National Organic Program Update

Organic Integrity from Farm to Table,
Consumers Trust the Organic Label

National Organic Standards Board Meeting

November 29 – December 2, 2011

Savannah, Georgia
Thank You for Five Years of Public Service

• Steve DeMuri, Handling Committee Chair
• Tina Ellor, Prior Crops Committee Chair
• Katrina Heinze, Materials Committee Chair
• Tracy Miedema, NOSB Chair
USDA Organic Listening Session
USDA Organic Listening Session
September 2011 | Washington, DC

• Goal: public feedback on USDA activities and priorities related to organic agriculture.

• Hosted by:
  – National Organic Program
  – USDA Organic Working Group
    (a USDA internal communications network)
Public comments and USDA response

- Coordination of research needs with the USDA research agencies.
  - USDA $475,000 grant to Oregon State University for non-antibiotic treatments for the control of fire blight in organic apple and pear crops.
  - Continue to provide input to USDA research agencies regarding NOP research needs.
Public comments and USDA response

- Training of USDA service providers (NRCS, FSA, RMA) to provide support to prospective/organic farmers
  - Effort funded by NOP, coordinated by the USDA Organic Working Group and USDA National Food and Agricultural Councils
  - “Organic literacy” training effort for all USDA staff nationwide. Includes training and printed materials for field offices.
Public comments and USDA response

• Protection of confidential business information and due process
  – NOP 2607—Instructions for the Disclosure of Information concerning USDA Certified Organic Operations—revised to incorporate comments received.
Public comments and USDA response

- Consistency in the interpretation and implementation of the USDA organic regulations.
  - New training modules to be presented at January 2012 certifier training: labeling, accreditation criteria, adverse action procedures, and GMO policy
  - Additional guidance under development
Public comments and USDA response

• Consideration of regulatory burden and costs of new efforts to improve organic integrity.
  – Recordkeeping requirements need to be adequate and reasonable. NOP training and audits will stress reasonable application of requirements.
  – Standardizing Organic System Plans, inspection reports and procedures will reduce redundancy
Public comments and USDA response

- Importance of the organic certification cost share program.
  - USDA supports continued funding of the program. The certification cost share programs are very important to the continued success of small and beginning producers and handlers.
  - NOP has worked with states to expand utilization of cost share programs.
  - 15% increase in cost share utilization in 2010.
Public comments and USDA response

- Consideration of compensation for damages from GE crops and greater efforts by USDA to protect organic farmers from GE contamination.
  - Secretary Vilsack appointed the Advisory Committee on Biotechnology for 21st Century Agriculture (AC21)
  - Sec. Vilsack charged the AC21 committee with suggesting possible compensation mechanisms to mitigate impact of unintended GE presence in organic and non-GE crops.
  - Next meeting (open public meeting) is Dec. 6-7 in Washington, DC
Public comments and USDA response

• Support for USDA to provide access to foreign organic markets through trade agreements.
  – The US/Canada Organic Equivalency Arrangement continues to work well, reduces costs and paperwork for organic producers and handlers.
  – USDA is optimistic about the prospect of an equivalency arrangement with the European Union and will pursue other arrangements that support market access and protect organic integrity.
NOP Priorities

• Protect organic integrity each and every day
• Implement NOSB recommendations
• Develop real-time database of organic operations

• Implement Quality Management System
• Support consistent and fair implementation of the USDA organic regulations
• Streamline process for handling complaints and appeals
Overview of Audits and Related Activities
Office of Inspector General Audit #1

• Conducted: March 2010

• Scope: Multiple mission-critical functions of NOP, including:
  – Compliance and enforcement
  – Oversight of certifying agents and State Organic Program
  – Statutory requirements (OFPA)
OIG Findings

• Complaint processing and enforcement needs to be more timely and robust
  – Strengthened enforcement procedures, utilization of civil penalties for willful violations

• Inadequate oversight of California’s state organic program
  – California SOP audited and corrective actions implemented to ensure proper implementation of program.

