Voluntary Labeling
Claims and Special Statements

Organic, Animal Production, Processing/Pathogen Reduction, "Fresh," and Other Claims on Labeling

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Labeling and Consumer Protection Staff
Food Safety and Inspection Service (FSIS), USDA

http://www.fsis.usda.gov/oppde/larc/

FSIS: 60,000 label sketches evaluated in 2001 – mostly complex labels bearing claims

Meat and Poultry Labeling Requirements
FMIA - 21 U.S.C. 601 et seq.
PPIA – 21 U.S.C. 451 et seq.

- A label is "a display of written, printed, or graphic matter upon the immediate container of any article."

- Labeling is "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

Labeling Compliance and Enforcement Matrix: Provided by Acts/Regulations/Policies/Guidelines

- Inspectors in official establishments
- Compliance Officers/Consumer Safety Officers in field and in distribution chain
- Inspectors at ports of entry for imports
- LCPS, Office of Policy, at headquarters
  - **develops labeling policy**
  - **conducts Prior Label Approval System**
  - **makes decisions on misbranding (and adulteration) situations -- labels rescinded**

Any carcass, meat, or meat product, or poultry product is "misbranded" if:

- labeling is false or misleading in any particular
- offered for sale under the name of another food
- an imitation of another food without proper labeling
- container is made, formed, or filled so as to be misleading
- package or other container does not bear required features, e.g., name/address of manufacturer/distributor/packer and quantity of contents
- required information is not prominent/conspicuous
- represented as a food with a Standard of Identity unless it conforms to the standard

Any carcass, meat, or meat product, or poultry product is "misbranded" if:

- falsely represented in labeling as food with a standard of fill
- not named by a common or usual name, if one exists, and does not bear common or usual names of ingredients on labeling
- represented in labeling as a food for special dietary use, unless the product conforms to FDA rules
- bears or contains artificial flavoring or coloring, or preservatives, that are not disclosed on labeling, if permitted
- fails to bear an inspection legend, handling statement, or other features established as necessary

FMIA - 21 U.S.C. 607 (d) *PPIA – 21 U.S.C. 458(b)*

Prior Labeling Approval Authority

Distinct Regulatory Approach for Labeling is Set by Law

- **Acts require food manufacturers to obtain prior approval for labels of meat and poultry products before products may be marketed**
- **"No article subject to this [Act] shall be sold or offered for sale …. But established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted."**
- **USDA interprets statutory language as mandating pre-approval of all food labels before products may be offered for sale**
- **Prior label approval (coupled with continuous inspection) has broad ramifications in terms of public policy and regulatory enforcement**

Responsibility for USDA's Pre-Market Label Approval Process Rests with FSIS [9 CFR 317.4 (Meat)/381.132 (Poultry)]

- **USDA has established requirements for the content and design of labels [9 CFR 317 *et seq.* (meat) and 381.115 *et seq.* (poultry)]**
- **Requirements are based on the statutory mandate to assure that labels are truthful, accurate, and not misleading, and that products are not misbranded**
- **Required labeling features in regulations are linked to misbranding provisions of Acts**
- **Policy Memos/Food Standards and Labeling Policy Book = interpretations of the Acts and regulatory requirements**

Generic Labeling Approval
[9 CFR 317.5 (Meat)/381.133 (Poultry)]

FSIS Prior Label Approval System has evolved over time

- **Effective July 1996, FSIS required only approval of sketch labeling and temporary approvals; plants must maintain labeling records**

- **Final Rule expanded the types of labels that can be applied to products without sending them to the Agency --- provided that they are in conformance with Acts, regulations, and policies (i.e., "generic approvals")**

- **Labels that can be generically approved include:**
  - **> products with standards of identity and that do not bear special claims or statements, guarantees, or foreign language**
  - **> single ingredient products without claims, etc.**
  - **> products with contract specifications for Federal government**
  - **> shipping containers; inspection legends**
  - **> prior approved sketch labeling with generic modifications**

Company Responsibilities - Label Approval

- Create a record of final labeling when minor changes occur, e.g, changes to net weight, vignette, serving instructions, etc.
- Create a record of final labeling for any other labeling, e.g., shipping containers, animal food, legends, inserts, etc.
- Maintain labeling records
  - Final labeling
  - Temporary approvals

