



National Organic Program

National Organic Standards Board

Woodland, CA, April 26, 2010

Miles McEvoy, Deputy Administrator



Topics

- Priorities
- Accomplishments
- OIG audit
- Pesticide residue testing
- Personnel and Budget
- Strategic planning
- Accreditation and equivalency
- Enforcement
- Program handbook
- November NOSB recommendations
- Corn Steep liquor
- Nutrient vitamins and minerals



Priorities

- Uphold and enforce the standards
- Implement and enforce the Access to Pasture final rule
- Develop strategic plan
- Website revision and improvements
- Implement the NOSB recommendations
- Peer review – NIST, ISO
- Quality system management
- Program handbook
- Training
- Organic database



Accomplishments

- Published Access to Pasture final rule – provide guidance and training to certifiers and certified operations
- Clarified requirements for liquid fertilizers with over 3% nitrogen
- Issued instructions on the eligibility of yeast for organic certification
- Provided instructions concerning the allowance of green waste compost
- Moved NOSB meeting out of DC
- Published tetracycline/sulfurous acid proposed rule
- Increased training – Savannah, Denver, Albany, LaCrosse, Nuremberg, Woodland
- Strengthened enforcement procedures – adverse actions, civil penalties
- Transparency – NOP monthly report, publication of suspended, reinstated and revoked operations.



Office of Inspector General

Audit of NOP

- More timely enforcement – complaints, violations
- Oversight of California’s state organic program
- Pesticide residue testing
- Accreditation and peer review
- Improve quality management system
- Provide clarity and consistency to certifiers
- Conduct audits of foreign certifiers



Corrective Action Plan

- Recommendations 1-6
 - Enforcement actions are being pursued, civil penalty procedures are being evaluated and updated, administrative sanctions policy developed, one \$6,000 civil penalty, improved complaint reporting and timeliness, procedures for monitoring continued compliance implemented, resolved or referred to OGC for adverse action all old complaints
- California State Organic Program (SOP)
 - Audit conducted in December 2009
 - New California SOP program implemented in 2010 includes corrective actions
- Periodic residue testing
 - Plan to require sampling later this year.



Periodic pesticide residue testing

- Sample collection procedures
- Sampling plan – what is sampled?
- Sample analysis – AMS lab in Gastonia, NC; multi-residue
- Results reported to certifier and certified operation
- Procedures for positive residue results – under 5% of EPA tolerance vs. over 5% of EPA tolerance levels
- Reporting results of testing to public/NOSB



Corrective Action Plan

- Revision of audit review criteria to include greater focus on materials, labels and access to pasture
- Annual summary of audit findings for continual improvement
- All foreign audits of accredited certifiers are complete
- Assessment of the NOP accreditation program by the National Institute of Standards and Technology in process



Corrective Action Plan

- NOP Program Handbook to provide guidance to certifiers and certified operations
- First edition summer 2010
- Implement quality management system – document control, records management, notification procedures to ACAs, certified operations



Age of enforcement

- Civil penalties
- Clarification and enforcement on access to pasture and labels
- Market surveillance – verify compliant labels
- Increased use of unannounced inspections
- Utilize pesticide residue sampling as required by OFPA to identify problems and enhance organic integrity
- Develop a system of risk based inspections

