National Organic Program
and
Implementation Issues

Bob Durst

Simple Organic Solutions

BobD@SimpleOrganicSolutions.com

www.SimpleOrganicSolutions.com

How many are currently processing organically?

How many are looking at organic processing as a potential market or growth area?

Have you been certified to the new NOP regulations?

How many have questions about the new regulations?

How many have reviewed your process/formulations to insure that they are compliant with the NOP?

Contact info:

Bob Durst

Simple Organic Solutions

P. O. Box 1310

Jefferson, OR 97352

541-740-6490

801-991-5660 (fax)

BobD@SimpleOrganicSolutions.com

www.SimpleOrganicSolutions.com

What is Organic Processing?

- Safe-Must be, just as NOG is
- Pesticide & Herbicide Free
  - What consumers expect
- Chemical & Preservative Free
  - What consumers perceive, not always the case
- Not Commingled-To insure the above two
- Healthy-No claims made

Simple Organic Solutions

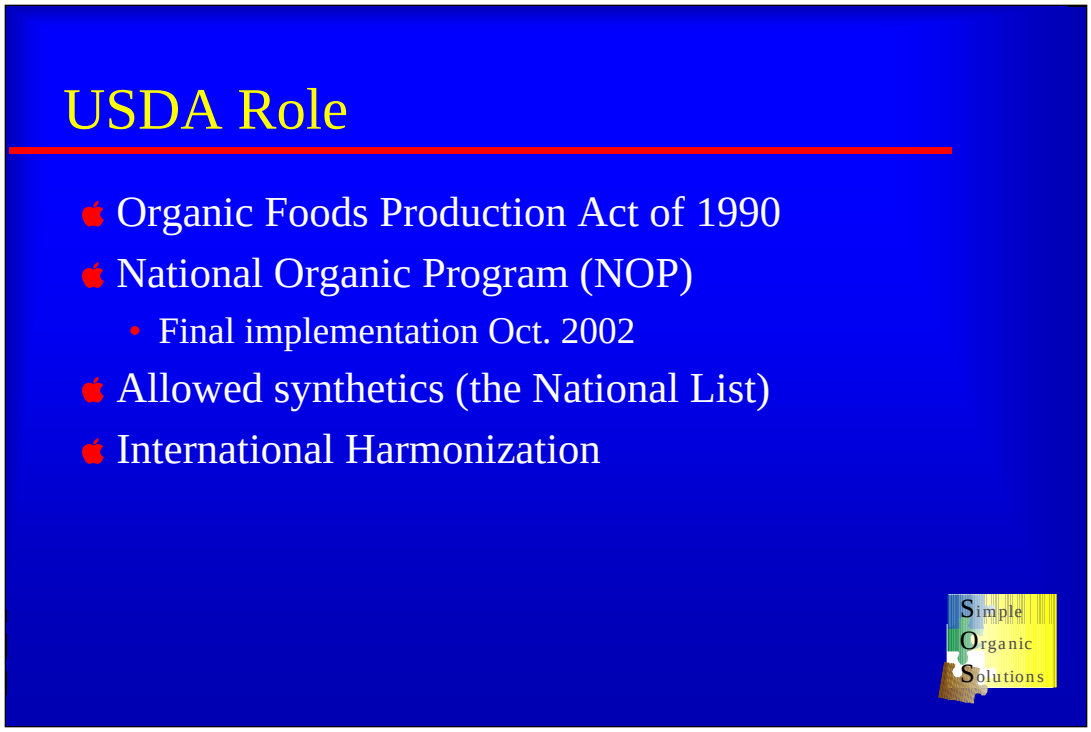
Discuss the difference between what people think organic means and what it is from the practical aspect of a processor.

Safe is still very (most!) important. Use of manure, unclear water, un-chlorinated water, no use of preservatives…are all of concern.

Pesticide free: one of the basic tenants of organic farming and processing. Those that are used have been shown to be non-toxic (insecticidal soaps, BT…)

Chemical free: perception, but not completely true. This was one cause of much of the controversy in the original bill, and continues to be one of the biggest undone parts of the bill-to be discussed later.

Healthy: USDA careful to not let organic be perceived as healthier or more nutritious than conventional-just different.



What:

Organic Foods Production Act of 1990 (OFPA). This is the National Organic Program. It is to be administered by USDA.

Allowed synthetics. This is the national list that will (hopefully) standardize synthetic inputs among all certifiers. Includes farm and livestock items, but for processing it is a very important document.

When:

Dec 97 initial proposal-disastrous. 275,000 mostly negative comments, March 2000 revised proposal-much better, 41,000 comments. Final rule Federal Register/ vol. 65, No. 249/ Thursday, December 21, 2000/ Rules and Regulations.

Why:

Slightly different standards among the different certifiers. Because of reciprocity they were allowing things that they wouldn't have if they were the certifier. Initiated by the certification agencies. Example: SO_2 in wine-allowed by OTCO, rejected by CCOF.

