

Oversight of Organic Products

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USDA National Organic Program





USDA National Organic Program

Implement Organic Foods Production Act:

- **USDA Organic Regulations**
Crops, livestock, handling, wild crops, labeling, certification, accreditation, National List
- **Accreditation and Oversight**
~90 authorized certifying agents worldwide
30,000 certified organic operations
- **Compliance and Enforcement**
Complaints, investigations, civil penalties, appeals
- **National Organic Standards Board**



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. Continual improvement

1. Clear/Enforceable Standards

Accomplishments

NOSB Implemented National List recommendations

NOSB Almost done with Sunset 2012

NOSB Residue testing proposed rule.

- Pasture rule implementation

Still Planned

NOSB Sodium nitrate

NOSB Vitamins + minerals

NOSB Origin of livestock

NOSB Aquaculture, mushrooms, pet food

NOSB Guidance (bulk products, seeds)



Pasture Rule - 2 Year Pulse Check

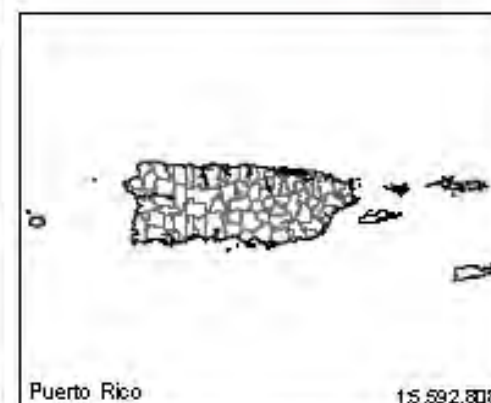
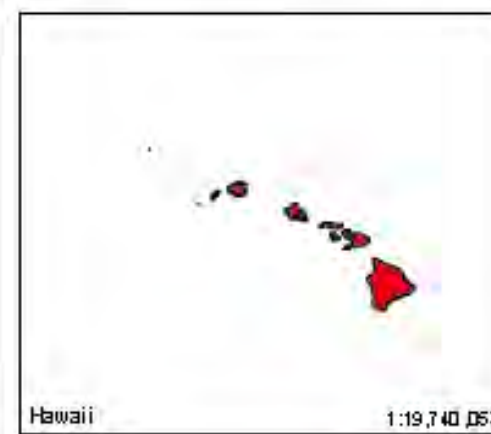
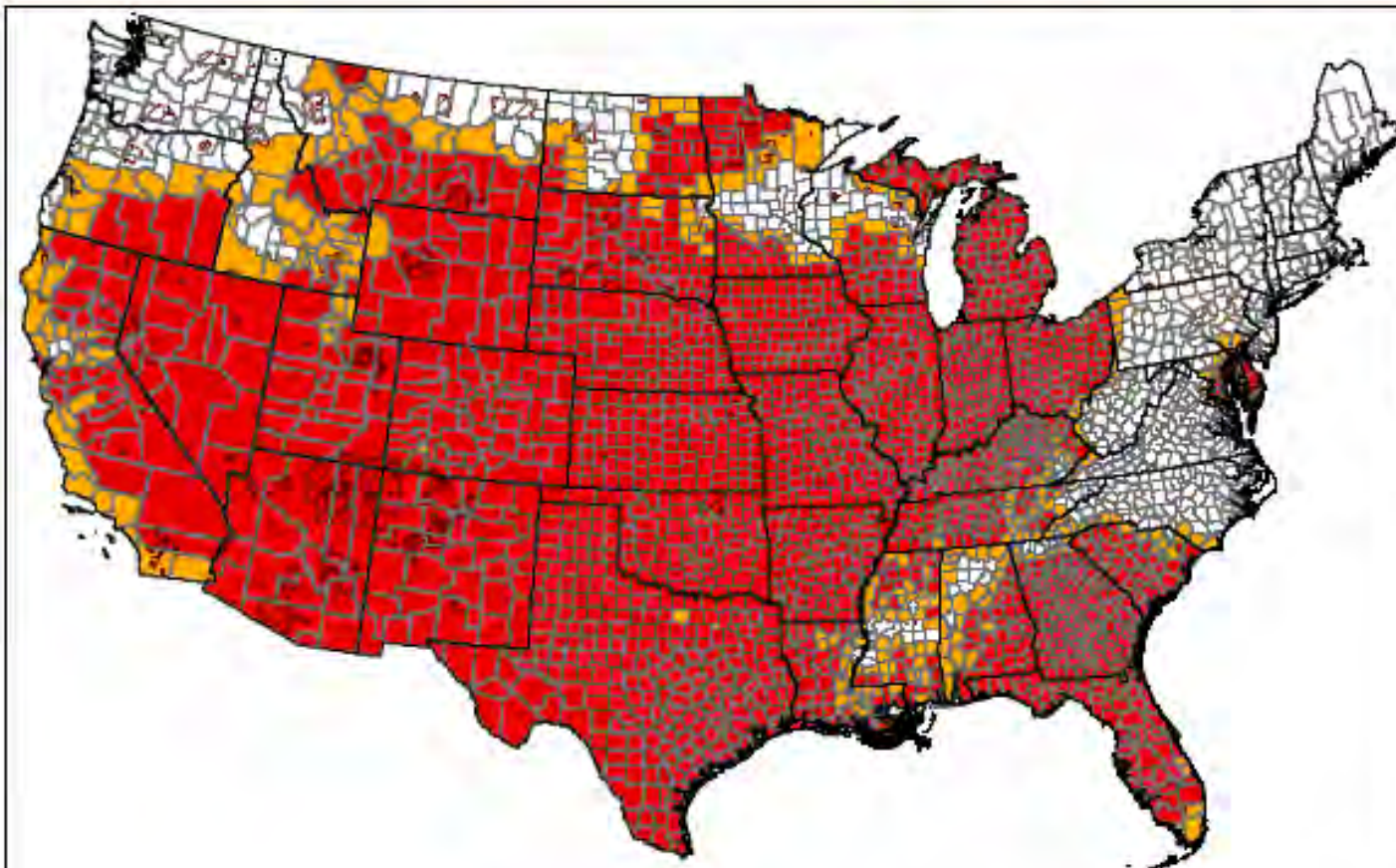
- Pasture visits/witness audits conducted in AZ, CA, CO, FL, IO, KY, LA, ME, MN, MT, NE, NV, NH, NM, NY, ND, OH, OR, SC, TX, PA, WA, WI
- Expanded pasture land
- Increased recordkeeping and inspection time
- Verifiable method to measure compliance with pasture based standard.
- General compliance with pasture rule