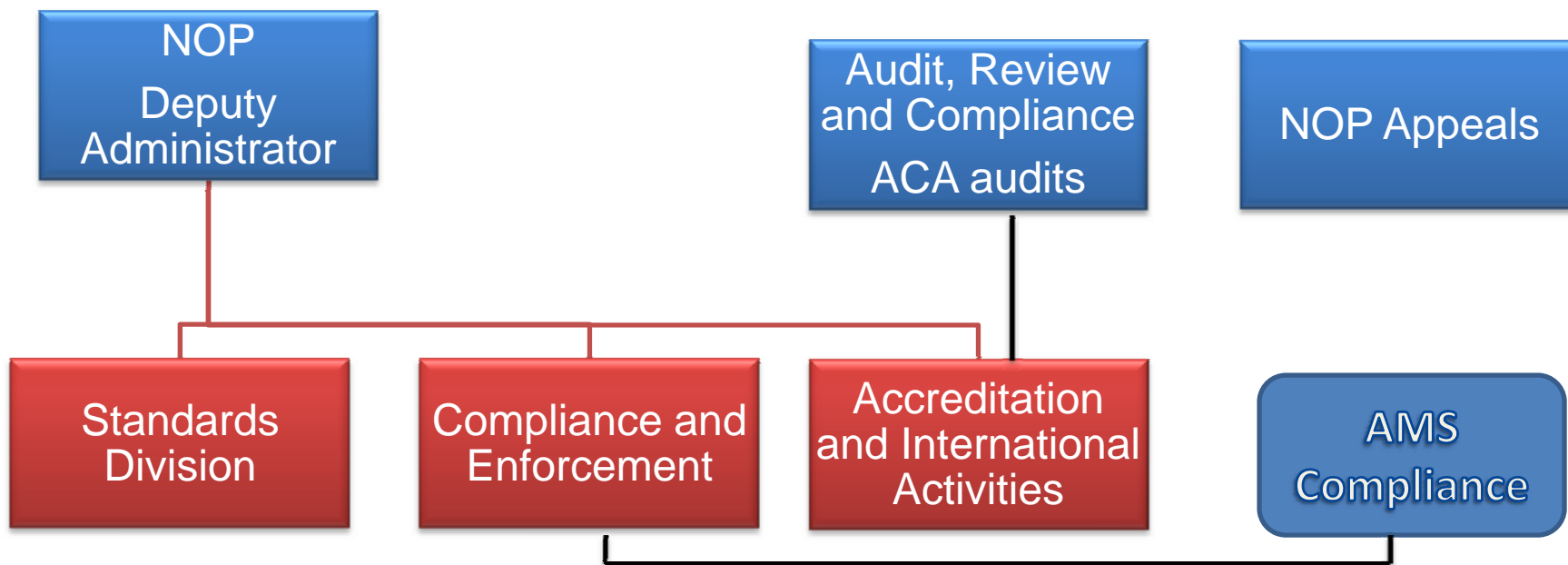


Certifier initiatives

- Up-to-date database of all certified operations
- Qualifications and accreditation of inspectors/auditors
- ISO Guide 65 compliant NOP accreditation program
- Training modules
- Provide technical assistance to certifiers regarding adverse action procedures (Notices of Noncompliance, Denial, Proposed Suspension, Mediation, Revocation, etc.)