This is the symbol that what all the fuss is about. Can't start using this symbol on packaging or advertising until the law becomes fully implemented in October this year.

Federal Register

vol. 65, No. 249

Thursday, December 21, 2000

Rules and Regulations.

The Act was published in December. The clock started on April 20, 2001. Everyone has 18 months to come into compliance.

Label cannot be used until October 21?, 2002 (18 months from implementation)

USDA rules not only set a minimum requirement , but effectively set a maximum standard. More about this later.

Changes came about because of effective lobbying by NFPA.

The NOP is a marketing program of USDA AMS. Neither the OFPA nor NOP address food safety nor nutrition.

I'll discuss these various aspects of the NOP in more detail

These are the main categories (related to processing) in the Act.

Definitions

- Organic
  - A labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part.
- Organic Production
  - A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.
- National List
  - A list of allowed and prohibited substances as provided for in the Act.

Simple Organic Solutions

A few pertinent definitions.
No “processors” nor “farmers” under USDA.

Organic is not an end product, but a system that achieves loftier goals than just the production of an end product.

This includes environmental stewardship, sustainability, social good, healthier food, etc.

National List to be discussed in more detail later.

Applicability

- What has to be certified
  - Any product represented as “Organic”
  - Any operation claiming to produce “Organic” products
- Exemptions and Exclusions
  - Must still comply with the law
  - <$5000 organic business
  - Distributors, shippers, storage facilities
  - Retail food establishment
  - Must keep records for at least 3 years

Simple Organic Solutions

This information is lifted and condensed directly from the bill

§ 205.100 Applicability

(a) … production or handling operation that produces “100 percent organic,” “organic,” or “made with organic…” must be certified …

(b) … production or handling operation … deemed to be certified under the Act until the operation’s next anniversary date of certification.

§ 205.101 Exemptions and exclusions

(a) (1) …gross agricultural income from organic sales < $5,000 annually

(2)…retail food establishment that handles organically produced agricultural products but does not process them

(3)…handles agricultural products that contain less than 70%organic ingredients

(b) (1)… handling operation …only sells “100 percent organic,” “organic,” or “made with organic…” and

(i) Are packaged … and (ii) Remain in the same package and are not processed while in the control of the handling operation.

(c) (1) Records maintained by exempt operations: (i) Prove ingredients were organically produced and handled; and (ii) Verify quantities produced from such ingredients.

(2) Records must be maintained for no less than 3 years beyond their creation …

This is the preview of the rest of the categories that will be discussed in more detail.

Historical adherence to a Minimalist and Natural approach. Reliance on basic processing techniques - i.e. cooking, baking, heating, drying, mixing, grinding, etc.

Precautionary Principle vs. Risk Assessment - burden of proof proving that a material or process is safe rather than assuming safety until risks outweigh the benefits.

Segregation from Non-Organic Food

All of these categories to be discussed in subsequent slides.

Inputs and the National List

- Nonagricultural Ingredients
  - Synthetics and non-Synthetics
    - » allowed-if on the National List
- Non-organically produced agricultural ingredients
  - Within the % labeling limits
- Not organic and not on the National List?
  - Can't use it
- Amending the list
  - Steam additives recently added

Simple Organic Solutions

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic"

(a) Nonsynthetics allowed: 20 categories with about 27 items

(1) Acids…(ii) Citric—produced by microbial fermentation of carbohydrate substances.
(5) Colors, nonsynthetic sources only.
(8) Enzymes …
(9) Flavors…no solvents … or any artificial preservative.
(19) Waxes—nonsynthetic.

(b) Synthetics allowed: about 36 listings

(4) Ascorbic acid.
(9) Chlorine materials—disinfecting and sanitizing food contact surfaces… residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
(19) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20,
(32) Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.
(34) Sulfur dioxide—in wine labeled "made with organic grapes,"…total < 100 ppm.

§ 205.606 Non-organically produced agricultural products allowed as ingredients in products labeled as "organic" or "made with organic".

…Any agricultural …product may be used … when the product is not commercially available in organic form.

five listings
(a) Cornstarch (native)
(b) Gums—water extracted only (arabic, guar, locust bean, carob bean)
(c) Kelp—for use only as a thickener and dietary supplement
(e) Pectin (high-methoxy)

§ 205.607 Amending the National List

(a) … the (NOSB) … evaluated … for inclusion on or deletion from the National List …
(c) A petition to amend the National List must be submitted to:
Program Manager
USDA/AMS/TMP/NOP
Room 2945, South Building
P.O. Box 96456
Washington, DC 20090–6456.