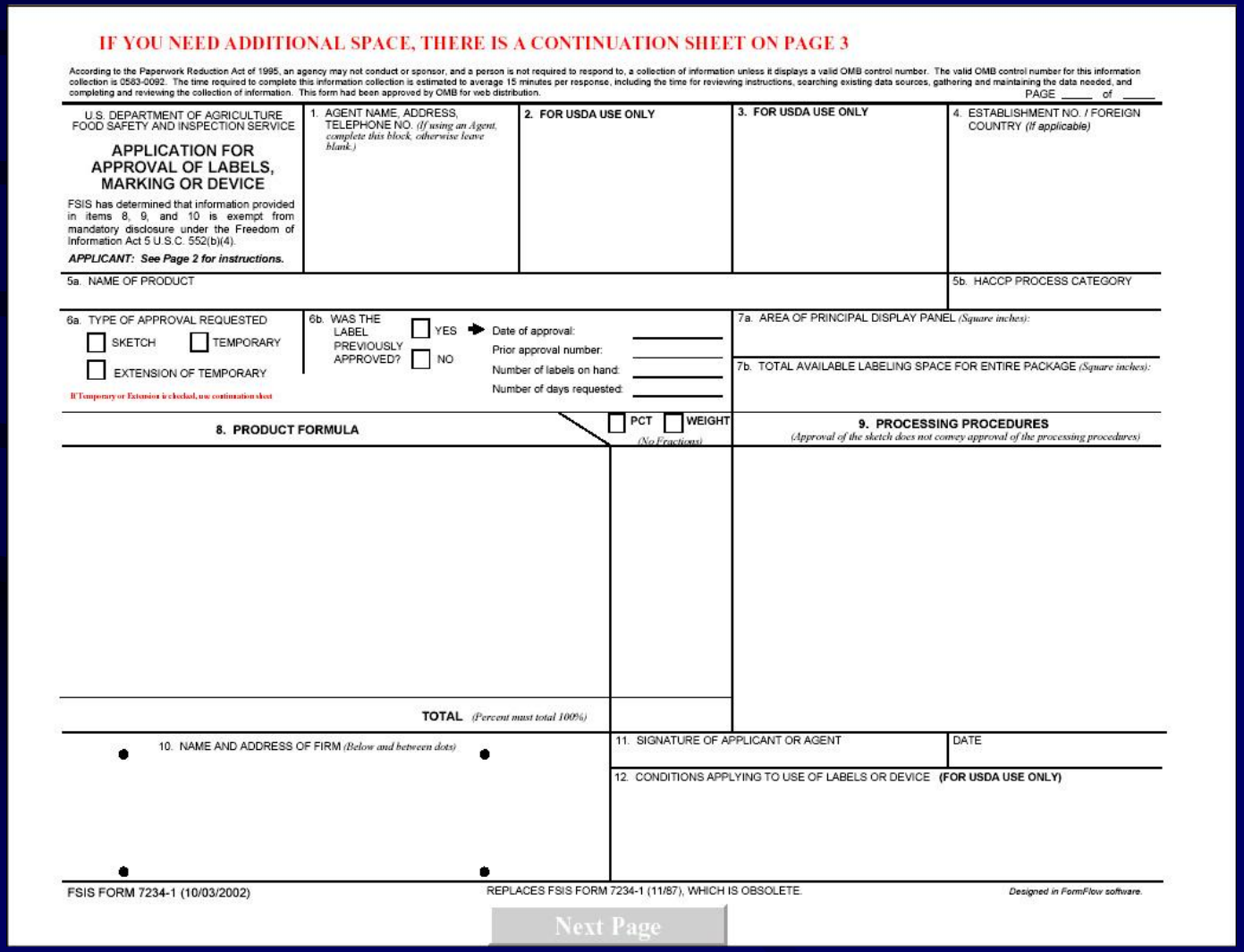
Procedures for FSIS Prior Label Approval System (PLAS)

- Procedures for label evaluation and approval - not codified in 9 CFR
- Process of label evaluation provided in FSIS Notices/Policy Guidance/Website
- Meat/poultry product manufacturers must examine and learn the statutory, regulatory, policy, and procedural requirements for labeling to be able to ship product in commerce that bears USDA mark of inspection

