



United States Dept. of Agriculture | Agricultural Marketing Service

# National Organic Program

Organic Integrity from Farm to Table  
Consumers Trust the Organic Label

National Organic Standards Board | April 26, 2011





# Overview

- Program update
- Materials
- Nutrient vitamins and minerals





# Protecting organic integrity

- Clear, enforceable standards
- Rigorous certification process
- Enforcement



# Program Update

- FY 2010 Budget = \$6.9 million
- FY 2011 Budget = requested \$3.1 million increase
- Final FY 2011 Budget reflects 2010 numbers - \$6.9 million
- FY 2012 request is for \$9.8 million
- Arthur Neal is now Deputy Administrator of the AMS Transportation and Marketing Program
- Ruihong Guo is Acting Associate Deputy Administrator
- New hires include Communications Director, more Ag Marketing Specialists



# Office of Inspector General (OIG)

## Audit of NOP – March 2010

### Findings

1. NOP needs to improve enforcement
2. Processing of complaints needs to be more timely
3. Oversight of California’s state organic program inadequate
4. Periodic residue testing not implemented
5. Peer review of NOP accreditation not performed
6. Inconsistent program requirements
7. Audits of foreign certifiers not conducted





# OIG Recommendations NOP Corrective Action Plan

- The OIG made 14 recommendations for program improvements.
- The NOP has completed corrective action on 13 out of 14 recommendations.
- Recommendation #9 Peer review panel, (in process)
  - National Institute of Standards and Technology (NIST) is conducting assessment of NOP Quality Management System,
  - New NOP procedure for annual review of NOP audits






**USDA Agricultural Marketing Service**

**National Organic Program**

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

**Strategic Plan  
2010 – 2012**

August 2010

United States Department of Agriculture (USDA)  
Agricultural Marketing Service (AMS)  
National Organic Program (NOP)  
Washington, DC

Strategic Plan: link from homepage  
[www.ams.usda.gov/NOPNationalOrganicProgramHome](http://www.ams.usda.gov/NOPNationalOrganicProgramHome)

**National Organic Program**

**Welcome to the National Organic Program**



**What is organic?**  
 Organic production is a system that is managed in accordance with the **Organic Foods Production Act (OFPA) of 1990 (PDF)** and regulations in Title 7, Part 205 of the Code of Federal 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. The National Organic Program (NOP) develops, implements, and administers national production, handling, and labeling standards.



Accreditation and Certification



Compliance and Enforcement



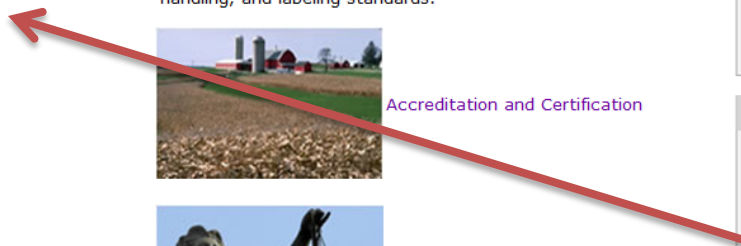
Consumers

**I Want Information On**

- o National List of Allowed and Prohibited Substances
- o NOP Regulations
- o International Agreements
- o Pasture Rulemaking Information
- o NEW: NOP Program Handbook
- o More...

**General Information**

- o Questions? See NOP-AQSS
- o NOP: Who We Are
- o [NOP Strategic Plan](#)
- o Contact Information
- o NOP Reading Room
- o NOP Job Openings



# 1. Quality management

- **Objectives**
  - **Develop and publish Quality Manual**
  - **Analyze existing processes and develop QMS aligned with ISO 17011**
  - **Implement and train NOP staff on the QMS**
  - **Conduct internal audits, management reviews and continuous improvement efforts**