OTCO: ingredients 91 allowed/restricted; aids 18 a/r; cleaners/sanitizers 20 a/r; pest control 18, 5 a/r

Lots of items not addressed by the National List.
Some recent changes addressing some of these issues:
Ammonium Hydroxide – For use as boiler water additive only with removal from the List October 21, 2005.
Cyclohexylamine and Octadecylamine – For use as a boiler water additive for packaging sterilization only.
Postassium Hydroxide –prohibited for lye peeling except for peeling peaches for (IQF) production.
Cellulose – For use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.
The following materials were determined to be synthetic and prohibited for use in organic processing:
Morpholine – The motion, to allow this for use as a boiler water additive for packaging sterilization only, failed.
Sodium Phosphates – The motion, to amend the current annotation by adding formulated with soymilk or dry soymilk products, failed. The current annotation remains as published in section 205.605(b)(33
The following Processing materials have been deferred until the May 2002 NOSB meeting:
Diethylaminoethanol
Glycerol Monooleate

Sanitation

- GMP (Good Manufacturing Practices)
  - Must be followed
- Cleaning
  - Standard cleaning practices with extra rinses
- Sanitizing
  - Cl, ClO_2, H_2O_2, peroxyacetic acid…
  - No Quats

Simple Organic Solutions

GMP:

for general plant sanitation and safety
Standard cleaning procedures with extra water rinses to insure removal of chemical cleansers.
May require more extensive equipment tear down and cleaning than is routinely done between runs.

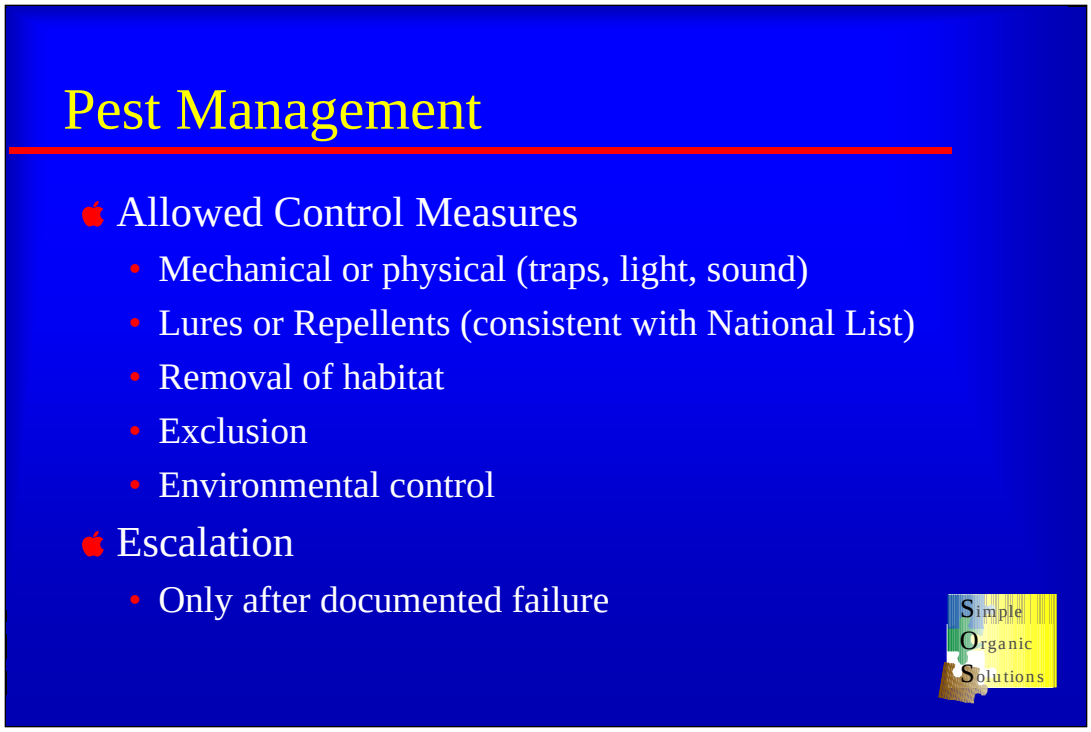
Cleaning:

Make sure there isn't any chance for co-mingling or contamination.
Generally the SOP's of a plant are still applicable to organic processing.
Some changes and awareness of potential contamination points or troublesome to clean areas are needed.

Sanitizing:

Don't quit cleaning, because the organic folks don't like chemicals. Extra rinses and the use of suitable chemicals are acceptable.
Reason for no quaternary ammonium based sanitizers (Quats). They are great sanitizers because they leave a residue and have a good kill spectrum and time. Because they leave a residue and don't rinse off well they are incompatible with organic processing. There may be a few exceptions, but don't rely on exceptions to allow their use-change to a compatible sanitizer.

New regulations may mean changes in allowed cleaners and sanitizers. Check with your certifier.



Pest control is one of the areas that will require the most changes. Not a lot of practical thought went into the regulations. It has always been are area poorly addressed by the industry and the NOP.

Rodent bait: not on the list-can't use it. Vitamin D3 is acceptable if you can find it in block form. How many are using it instead of one of the anti-coagulation types?