Types of Products for Which Sketch Labels Must Be Submitted to FSIS for Evaluation/Approval

- Non-standardized products (products without standards in the regulations or Food Standards and Labeling Policy Book)
- Non-amenable products
  - Products produced under Voluntary Inspection Service for exotic and other animals, e.g., venison, pheasant
  - Products under voluntary Food Inspection Service, e.g., cheese sandwiches
  - Certified pet foods
- Multi-ingredient standardized products with labels bearing claims, guarantees, or foreign language

Label Submission Checklist √
USDA/FSIS Label Submission Form 7234-1



IF YOU NEED ADDITIONAL SPACE, THERE IS A CONTINUATION SHEET ON PAGE 3

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0583-0092. The time required to complete this information collection is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This form had been approved by OMB for web distribution.

PAGE ____ of ____

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

APPLICATION FOR APPROVAL OF LABELS, MARKING OR DEVICE

FSIS has determined that information provided in items 8, 9, and 10 is exempt from mandatory disclosure under the Freedom of Information Act 5 U.S.C. 552(b)(4).

APPLICANT: See Page 2 for instructions.

1. AGENT NAME, ADDRESS, TELEPHONE NO. *(If using an Agent, complete this block, otherwise leave blank.)*

2. **FOR USDA USE ONLY**

3. **FOR USDA USE ONLY**

4. ESTABLISHMENT NO. / FOREIGN COUNTRY *(If applicable)*

5a. NAME OF PRODUCT

5b. HACCP PROCESS CATEGORY

6a. TYPE OF APPROVAL REQUESTED
☐ SKETCH ☐ TEMPORARY
☐ EXTENSION OF TEMPORARY
If Temporary or Extension is checked, use continuation sheet

6b. WAS THE LABEL PREVIOUSLY APPROVED? ☐ YES ☐ NO
Date of approval:
Prior approval number:
Number of labels on hand:
Number of days requested:

7a. AREA OF PRINCIPAL DISPLAY PANEL *(Square inches):*

7b. TOTAL AVAILABLE LABELING SPACE FOR ENTIRE PACKAGE *(Square inches):*

8. **PRODUCT FORMULA** ☐ PCT ☐ WEIGHT *(No Fractions)*

9. **PROCESSING PROCEDURES**
(Approval of the sketch does not convey approval of the processing procedures)

TOTAL *(Percent must total 100%)*

10. NAME AND ADDRESS OF FIRM *(Below and between dots)*

11. SIGNATURE OF APPLICANT OR AGENT

DATE

12. CONDITIONS APPLYING TO USE OF LABELS OR DEVICE **(FOR USDA USE ONLY)**

FSIS FORM 7234-1 (10/03/2002)

REPLACES FSIS FORM 7234-1 (11/87), WHICH IS OBSOLETE.

Designed in FormFlow software.

Next Page

Required Information on a Label (9 CFR 317.2/381 Subpart N)

Up to 8 required features

- Product name
- Handling statement
- Inspection legend (including Est./Plant number)
- Net weight statement
- Ingredients statement
- Signature Line (Address line)
- Nutrition facts
- Safe handling instructions

Certain features must be in particular locations

9 CFR 317.17 (Uncured Product)

Process Verified


INSIDE
COOKING GUIDE
The Keppy Family, Durant, IA
One of the many American Farm
Families of Farmland.
Farmland.
Good Food from the Heartland™
ALL NATURAL*
Fresh Pork
U.S. Source Verified
No Added Hormones**
No Antibiotic Growth Promotants***
*No Artificial Ingredients
*Minimally Processed
**Federal regulations prohibit the use of hormones in pork.
***Verified by Quality Foods Consulting
See back of label for details about claims
Farmland Foods, Inc., Dist. Kansas City, MO 64195
USDA
PROCESS
VERIFIED
KEEP REFRIGERATED
SERVING SUGGESTION


Prairie Grove Farms®
PRODUCT OF U.S.A.
100% Natural* Pork
*NO Artificial Ingredients. Minimally Processed
PORK LOIN BACK RIBS
No Antibiotics Or Artificial Growth Stimulants Used...Ever
NO WATER OR PHOSPHATES ADDED
KEEP REFRIGERATED
USDA PROCESS VERIFIED
**Program Claims on the Back of this Package
U.S.

