELEVANT AREAS OF THE RULE:

NOP Regulation and Policy statements:

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or that include organic ingredients must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid

¹ <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5100161>

ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.

(c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

§ 205.2, Terms Defined:

Ingredient: any substance used in the preparation of an agricultural product that is still present in the final commercial product that is consumed

Processing Aid (NOP definition, based on FDA regulation at 21 CFR 100 (a)(3)(ii) Foods Exempt from Labeling):

1. A substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its final form.
2. A substance that is added during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and
3. A substance that is added to a food for its technical or functional effect in the processing but is present in the finished food in insignificant levels and does not have any technical or functional effect on that food.

IV. DISCUSSION:

In 2012 the CAC subcommittee discussed this issue in detail and issued a discussion document with a request for public comment prior to the Public Meeting in October 2012. The NOSB received a substantial body of public comment with detailed recommendations for change. These comments came from Accredited Certifying Agencies, non-profit organizations, research groups and trade associations, and they are included in the brief discussion below.

1. Regulatory change:

There is broad consensus that the standard practice is to divide the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total net weight (excluding water and salt) of all ingredients. Thus a simple change to the Regulation at 205.302 is needed to clarify that the calculation of percentage organic ingredients should be made based on "all ingredients" not "finished product" because most products lose weight during processing.

2. Self-calculating Forms:

Formulated multi-ingredient NOP-certified products contain organic ingredients that are either single or multiple-ingredient ingredients. Certified handlers adding an organic ingredient to a formulated product need to understand that the ingredient may contain anywhere between 95% and 100% organic ingredients. For a multi-ingredient certified product used as an ingredient in a multi-ingredient product, the actual organic content must be obtained. Otherwise the ingredient should be calculated at either 95% organic or 70% organic depending on how the product is classified on the certificate.

Thus, to ensure uniformity in making these calculations a number of certifiers use self-calculating forms, samples of which were sent to the NOSB. Certifiers provide these forms to handlers, and there is broad consensus that self-calculating tools are very useful, but one standard NOP generated form is not required.

One certifier noted that being able to provide useful and coherent tools for clients was a point of differentiation for a certifier.

A sample template of a self-calculating form could be included on the NOP website to demonstrate inclusion of all ingredients; show how to exclude water and salt, list supplier of ingredient, percentage organic content of each ingredient, percentage in formulation, and the self-calculating column showing actual organic percentage of each ingredient. Such a sample form should show how to list processing aids separately.

3. Salt Excluded:

Commenters all agree that the only salt which may be excluded is sodium chloride. Potassium chloride is on the National List as an allowed non-synthetic and should be calculated as a non-organic ingredient.

Standard practice is to require any additives, such as anti-caking agents, added to the salt to be on the National List at 205.605 or 205.606. If salt containing an additive on the National List is added to a certified product the additive cannot be excluded. Therefore the product may not be labeled as 100% organic.

4. Water Excluded:

Commenters provided considerable discussion, and raised numerous questions on this complex issue.

In August 2002 the NOP issued a policy memo addressing the exclusion of water when calculating percentage organic ingredients in multi-ingredient food products. This information is incorporated in the NOP Handbook as Policy Memo 11-9.² This memo includes reference to 21CFR 131-169 for food and 21CFR 101.30 for vegetable and fruit juices. Several major certifiers find that the FDA is out of date in addressing water content in standardized foods.

Several commenters noted that the lack of a standard of identity for many standardized foods is an impediment to consistency and accuracy in calculating water to be excluded. There is a need for clarification and detailed guidance from the NOP on this topic.

5. Processed single ingredients:

A specification sheet for a product such as "organic" olive oil could be of great assistance to the organic baker making a multi-ingredient product, but this is often not available.

6. Multi-ingredient ingredients:

Several commenters expressed frustration at how to calculate percentage organic when adding a purchased multi-ingredient ingredient, such as chocolate chips to a product and suggested that a specification sheet be provided if requested by handler.

7. Organic label versus organic content:

There were a number of comments related to the fact that the issue of organic **content** contribution versus organic **labeling** claim creates confusion and leads to a lack of consistency in interpretation when formulating multi-ingredient products.

Organic operations want their crops and ingredients to be in the 100% organic category on certificates so that buyers calculate their content at 100% in finished products. If certifiers had clear permission to assume 100% organic content for single-ingredient ingredients and crop

² <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088954>

ingredients in the “organic” category this would remove some of the inconsistencies.

Very few products actually make the 100% organic claim on the retail label.

As noted by the range of comments received by the NOSB there is a lack of consistency in determining organic percentages for ingredients treated with processing aids. Often single ingredients such as flour, oil or sugar or crop ingredients such as apples do not meet the 100% organic category due to permitted, but non-organic processing aids (filtration materials in the case of oil, wash water in the case of apples) They will be listed on an organic certificate by the certifier as “organic”. However common sense tells you that they may contribute more than 95% organic content to the finished product formula.

The organic content of a product is based on the percentage of organic ingredients. The use of non-organic processing aids prevents a product being labeled as 100% organic but the product contains 100% organic **ingredients** and can be calculated as such when determining an organic percentage. For Example: Pear Juice Concentrate may be formulated using 100% organic pears, NOP-compliant non-organic enzymes as processing aid, and NOP-compliant non-organic Diatomaceous Earth as a filter aid. For calculation purposes however the pear juice should be calculated at 100% organic in the formulation because all of the ingredients are 100% organic.

8. Raw Agricultural Ingredients:

The lack of a statement of specific percentage of organic content on either the organic certificate or product specification sheet, if one is available, requires additional work for both the certifier and handler. The inclusion of such information on the certificate would be helpful.

Single raw crop ingredients such as carrots or pears, can be listed as “100% organic” on the Certificate (or attached addendum list) issued by the certifier to the Handler. In many cases however the Certificate and attached list simply states “organic”. Thus, when making a multi-ingredient product, those ingredients listed as “organic” on their certificates must be calculated at the default 95% organic calculation. While there may be some instances where a raw crop has been changed, such as adding a wax coating to a cucumber, all commenters agreed that it is reasonable to assume that a single raw crop ingredient should be considered 100% organic for content.

The recommendations following reflect the public comments received prior to the Public Meeting and presented at the Public Meeting.

V. RECOMMENDATIONS:

1. Proposed Regulatory Change

The CACS proposes a change to the regulations at 205.302(a) as follows with proposed deletions with strike through and additions in bold italics:

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” or that include organic ingredients must be calculated by:

- (1) Dividing the total net weight (excluding water and salt) of combined organic

ingredients at formulation by the total weight (excluding water and salt) of ~~the finished product~~ **all ingredients**.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of **all ingredients** ~~the finished product~~ (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of **all** the ingredients. (3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of **all ingredients**

(b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.

2. Self-Calculating forms

Section 205.302 (c) states:

(c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

The CACS proposes that handlers utilize a self-calculating form of their own, or utilize a form provided by their certifier so that a uniform method of calculation is clearly established. One standard NOP generated form is not required.

3. Salt Excluded.

The CACS proposes that the only salt excluded from the calculation is sodium chloride.

Potassium chloride, listed on 205.605 and any item on the National List such as magnesium chloride or magnesium sulfate used as an ingredient shall be counted in the organic content calculation.

Standard practice is to require any additives, such as anti-caking agents, added to the salt to be on the National List at 205.605 or 205.606. If salt containing an additive on the National List is added to a certified product the additive cannot be excluded. Therefore the product may not be labeled as 100% organic

4. Water Excluded

Water is excluded from the percentage calculation.

The CACS proposes extensive, detailed and clear NOP guidance to drive consistency among handlers and certifiers to determine how much water should be excluded from certain multi-ingredient formulations that include such ingredients as chicken soup, soy "milk", almond "milk", fruit juice, vegetable juice, or ready to drink teas.