Only after failure of allowed control measures can you escalate your treatments. This also implies no preventative measures unless you document that without them, you will (not might!) have a problem. Any government mandated controls are still allowed.

§ 205.271 Facility pest management practice standard.

(a) The handler must use management practices to prevent pests, including but not limited to:
(1) Removal of pest habitat, food sources, and breeding areas;
(2) Prevention of access to handling facilities; and
(3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction.

(b) Pests may be controlled through:
(1) Mechanical or physical controls including but not limited to traps, light, or sound; or
(2) Lures and repellents using nonsynthetic or synthetic (on) the National List.

(c) If the practices … are not effective to prevent or control pests, a nonsynthetic or synthetic substance consistent with the National List may be applied.

(d) If the practices …above… are not effective to prevent or control facility pests, a synthetic substance not on the National List may be applied: Provided, That, the handler and certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.

(e) The handler of an organic handling operation who applies a nonsynthetic or synthetic substance to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.

(f) Notwithstanding the practices provided for in paragraphs (a), (b), (c), and (d) of this section, a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations:

Provided, That, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

Production and Handling

- Organic Handling Requirements
  - Acceptable processes
  - Allowed ingredients
- Processing Aides
  - National list
  - Steam additives
- Commingling
- Contact with Prohibited Substances

Simple Organic Solutions

Definition: Handler: Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

§ 205.270 Organic handling requirements.

(a) Mechanical or biological methods…cooking, freezing, canning, packaging…for the purpose of retarding spoilage or … preparing the agricultural product for market.
…no ionizing radiation
<ingredients discussed later>

(c) The handler … must not use … (1) Practices prohibited…(2) …volatile synthetic solvent or other synthetic processing aid…

Processing aides:
National list requirements
Steam additives: Ammonium Hydroxide – For use as boiler water additive only with removal from the National List October 21, 2005.

Cyclohexylamine, Octadecylamine – For use as a boiler water additive for packaging sterilization only.

Commingling: must not happen. Organic handling plan must specify how you will prevent any contamination.

Contact with Prohibited Substances: Must not occur. This includes packaging, labels, reusable containers, etc. that may be treated, as well as ingredients.

Commingling and Product Integrity

- Process Scheduling
  - OG after cleanup, NOG later
- Changeover procedure
  - Equipment that can't be completely cleaned out
- Plant fumigation/pest management
  - Still must follow GMP, OG rules very restrictive
- Packaging, Storage, Transportation
  - Must insure no contamination

Scheduling:

Do OG after a full plant cleanup if at all possible.

Generally organic runs are small and can be scheduled to run first.

Easier to change from organic to conventional than vise versa.

Changeover:

Continuous running equipment that can't easily be thoroughly cleaned can be accommodated with a suitable (documented) purge.

Pest Management:

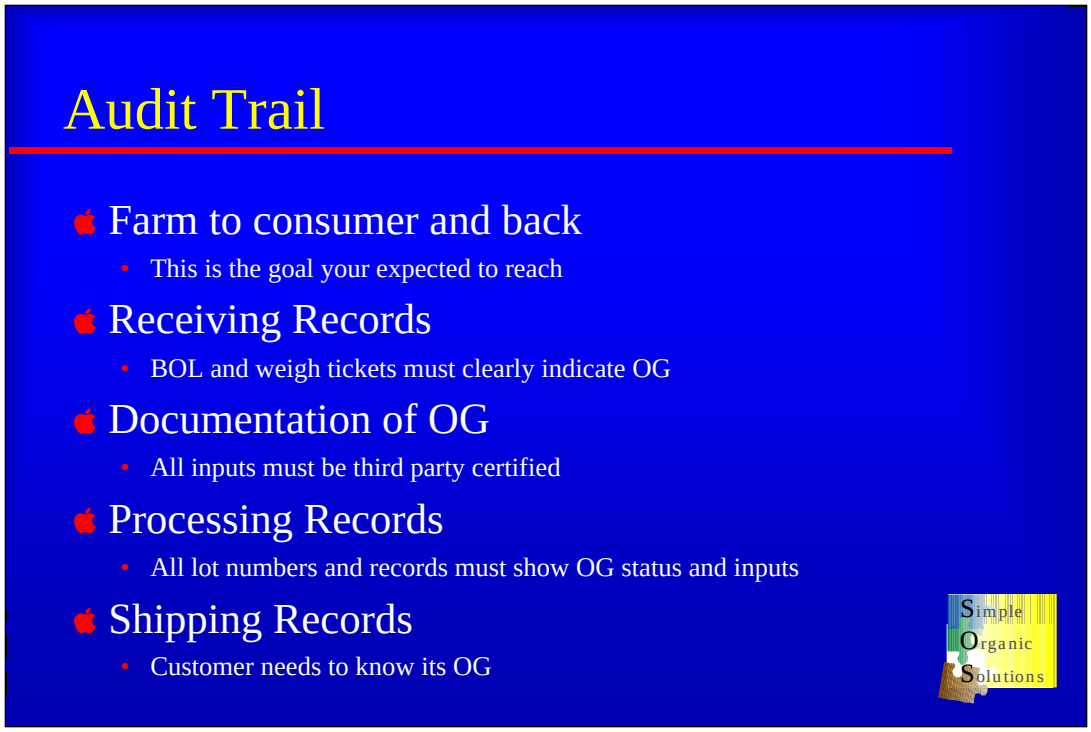
Exclusion and cleanliness are the best prevention.