Organizational Structure

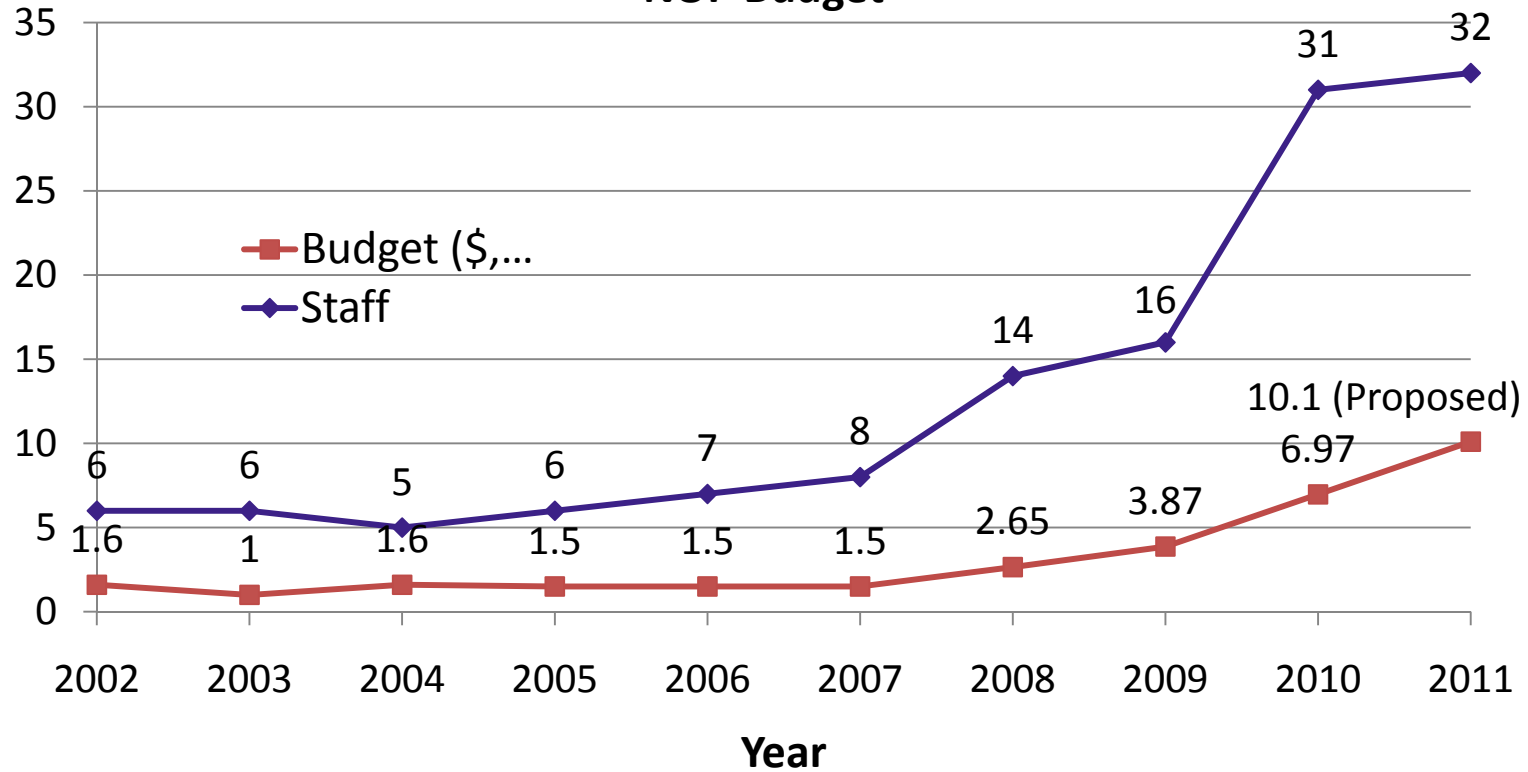




Year	Budget	# staff
2002	\$ 1.6 million	6
2003	\$ 1.0 million	6
2004	\$ 1.6 million	5
2005	\$ 1.5 million	6
2006	\$ 1.5 million	7
2007	\$ 1.5 million	8
2008	\$ 2.65 million	14
2009	\$ 3.87 million	16
2010	\$ 6.97 million	31
2011 (President's budget)	\$10.1 million	32



NOP Budget





FY 2010 Budget

- NOP Salaries and Benefits - \$3.9 m
- NOP administrative support – \$0.3 m
- AMS overhead - \$0.7 m
- NOP Appeals - \$0.3 m
- AMS compliance – 0.2 m
- NOSB - \$0.1 m
- Travel - \$0.2 m
- Goods and Services - \$0.3 m
- Technical Reports – Science and Technology - \$0.2 m
- Database – \$0.3 m
- Residue testing - \$0.3 m
- Projects – NIST, training, Program Handbook - \$0.2 m



Personnel

Office of the Deputy Administrator

- Miles McEvoy
- Arthur Neal, Associate
- Katherine Benham – Advisory Board Specialist/Office Manager
- Valerie Thorne – Secretary
- Lisa Ahramjian – NOSB Executive Director (starts May 10)
- Judy Ragonesi – Training Manager
- Grants Specialist – cost share program (unfilled)
- Quality Manager (unfilled)

Accreditation and International Activities Division

- Mark Bradley – Director
- JD Melvin – International
- Bob Pooler – Accreditation
- Mary Lou Lusby - Accreditation
- Meghan Kuhn – NOP technical expert
- Lars Crail – NOP technical expert
- Catherine Cash – NOP tech expert



Personnel

Compliance and Enforcement

Division

- Ruihong Guo – Director
- Valerie Schmale
- Tammie Wilburn
- Andrew Regalado
- Kristin Thornblad
- Lorraine Coke
- Renee Mann

Standards Division

- Director (unfilled)
- Shannon Nally – Acting Director
- Toni Strother
- Valerie Frances
- Stacy Jones
- Lisa Brines, Ph.D
- Emily Brown Rosen
- Mark Keating
- Food Scientist (unfilled)
- Livestock specialist (unfilled)