# 1. Quality management

- **Performance**

- **Quality Manual published in August 2010**
- **ARC and NOP collaborated to analyzed and improve accreditation and audit procedures to align with ISO 17011. Training conducted on new system in March-April 2011.**
- **Implementation and training of NOP staff on the QMS is ongoing. Each division has an Assistant Quality Manager to assist in training and implementation.**
- **Mid-year assessment of strategic plan. NOP integration team is making improvements. Internal audit and management review to occur later this year.**

## 2. Standards - consistency

- Objectives
  - Publish Program Handbook
  - Develop and publish additional organic practice standards
  - Implement NOSB recommendations
  - Develop system to respond to questions and interpretations of NOP regulations

## 2. Standards

- Performance
  - Published Program Handbook, 1<sup>st</sup> and 2<sup>nd</sup> edition.
  - Residue testing rule in clearance, other practice standards and National List rules under development or in clearance.
  - Provided training to NOP auditors on Program Handbook.
  - New internal public inquiries tracking and documentation system under development.

## 2. Standards

- Since October 2010, published rules, guidance and notices including:
  - Proposed Rule – National List for crops/processing (lecithin, cheesewax, acidified sodium chlorite, orange pulp, Pacific kombu seaweed);
  - Final Rule – National List for crops/processing (aqueous potassium silicate; sodium carbonate peroxyhydrate; gellan gum; tragacanth gum, fortified cooking wines)
  - Proposed Rule - Sunset 2011;
  - Notice – Draft Guidance for Made with Organic ingredients and labeling;
  - Notice – Draft Guidance for Wild Crop, Poultry, Commingling, Compost and Chlorine;
  - Second edition of Program Handbook (Jan 2011) – including residue testing instructions;
  - Notice – Section 610 Review per requirements of Regulatory Flexibility Act;
  - Notice – Information Collection per requirements of OMB; and
  - Final Rule – National List for livestock (methionine).

## 2. Standards

- Forthcoming rules, guidance and policies (anticipated Spring-Summer 2011):
  - Advanced Notice of Proposed Rulemaking – Sunset 2013;
  - Proposed Rule – Periodic Residue Testing;
  - Proposed Rule – National List for livestock (fenbendazole, moxidectin);
  - Notice – Final Guidance for Wild Crop, Poultry, Commingling, Compost and Chlorine;
  - Notice – Ruminant Slaughter Stock under Access to Pasture;
  - Final Rule – National List for crops/processing (lecithin, cheesewax, acidified sodium chlorite, orange pulp, Pacific kombu seaweed);
  - Final Rule - Sunset 2011;
  - Notice – Draft Guidance on Seed/Annuals/Planting Stock (including commercial availability), Livestock Feed Additives, Kelp, and Responding to Positive Residue Testing Results;
  - Third edition of Program Handbook (July 2011).



# 3. Accreditation - oversight

- **Objectives**
  - Conduct thorough and timely audits of certifiers, state organic programs and foreign governments.
  - Develop real-time database for certified operations.



# 3. Accreditation - oversight

- **Performance**

- All foreign audits completed and on schedule.
- Implemented requirement for pre-decisional audits prior to granting accreditation, 3 pre-decisional audits conducted in 2010.
- Completed assessment of Canadian Organic Regime and California State Organic Program.

# 3. Accreditation - oversight

- **Performance**

- Developed new audit review checklist that will be implemented in 2011. New checklist will score certifiers for % compliance with accreditation requirements.
- Established designated accreditation specialists to provide technical support to certifying agents.
- Removed accreditation from two accreditation agents through settlement agreements.



# International Activities

- U.S. – Canada Organic Equivalency Arrangement
  - Technical working group, steering committee, mutual peer assessment, request to remove stocking rates critical variance for ruminants
- EU equivalency
  - EU mission in October 2010, US assessment of EU program later this year.
- Other priorities – China, Korea, Japan

# 4. Compliance and Enforcement

- **Objectives**
  - Handle complaints and enforcement actions in a timely manner.
  - Classify and prioritize complaints
  - Develop on-site investigative procedures and penalty matrix.