5. Processed Single Ingredients.

Handlers or certifiers may request specification sheets from manufacturers of processed single ingredients if they desire more verification that the ingredient was not processed in a way that there would be remaining non-organic components in the single ingredient product. Examples of such ingredients include oil, flour, sugar, and syrup.

6. Multi-ingredient ingredients;

Formulated multi-ingredient NOP-certified products contain organic ingredients that are either single ingredients or multi-ingredient ingredients. For multi-ingredient products added to the formula of another product, such as chocolate chips where as much as 5% of the ingredients may be non-organic, the actual organic content must be obtained if the contributing content is above 70% organic or 95% organic. Otherwise the ingredients should be calculated at either 95% organic or 70% organic depending on how the product is classified on the certificate.

Handlers must provide certifiers with supporting documentation that substantiates the organic content claim of a multi-ingredient product used in a production formulation submitted for approval.

7. Organic Label versus Organic Content:

As specified in 205.302, the organic content or percentage of a product is based on the percentage of organic ingredients. Sanitizers and processing aids are not ingredients; therefore they should not impact the organic percentage of a product. The use of a non-organic processing aid prevents the single ingredient product from being labeled as 100% organic, but the product continues to contain 100% organic ingredients and can be calculated as such when it is calculated into a multi-ingredient organic product

8. Raw agricultural and Single-ingredient ingredients can be assumed by handlers, manufacturers and certifiers to contribute 100% organic content in a multi-ingredient formulation, even if they are listed as "organic" on a certificate, except where it is clear that the ingredient is significantly different from the raw condition.

9. NOP Guidance

The NOSB recommends that the NOP establish and maintain an easily accessible website with examples of how to calculate percentage organic ingredients in multi-ingredient products, and related topics such as how to determine when a processing aid becomes an ingredient in calculation, and how to determine excluded water.

Motion to accept and forward to the full Board the proposal on Calculating % of organic ingredients in multi-ingredient products as amended

Subcommittee Vote:

Moved: Jean Richardson Second: Joe Dickson

Yes: 7 No: 0 Absent: 1 Abstain: 0 Recusal: 0

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date:

Subject:

Chair:

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other:

Statement of Recommendation: (Motion # 1)

Motion to classify Biodegradable biobased mulch film as synthetic.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

While the building blocks of the polymers that make the mulch films are often starches and other non-synthetic components, there are some synthetic additives to help the films hold together and add pigment.

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

Statement of Recommendation: (Motion # 2)

Passed

Petition to list Biodegradable biobased mulch films on §205.601(b)(2) Mulches:

See attached Statement of Recommendation (Motion # 2) for further detail

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

The NOSB sees the approval of these materials as an opportunity to reduce pollution substantially without sacrificing organic farming principles. The first several criteria apply to those certifiers and Material Review Organizations (MROs) that will determine allowed products. The last clause is the only one that refers to a grower's responsibility and correspondingly what the certifier must evaluate. The annotation has been crafted to be as specific as possible to ensure that only acceptable products are reviewed and allowed for organic farming.

Rationale behind the annotation and some accompanying issues are attached.

Committee Vote:

Moved: Zea Sonnabend

Seconded: Harold Austin

Yes: 12

No: 3

Abstain: 0

Absent: 0

Recuse: 0

Statement of Recommendation (Motion #2)

Petition to list Biodegradable biobased mulch films on §205.601(b)(2) Mulches:

(iii) Biodegradable biobased mulch films to be reviewed meet the following criteria:

(A) Completely biodegradable as shown by:

1) meeting the requirements of ASTM Standard D6400 or D6868 specifications, or of other international standard specifications with essentially identical criteria, i.e. EN 13432, EN 14995, ISO 17088; and

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

(B) Must be biobased with content determined using the ASTM D6866 method;

(C) Must be produced without organisms or feedstock derived from excluded methods; and

(D) Grower must take appropriate actions to ensure complete degradation.

In addition, add the following definition to 205.2

Biobased: organic material in which carbon is derived from a renewable resource via biological processes. Biobased materials include all plant and animal mass derived from carbon dioxide recently fixed via photosynthesis, per definition of a renewable resource (ASTM).

Rationale Supporting Recommendation (including consistency with OFPA and NOP)

The NOSB sees the approval of these materials as an opportunity to reduce pollution substantially without sacrificing organic farming principles. The first several criteria apply to those certifiers and Material Review Organizations (MROs) that will determine allowed products. The last clause is the only one that refers to a grower's responsibility and correspondingly what the certifier must evaluate. The annotation has been crafted to be as specific as possible to ensure that only acceptable products are reviewed and allowed for organic farming.

Rationale behind the annotation and some accompanying issues:

Introductory Text

The term "Biodegradable biobased mulch film" reflects the Board's intention to define bio-based so that this category would not allow products, for example those made from aliphatic aromatic copolymers (AACs), which come from petroleum. The definition of biobased is provided in addition to the annotation to make this as clear as possible.

The Board chose to not use the word "bioplastic" because OFPA and the NOP rule encourage biodegradable mulches and have clauses that prohibit plastic that is not removed at the end of the season. The NOSB adopts the interpretation that these mulches biodegrade and the process of biodegradation is equivalent to removal of the substance at the end of the growing season.

“(A) Completely biodegradable as shown by..... “

The standards referred to here will cover the range of products in a range of temperatures and environments. The Board understands that the ASTM 6400 will involve testing for any residues and ecotoxic effects.

“(B) Must be biobased with content.....“

The Board has also provided a good definition of ‘biobased material’ to ensure that this testing protocol is meaningful.

“(C) Must be produced without organisms or feedstock derived from excluded methods.”

While the NOSB has some concerns about consistency between this and excluded methods in other soil inputs, since this will be a brand new category of materials to the Board intends to shut the door to GMOs at the outset. The annotation regarding GMO feedstock is not to be construed as carrying over to other soil applied materials.

“(D) Grower must take appropriate actions to ensure complete degradation.”

It is expected that NOP, in conjunction with the NOSB, will develop guidance that explains proper practices for utilizing the biodegradable mulch film. In addition, it is expected that the inspection process and certification review will determine that biodegradation of the mulch film is occurring so that it does not accumulate in the fields where it is used.

It is the Board’s belief, in submitting this recommendation, that biodegradable mulch film made with nanomaterials is prohibited under the listing on the National List. While the NOSB established a working definition of nanomaterials in 2010, the clause in the Crops Subcommittee proposal prohibiting nanomaterials was removed due to the current lack of an officially-recognized definition of nanomaterials.

The Board continues to support the prohibition of nanomaterials as defined in 2010:

Engineered nanomaterials: substances deliberately designed, engineered and produced by human activity to be in the nanoscale range (approx. 1-300 nm) because of very specific properties or compositions (e.g., shape, surface properties, or chemistry) that result only in that nanoscale. Incidental particles in the nanoscale range created during traditional food processing such as homogenization, milling, churning, and freezing, and naturally occurring particles in the nanoscale range are not intended to be included in this definition. All nanomaterials (without exception) containing capping reagents or other synthetic components are intended to be included in this definition.

In a December 17, 2010 Memorandum to the NOSB, the NOP responded as follows:

The NOP understands that the NOSB considers nanomaterials to be synthetic and prohibited under the National Organic Program..... The NOP accepts the NOSB recommendation and intends to gather additional information about how nanomaterials are regulated and used in agricultural production and handling.

The Board would like the proposed guidance regarding appropriate grower actions to be added to the Crops Subcommittee workplan. Additionally, the Board would like unanswered questions, especially those concerning possible long-term impacts of biodegradable mulch film on soil health, to be added to the Materials Subcommittee research priorities for the coming year as a high priority topic, in order to provide more complete data for the sunset decision.