Details

- Dr. Kerry Smith – Access to Pasture training
- Soo Kim - Writer
- Lee Cliburn – National List rule writing
- Dana Stahl – Quality Manual



USDA Organic Initiatives

- USDA Organic Plan under development – all USDA agencies and mission areas are contributing to the plan.
- AMS Organic Market News –
 - National Fruit and Vegetable Organic Summary. Available free every Tuesday at www.ams.usda.gov/mnreports/fvworganic.pdf, the new report provides an easy-to-use summary of the market data, including wholesale and shipping point prices and movement data.
- NRCS – Organic Transitions Program, EQIP funding
- FAS/NOP MOU – oversight of foreign organic operations, HTS codes
- USDA Organic Coordinator position
- Research in OREI, SARE and ARS



NOP Strategic Planning Update

- NOP is currently engaged in a strategic planning process, being conducted in segments between March and July 2010.
- Objectives of the strategic planning process are to:
 - Reaffirm the NOP mission and shared sense of purpose
 - Identify the key customers and audiences of the NOP and NOSB, and their respective needs and interests
 - Develop and prioritize clear goals, objectives, and actions
 - Develop performance measures that will assess success
 - Establish a communication plan as we move our plan into operation
 - Align NOP with critical goals in the USDA and AMS strategic plan



Initial Draft: NOP Strategic Goals

- Develop, publish, and maintain a documented quality management system (QMS) for the efficient and effective operation of the NOP
- Develop, communicate, and apply clear and consistent NOP standards in a uniform manner across all stakeholder groups
- Enhance compliance with and enforcement of the organic label
- Improve NOP communication with internal and external stakeholder groups
- Continue to build and develop an effective and well-trained NOP team

Developing NOP goals in a work in progress. We welcome your feedback!



We Invite Your Input!

- Step 1: One Day Strategic Planning Session with NOP Staff – March 2010
- Step 2: Feedback from NOSB and Other Stakeholders – April and May 2010
- Step 3: Two-Day Internal Planning Session – 14-15 June 2010
- Step 4: Strategic Plan Review and Rollout – June and July 2010

The Executive Summary from our March 2010 session is available for review and comment. We ask that you send any feedback to the planning facilitator by 20 May 2010.



Accreditation and International Activities Division – Mark Bradley, Director

- Audits prior to new accreditations
- NOP technical experts on all audits
- Foreign assessments– Ghana, Argentina, Israel and India planned for 2010
- Increased accountability – Annual Updates, adverse action procedures, lists of certified operations



Recognition agreements

- Denmark assessed in March
- Israel scheduled for May
- India scheduled for September
- New application from Thailand



Equivalency

Canada – Mutual assessment of programs to occur later this year

European Union – The USDA and the EU have expressed interest in establishing an equivalency agreement. Meetings will be occurring later this year.



Harmonization

- Standards – are they equivalent not identical
 - limited differences between organic standards – sodium nitrate, antibiotics, inert ingredients
- Certification requirements –
 - Inspection during transition, Organic System Plans
- Accreditation systems –
 - Private vs. government oversight



Benefits of equivalency

- Organic producers have expanded market access – especially important for small producers who cannot afford multiple certifications
- Certifiers have less audits – one audit suffices for providing access to both US and Canadian market
- Certifiers can choose accreditation system – e.g. NOP or CFIA
- Reduces paperwork and costs



Other considerations

- Reduces direct oversight of certifiers – certifiers that were previously accredited under both systems may now be accredited and audited under only one system.
- Accreditation system relies on multiple evaluation bodies
- USDA organic may be NOP certified or CFIA certified



State Organic Programs

- Utah has withdrawn
- California is under review – corrected 7 out of 8 findings
- California additional requirements – registration for certifiers and organic operations
- No new inquiries from other states



Compliance & Enforcement Division – Ruihong Guo, Director

New and revised procedures

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



Complaint Status

Between 10/1/2009 and 3/31/2010,

- Complaints Carried-over from Previous Years: 70
- New Complaints Received: 86
- Total Complaints: 156
- Complaints Closed: 62
- Ending Complaint Inventory: 94
- Complaints over 270 days: 18
- Complaints over 180 days: 16
- Average Time for Case Closure: 186



