



National Organic Program

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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



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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



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USDA Organic Listening Session



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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.



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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
 - Noncompliance notices: improper compliance procedures, inadequate review of Organic System Plans, and inconsistent application of the USDA organic regulations.



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



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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.



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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



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Overview of Audits and Related Activities



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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
 - Publications: Quality Manual, Program Handbook, Strategic Plan, Pasture rule, nine new draft guidance documents, seven new final guidance documents
- 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.





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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



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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.



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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



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NOP Update Activities & Priorities



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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



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Standards Update

- Accomplishments since October 2010 (FY 2011)
- 2012 Preview: What's next?



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Practice Standard Accomplishments

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



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National List Accomplishments

- Final Rule for crops/processing (aqueous potassium silicate; sodium carbonate peroxyhydrate; 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 attapulgate)
- Proposed and Final Rules - Sunset 2011
- Advanced Notice of Proposed Rulemaking – Sunset 2013



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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



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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



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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



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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.



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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.



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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.



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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.



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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



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“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.



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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.



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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.



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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.



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2012 NOSB Members



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Welcome to the NOSB!

- Member, Producer
- Member, Scientist
- Member, Environmentalist
- Member, Handler
- Member, Consumer / Public Interest



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Thank you for
your input while
we continue
improving NOP!

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



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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



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Previous Work: Classification of Materials

NOSB Formal Recommendations

- April 20, 2011
- May 24, 2010
- November 5, 2009
- August 17, 2005



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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



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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