No warehouse fumigation or fogging while organic product is present.

No warehouse fumigation or fogging of labels, packaging material, containers, etc.

Packaging:

No preservatives allowed in the packaging.



In CA all documents must contain the COFA wording.
“Grown and processed in accordance with the California Organic Foods Act of 1990”

Farm and back:

Requirement is to be able to track all the ingredients from a retail package back to the farm(s) and fields of origin.
Only responsible for the audit integrity from receiving to shipping dock.
Not difficult to do with proper record keeping.

Receiving:

Make sure lot numbers and/or farm and field of origin are clearly marked.

Documentation:

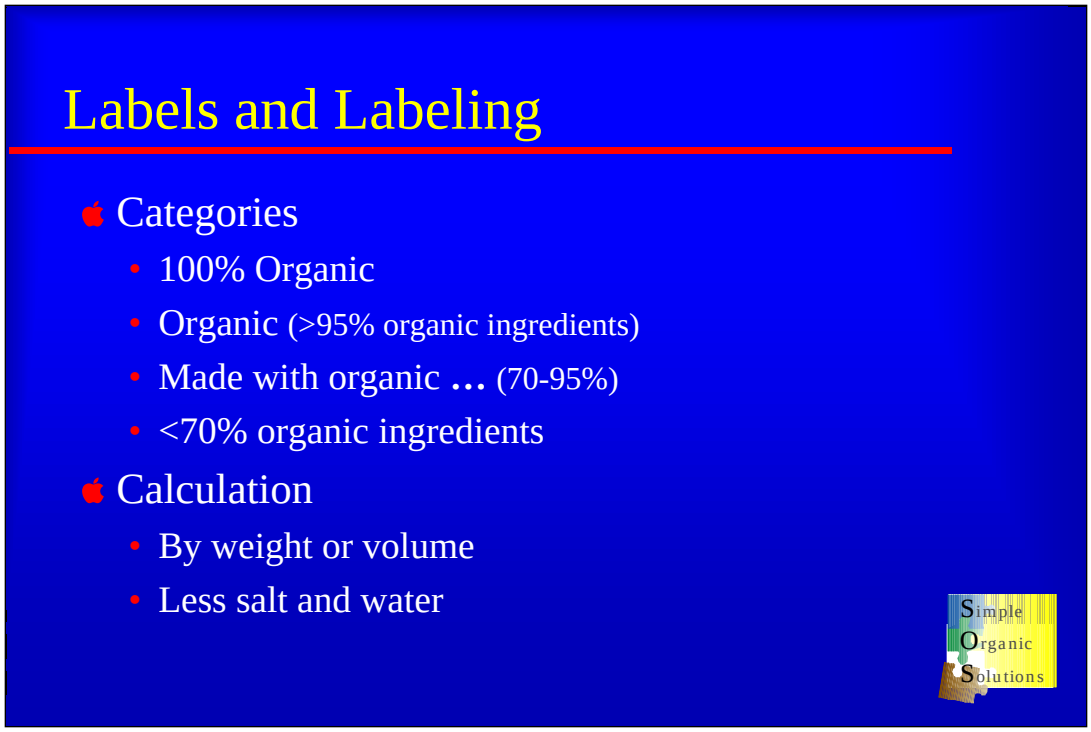
All inputs must be accompanied by valid organic grower or processor certificates.
Processing aids and non-organic ingredients must have appropriate documentation that they are acceptable, and haven’t been subjected to prohibited practices.

Processing records:

Must indicate all inputs to product with lot numbers and amounts.

Shipping records:

Must indicate organic status of shipment, and lot numbers of product.



No health claims can be made. FDA and FSIS labeling regulations still apply.

§ 205.302 Calculating the percentage of organically produced ingredients.

(a) The percentage … must be calculated by:

(1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product.

(2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being **reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations** of the ingredients and finished product.

(3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.

(b) The percentage of all organically produced ingredients in an agricultural product must be **rounded down to the nearest whole number**.

(c) … percentage … determined by the handler who affixes the label on the consumer package and verified by the certifying agent …

Can’t have both an organic form and non-organic form of the same ingredient unless no organic claims are made about that ingredient.

