



# National Organic Program

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

National Organic Standards Board

Madison, Wisconsin – October 25, 2010

Miles McEvoy, Deputy Administrator



# Priorities

- Uphold and enforce the standards
- Implement and enforce the Access to Pasture final rule
- Implement Strategic Plan
- Implement the NOSB recommendations
- Quality management system
- Increased oversight over foreign operations
- Training and accountability of certifiers



# Accomplishments

- Completed Quality Manual, Program Handbook and Strategic Plan
- Published draft guidance
- Increased oversight of domestic and foreign certifying agents – Ghana, China, Mississippi, Ohio, Maine
- Strengthened enforcement procedures
- Transparency and communication – NOP Report; publication of suspended, reinstated and revoked operations; NOP responses to NOSB recommendations.



United States Department of Agriculture  
Agricultural Marketing Service

National Organic Program | Oct. 2010



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

#### Organic Officials Assess Certifiers Operating in China



Shandong province producers show off their harvest bounty of peanuts.

NOP auditors Dr. Ruihong Guo and Mr. Lars Crail traveled to the People's Republic of China in September to conduct a multi-faceted assessment mission. Foremost on their task list was to review and audit the activities of four organic certifying bodies operating in China: EcoCert, BCS, IMO, and CERES.

Currently there are 575 NOP certified operations and 9 certification bodies in China. According to Lars, the figure has surged from 230 in 2007 largely because of continued demand by U.S. consumers for organic products.

China's contribution to this effort is primarily organic raw ingredients, including soybeans, herbs, peanuts, tea, ginger, and other fruits and vegetables. These items

are shipped dry, frozen, or in liquid bulk form for final processing in the United States.



# Office of Inspector General

## 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



# Fourteen Recommendations NOP Corrective Action Plan

- Recommendations 1-6 (complete)
  - Enforcement actions pursued, eight civil penalties issued, improved complaint reporting and timeliness, procedures for monitoring continued compliance implemented, resolved all old complaints
- #7 - California State Organic Program (SOP) – (complete)
  - Audit conducted in December 2009
  - New California SOP program implemented in 2010
- #8 - Periodic residue testing (in process)
  - Rulemaking to require testing under development.



# Corrective Action Plan

- #9 Peer review panel, (in process)
  - NIST is conducting assessment of NOP Quality Management System, new NOP procedure for annual review of NOP audits
- #10 Accreditation process (complete)
  - Revised the NOP audit review criteria, implemented annual review of NOP audits
- #11 Clarify program requirements (complete)
  - Program Handbook and draft guidance published.



# Corrective Action Plan

- #12 Organic certificates (complete)
  - Published instructions on Organic Certificates, responded to NOSB recommendations, rule making to follow
- #13 Disseminate guidance in a standardized method (complete)
  - Program handbook, draft guidance, policy memos
- #14 Improve oversight of foreign certifying agents (complete)
  - All foreign audits complete and on schedule. Additional foreign audits conducted – Ghana, China





# New OIG audit – Organic Milk

- Evaluate whether milk marketed as organic meets NOP requirements.
- Assess the adequacy of the AMS oversight provided by certifying agents.



**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

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

#### General Information

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



# NOP Strategic Plan

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

## **MISSION:**

The NOP facilitates trade and ensures integrity of organic agricultural products by consistently implementing organic standards and enforcing compliance with the regulations throughout the world.



# 1. Quality management

- **Develop, implement, and maintain a quality management system (QMS) for the efficient and effective operation of the NOP.**
  - **Quality Manual**
  - **ISO 17011**
  - **Peer review by National Institute of Standards and Technology**
  - **Effective, consistent, efficient, scalable**



## 2. Standards - consistency

- **Develop and communicate clear and consistent NOP standards in a uniform manner.**
  - **Program Handbook – Guidance and Instructions**
  - **Policy Memorandums**
  - **Training of certifying agents**



## 3. Accreditation - oversight

- **Enhance compliance with and enforcement of organic regulations.**
  - **Audits of certifying agents**
  - **Continuous improvement, training, technical assistance**
  - **Accountability, consistent application and implementation of the standards**