Some members of the Board who did not support the final annotation noted a concern that explicit language requiring removal (or in this case complete degradation) of plastic or synthetic mulch at the end of each harvest or growing season was removed from the Crops Subcommittee proposal. Additionally, some Board members felt that the Board should retain the listing as originally petitioned, "Biodegradable Mulch Film Made from Bioplastics", due to the nature of the material under review and the testimony of the petitioner and others on the definition of plastic (albeit biodegradable).

Committee Vote:

Moved: Zea Sonnabend

Seconded: Harold Austin

Yes: 12 No: 3 Abstain: 0 Absent: 0 Recuse: 0

**National Organic Standards Board
Crops Subcommittee
Petitioned Material Proposal
Biodegradable Mulch Film Made from Bioplastics**

August 15, 2012

Introduction

A petition was submitted requesting the addition of biodegradable biobased bioplastic mulch to section 205.601(h) of the National List. This petition involves definitions of new substances, which the subcommittee recommends be incorporated into the listing. The subcommittee explicitly seeks public comment on the definitions and possible restrictions on use.

Background

Biodegradable mulch film made from bioplastics is petitioned to section 205.601 of the National List for use in organic crop production. This is an alternative to petroleum-based plastic mulches that do not completely biodegrade. Over the past 50 years much research and development has gone into developing biodegradable mulches which are the subject of this petition. As product development has been underway, removal and disposal of polyethylene plastic mulches has become increasingly difficult because its removal is time-consuming, delays cover cropping and must largely be sent to landfills. The OFPA requires the removal of plastic mulches at the end of the growing or harvest season (7 U.S.C. 6508).

The petitioner argues that OFPA's mention of plastic was not intended to refer to biodegradable mulch film. Biodegradable mulch is intended to biodegrade by the end of the season or prior to the beginning of the following season. This distinction leads us to question whether the approval of the petition would require a rule change to allow the mulch to biodegrade in the field or whether the two substances should be treated as separate and distinct. However, bioplastics are defined in terms of "plastics," according to the petitioner, "Biodegradable Plastic Mulch is defined as plastic mulching material that meets both of the following requirements." Furthermore, bioplastics fit the definition of plastic, "Any of various organic compounds produced by polymerization, capable of being molded, extruded, cast into various shapes and films, or drawn into filaments used as textile fibers." (*American Heritage Dictionary*) The petition defines biodegradable mulch film as mulching materials that:

- 1) meet the requirements of ASTM International (formerly American Society for Texting and Materials) Standard D6400 or D6868 specifications, or of other international standard specifications with essentially identical criteria, i.e. EN 13432, EN 14995, ISO 17088; and
- 2) show at least 90% biodegradation absolute or relative to microcrystalline cellulose² in less than two years, in soil, tested according to ISO 17556 or ASTM 5988.

Additionally, the petitioner suggests that the reference to “fully biodegradable” in section 205.206(c)(1) be defined when referencing bioplastic degradation in soil. Full biodegradation is covered under several standards which discuss the compostability of the petitioned product. These include, American Society for Testing and Materials (ASTM) Standard D5988 (biodegradability of bioplastic in soil), ASTM Standard D6400 (biodegradability of bioplastic in compost), and ASTM Standard D6868 (biodegradability of bioplastic specifications). The ASTM definition of “biodegradable plastic” is, “a degradable plastic in which the degradation results from the action of naturally occurring microorganisms such as bacteria, fungi, and algae.”

The petition further clarifies, that according to the European Bioplastics’ definition, bioplastics are biobased, biodegradable, or both. The ASTM definition of “biobased material” is “organic material in which carbon is derived from a renewable resource via biological processes. Biobased materials include all plant and animal mass derived from carbon dioxide recently fixed via photosynthesis, per definition of a renewable resource.” Biobased materials are certified using the ASTM D6866 method, which certifies the biologically derived content of bioplastics.

The petition provides the following description: biodegradable films are produced from bioplastics that meet standards for aerobic biodegradation in soil. These bioplastics are comprised of structural units which may be easily broken down into carbon substrates by soil microorganisms. Under aerobic conditions, these microorganisms are able to utilize the carbon substrates as a food source. This metabolism of the carbon substrates ultimately results in two simple compounds – carbon dioxide and water.

Relevant areas in the Rule

OFPA §6508 (c) says

For a farm to be certified under this chapter, producers on such farm shall not -
...(2) use plastic mulches, unless such mulches are removed at the end of each growing or harvest season;

The regulations provide at §205.206(c) that

Weed problems may be controlled through:

... (6) Plastic or other synthetic mulches: *Provided*, That, they are removed from the field at the end of the growing or harvest season.

And the National List includes at §205.601(b)(2)

Mulches.

...(ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).

Discussion

Neither conventional plastic mulch nor biodegradable bioplastic mulch can perform all of the functions—particularly, feeding the soil—that organic mulches perform. However, there are times—such as when cold soil is a problem—when the qualities of plastic or bioplastic have been viewed as necessary. As always, it is our understanding that the

use of synthetic mulch products will be limited to those circumstances when natural organic mulches are inappropriate or impossible to use. When this is the case, it makes sense to use a material that degrades in place rather than one that is removed and taken to a landfill. On the other hand, the subcommittee believes that it may be difficult to separate claims from truth concerning biodegradability and the source of the material. In addition, the subcommittee would like to make a robust recommendation that correctly describes biodegradable biobased bioplastic mulches that meet the three criteria above. According to the European Bioplastics definition, bioplastics are biobased, biodegradable, or both. The committee intends this recommendation to cover those bioplastics that are both biobased and biodegradable.

The subcommittee understands the importance of a definition, which it is proposing, and is particularly interested in public comment on the biobased classification and the ASTM standard. Meeting this standard, however, does not automatically ensure that the mulch will be “removed from the field at the end of each growing or harvest season.” This removal may require steps like tilling the film into the ground. The subcommittee therefore proposes the annotation that growers take appropriate actions to guarantee that the mulch decomposes within the appropriate time frame.

Evaluation Criteria

(Applicability noted for each category; Documentation attached)
(see “B” below)

Criteria Satisfied?

- | | |
|--|---|
| 1. Impact on Humans and Environment
<input type="checkbox"/> N/A | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Essential & Availability Criteria
<input type="checkbox"/> N/A | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. Compatibility & Consistency
<input type="checkbox"/> N/A | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No |
| 4. Commercial Supply is Fragile or Potentially Unavailable
<input checked="" type="checkbox"/> N/A
as Organic (only for § 205.606) | <input type="checkbox"/> Yes <input type="checkbox"/> No |

Substance Fails Criteria Category: [] **Comments:**

Proposed Annotation:

List on §205.601(b)(2) Mulches: (iii) Biodegradable biobased bioplastic mulch meeting the following criteria: (A) Completely biodegradable as shown by: 1) meeting the requirements of ASTM Standard D6400 or D6868 specifications, or of other international standard specifications with essentially identical criteria, i.e. EN 13432, EN 14995, ISO 17088; and 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; (B) Biobased certified using the ASTM D6866 method; (C) Must be produced without excluded methods; (D) Must be produced without engineered nanomaterials; and (E) Grower must take appropriate actions to ensure complete degradation at the end of each growing or harvest season.

³Substance was rejected by vote for amending National List to § 205. Describe why material was rejected:

⁴Substance was recommended to be deferred because

If follow-up needed, who will follow up:

Approved by Subcommittee Chair to Transmit to NOSB

Jay Feldman, Subcommittee Chair

August 15, 2012

NOSB Evaluation Criteria for Substances Added To the National List

Category 1. Adverse impacts on humans or the environment?