Label Categories & Production Practices

Label	Excluded methods	Substances	Sulfites
100% Organic	No	No	No
Organic			
95% organic	No	Nat'l List	No
5% non-organic	No	Nat'l List	No
Made with Organic			
70-95% organic	No	Nat'l List	Wine
5-30% non-organic	No	Anything	Yes
< 70% Organic			
<70% organic	No	Nat'l List	Wine
>30% non-organic	Allowed	Anything	Yes

This is a simplified form of Table 1, page 80578 of the Federal Register listing. See the real table for all the details.

This table shows the label categories and what is acceptable in each of them.

In "Organic" products (what about "Made with Organic …" products?), if an ingredient is available in organic form, it must be used. This brings up the concept of commercial availability. Must the organic form be used regardless of price or quality? There has been much discussion of what this means. No final definition at this point.

Excluded methods include GMO's, sewage sludge, and ionizing radiation.

Incidental contamination by GMO's is another hotly debated topic. No decision has been made at this point, as some compromise between practical and ideal will have to be reached. The genie is out of the bottle and zero contamination is an unreachable level at this point. This debate is similar to that which has been applied to incidental or unavoidable pesticide or herbicide contamination. These are currently set at 5% of the FDA action level.

Substances used as ingredients or processing aids must be on the National List.

Use of statement "organic when available" is not allowed at all.

Use of both an organic and non-organic form of an ingredient is not allowed if any organic claim is made about that ingredient. That ingredient also can't be used in calculating the organic %.

Labeling Product Packages

Label	Principal Display Panel	Information Panel	Ingredient statement
100% Organic	100% Organic USDA & Certifier seal	Certifying agent 100% organic	Organic A, Organic B
Organic	Organic '*name*' % organic USDA & Certifier seal	Certifying agent % organic	Organic A, Organic B, C, D
Made with Organic …	Made with organic '*name*' % organic Certifier seal No USDA seal	Certifying agent % organic No USDA seal	Organic A, Organic B, C, D
< 70% Organic	No organic claim No USDA seal No Certifier seal	% organic No USDA seal No Certifier seal	Organic A, B, C, Organic D

Optional Required

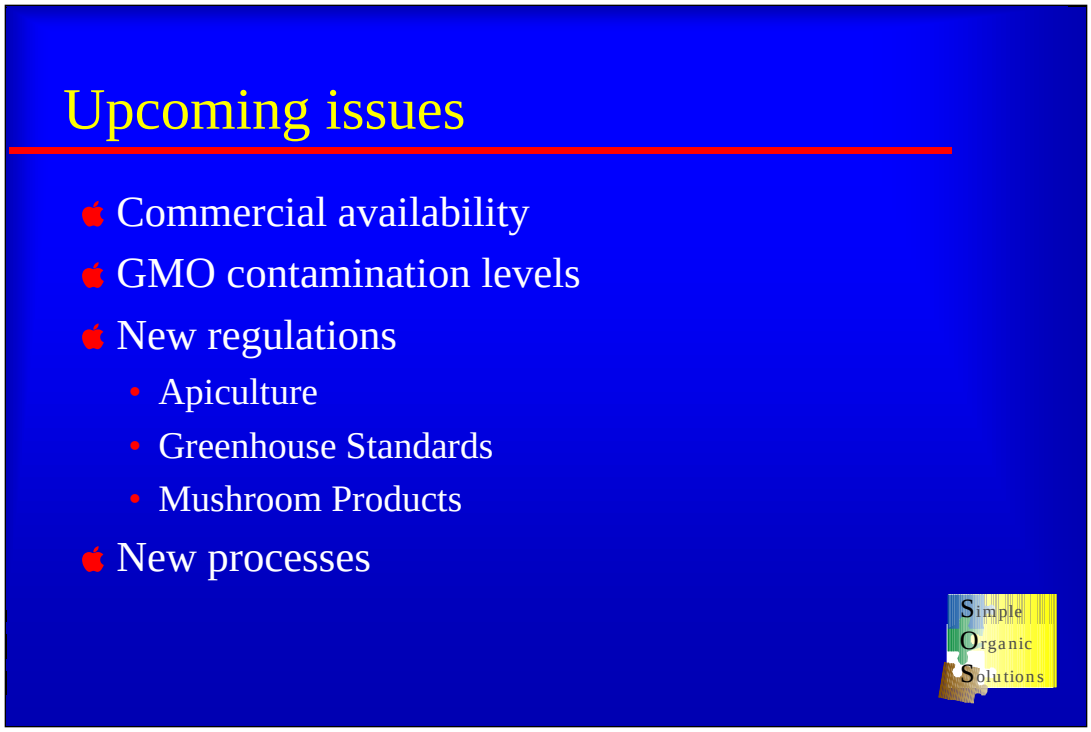
Simple Organic Solutions

This is a simplified form of Table 2, page 80580 of the Federal Register listing. See the real table for all the details.

Yellow items are optional. Red items are either required, or prohibited as noted.