## 4. Compliance and enforcement

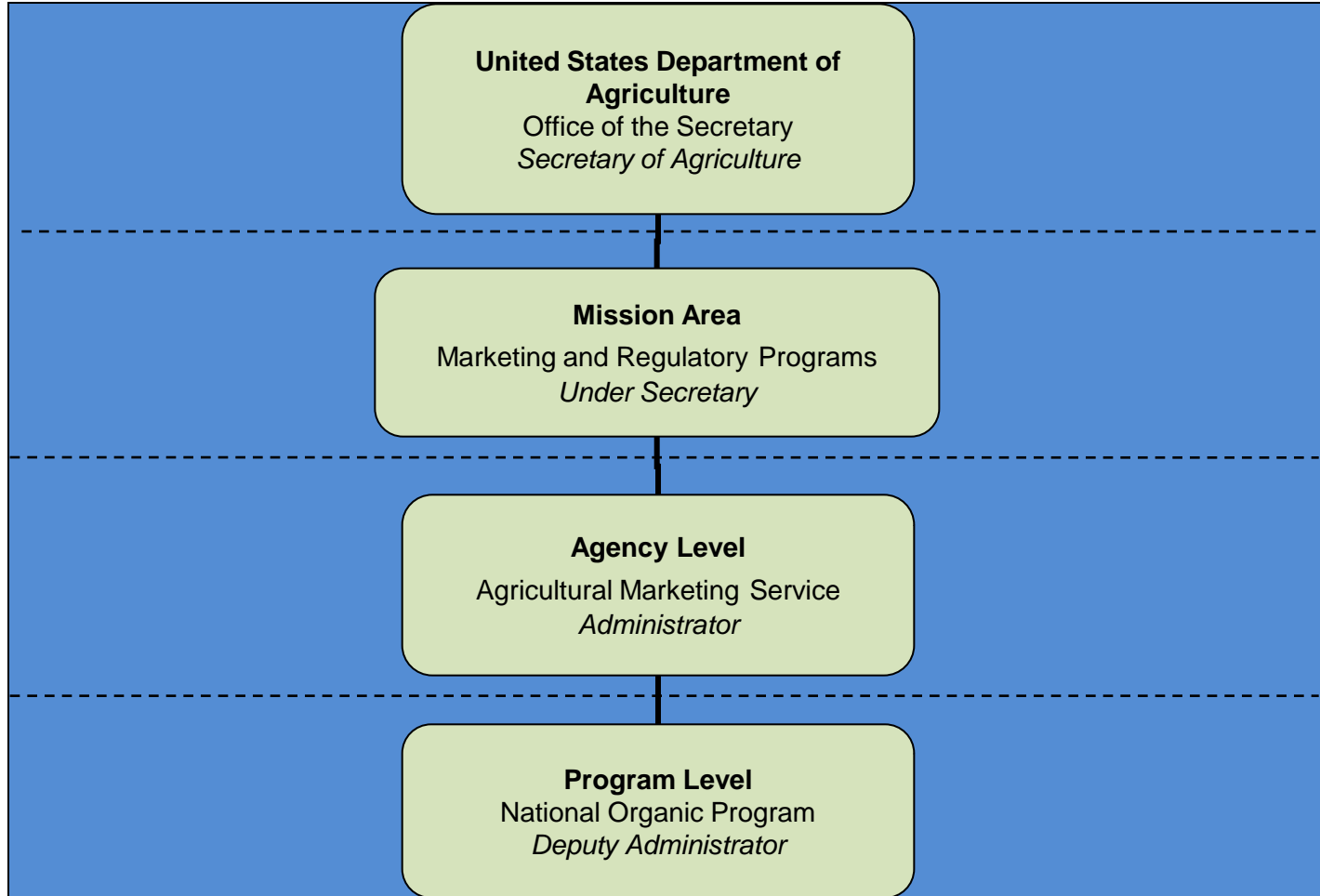
- **Ensure consistent application of the NOP regulations by the ACAs, State Organic Programs, and via International Agreements.**
  - **Complaint handling**
  - **Investigations**
  - **Civil penalties, penalty matrix**
  - **Appeals, hearings, due process**