Substance: Biodegradable Mulch Film Made from Bioplastics

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Are there adverse effects on environment from manufacture, use, or disposal? [§205.600 b.2]		x		TER 525-531: The production of PLA & PHA involves fermentation processes & feedstocks derived from natural sources (with the exception of genetically-modified organisms). The potential for environmental contamination from these products is limited, with the exception of the metal salt catalysts used to polymerize PLA (Bastioli, 2005). No reports of tin contamination from production of bioplastics were found.
2. Is there environmental contamination during manufacture, use, misuse, or disposal? [§6518 m.3]		x		TER 533-537: Many of the feedstocks used in the production of AAC could be hazardous if they were spilled or discharged into the environment during manufacture & processing. No specific reports of environmental contamination from these compounds as a result of manufacturing bioplastics were found. Systematic reviews of the environmental impact from manufacturing of bioplastics were not found. TER 547-550: Erucamide, glycerol, and stearic acid amide could be released to the environment through multiple manufacturing processes, including bioplastics production. No research reports were found that described environmental releases of these

				chemicals from bioplastics manufacturing.
3. Is the substance harmful to the environment and biodiversity? [§6517c(1)(A)(i);6517(c)(2)(A)i]		x		TER 614-621: The researchers concluded that using PE mulch may have a harmful effect on the environment due to increased runoff & is less sustainable than vegetative mulch (Rice et al., 2001). Based on their similarities in construction & intended use, bioplastic mulches would likely have similar environmental impacts to PE mulch, though their greater tendency to degrade sooner than PE mulch may decrease some of the adverse environmental impacts. TER 623-627: Anaerobic degradation of bioplastics may produce methane (greenhouse gas). Research was not found that quantified methane emissions from bioplastic mulch use. Degradation of bioplastic mulches must take place in an aerobic environment in the soil to prevent methane emissions. TER 629-630: Adverse environmental impacts from the use of bioplastic mulches are only likely to occur if the material does not completely biodegrade in soil. TER 652-657: Some reports have shown that bioplastics containing terephthalic acid at concentrations over 50% do not completely biodegrade in soil (Bastioli, 2005).
4. Does the substance contain List 1, 2 or 3 inerts? [§6517 c (1)(B)(ii); 205.601(m)2]			x	
5. Is there potential for detrimental chemical interaction with other materials used? [§6518 m.1]		x		TER 566-567: The plastics are inert in the soil when they are intact, and are biodegraded by soil microorganisms.
6. Are there adverse biological and chemical interactions in agro-ecosystem? [§6518 m.5]		x		TER 582-587: Given the complete aerobic biodegradation of bioplastic mulches, the by-products are carbon dioxide, water, & soil biomass. Soil biomass refers to the total amount of microorganisms in the soil, excluding plant roots & macrofauna (NRCS, 2012). The increase in biomass may cause a concomitant increase in the populations of microorganisms that degrade the mulches on a local basis. This could lead to changes in the population dynamics of microorganisms in the soil. TER 593-595: Complete degradation of the bioplastics

				depends on blending the polymers to maximize degradability & depends on the composition of soil microorganisms.
7. Are there detrimental physiological effects on soil organisms, crops, or livestock? [§6518 m.5]		x		TER 352-354 ASTM standard D5988 is designed to be applicable to bioplastic materials that are “not inhibitory to the bacteria & fungi present in the soil”...it could be assumed that the bioplastic does not inhibit soil bacteria or fungi by its breakdown processes. TER 357-358: Many bacteria & fungi in the soil can use bioplastics derived from starch as a carbon source (Shah et al., 2008). TER 409-410: Biochar, a method of generating carbon black for soil amendment, may help promote nutrient use efficiency in treated soils (Chan, 2008; Hunt, 2010).
8. Is there a toxic or other adverse action of the material or its breakdown products? [§6518 m.2]		x		TER 446-447: Studies were not found that specifically assessed the ecotoxicity of bioplastics following degradation in the soil, & a better understanding of bioplastic degradation & soil environmental effects is needed. TER 462-466: It seems unlikely that the source material (the bioplastic film) would interact with other organisms & cause toxicity. The material is manufactured to remain intact & inert during its intended use, then (ideally) break down at the end of the season.
9. Is there undesirable persistence or concentration of the material or breakdown products in environment? [§6518 m.2]	x	x		TER 330-333: The petitioner states that biodegradable mulch film is defined in two ways...Second, by “show[ing] 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.” TER 347-350: ISO 17556 & ASTM 5988 are equivalent standards. They “describe the standard test method for determining aerobic biodegradation of plastic materials in soil.” This standard is most applicable to the proposed use of the bioplastic mulch because the mulches will be left in the field at the end of the season to biodegrade according to their petitioned use. TER 356-357: Biodegradability is quantified by measuring the amount of carbon dioxide released from the soil over time. TER 362-370: degradation occurs quicker when chiseled or tilled into

			<p>the soil during times of warm temperatures & moisture in soils with high organic matter. TER 374-375: Hydrolysis breaks PLA into lactic acid & water-soluble compounds. Once this breakdown occurs, PLA is completely mineralized to CO₂, water, & biomass. TER 384-386: Degradation of PHA occurs by enzymatic hydrolysis at the surface of the film, which is carried out by soil microbial populations. Hydrolysis breaks the PHA polymers into oligomers & monomers which are subsequently consumed & assimilated by microbes in the soil as nutrients. TER 395-399: All of the commercially available AAC polymer materials contain terephthalic acid, which is most responsible for determining the degradation rates in AAC plastics. As the fraction of terephthalic acid increases, the degradation rate decreases. No significant biological degradation was found when the molar fraction of AAC was increased to more than 60%, which is thought to be due to the relatively low melting point of terephthalic acid (Bastioli, 2005). TER 405-410: Carbon black is elemental carbon in the form of a particulate that is manufactured from burning or partial combustion of hydrocarbons (NLM, 2011)...it is resistant to breakdown in the soil environment. TER 412-419: Titanium dioxide is found as the minerals rutile, octahedrite, brookite, ilmenite, & perovskite. Titanium dioxide may persist in soil as the by-product of titanium tetrachloride hydrolysis (ATSDR, 1997), so it may persist from use in bioplastic mulch as well. Titanium dioxide may settle out into sediments & persist for long periods of time (ATSDR, 1997). The compound is characterized by ATSDR as “ a very inert compound” (ATSDR, 1997). TER 421-425: Erucamide (plasticizer) binds strongly to soil & sediments in water & is likely to bioconcentrate in aquatic organisms, meaning it will occur at higher levels up the food chain (NLM, 2011). The physical properties of erucamide suggest that the material will persist in</p>
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				the environment, and would be found in the water, soil & air if released (NLM, 2011). TER 427-431: Glycerol (plasticizer) released to the environment will be present as both a vapor & a particle in the atmosphere, but will be degraded within hours (NLM, 2011). The potential for bioconcentration in aquatic organisms is low for glycerol in aquatic environments (NLM, 2011).
10. Is there any harmful effect on human health? [§6517 c (1)(A)(i); 6517 c(2)(A)i; §6518 m.4]		x		TER 663-673: Pesticide runoff may be increased if plastic mulches are used in agricultural production due to the creation of impervious surfaces (Rice et al., 2001). The increase in pesticide loads may lead to an overall increase in the pesticide load in waterways which could potentially impact human health by causing increases in pesticide loads in downstream drinking water sources. No other reports of impacts on human health from the use of bioplastic mulches were found in the published literature.
11. Is there an adverse effect on human health as defined by applicable Federal regulations? [205.600 b.3]			x	
12. Is the substance GRAS when used according to FDA's good manufacturing practices? [§205.600 b.5]			x	
13. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 b.5]			x	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance formulated or manufactured by a chemical process? [6502 (21)]	x			TER 294-296: Bioplastic mulches are manufactured with the addition of synthetic plasticizers and colorants which are added using a synthetic process.
2. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral, sources? [6502 (21)]	x			TER 301-302: To develop PLA the lactic acid monomers must be polymerized. This is accomplished through the use of a chemical catalyst. TER 302-305: Fermentation is a naturally occurring process, but under laboratory conditions, the feedstocks and environmental conditions are manipulated in order to provide an environment that is most conducive to production of PLA, a process which would be unlikely to occur in nature. TER 309-310: Researchers have developed genetically-engineered bacterial strains that produce PHA more efficiently & in differing polymer amounts. TER 313-315: PHA production by fermentation is a natural process, but the conditions used in laboratories to maximize yields and polymer amounts are not naturally occurring. TER 317-319: Some feedstocks used to produce AAC are naturally occurring, but the chemical processes used to refine them for use do not occur in nature, nor do the synthetic processes that are used to create the ester linkages.
3. Is the substance created by naturally occurring biological processes? [6502 (21)]	x	x		
4. Is there a natural source of the substance? [§205.600 b.1]			x	
5. Is there an organic substitute? [§205.600 b.1]			x	
6. Is the substance essential for handling of organically produced agricultural products? [§205.600 b.6]			x	
7. Is there a wholly natural substitute product? [§6517 c (1)(A)(ii)]	x			TER 679-682: The petitioned substance would be an alternative to synthetic, non-degradable substance, polyethylene plastic mulch. Bioplastic mulch is