Complaint Status

Between 10/1/2009 and 3/31/2010,



Complaint Status

Between 10/1/2009 and 3/31/2010, we issued

- 28 warning letters
- 1 notices of noncompliance



Complaint Status

Between 10/1/2009 and 3/31/2010,

- 1 case collected civil penalty through settlement agreement
- 12 cases resulted in product label changes
- A total of 123 product labels were changed
- 8 cases resulted in production process changes
- 20 cases resulted in website changes
- 3 operations became certified



Standards Division – Shannon Nally, Acting Director

- Rulemaking – Practice Standards, National List
- NOP Program Handbook – instructions and guidance
- National List petition process



Under development

- “Made with organic (specified ingredients or food group(s))”
in clearance –draft guidance – 60 day comment period
 - 1) the use of the term “organic” in brand and company names on principal display panels,
 - 2) the use of non-organic ingredients in “made with organic [specified ingredients or food groups]”products, and
 - 3) the use of percentage of organic ingredients statements within the “made with organic [specified ingredients or food groups]” labeling category.



NOP Program Handbook

- Instructions/Procedures
 - Information to certifying agents concerning accreditation requirements
 - Examples – accreditation procedures, enforcement procedures
- Guidance
 - Clarification of existing regulation
 - Draft guidance published in Federal Register with 60 day comment period
 - Examples – Outdoor access for poultry, commercial availability of seeds



NOP Program Handbook

OIG findings

- Periodic residue testing
- Outdoor access for livestock
- Organic certificates
- Changes in ownership
- Preventing commingling
- Noncompliance procedures
- Organic System Plans
- Inadequate records

NOSB recommendations

- Commercial availability of seeds
- Biodiversity
- Grower Groups
- Organic research
- Compost
- Chlorine
- Private labels



National List rulemaking in progress

- Final sulfurous acid, tetracycline
- Final 606 rule
- Final rule - TM-08-06
 - Potassium silicate, sodium carbonate peroxyhydrate, gellan gum, cooking wine, tragacanth gum
- Proposed rule
 - NOP 09-02 – microcrystalline cheesewax (601), myrrh essential oil (606), dried orange pulp (606), pacific kombu (606), sodium chlorite acidified (605), removal of lecithin-bleached from 605(b), add lecithin-unbleached to 606
 - NOP 09-03 – fenbendazole, moxidectin
 - NOP 09-04 – injectable vitamins and minerals, change annotations to excipients, chlorhexidane, xylazine



Practice standards

1. Origin of Livestock – proposed rule in 2010
2. Apiculture
3. Mushrooms
4. Standardization of Certificates
5. Pet food
6. Aquaculture
7. Greenhouses



NOSB nominations open

5 openings for the NOSB

- Two producers
- Two consumer/public interest groups
- One certifier

Nominations due by July 17, 2010

5 year terms start in January 2011



Plans for FY 2011 – resource dependent

- Proposed rules for apiculture, mushrooms, pet food, standardized certificates, civil penalties
- Support ISO accreditation for all NOP accredited certifiers
- Align NOP regulations with ISO Guide 65
- Expanded oversight of foreign accredited certifiers, recognition agreements
- Pursue additional equivalency arrangements



NOP response to NOSB

- Expiration dates on certificates, standardized certificates
- Sunset Review
- November 2009 materials recommendations
 - Sunset 2011
 - Petitions and annotation changes
- Excipients – the NOP concurs with adding “or approved by APHIS” to the annotation, the NOP finds “animal health care products” to be a vague term and awaits further clarification



NOP response to NOSB

- Vaccines –
 - The NOP is seeking legal review from the Office of General Counsel
 - The NOP is seeking a technical review to report on the status of GMO vaccines and the economic impact of using commercially availability criteria for vaccines.
- Shellfish – Accepted
- Animal Welfare – Important area, more work needed
 - Impact of Pasture rule on recommendation
 - Suggest including transportation and slaughter handling in recommendation



NOP response to NOSB

- Classification of Materials
 - Important and complex work, hard to draw the line between synthetic and natural
 - Support the 2 vote system to clarify decisions
 - Definitions need additional work
- NOSB Policy Manual changes – changes have been made
- Retail Certification
- Cosmetics



Cosmetics

- The NOP will collaborate with FDA and FTC to understand the issues associated with the use of the term “organic” in personal care products. Collaborative and comprehensive approach aligned with each respective agencies regulations.
- The NOP will gather information possibly through a public survey or Advanced Notice of Proposed Rulemaking.