2012 drought

- Most severe drought since 1988
- Temporary variance approved – non-irrigated land only, reduced DMI from pasture from 30% to 15%



2012 Secretarial Drought Designations - All Drought



Disaster Incidents as of 10/10/2012

-  State Boundary
-  County Boundary
-  Tribal Lands

Total All Drought Approved Designations as of October 10, 2012

-  Primary Counties: 2,100
-  Contiguous Counties: 323

1:23,520,203



USDA Farm Service Agency
Production, Emergencies and Compliance Division
Washington, D.C.
October 10, 2012



2. Communication

Accomplishments

- Organic Literacy Initiative
- Newsletter
- NOP Organic Insider / website

Still Planned

- Outreach to increase number of certified operations
- Improved web platform


Learn How USDA Supports Organic Agriculture

Information on Organic Agriculture for
Farmers, Ranchers, and Businesses



www.ams.usda.gov/organicinfo

U.S. Department of Agriculture



Ever struggle to find info on a USDA program?

USDA's Organic Literacy Initiative will:

- Help users find information on organic and organic-related USDA programs.
- Improve customer service.
- Help farmers and businesses determine, “Is organic an option for me?”



3. Transparency

Accomplishments

- Posting improved list of certified operations
- Posting suspended + revoked operations
- Posting fraudulent certificates

Still Planned

- Posting certifiers' corrective action reports
- Posting cease + desist letters
- Increasing transparency of NOSB members interests



4. Certification

Accomplishments

- ~50 audits of certifiers in 2012
- NCAT publications: developing OSPs

NOSB

Instructions to certifiers (penalty matrix, unannounced inspections, etc.)

Still Planned

93% compliance with accreditation requirements, increased focus on biodiversity.

NOSB

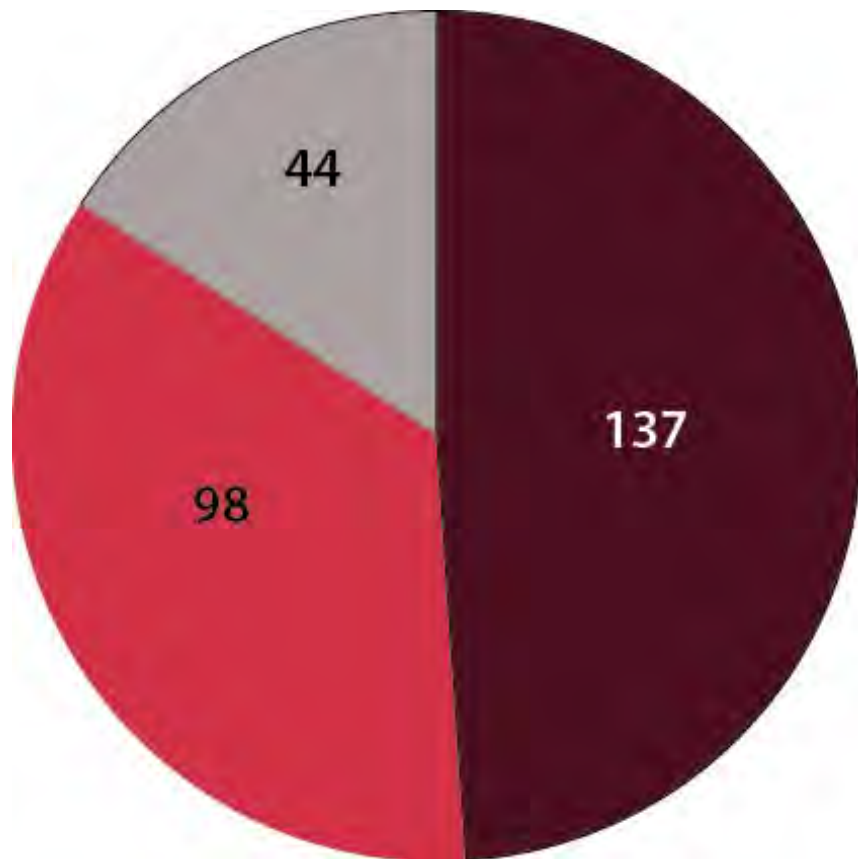
groups

NOSB




Classification, permitted substances list, MROs



5. Complaints



Case Distribution

-  Uncertified Operations
-  Labeling Violations
-  Prohibited Substances and Methods



In FY 2012, NOP

- Average days to closure for open cases –
 - FY 2010 – 269
 - FY 2011 – 204
 - FY 2012 - 80



6. Penalties

Accomplishments

- 9 civil penalties for willful violations totaling \$120k
- Suspended / revoked over 263 operations

Still Planned

- Explore alternate ways to enforce USDA organic standards to the fullest extent of the law

7. Market Surveillance

Accomplishments

- Compliance visits to small number of markets

Still Planned

- Implement market surveillance program





8. Unannounced Inspections

Accomplishments

NOSB

Published instruction: certifying agents should conduct unannounced inspections on 5 percent of the operations they certify

Still Planned

- Address at annual certifying agent training
- Evaluate during certifying agent compliance audits



9. Periodic Residue Testing

Accomplishments

- Published proposed rule.
- Published instructions on responding to positive residues, selecting labs, target prohibited pesticides list.

Still Planned

- Publish final rule (soon).
- Publish updated instructions.
- Assess compliance during certifying agent audits.