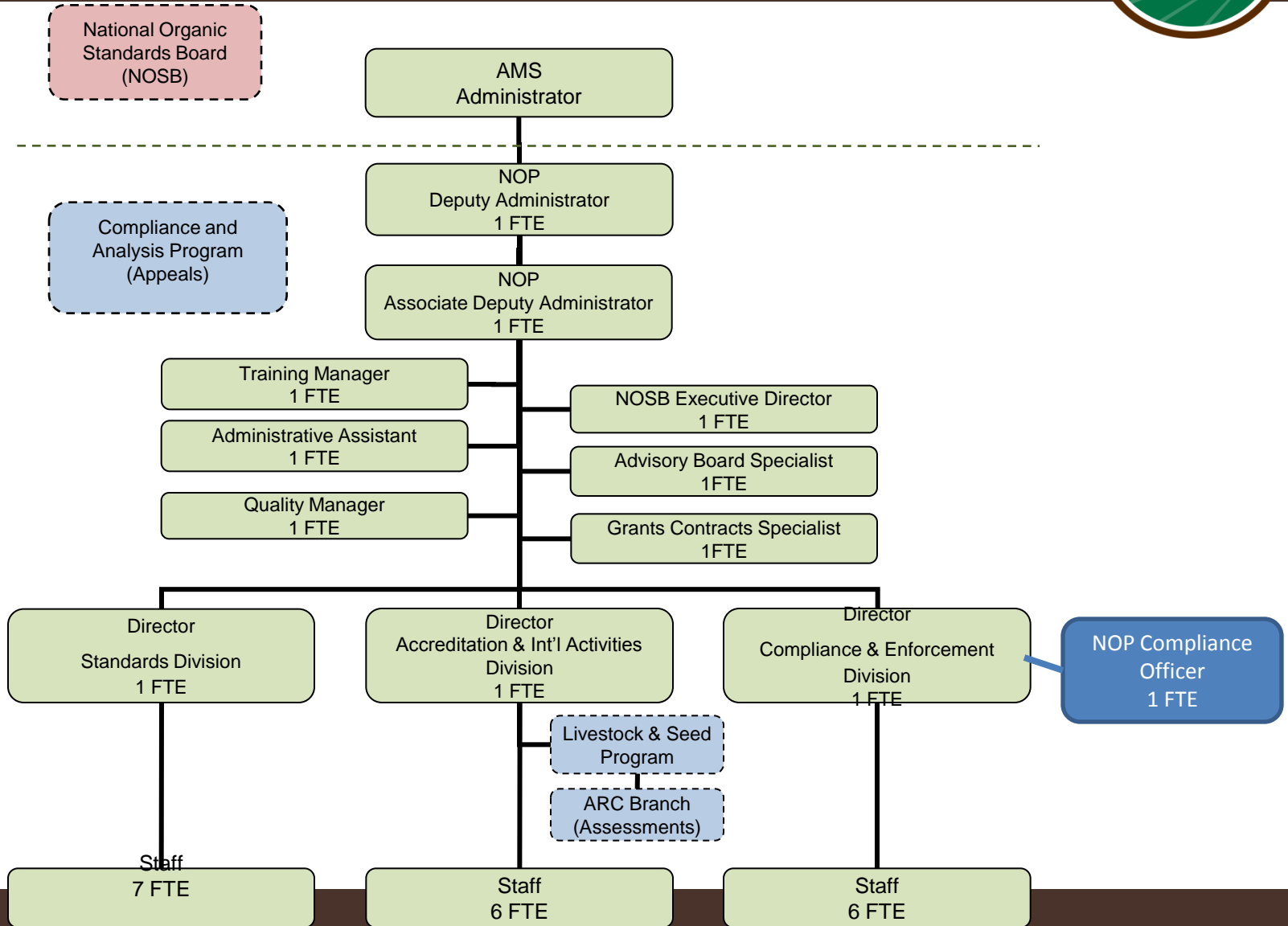


## 5. Management strategy

- **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**









Year	Budget	# staff
2002	\$ 1.6 million	6
2003	\$ 1.0 million	6
2004	\$ 1.6 million	5
2005	\$ 1.5 million	6
2006	\$ 1.5 million	7
2007	\$ 1.5 million	8
2008	\$ 2.65 million	14
2009	\$ 3.87 million	16
2010	\$ 6.97 million	31
2011 (President's budget)	\$10.1 million	32



## New staff

- Melissa Bailey, Standards Director
- Betsy Rakola, Cost Share Program Manager
- Patricia Atkins, Secretary
- Details – John Punzi, Lee Cliburn
- Public Affairs – Soo Kim
- AMS Compliance – Jeff Sotosky



## Organic Certification Cost Share Programs

### Eligibility

- **Certified organic** producers and handlers

### Mechanism

- **Cooperative agreements** with state agencies

### Total Funding

- **\$6 million** for FY11 reimbursements

### Total Reimbursement

- **75%** of certification costs, maximum of **\$750** annually



# Authorization and Funding

Two programs: Ag. Management Assistance and  
National Cost Share

**AMA:** approx. \$1.5 million annually from 2001  
Federal Crop Insurance Act

**NCS:** \$22 million allocated in the 2008 Food,  
Energy and Conservation Act



# Goal: Increase Awareness and Participation

For the last two years, only 74% of budgeted funds have been spent by states.