Materials Update:

Corn Steep Liquor

National Organic Standards Board Meeting

April 26, 2010

Lisa M. Brines, Ph.D., Agricultural Marketing Specialist

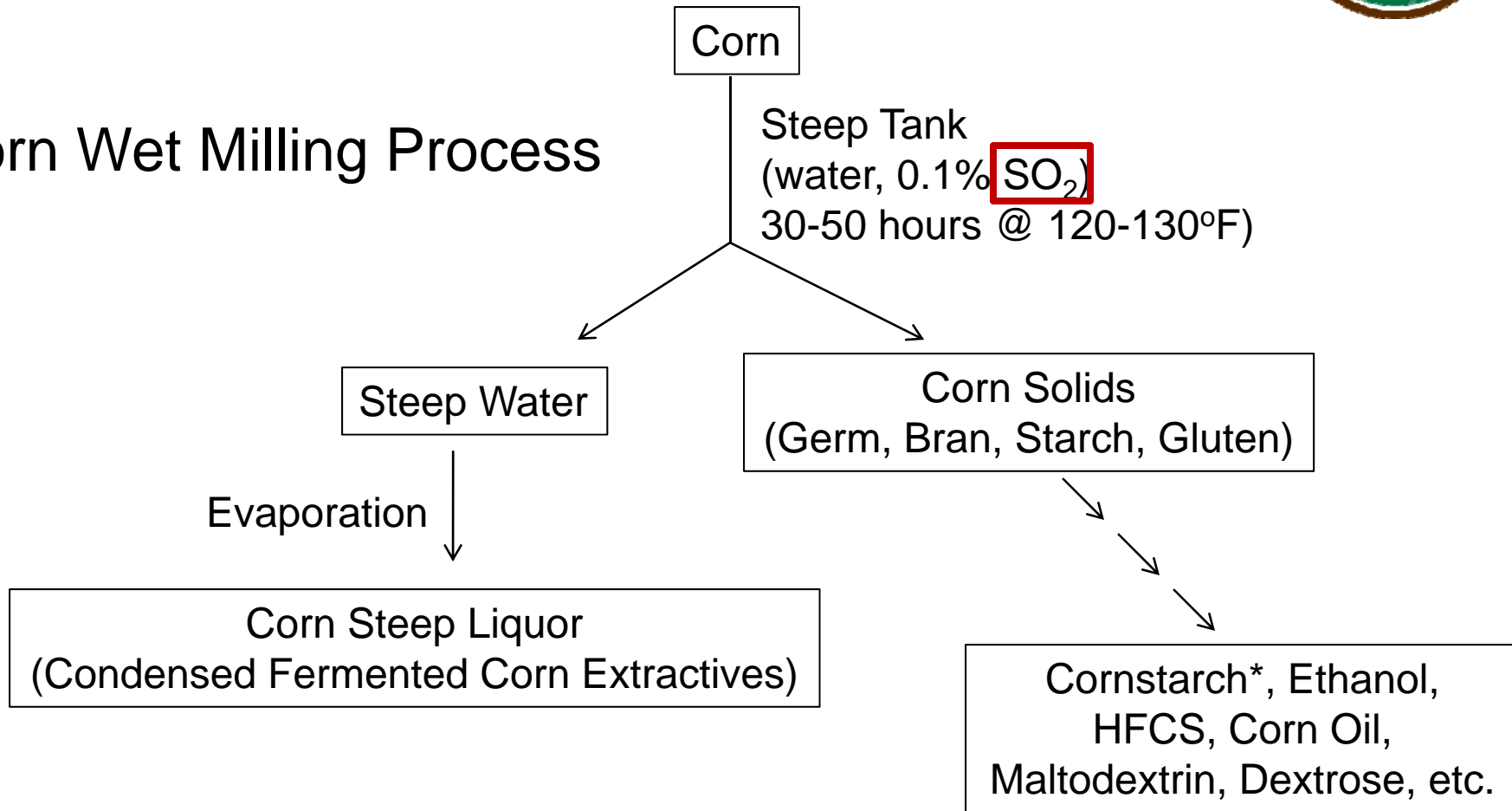


Corn Steep Liquor (CSL)