• Periodic residue testing not implemented
  – Proposed rule published and the final rule expected out next year.
OIG Findings

• Peer review of NOP accreditation not performed
  – NIST assessment completed, corrective actions are in process.

• Inconsistent program requirements

• Audits of foreign certifiers not conducted
  – Increased oversight of domestic and foreign certifying agents
Office of Inspector General Audit #2

• Timing: Ongoing

• Scope: Organic milk
  – Evaluate whether milk marketed as organic meets NOP requirements.
Office of Inspector General Audit #3

• Timing: Ongoing

• Scope: National List and NOSB
  – National List
    Evaluate process for adding substances to National List of Allowed and Prohibited Substances
National Institute of Standards and Technology (NIST) Assessment

- Peer review is required by OFPA and the NOP regulations.
- The March 2010 Office of Inspector General audit found that peer review had never been conducted.
- First phase completed in July 2011: 28 findings, 4 observations
- NOP Corrective actions in process.
NIST Findings

• Overall, NOP is designed to fulfill the requirements of USDA organic regulations. NOP documentation is organized in accordance with these requirements.

• The ISO/IEC 17011 elements not required in the USDA organic regulations are not always thoroughly presented in the documentation.

• Additional work is necessary to align with 17011.

• NOP’s cooperation and timeliness allowed for an efficient and thorough document review.
NIST Audit: NOP Actions

• Revised work agreement with NOP auditors
• Updated website to better communicate information on certification, accreditation, and related activities
• Drafting proposed regulation to remove FACA requirement related to accreditation
• Improving document and record control procedures
NOP Update
Activities & Priorities
NOP Accreditation Program

• Improved the accreditation process from implementation of QMS aligned with ISO 17011
• Revised audit checklist based on certification and accreditation sections of NOP regulations.
• 2012 audits will focus on pasture rule implementation, grower group certification, materials review and approval process, conflict of interest, certifier compliance procedures
Standards Update

• Accomplishments since October 2010 (FY 2011)
• 2012 Preview: What’s next?
Practice Standard Accomplishments

- Proposed Rule – Periodic Residue Testing
- Final Rule/comment discussion – Access to Pasture for Ruminant Slaughter Stock
National List Accomplishments

• Final Rule for crops/processing (aqueous potassium silicate; sodium carbonate peroxhydrate; gellan gum; tragacanth gum, fortified cooking wines)
• Final Rule livestock (methionine)
• Proposed Rule for crops/processing (lecithin, cheesewax, acidified sodium chlorite, dried orange pulp, Pacific kombu seaweed)
• Proposed rule for livestock (fenbendazole, moxidectin)
• Proposed Rule for crops/livestock/processing (tetracycline, formic acid and attapulgite)
• Proposed and Final Rules - Sunset 2011
• Advanced Notice of Proposed Rulemaking – Sunset 2013
Guidance Accomplishments

• Draft and Final Guidance for Wild Crops, Commingling, Compost and Chlorine

• Draft Guidance for Made with Organic products ingredients and labeling

• Draft Guidance on Seed/Annuals/Planting Stock (including commercial availability), Livestock Feed Additives, Kelp, and Responding to Positive Residue Testing Results;

• Program Handbook 2nd ed.(Jan 2011) and updates - residue testing instructions, policy memos on use of GMOs and textile labeling
Practice Standards: 2012 Preview

- Final Rule – Residue testing
- Proposed Rule - Organic pet food standards
- Proposed Rule – Remove FACA requirement from 205.509
- Proposed Rule – origin of livestock
National List: 2012 Preview

- Final Rule for livestock (fenbendazole, moxidectin)
- Final Rule for crops/processing (lecithin, cheesewax, acidified sodium chlorite, dried orange pulp, Pacific kombu seaweed)
- Final Rule for crops/livestock/processing (tetracycline, formic acid, attapulgite)
- Proposed Rule – Methionine
- Proposed and Final Rule – Sunset 2012
Guidance: 2012 Preview