				produced through synthetic processes as previously described, but is created to be biodegradable, a reason for its petitioned use in organic agriculture. TER 684-690: Mulches made from biomass include bark, cocoa-bean hulls, corncobs, grass clippings, leaves, pine needles, sawdust, straw, & wood chips. Biomass mulch availability may depend on what types of plants or crops are available in the area & the type of crop they are used in.
8. Is the substance used in handling, not synthetic, but not organically produced? [§6517 c (1)(B)(iii)]			x	
9. Is there any alternative substances? [§6518 m.6]	x			TER 717-721: Living mulch involves planting a low-growing cover crop that is effective at competing with weed species. The drawback is that living mulches compete for nutrients & water & reduce yields. Reports discuss the need to strike a balance between environmental impact, cost, ease of use, & crop yields to determine which alternative is most beneficial for individual farms & crops.
10. Is there another practice that would make the substance unnecessary? [§6518 m.6]		x		

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

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

Question	Yes	No	N/A ¹	Documentation (TAP; petition; regulatory agency; other)
1. Is the substance compatible with organic handling? [§205.600 b.2]			x	
2. Is the substance consistent with organic farming and handling? [§6517 c (1)(A)(iii); 6517 c (2)(A)(ii)]	x	x		The substance is of synthetic origin but appears to completely biodegrade in a two-year timeframe. This serves as an alternative to the current practice of using synthetic, non-degradable, polyethylene plastic mulch.
3. Is the substance compatible with a system of sustainable agriculture? [§6518 m.7]	x			
4. Is the nutritional quality of the food maintained with the substance? [§205.600 b.3]			x	
5. Is the primary use as a preservative? [§205.600 b.4]			x	
6. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law, e.g., vitamin D in milk)? [205.600 b.4]			x	
7. Is the substance used in production, and does it contain an active synthetic ingredient in the following categories:		x		
a. copper and sulfur compounds;				
b. toxins derived from bacteria;		x		
c. pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals?		x		
d. livestock parasiticides and medicines?		x		
e. production aids including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleaners?		x		TER 218- 221: Bioplastic mulch is used as a production aid, but is not technically considered a row cover because they increase soil temperature, reduce weed pressure, maintain soil moisture levels, and may help extend the growing season.

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.

NOSB Evaluation Criteria for Substances Added To the National List

Category 4. Is the commercial supply of an agricultural substance as organic, fragile or potentially unavailable? [§6610, 6518, 6519, 205.2, 205.105 (d), 205.600 (c) 205.2, 205.105 (d), 205.600 (c)] **Substance: Name**

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

barriers, or civil unrest that may temporarily restrict supplies; or				
e. Are there other issues which may present a challenge to a consistent supply?			x	

¹If the substance under review is for crops or livestock production, all of the questions from 205.600 (b) are N/A—not applicable.



National Organic Standards Board Training: Operating Guidelines

Agricultural Marketing Service | National Organic Program
February 2016





- 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 a 2 month long recruitment period
3. Review applications for completeness and basic qualifications, i.e., fit with 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's 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



- 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



Federal Advisory Committees
and the Ethics Rules:
An Overview for the:
National Organic Standards Board



Federal Advisory Committees and the Ethics Rules

Presenter:

Stuart Bender

Director, USDA Office of Ethics

- Stuart.Bender@oe.usda.gov
- (202) 720-2251

WHAT IS AN ADVISORY COMMITTEE?

Committee, board, panel, or other similar group –

- Established by statute or established or utilized by either the President or an agency official
- For the purpose of obtaining advice or recommendations on "issues or policies within the scope of an agency official's responsibilities"

ADVISORY COMMITTEES

- Committee Charter established with mission and duties
- Fair and balanced Committee Membership
- Designated Federal Official (DFO)
- Open meetings, noticed in Federal Register
- Charter expires after 2 years, unless provided otherwise

ADVISORY COMMITTEE MEMBERS

- Designation of members as either:
 1. Regular Government Employees,
 2. Special Government Employees,
or
 3. Representatives.

A REGULAR GOVERNMENT EMPLOYEE:

- Full-time or permanent part-time employee
- Paid a Federal salary
- **Subject to Federal employee ethics laws and rules**
- **May submit an ethics Financial Disclosure Report (depending upon position)**

A SPECIAL GOVERNMENT EMPLOYEE (“SGE”):

- Performs temporary duties
- On a full-time or part-time basis
- With or without compensation
- Not to exceed 130 days for all Federal service during a 365-day period (**part of a day counts as full day**)
- **Usually a Subject Matter Expert**
 - **“I” Statements (“I believe, in my expert opinion”)**
- **Subject to Federal employee ethics laws and rules**

A “REPRESENTATIVE” :

- Not a Federal employee
- Only represents specific interest or group (e.g. industry, consumers, labor)
- “We” statements (“We farmers believe...“)
- Represents a “particular bias” or a particular perspective.

A Representative

- **If you are appointed as a “Representative”**
 - Your purpose is to represent the viewpoints of a non-Federal organization or group.
- - This means you are **not** serving as an employee of the Federal government.
- Since you are not a Federal employee, you are not subject to the specific ethical laws or rules governing the conduct of Federal employees.
- **However, common sense ethical obligations still apply to you:**

A “REPRESENTATIVE” :

- Required to maintain your integrity – by not seeking your own personal benefit. This means:
- Fully and immediately disclose to the DFO and Chairperson any conflicts of interest or any “appearance” issues.
- **This may require you to prudentially disqualify (recuse) yourself** if a particular matter involving specific parties (such as a specific contract, grant, loan or cooperative agreement) involves your own financial interests or those of your spouse, minor child or business partner, employer or future employer.

A “REPRESENTATIVE” :

- Don’t accept improper gifts (from those seeking action from the Board).
- Don’t misuse internal non-public government information
- Use government property and time properly.
- Don’t engage in partisan political activities while performing your Board duties or while in a Federal building.
- Immediately disclose to the DFO and Chairperson if you or your employer enter into a lawsuit against USDA or its subagencies.

SGE ETHICS REQUIREMENTS

- Must submit a Financial Disclosure Report to the Office of Ethics
- Report is Reviewed for Conflicts of Interest
- SGE Should Promptly Notify DFO about Ethics Issues
- Must Receive Annual Ethics Training

IF SGE, THEN CONFLICTS RESTRICTIONS APPLY (Part 1)

- Prohibited from accepting anything in return for being influenced in performing official duties.
- This includes gifts, job offers, gifts offered to spouse or dependent children.