Approximately 45% of certified organic operations in the US receive reimbursements

NOP seeks to increase participation significantly



## New projects

- ATTRA – Organic System Plans
- Pesticide residue testing project – 6 commodities, results available in early 2011
- Business Process Analysis – prelude to NOP database
- Development of a penalty matrix
- Technical reports
- Assistance with rule writing
- Cosmetics – collaborating with FDA, market study





## Standards Division – Melissa Bailey, Director

- Rulemaking – Practice Standards, National List
- NOP Program Handbook – instructions and guidance
- National List
  - petition process
  - Technical reports
  - Sunset review by the NOSB
- Interpretations, provide consistency to certifiers and certified operations.



# NOP Program Handbook

- Guidance
  - Clarification of existing regulation
  - Organic certificates
  - Liquid fertilizer
- Instructions/Procedures
  - Information to certifying agents concerning accreditation requirements
  - Responsibilities of certified operations changing certifying agents
  - Accreditation procedures
  - Enforcement policy



## Draft guidance

- Wild crop certification
- Compost
- Chlorine
- Commingling
- Outdoor access for poultry

### Under development

- Nutrient Vitamins and Minerals
- “Made with organic ingredients”



# Rulemaking

1. Pesticide residue testing
2. Origin of Livestock
3. Streamlining appeals process
4. Apiculture
5. Mushrooms
6. Pet food
7. Aquaculture
8. Greenhouses



## Access to Pasture implementation

- Notified certifiers that full assessments for compliance with new pasture rule needs to occur during the 2010 grazing season.
- NOP is conducting assessments during the implementation period.

## Made with organic labeling

- Guidance for percentage claims and allowed ingredients out early next year.
- Rule making needed to address the use of “organic” in the brand name on the principal display panel



# Accreditation and International Activities Division – Ruihong Guo, Director

- ~ 95 Accredited Certifying Agents (ACAs)
- NOP audits of certifying agents – pre-decisional, mid-term, renewal, compliance assessments
- State Organic Programs
- Reinstatements and Temporary Variances
- Recognition agreements
- Equivalency arrangements



## Accreditation and International Activities Division – new initiatives

- Audits prior to new accreditations
- Additional audits conducted – Ghana, China, Mississippi conducted in 2010
- Increased accountability – Annual Updates, adverse action notices, lists of certified operations
- Organic Harmonized Trade Codes



# 6 Recognition Agreements and One Equivalency Agreement







# Compliance & Enforcement Division – Mark Bradley, Director

## **New and revised procedures**

- Complaint Handling Procedures –goal to close cases within 180 days
- Enforcement Policy
- Enforcement Actions Follow-up Monitoring
- Civil Penalty procedures – evaluating NOP authority, rule change
- Publication of Suspensions, revocations, reinstatements, civil penalties
- Penalty matrix development



# Age of enforcement

- Civil penalties
- Three additional compliance officers
- Revised enforcement procedures –
- Proposed streamlining of appeals process



## Civil penalties

- § 205.100 (c) Any operation that:
- Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$11,000 per violation.



# Civil penalties

“Per Violation” may be defined as (but not limited to):

- Per regulatory citation violated, Per purchase order, invoice, or bill of lading
- Per shipment, Per box, Per product label, Per package

The determination of what unit to use to count violations will be based on what is reasonable and what is supported by the evidence obtained through investigation (i.e. packages obtained, inspections, photographs, testimonials, purchase orders acquired, website printouts).



# Civil penalties

- Minor Noncompliance is defined as a violation that is correctable, does not affect the integrity of the organic system or the organic product, and does not preclude the certification or continued certification of an otherwise qualified organic producer or handler. Examples of a “minor noncompliance” include failure to submit information on time, failure to update the organic system plan, and inadequate record-keeping.



# Civil penalties

- Major Noncompliance is defined as a violation of organic standards that affects the integrity of the organic system or the organic product and precludes the certification or continued certification of a producer or handler. Examples of a "major noncompliance" include the application of a prohibited substance, the commingling of organic with nonorganic products, the contamination of organic products with prohibited substances, and the failure to correct a minor noncompliance.
- Willful violation refers to an intentional violation of the Act or plain indifference to its requirements.



# Civil penalties

- 8 civil penalties issued in 2010
- 6 civil penalties issued to non-certified operations for making organic claims
- 2 civil penalties to certified operations, one for using non-organic seeds in organic sprout production, the other for using organic ingredients from a falsified certificate.



# Enforcement policy

- NOP noted that problems with investigations and enforcement actions
  - Inadequate investigations
  - Errors in adverse action notices
- NOP decided to monitor/supervise certifiers investigations – collaborate for training and effectiveness.