10. Continual Improvement

Accomplishments

- Training webinars + modules
- Audits with increased rigor
- Outreach materials
- National List “Sunset” dates

Still Planned

- Modernizing list of certified operations
- Annual training for certifiers
- Oversight of international agreements



Peer review

- Required by Organic Food Production Act
- National Institute of Standards and Technology (NIST) review
- Corrective Actions completed
- 2013 – American National Standards Institute (ANSI) will conduct peer review



Office of Inspector General

- 2010 audit – all 14 recommendations have been addressed and closed.
- OIG Milk Audit – Phase 1
 - 4 findings
 - Corrective actions in progress
- OIG National List/NOSB audit
 - No findings



How Does This Fit Into NOP's Strategic Plan?

Clear
Standards

Consumer
Protection

Market
Access

Information
Technology



2012 Focus Areas



Sunset 2012

To avoid expiration, renewals/changes to over 200 substances (example: baking soda)

Pending: sodium nitrate + vitamins/minerals



Amendments to allowed/prohibited substances

Address expiration dates in allowances for methionine and tetracycline



Certifying agent compliance audits

Must be audited every 2.5 years



2012 Focus Areas (cont.)

- Periodic residue testing
- Pasture rule compliance
- Penalty matrix
- FDA food safety rules + organic standards
- European Union trade partnership
- Organic Literacy Initiative
- Better communication of actions/requirements



2013 Focus Areas



Sunset 2013 (*many less substances than 2012*)

- Origin of livestock
- Pet food standards
- Aquaculture standards
- Implementation of residue testing requirements
- Guidance documents, including:
 - Organic seeds, grower groups
 - “Made with” organic, organic in the brand name
 - Inspector qualifications
 - Handling bulk organic products
- Classification of materials / permitted substances

Organic Pet Food: Lifecycle of a “Rule”

What takes
so long?

Final Rule

Public Comments

Proposed Rule

NOSB
recommendation

Working group
recommendation



Organic Pet Food: Lifecycle of a “Rule”



**Vitamins +
minerals
unique to
pets**

**FDA and
AAFCO
standards**

**Economically
significant!**



2013 Focus Areas (cont.)

- Market surveillance
- OIG milk audit part II
- Verification of international trade partnerships
- Additional international market access.
- Posting additional audits/compliance info
- List of certified operations
- Stakeholder engagement
- NOSB support/coordination



Criteria for Handling Ingredients

- OFPA permits exceptions if the use of such substance:
 - Would not be harmful to human health or the environment
 - Is necessary to the production or handling of agricultural product because of the unavailability of wholly natural substitute products; and
 - Is consistent with organic farming and handling
- National List is based on proposals from the National Organic Standards Board
- NOP cannot add a substance to the National List that has not been recommended by the NOSB



NOSB Evaluation Criteria

- The potential for detrimental chemical interactions with other materials
- The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment
- The probability of environmental contamination during manufacture, use, misuse or disposal of such substance



National Organic Program

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NOSB Evaluation Criteria (cont.)

- The effect of the substance on human health
- The alternatives to using the substance in terms of practices or other available materials
- Its compatibility with a system of sustainable agriculture



Additional Criteria for Processing Substances

- The substance cannot be produced from a natural source and there are no organic substitutes
- The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling
- The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations



Additional Criteria for Processing Substances (cont.)

- The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;
- The substance is listed as GRAS by FDA when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and
- The substance is essential for the handling of organically produced agricultural products.



Overlap with Other Regulations

- National List substances must meet certain eligibility requirements
- FDA or EPA must have authorized the substance for the petitioned use in conventional (i.e., non-organic) production or handling, if applicable



Additional Requirements for Handling

In addition to FDA requirements, non-organic ingredients and processing aids must not be produced using:

- Excluded methods (genetic engineering)
- Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26
- Sewage sludge (biosolids) as a fertilizer

§ 205.105



United States
Department of
Agriculture



CELEBRATING 10 YEARS OF

USDA ORGANIC

WWW.AMS.USDA.GOV/ORGANICINFO

Thank you Barry Flamm





Thank You

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