IF SGE, THEN CONFLICTS RESTRICTIONS APPLY (Part 2)

- Prohibited from participating personally and substantially in particular matters affecting their financial interests or interests of certain others (such as outside employers) or potential employers with whom they are negotiating for employment. (18 U.S.C. 208
The Conflicts of Interest Ban)

IF SGE, THEN CONFLICTS RESTRICTIONS APPLY (Part 2)

- If you discover you have a potential conflict of interest, you must:
 - Notify your DFO and Chair immediately
 - Not work on matters in which you have a financial interest -- or an “imputed” interest – until you discuss with the Office of Ethics
 - Implement a recusal, if determined to be necessary

Note: This is a Criminal Statute.

IF SGE, THEN CONFLICTS RESTRICTIONS APPLY (Part 3)

Post-Employment Restrictions (18 U.S.C. 207):

- Prohibition on representations back to the Executive Branch on the SAME particular matters involving specific parties while serving the Government
- Prohibited for two years from representing on such matters under their supervision during last year of service
- Other restrictions may apply

STANDARDS OF CONDUCT RESTRICTIONS OF NOTE TO SGEs

- No gifts from prohibited sources for service.
- No participation in particular matters affecting “covered relationships.”
- No unauthorized disclosure of nonpublic information.
- No honorary degrees without prior ethics approval.
- No fundraising from persons whose interests they can substantially affect in official duties.

STANDARDS OF CONDUCT RESTRICTIONS OF NOTE TO SGEs

- No unauthorized use of title or position for private personal use or endorsement of third party.
- No compensation for outside teaching, speaking or writing related to official duties – BUT, no restriction on teaching regular university courses.
- Cannot be an expert witness (except for US) before a Federal court or agency, if US is a party or has an interest in litigation.
- Restrictions on Political Activities (the Hatch Act) apply to SGEs on those days they are officially serving.

Questions?

Stuart Bender

Director, Office of Ethics

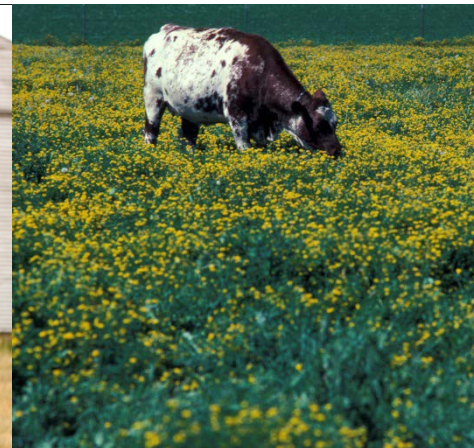
- Contact Info: (202) 720- 2251
- Stuart.Bender@oe.usda.gov



USDA Resources for Organic

Betsy Rakola, Organic Policy Advisor

NOSB Ethics Training
March 28, 2016





Topics

- USDA strategic goals for organic
- USDA programs supporting organic
- Research priorities & the Organic Working Group



USDA Vision: Departmental Goals & Strategies for Organic



USDA Goals and Vision for Organic

- USDA Strategic Plan
- Departmental Guidance
- Organic Working Group





- **Goal:** increase the number of certified organic operations to 20,000 by 2018
- **Strategy:**
 - Research and education
 - Outreach to farmers through field offices
 - Risk management tools (crop insurance)
 - Reduce paperwork / eliminate duplication
 - Make certification simpler – small & beginning farmers





USDA Secretary Tom Vilsack's May 2013 departmental guidance on organic agriculture instructed all agencies to incorporate organic into their mission and outlined 5 priorities:

- Reducing barriers to small & beginning farmers
- Training and outreach
- Growing the sector
- Research
- Data



- The Organic Working Group (OWG) is led by the Agricultural Marketing Service's Organic Policy Advisor
- It has members from all across USDA
- The OWG tracks progress against the Secretary's annual goals for organic
- External speakers present at OWG meetings and brown bag lunches
- Coordination with local & regional, sustainability, coexistence, beginning farmers, and veterans initiatives



USDA United States Department of Agriculture

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Overview

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- Is Organic an Option for Me?
- Organic Fact Sheets
- Organic 101 Blogs

Programs and Services

- View Organic Standards
- Become Certified Organic
- Find Financial Resources for Farmers
- Learn About Research and Education
- Get Production and Conservation Assistance
- Buy Improved Crop Insurance
- Access Economic and Market Information
- Import or Export Organic Products
- Contact Your Local Field Office

Sign Up

Get updates on USDA's Organic topic with your email address:

Is Organic an Option for Me?

Are you thinking about transitioning to organic? Learn how the USDA supports organic agriculture through standards, enforcement, certification, market information, funding, extension, and research.

4/6



Organic Agriculture

USDA is committed to helping organic agriculture grow and thrive. To help meet Secretary Vilsack's goal of increasing the number of certified organic operations, USDA is [delivering results](#) through its many programs which serve the growing organic sector. October 2012 marked the 10th anniversary of the USDA Organic Seal, and we are proud that it has become a leading global standard.

What is Organic Agriculture?

Organic agriculture produces products using methods that preserve the environment and avoid most synthetic materials, such as pesticides and antibiotics. USDA [organic standards](#) describe how farmers grow crops and raise livestock and which materials they may use.

Organic farmers, ranchers, and food processors follow a defined set of standards to produce organic food and fiber. Congress described general organic principles in the Organic Foods Production Act, and the USDA defines specific organic standards. These standards cover the product from farm to table, including soil and water quality, pest control, livestock practices, and rules for food additives.

Organic farms and processors:

- Preserve natural resources and biodiversity
- Support animal health and welfare
- Provide access to the outdoors so that animals can exercise their natural behaviors
- Only use approved materials
- Do not use genetically modified ingredients
- Receive annual onsite inspections

Organic Literacy Initiative Snapshot



USDA Organic 101
What Does the Organic Label Mean?
How Does USDA Support It?

The USDA Organic logo is positioned to the right of the title.

Is Organic An Option For Me?
Information on Organic Agriculture
for Farmers, Ranchers,
and Businesses

This brochure provides an overview of organic regulations and how USDA supports organic agriculture. It includes information on funding opportunities, and education.

For more information, visit www.ams.usda.gov. If viewing this brochure online, use the "Print" button.

The USDA logo is located at the bottom left of the text area.

USDA Organic Resource Guide 2015
Your Guide to Organic and Organic Related USDA Programs

A stylized green leaf icon with a red outline is positioned to the right of the title.

USDA Organic 201
A Closer Look at the U.S. Department of
Agriculture's Organic Regulations

The USDA Organic logo is in the bottom right corner.The USDA logo is in the bottom right corner.



BRIDGES TO OPPORTUNITY

FARM SERVICE AGENCY



- Start FARMING
- NEW FARMERS
- WOMEN IN AG
- YOUNG FARMERS
- VETERANS
- FARMS IN TRANSITION

New Farmers

Discover it here.

Agriculture is full of exciting and rewarding opportunities. Farming is a tough job, but at the heart of it all, you'll see a vibrant community contributing to the future of our nation's health and food security.

Find the resources you need to get started or personalize your search with our [Discovery Tool](#).