- CSL is a byproduct of the corn wet milling process
- CSL is currently used as an input (liquid fertilizer) for organic crop production
- CSL has previously been considered nonsynthetic (natural) by ACAs and OMRI
- CSL was recently re-evaluated by OMRI and determined to be synthetic
- NOP requests that the NOSB evaluate CSL for use in organic crop production



Corn Wet Milling Process



*Cornstarch (native) is currently on §205.606



Alternatives to Sulfur Dioxide

- Processing for certified organic corn cannot use sulfur dioxide
- Nonorganic materials must be on the National List. Examples:
 - Nonsynthetic enzymes - listed on §205.605(a)
 - Lactic acid - listed on §205.605(a)
 - Ozone - listed on §205.605(b)
 - Other materials for pH adjustment on §205.605



Questions for Discussion

- Is corn steep liquor synthetic or nonsynthetic if produced using sulfur dioxide?
- Would the use of sulfur dioxide make any other corn-derived products synthetic?
 - Cornstarch (native) is currently on §205.606



Next Steps

- NOP requests that NOSB provide a formal recommendation regarding the classification of CSL at next NOSB Meeting (Fall 2010)
- If CSL is nonsynthetic, it will continue to be allowed as an input for organic crop production
- If CSL is synthetic, future use for crop production will be prohibited unless petitioned to the National List



Nutrient Vitamins and Minerals



1995 NOSB Recommendation

- “Upon the implementation of the National Organic Program, the use of **synthetic vitamins, minerals,** and/or **accessory nutrients** in products labeled as organic must be limited to that which is **required by regulation** or **recommended for enrichment and fortification by independent professional associations.**”



NOP regulations

- 7 CFR 205.605(b)
 - Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.



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
- The NOP determination was never publically disseminated and was not done through a transparent process.



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.

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).



205.605(b): Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

Nutrients listed in 21 CFR 104.20(d)(3)

Protein	Thiamin (Vitamin B₁)	Pantothenic acid (Vitamin B₅)
Vitamin A	Riboflavin (Vitamin B₂)	Phosphorus
Vitamin C	Niacin (Vitamin B₃)	Magnesium
Calcium	Vitamin B₆	Zinc
Iron	Folate (Vitamin B₉)	Iodine
Vitamin D	Vitamin B₁₂	Copper
Vitamin E	Biotin (Vitamin B₇)	Potassium



21 CFR 104.20(f)

Nutrient(s) may be added to foods as permitted or required by applicable regulations established elsewhere in this chapter.

Office of Nutrition, Labeling and Dietary Supplements

21 CFR 104.20(f) includes only nutrients listed in 104.20(d)(3) *except*

- Foods with a standard of identity, 21 CFR Parts 130-169 (e.g. enriched flour)



21 CFR 104.20 does not include:

- Fatty acids (DHA, ARA), taurine, choline, carnitine, phytochemicals
- Nutrient vitamins and minerals used in pet food
- FDA does not define “accessory nutrients”
- Accessory nutrients are not on the National List



NOP Action Plan

- Previous NOP interpretation of nutrient vitamins and minerals allowed under 205.605(b) was incorrect.
- The NOP recognizes that many certifiers and certified operations made business decisions based on the 2006 NOP interpretation.
- The NOP plans to publish draft guidance later this year that will clarify the FDA interpretation of 21 CFR 104.20 – only nutrient vitamins and minerals listed in 104.20(d)(3) and those with standards of identity in 21 CFR Parts 130-169 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.



Additional Steps

- NOP requests that the NOSB reevaluate their recommendation for nutrient vitamins and minerals (accessory nutrients) during the 2012 sunset process.
- In the future the NOP will not be making policy decisions in letters, all policy decisions will be handled through the federal register and in compliance with Executive Order 12866.
- 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.