# 4. Compliance and Enforcement

## • Performance

- Closed 71 complaints in first 6 months of fiscal year 2011, improving the closure rate by 15% over 2010.
  - 36 complaints alleged the representation of products as organic without certification.
  - 11 complaints alleged labeling violations of certified products.
  - 2 complaints alleged the use of a fraudulent NOP certificate .
- Streamlined complaint intake procedures by establishing internal investigative priority policy.

# 4. Compliance and Enforcement

- **Performance**

- Collected 8 civil penalties for willful violations of the NOP regulations in first 6 months of fiscal year 2011, compared to 10 civil penalties collected in FY2010.
- Implemented enforcement action procedure of publishing notices of NOP fraudulent certificates.
  - Two notices have been published to date. Both involved an international operator's misrepresentation of agricultural products as certified organic through falsification of an approved Accredited Certifying Agent's certificate.

# 5. Management strategy

- Effectively manage the human resources, communication, and administrative activities of the NOP.
  - National Organic Standards Board
  - Cost Share Programs
  - Human resources, civil rights
  - FOIA, Transparency, Communication

# 5. Management strategy

- **Performance**

- Developed employee handbook for NOP staff.
- NOP Organic Insider developed to disseminate information.
- Certifier trainings, numerous presentations
- New technical report contractor; should expedite response time to TR requests from NOSB.
- New internal petitioned substances database.
- Met federal requirements for disclosing information and redacting non-disclosable info under the Freedom Of Information Act.



# Positive trends



- *Certifiers effective in protecting organic integrity*
- *Vast majority of organic operations comply with organic standards*
- *Organic products have minimal pesticide residues*





# Materials used in organic agriculture

- Long history of use
- Consistent with organic principles
- The Organic Food Production Act (OFPA) does not state that the list of allowed materials should be minimized.





# Crop materials – over 500 natural substances and 88 synthetics

- Greenhouse, potting soils
- Compost, manure, rock minerals, soil amendments, liquid fertilizers, micronutrients
- Pest Control – botanicals, dormant oils, Bt, sulfur, pheromones
- Inert ingredients
- Crop production aids – gibberellic acid, cytokinins,



# Livestock materials – over 400 naturals and 38 synthetics

- Livestock feed
  - Feed additives – vitamins, minerals, methionine
  - Feed supplements – molasses (must be organic)
- Health care
  - Vaccines
  - Health care – medications, probiotics, excipients





# Handling – Post-harvest substances, processing aids & ingredients

Both naturals and synthetic must be listed.

- 28 Naturals –§205.605(a)
- 44 Synthetics –§205.605(b)
- Agricultural – must be organic or
  - 43 agricultural substances on §205.606, must be organic or not commercially available as organic





# Handling – Post-harvest substances, processing aids & ingredients

- Natural - citric acid, bentonite, dairy cultures, enzymes, flavors, microorganisms, waxes
- Synthetic – Ascorbic acid, baking soda, baking powder, chlorine, ethylene, glycerin, vitamins and minerals, xanthan gum
- Agricultural – 19 colors, casings, celery powder, fish oil, gelatin, gums, kelp, cornstarch, wakame seaweed,



# Organic Foods Production Act

- Designed to respect the authority of the organic community through the National Organic Standards Board (NOSB)
- Natural substances (non-synthetics) allowed unless prohibited.
- Synthetic substances prohibited unless allowed (NOSB recommendation and rulemaking to add substance to National List)
- OFPA has no restrictions regarding length of materials list

# NOSB

- NOSB has statutory authority to review and recommend approval of the following classes of materials:
  - Synthetics in crop production
  - Synthetics in livestock production
  - Non-synthetics and synthetics in organic handling - Ingredients and processing aids
- NOSB recommends prohibitions on natural substances.
- NOSB advises the Secretary on any other aspect of the implementation of the NOP.