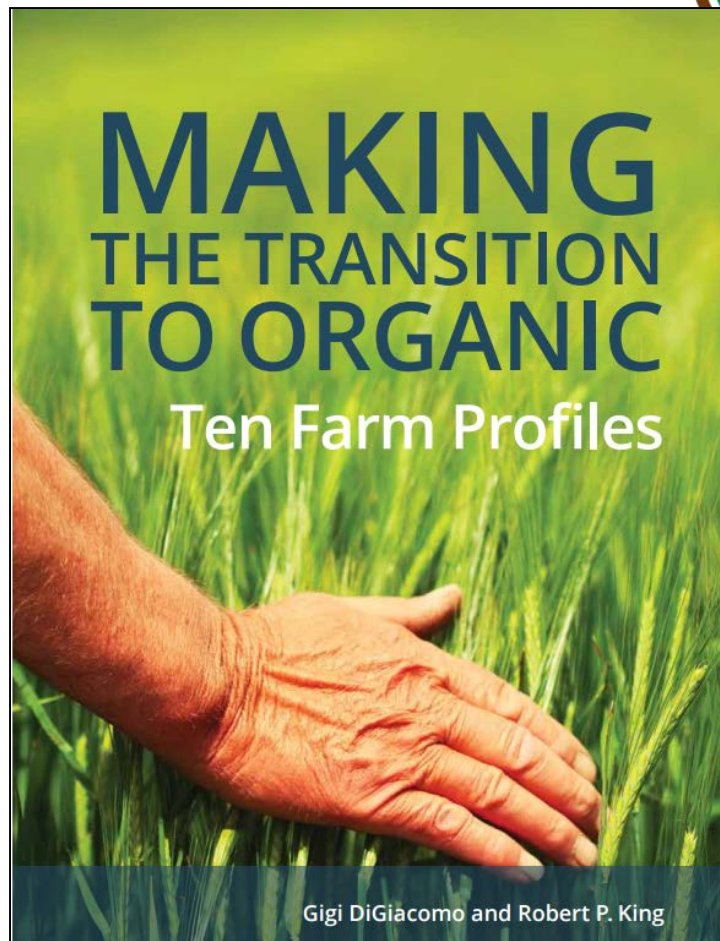
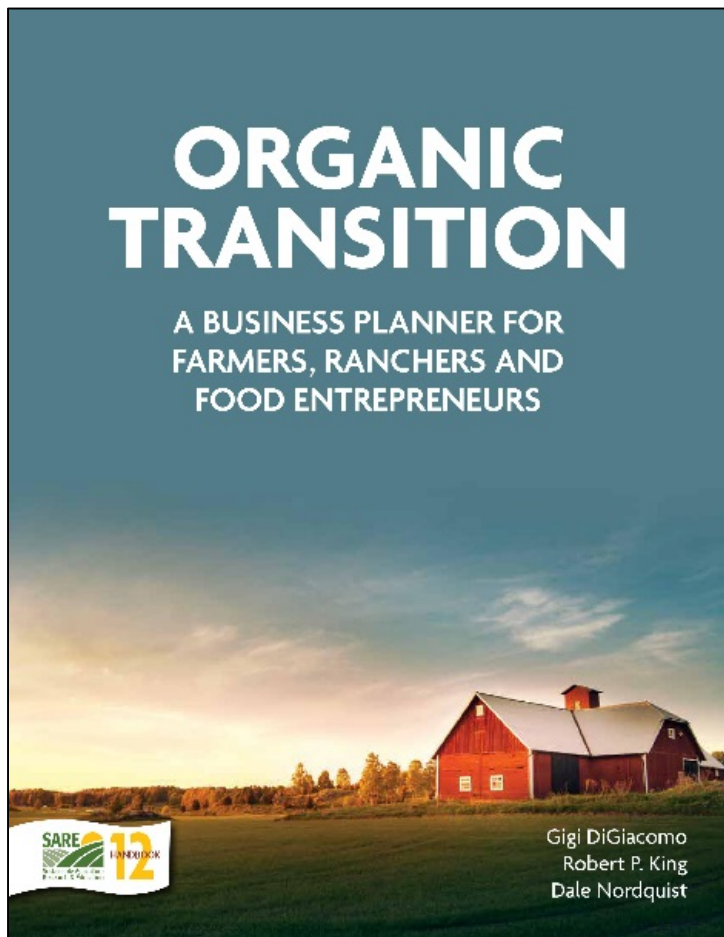


USDA Programs for Organic and Transitional Producers



USDA Programs Overview:

- Educational resources
- Certification cost share
- Conservation technical assistance
- Crop insurance
- Loans & price information
- Research & data



eorganic.info/ToolsForTransition



AMS Organic Certification Cost Share Programs

- Reimbursements for up to 75% of the cost of certification
- About \$12 million available annually, through 2018
- Administered through State departments of agriculture

www.ams.usda.gov/services/grants/occsp



- Conservation technical assistance
 - Conservation planning for the transition to organic
- Financial assistance
 - Example: Environmental Quality Incentives Program - Organic Initiative

www.nrcs.usda.gov/organic



Loans & Financial Assistance

- Loans for
 - Storage facilities
 - Farm ownership
- Financial assistance for crop losses due to natural disasters
- Interim financing after harvest



Crop insurance tools for organic producers

- Options for specific organic crop prices
- Insurance based on organic or transitional contracts
- Revenue insurance for diversified farms

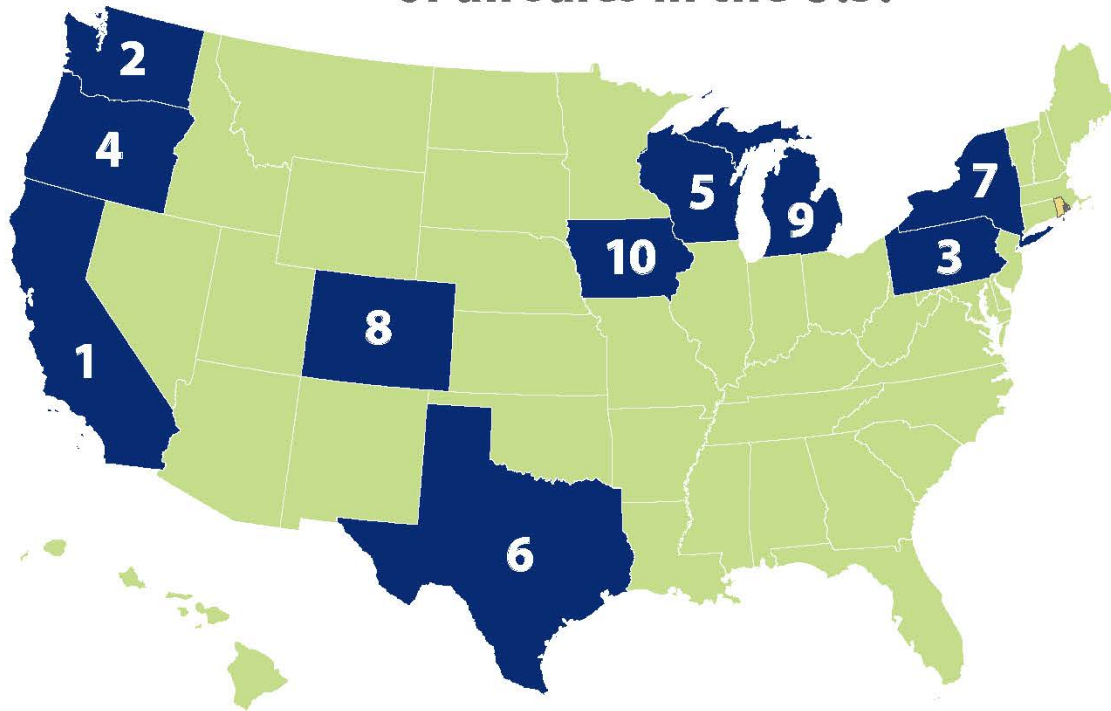
- More tools to come soon!



Data & Research

Top Ten States in Organic Sales, 2014

These states account for 78%
of all sales in the U.S.