• Final Guidance – “Made with Organic” products composition and labeling
• Final Guidance - Seed/Annuals/Planting Stock (including commercial availability), Livestock Feed Additives, Kelp, and Responding to Positive Residue Testing Results
• Draft Guidance – Certification of handlers of bulk organic products
• Draft Guidance – Post-harvest materials
• Draft Guidance – Classification of materials
• Draft Guidance – Organic Seafood/Aquaculture Labeling
Pending Actions: NOSB National List Recommendations

- Injectable trace minerals, vitamins and electrolytes (L)
- Chlorhexidine (L)
- Xylazine (L)
- Excipients (L)
Pending Actions: NOSB Practice Standard Recommendations

• Mushrooms
• Greenhouses
• Apiculture
• Aquatic animals
• Outdoor access for poultry
Appeals

- OFPA sec. 2121 – Secretary shall establish expedited administrative appeals process.

- In 2009 the average timeline for appeal decisions was 2 years.

- New initiative to reduce appeals time.

- More resources directed to appeals (Appeals staff, Office of General Counsel)

- Appeals staff conduct early analysis to determine potential settlement options.

- Currently almost all 2010 appeals closed, goal is to close appeals within 90-180 days of appeal filing date in 2012.
Complaint Management Update

Since October 2010:

• Received and commenced investigative activities on 181 complaints, representing a 15% increase from Fiscal Year 2010.

• Closed 128 complaints, representing a 20% increase from Fiscal Year 2010.

• Achieved a 177-day average time period for complaint closures.
Enforcement Update

Since October 2010:

• Issued 10 civil penalties through settlement agreements for willful violations of the USDA organic regulations.

• Implemented enforcement action procedure of publishing notices of NOP fraudulent certificates.
  – Three notices have been published to date. Each involved an international operator’s misrepresentation of agricultural products as certified organic through falsification of an NOP certificate.
Key Priorities for FY2012

• Develop formal scoring matrix and publish guidance to ensure consistency and fairness in civil penalties and other enforcement actions.

• Work with other AMS and USDA stakeholders to improve the timeliness and tracking of post-decision activities (such as civil penalty collections).

• Continue to refine case management procedures to reduce time to closure while maintaining investigative rigor.

• Develop tools to point non-certified violators of the organic regulations towards a path of certification, to enable them to become compliant community members.
NOP Response to Seattle NOSB Meeting – April 2011

• Sunset 2012 including annotation changes
  – First time NOP is changing annotations during sunset.
  – NOP will propose to amend the nutrient vitamins and minerals annotation.
  – NOP will propose annotations for hops, sodium nitrate and chlorine

• No decisive vote to classify corn steep liquor (CSL)
  – NOSB did not decide whether CSL is natural or synthetic
  – CSL retains status as natural substance
“Other Ingredients”

• Overview: Request for Clarification of “Other Ingredients” in Processed Organic Products
National List Setup

- Organic Foods Production Act grants NOSB authority to recommend substances for inclusion on the National List.
- All synthetics used in organic crop and livestock production must be on National List.
- All nonagricultural substances used in processed organic food must be on National List.
What Are “Other Ingredients?”

- Formulated products often include “other ingredients.”
- For example:
  - Pesticides include inert ingredients
  - Medications include excipients
  - Feed supplements include minor ingredients
  - Enzymes include carriers, stabilizers and preservatives.
Crop and Livestock: What’s Allowed

Crop input materials (fertilizers, soil amendments, pesticides) may contain ingredients that are:

- Natural (nonsynthetic)
- Listed under 205.601
- EPA List 4 (pesticide formulations only); EPA List 3 (passive pheromone dispensers only)

Livestock input materials (feed supplements, medications) may contain ingredients that are:

- Feed, feed additives, supplements: All agricultural ingredients in ingredients list must be organic
- Natural (nonsynthetic) substances allowed.
- Synthetics listed on 205.603.
- Excipients (allowed in FDA-approved medications only).
Processing Substances: What’s Allowed

• Processed organic foods may contain nonagricultural minor ingredients or processing aids that are listed on 205.605:
  – Examples: natural flavors, microbial products, vitamins, and enzymes.