# National Organic Program

- Supports the work of the NOSB
  - Liaison between NOSB and National List petitioners
  - Coordinates development of technical reports by 3<sup>rd</sup> party contractors
  - Takes notes for NOSB committee work
  - Facilitates logistics of the NOSB meetings
  - Ensures a public and transparent process
- The NOP respects the work of the NOSB and strives to implement their recommendations.

# NOP responsibility

- Clear, enforceable standards including a clear list of allowed substances.
- Cannot add substances to the National List unless the NOSB has reviewed and recommended adding materials to the National List.
- Ensure NOSB recommendations are clearly defined and follow the process outlined in OFPA, the NOP regulations, and the NOSB Policy Handbook.



# Respect

- Reasonable and well-intentioned people have different opinions and perspectives.
- Spirited debate and public input
- We are all part of the same organic community, we will not always agree, and we should respect the process and the decisions made by the NOSB.



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# Nutrient Vitamins and Minerals



# 1995 NOSB Recommendations

- Vitamins and minerals required by law
- Accessory nutrients allowed or supported by independent professional organizations
- Nutrients not specifically classified as vitamins and minerals.
- Omega-3 fatty acids
- Inositol, Choline, Carnitine, Taurine
- Open ended list to support continued development of nutritionally rich foods

# Nutrient Vitamins and Minerals

National List, 7 CFR 205.605 (b) *Synthetics allowed:*

Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

**The reference states that only vitamins and minerals are allowed, nutrients that are not vitamins or minerals are not referenced in the National List – 205.605(b).**

# Background

- In 2006, NOP received a complaint alleging violation to the National Organic Standards for certified organic products that contained accessory nutrients
- NOP determined that accessory nutrients were allowed based on an interpretation of 7 CFR 205.605(b), 21 CFR 104.20, and past NOSB recommendations
- In 2008, the NOP determined that lutein ester did not fall under the FDA fortification policy and was not allowed in organic foods. The letter also stated that only nutrients listed in 21 CFR 104.20(d)(3) were allowed.



# Food and Drug Administration – Center for Food Safety and Applied Nutrition

- Limited scope of the regulatory citation, Nutritional Quality Guidelines for Food, 21 CFR 104.20
- 21 CFR 104.20 does not cover the use of nutrients such as taurine, DHA, ARA, lycopene, lutein,
- Does not include nutrients used in infant formula or pet food
- FDA does not define “accessory nutrients”
- FDA suggested that 21 CFR 101.9, 107.100 and 107.10 are the appropriate regulatory references to include essential and approved vitamins, minerals and other nutrients for infant formula and the fortification of foods.



# NOP Action Plan

- The NOP lacks a clear list of nutrients, vitamins and minerals allowed in organic food products.
- Previous NOP interpretation of nutrient vitamins and minerals allowed under 205.605(b) was incorrect.
- The NOP recognizes that many certified operations made business decisions based on the 1995 NOSB recommendations and statements provided previously by the program.
- The NOP plans to publish draft guidance that will clarify the FDA interpretation of 21 CFR 104.20 – only nutrient vitamins and minerals listed in 104.20(d)(3) and those identified as essential nutrients in 21 CFR 101.9 are allowed under the NOP standards.





# NOP Action Plan

- The NOP plans to provide a transition time for businesses to reformulate products to comply with the regulations as per the FDA interpretation
- The draft guidance will be published in the Federal Register with a 60 day comment period for the draft guidance
- The NOP will publish final guidance after considering the comments received.







# NOP Action Plan

- Nutrients, vitamins and minerals required for pet food will be covered by separate rulemaking.
- DHA, ARA, choline and taurine have been petitioned and are awaiting board action.
- The NOP advises companies that they may petition to add substances to the National List including nutrients, vitamins and minerals not allowed under 21 CFR 104.20.



# Summary

- NOSB needs to review and approve all substances on National List
- Clear list of allowed and prohibited substances is needed
- Open and transparent public process is essential.
- Adequate time is needed for organic trade to petition substances not included under 21 CFR 104.20, for NOSB to review, and for any rulemaking to be completed.



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**We are all in this together!**





**Thank You**



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