End of talk

- This was where time ran out at NWFPA. The remainder of the slides are included here for your reference



Commercial availability:

What criteria will be used to determine if a product is commercially available? If price point set too low, no incentive to enter the marketplace. If too high, goods may be priced too high for consumer acceptance.

GMO contamination:

Can't avoid it, but at what level do you accept it. If an organic corn silo is found to have a detectable level of GMO (sensitive test will pick up very low levels) does it loose it's organic integrity or is .01%, .1% or 1% acceptable?

National Organic Standards do not currently exist for apiculture, greenhouse, or mushroom production. Until USDA publishes National Organic Standards for such production methods, producers using such methods may continue to produce and label their products as organic, under the following conditions:

Production/Handling-Apiculture, Greenhouse, Mushroom

1.The production or handling operation, … must be certified by a USDA- accredited certifying agent.

2.The production … must comply with the apiculture, greenhouse, or mushroom standards of the USDA-accredited certifying agent.

3.Seedlings produced in a greenhouse in compliance … may be used as transplants in an outdoor crop production system …

4.The products of such production methods shall **not display the USDA seal**.

5.… **must display the certifying agent's seal** or other identifying mark.

6.… not be used in multi-ingredient products labeled "100 percent organic.

7.… identified as organic in multi-ingredient products labeled as "organic" provided the finished product contains at least 95 percent of ingredients certified to the National Organic Standards. … **the products … shall not be used to qualify a multi-ingredient product for labeling as "organic."**

Multi-ingredient products qualified under the National Organic Standards to be labeled as "organic" that also contain ingredients from apiculture, greenhouse, or mushroom production may display the USDA seal.

8.… identified as organic in multi-ingredient products labeled as "made with organic" provided the finished product contains at least 70 percent of ingredients certified to the National Organic Standards. … **the products … shall not be used to qualify a multi-ingredient product for labeling as "made with organic."**

Guidelines for determining what processing technologies shall be reviewed by the NOSB

1) Processes that are mechanical or biological are allowed …. Any process that does not cause a change in the food, … would not need to be reviewed.

2) Processes … intended to make or break covalent chemical bonds are subject to review by the NOSB before being allowed in the processing of organic food products. (Ex. **Chemical carbohydrate conversions processes**)

3) Processes in which (introduce non-NL items) are subject to review by the NOSB before being allowed …. The materials not allowed in §205.605 that are introduced into the food would also need to be petitioned. (Ex. **Hydrogenation of oil**)

4) Processes in which specific chemical components of the food are selectively and purposely removed during the process via a chemical process vs. a mechanical process are subject to review by the NOSB before being allowed in the processing of organic food products. (Ex. **Ion Exchange**)

5) Any other process not covered by the above listed guidelines shall be submitted for review. (Ex. **UV light**)

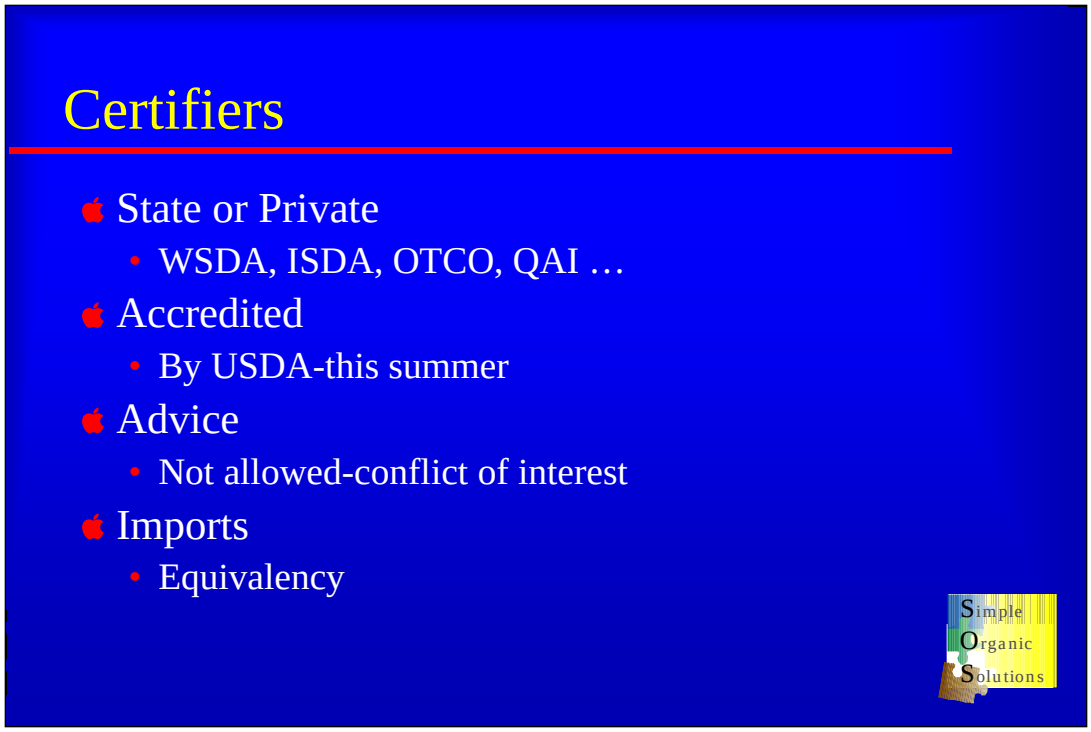
Who: Private: Oregon Tilth, CCOF, FVO, OCIA, QAI, OGBA, others
State: Washington, Idaho, Texas, Colorado, New Mexico…
International:

What: Definition of Certifying Agent
An independent public or private organization that uses on-site inspections and document review to verify that farmers, handlers, and processors are producing and handling food in accordance with applicable state, federal, and private organic standards.
These will be the organizations actually going into the plants to do the certifications and insure compliance with the bill.

When: OFPA originally published in 1990
NOP first in March 2000
Final rule Dec 2000
Takes effect April 2001 with 18 month to fully comply (October 2002)

Why: **Anyone making organic claims will have to be third party certified.**

Cost estimates:	small farm	med farm	large farm
OTCO-in	608	1603	2517
OTCO-out	768	1698	2852
WSDA	480	1555	3040



State can set higher standards, but private can't. State program would have to be approved by USDA. Only applies to product produced in that state. Can't be used as a trade barrier.

Accreditations will be announced by USDA ≈1 year from implementation for first group of certifiers that apply. Should be announced this summer.

If certifier is accredited, processors will be considered in compliance until the processors next renewal date.

Consulting or advice by certifier: specifically prohibited. Potential for conflict of interest. Don't know whether that extends to the inspector,but it probably does.

Inspectors are the eyes and ears of the certifying agents. They may be independent contractors or staff.

Can't force use of certifier (or USDA) label.

Importation requires that USDA recognize the foreign certifier as meeting the same standards as domestic production.

Legislative changes in WSDA program won't occur until '02.

Oregon wants input about what to do. Write to ODA.

Last session Senate Bill 312 failed to go anywhere due to lack of industry support. This would have added a license fee (the sticking point) and 2 people to enforce the law at the state level. Since you are all the honest ones, you stand to loose by not having the state involved. If someone acts fraudulently, there will be no one to turn to short of the Feds. Small price to pay for keeping the industry honest and the unscrupulous operators off the shelves.

Inspection Process

- Who to contact
  - Listed at end of presentation
- How to prepare
  - Before applying-Organic Handling Plan
  - Before the inspection
- What to expect
  - Inspector activities
  - Advice
  - Spot inspections

Simple Organic Solutions

Preparations:

Organic handling plan: this is the master document that needs to be prepared early to determine what all else is needed. Certifier and inspector are no longer allowed to offer advice about how to comply.

Forms from the certifier. Water reports, State (Federal) inspection reports, certified fruit sources, MSDS on cleaners, sanitizers, boiler chemicals.

What to expect:

Outline of inspection process. Inspector is the eyes and ears of the certification agency. It is the certifier that has the final say in what is necessary to get certified.

Plant walk through, following product from receiving , to warehousing, staging, processing, packaging and final warehousing.

Paper trail of all of the above

Receiving records, organic certificates, BOL's, processing records, batch numbering, lot numbering, etc. and finally shipping records. Mock product recall to insure paper trail is intact. Product audit: full pounds in/ pounds out for an item or two.

Other items:

Sanitation chemicals and cleaning logs; pest management chemicals and logs.

Spot Inspections:

Certifiers reserve the right and are being required by ISO regulations to perform unannounced spot inspections occasionally. They just started doing these in 2000. OTCO will do about 10% unannounced plant inspections per year.

Contacts

- USDA
  - http://www.ams.usda.gov/nop/index.htm
- Oregon Department of Agriculture
  - Ron McKay 503-986-4720
- Washington State Department of Agriculture
  - Miles McEvoy 360-902-1924
- Oregon Tilth
  - 503-378-0690
- Simple Organic Solutions
  - Bob Durst 541-740-6490

Richard Mathews
Acting Program Manager
USDA-AMS-TM-NOP
Room 2510-South Building
1400 and Independence Avenue, SW
Washington, DC 20250-0020
202-720-3252

Oregon Department of Agriculture
635 Capitol St. N. E.
Salem, OR 97301
Ron McKay
503-986-4720

Oregon Tilth
1860 Hawthorne NE Suite 200
Salem, OR 97303
503-378-0690

Washington State Department of Agriculture
Organic Food Program
PO Box 42560
Olympia, WA 98504-2560
Miles McEvoy
360-902-1877

Idaho State Department of Agriculture
P. O. Box 790
Boise, ID 87301-0790
Margaret Messner
208-332-8620

QAI
12526 High Bluff Dr. Suite 300
San Diego, CA 92130
858-792-3531