• When used as a formulated product, 205.605 substances used in commercial food preparation often contain “other ingredients:”
  – Examples: carriers, stabilizers and preservatives.
  – In most cases, FDA considers these “other ingredients” as incidental and they are not required to be listed on the ingredients list.
  – Are “other ingredients” that are not specifically listed on the National List allowed?
Which “Other Ingredients” Are Allowed?

- OFPA requires that each non-agricultural ingredient be specifically allowed. Many of these “other ingredients” in 605 substances aren’t on the National List.
- The NOP, certifiers and the organic trade have allowed “other ingredients” (unless annotations limit “other ingredients”) (e.g. natural flavors and solvents)
- Additional clarity is needed: request for NOSB to specify which “other ingredients” are allowed.
Request to NOSB

• NOP is requesting that NOSB clarify what “other ingredients” are allowed in non-agricultural substances listed under 205.605.

• NOSB needs to develop a comprehensive recommendation on “other ingredients” in 205.605 substances.

• In the meantime, the NOSB should include reference to “other ingredients” in the background of their recommendation. Any recommended restrictions should be part of the recommended annotation.

• Clarification from the NOSB regarding the allowance or restriction of “other ingredients” will provide consistency to the organic trade, consumers and certifiers as the NOP codifies these recommendations into regulations.
Comments on NOSB Proposals

- **Inspector qualifications.** The USDA Fruit and Vegetable Program licenses hundreds of state inspectors. NOP could develop a similar process for licensing organic inspectors.

- **Organic research needs.** NOP is collaborating with the Agricultural Research Service on technical report review and priority research needs of organic community.

- **Conflict of interest.** NOSB members are appointed because they have interests. They represent a specific interest or group (e.g. producers, handlers, scientists, consumers, etc.). Representatives articulate the interests of their particular group and are not appointed to provide independent expert advice. They represent a particular bias. It is important for all perspectives of the organic community to have a voice in the process.
2012 NOSB Members
Welcome to the NOSB!

- Member, Producer
- Member, Scientist
- Member, Environmentalist
- Member, Handler
- Member, Consumer / Public Interest
Thank you for your input while we continue improving NOP!

www.ams.usda.gov/nop | 202-720-3252
Classification of Materials

• Under the Organic Foods Production Act, classification is necessary for determining eligibility and placement on the National List

• Crop and Livestock Production:
  – Natural or Synthetic
  – Non-Agricultural or Agricultural (Livestock)

• Handling
  – Agricultural or Non-Agricultural
  – Non-Agricultural: Synthetic or Natural
Previous Work: Classification of Materials

NOSB Formal Recommendations

- April 20, 2011
- May 24, 2010
- November 5, 2009
- August 17, 2005
Previous Work: Classification of Materials

- Joint Materials and Handling Committee
- Draft Guidance: March 1, 2010
- Discussion Document: October 19, 2007
- Recommendation: September 9, 2009
- Materials Working Group
Determining Classification

• Most substances are straightforward to classify; some substances are more challenging

• Classification is currently done by NOSB, certifying agents, and material review organizations

• For production, NOSB generally only receives petitions for substances petitioned for use as synthetic; natural substances are not typically reviewed by NOSB

• For handling, only agricultural substances are subject to commercial availability

• NOP regulations need to be clear and applied consistently
Guidance on Classification of Materials

- NOP is developing draft guidance based upon the November 2009 NOSB Recommendation for Classification of Materials
- NOP will engage NOSB Materials Committee for initial feedback
- Draft guidance will be available for public comment before the NOP issues final guidance
Key Elements

• Separate decision trees for production and handling
• Example materials
• Clarification of the distinction between extraction, manufacture, and formulation
• Draft guidance will be available for public comment before the NOP issues final guidance
Related Guidance: List of Permitted Substances

- NOP plans to publish draft guidance on a generic list of substances allowed for use in organic crop production
- List will include allowed natural and synthetic substances
- Will ensure consistency in decision making