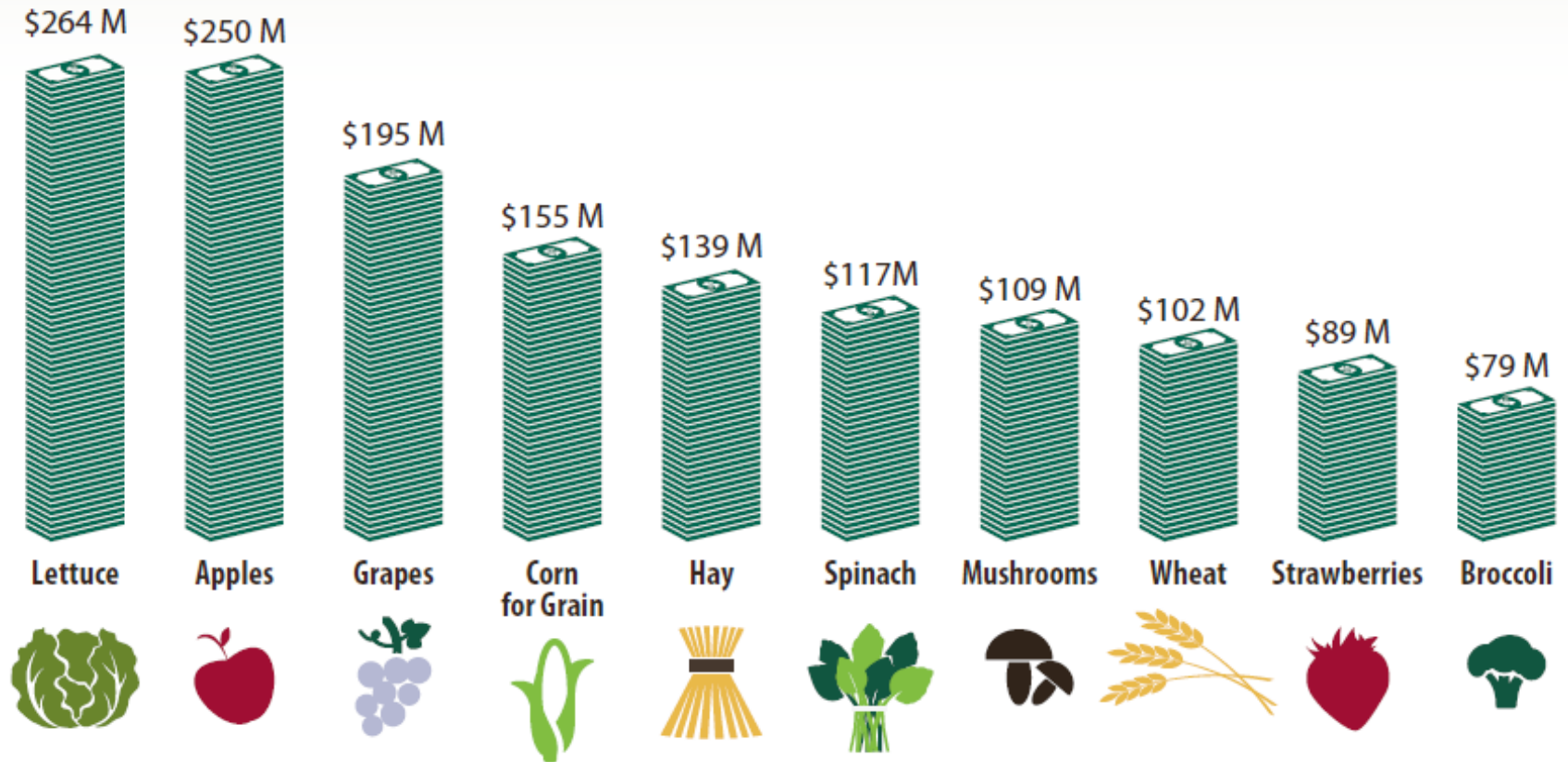
California	\$2.2 B
Washington	\$515 M
Pennsylvania	\$313 M
Oregon	\$237 M
Wisconsin	\$201 M
Texas	\$199 M
New York	\$164 M
Colorado	\$147 M
Michigan	\$125 M
Iowa	\$103 M

www.agcensus.usda.gov

U.S. Department of Agriculture
National Agricultural Statistics Service

USDA CENSUS OF
AGRICULTURE

U.S. Top 10 Organic Crops by Sales, 2014



www.agcensus.usda.gov

U.S. Department of Agriculture
National Agricultural Statistics Service

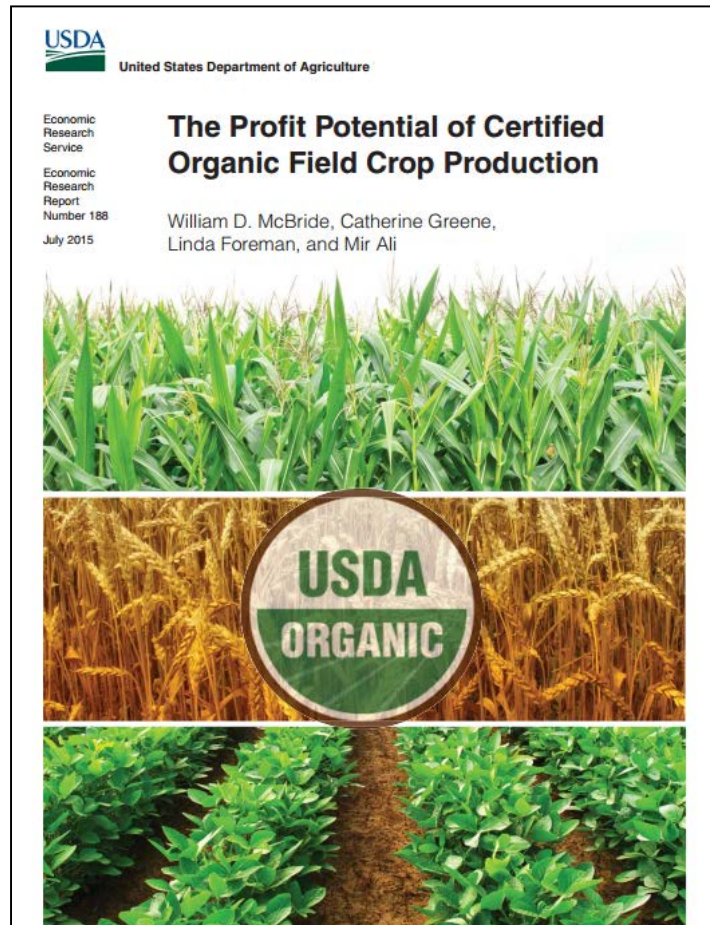
USDA CENSUS OF
AGRICULTURE



Profit Potential of Certified Organic Field Crop Production

- Organic producers are less likely to work off-farm
- Different cultivation practices – more mechanical weed control, more diverse crop rotations
- Despite higher per-acre costs, organic has greater returns

www.ers.usda.gov





ARS long-term, side-by-side field trials





- How do NOSB research priorities impact USDA?
 - Organic Policy Advisor & AMS leadership share the NOSB's annual priorities with USDA research leaders
 - Some USDA grant programs reference the priorities in their Requests for Applications
 - Organic Research and Extension Initiative
 - Organic Transitions
 - Sustainable Agriculture Research & Education program
 - Broader research programs may incorporate relevant priorities
 - Example: Specialty Crops Research Initiative may fund citrus greening, fire blight research



- What are some suggestions going forward?
 - Refine research priorities to target specific goals
 - Prioritize listed topics to aid grant-funding agencies
 - Provide short (1-2 page, bulleted) executive summaries
- How can USDA help?
 - Distribute organic research priorities and explain unique needs
 - Provide information to the Board on funded research projects
 - Facilitate conversations with research leaders



Thank you

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USDA Organic Policy Advisor

www.usda.gov/organic

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