# New enforcement policy

- Collaborate with certifiers and other authorities (e.g. EPA, FDA, state authorities)
- Review reports of investigations to determine next steps
  - If minor violations let certifiers handle
  - If willful violations then NOP issues adverse action



## Positive trends

- Certifiers are effective in protecting organic integrity in the majority of situations
- Vast majority of organic operations comply with the organic standards
- Samples are generally free of pesticide residues



- Over the last 16 years, the AMS Pesticide Data Program has tested 1,351 organic samples of mostly fruits and vegetables, representing 1.3% of the total number of samples tested (107,503).
- The average risks associated with pesticide residues in organic food appear to be declining.



- 43 out of 1,351 (3.2%) of organic samples contained residues above 5% of the EPA tolerance level
- 63 out of 1,351 (4.7%) of organic samples had residues from inadvertent sources – below tolerance
  - Residues from residual soil contamination, spray drift



## Limitations

1. Subpoena authority lacking in OFPA. Certifiers/NOP does not have authority to subpoena records – e.g. Promiseland
2. Lengthy appeals process.
  - For willful violations NOP is filing complaints to assess civil penalties and avoid mediation and appeals
  - NOP is proposing to delete requirement that certifiers can appeal adverse actions to the AMS Administrator.
3. Input approval – No accreditation program for input approval programs.



## Protecting Organic Integrity

1. Clear, enforceable standards
2. Notification to certifiers, organic producers and handlers concerning changes/clarifications to the standards.
3. Transparency of suspensions, revocations adverse actions, and sanctions



## 4. Quality verification process.

- Organic system plans – thorough and complete
- Quality review of plans
- Inspections by qualified and skilled auditors
- Sales and yield audits
- Feed audits
- Inspection of non-organic areas of operation
- Timely notices by certifier and continual monitoring.



## 5. Complaint handling

- File complaints at [NOPcompliance@usda.gov](mailto:NOPcompliance@usda.gov)
- Effective, timely, thorough
- Thorough investigations by qualified investigators
- Allegations can be confirmed or could be determined to have no basis in fact.

## 6. Penalties for willful violations

## 7. Market surveillance inspections

## 8. Unannounced inspections – risk based





9. Periodic pesticide residue testing

10. Monitor use of organic-like claims and take action as appropriate to protect organic label

11. Improve quality of inspections, certifiers

- Training, testing
- Conflict of interest (e.g. funding conflict)
- Certifier limited resources – reluctance to raise fees to improve services



# April NOSB recommendations

- Sunset 2011
- Sunset 2012
- Methionine Interim Rule –
  - Comment period closes today, October 25, 2010
  - Final rule by end of March, 2011
- Methionine step down – requesting more justification for the step down numbers



# April NOSB recommendations

## Clarification on livestock health care

- Organic calves fed organic milk treated with an allowed synthetic input – NOP accepts NOSB clarification

## Inerts in pesticides

- NOP is collaborating with EPA
- NOP regulations more prescriptive than most foreign organic standards



# April NOSB recommendations

Greenhouse recommendation accepted

Inert Atmospheric gases – packaging aids?

- Gases are regulated by FDA as direct food substances, not as packaging or packaging aids.
- Nitrogen and carbon dioxide are allowed.
- Argon is not listed and not allowed.



# Classification of materials

- Classification of materials is related to the category of use (e.g. crop production, livestock, handling).
- Crops and livestock - is the substance synthetic or natural?
- Processing (ingredients, processing aids) - is the substance agricultural or nonagricultural – most critical , then synthetic or nonsynthetic
- Chemical change definition conflicts with common understanding of chemical change.



## Vaccines

- 205.105(e) prohibits excluded methods (genetically modified organisms)
- Except vaccines produced through excluded methods may be allowed if approved according to 205.600(a)
- NOSB has not approved vaccines produced through excluded methods according to 205.600(a)
- NOSB may review vaccines produced under excluded methods as a class of substances.



# Sodium nitrate

Sodium nitrate – natural substance – prohibited except allowed for up to 20% of nitrogen needs of the crop.

U.S. organic standards only organic standard that allows sodium nitrate.

High sodium content can negatively affect soil quality.

Affects ability to access foreign organic markets.

NOP requests that NOSB reviews allowance.



# Guidelines for removing substances (non-sunset) from allowed inputs list

Notification of all affected parties within 120 days

- NOP notifies certifiers, state organic programs, foreign governments within 60 days.
- Certifiers, foreign governments notify producers and handlers within 120 days.

Prohibited substance removed from input stream 24 months after NOSB decision.





# Organic Integrity from Farm to Table

## Consumers Trust the Organic Label

**Thank you**