FSIS Promotes and Strictly Enforces Product Standards of Identity

Food Standards Guide Labeling

- Examples:
  - Ham; Ham with Natural Juices; Ham Water Added; Ham and Water Product
  - Hot Dogs/Frankfurters: maximum 40% fat and water
  - Ground Beef: May contain no more than 30% fat and **only** non-fluid seasonings and true spices
  - Veal Cutlet: Single slice of veal from the round

New Standard of Identity for a Hot Dog?

Claims and Special Statements

Implications for manufacturers:

- ☺ **Prior Labeling Approval System means decisions about truthfulness and that label is not-misleading are made before products can be marketed**
- ☺ **USDA mark of inspection = conveys that everything about the label is truthful and not misleading, and that product was produced safely, and contains only safe and suitable ingredients**

Labeling Terms: “Fresh” on Poultry (9 CFR 381.129); “Fresh” on Meat (9 CFR 317.8(b)(6)

- May not be used to designate a product that contains sodium/potassium nitrate/nitrite or has a brine concentration of 10% or more
- May not be used to describe poultry carcasses or parts when the internal temperature has ever been below 26° F
- May not be used on labels of cured or salted meat products

Labeling Terms: Geographic Claims (9 CFR 317.8 (b)(1))

- Terms with geographic reference other than that in which prepared need qualification: “style,” “type,” “brand”
- “Farm” or “country” should not be used on labels if the products are not prepared in the farm or country
- Sausage containing cereal should not be labeled “farm style” or “country style”

Country of Origin Required on Principal Display Panel for Imports

("Product of USA" for Exports)

Ingredients: pork, water, salt, sodium phosphate, sodium nitrite

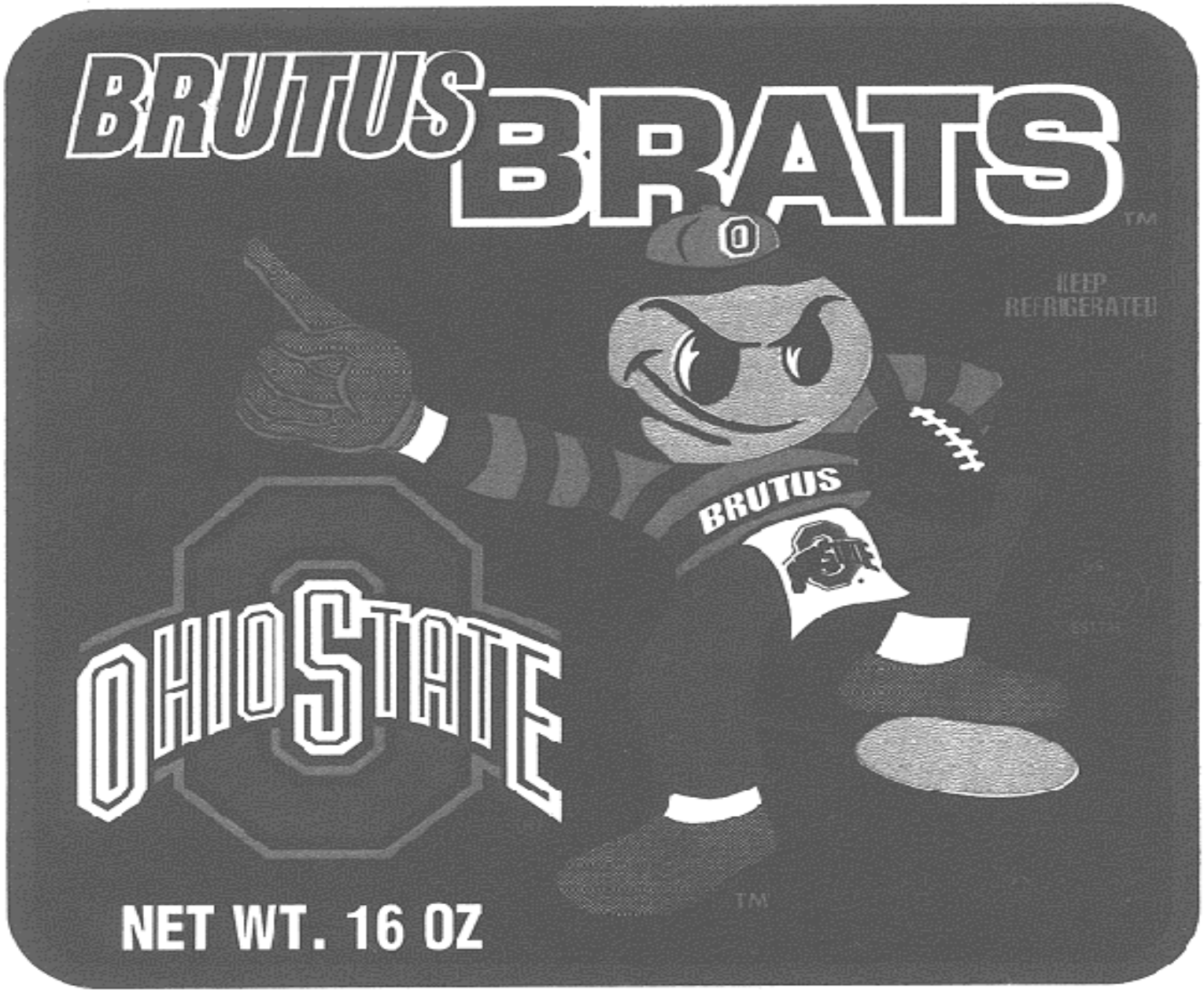
Distributed by Ace Food Products, New York, New York 06543

Denmark
9236

DeVorck's Finest Canned Ham, Sliced

Product of Denmark

NET WT. 16 OZ. (1 LB.)/454g


BRUTUS BRATS
KEEP REFRIGERATED
BRUTUS
OHIO STATE
NET WT. 16 OZ

BRUTUS™ BRATWURST

SAFE HANDLING INSTRUCTIONS

This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if this product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

Keep refrigerated or frozen. Thaw in refrigerator or microwave.

Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat.

Cook thoroughly.

Keep hot foods hot. Refrigerate leftovers immediately or discard.

Nutrition Facts

Serving Size 1 Link Pan Fried (68g)
Servings Per Container 5

Amount Per Serving		
Calories 220	Calories from Fat 160	
		% Daily Value*
Total Fat 18g		**27%**
Saturated Fat 7g		**34%**
Cholesterol 20mg		**7%**
Sodium 80mg		**3%**
Total Carbohydrate 1g		**0%**
Dietary Fiber 1g		**2%**
Sugars 0g		
Protein 13g		
Vitamin A 0% • Vitamin C 0%		
Calcium 2% • Iron 8%		

*Percent Daily Values are based on a 2,000 calorie diet.

INGREDIENTS: PORK, WATER, SALT, NATURAL FLAVORINGS, DEHYDRATED ONIONS, DEXTROSE, MONOSODIUM GLUTAMATE.

COOKING SUGGESTIONS: SIMMER LINKS IN WATER (1/4 CUP PER POUND) FOR 15 TO 20 MINUTES OR MICROWAVE 3 TO 5 MINUTES. BROWN ON ALL SIDES IN SKILLET, ON GRILL, OR UNDER BROILER. COOK UNTIL MEAT IS NO LONGER PINK.

COLLEGIATE LICENSED PRODUCT

0 73593 01787 8

OHIO PACKING COMPANY
COLUMBUS, OH 43219

Ready-To Eat (RTE) Meat and Poultry Products

- **9 CFR Part 430**
- **Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products Final Rule (June 6, 2003) (68 *FR* 34208)**
- **Post-lethality controls required, e.g., use of antimicrobial agents/processes/sanitation procedures**
- **Claims and special statements may be made on labeling, e.g., "Contains sodium diacetate and sodium lactate to prevent the growth of Listeria monocytogenes"**

Labeling - Not Ready to Eat Products

- A product containing a meat or poultry component that has received a lethality treatment for pathogens
- Can also include dry cured products, e.g., country ham
- Also contains non-meat/poultry component in need of a lethality treatment
- Includes meals, dinners and frozen entrees
- Cooking and preparation instructions on the product are sufficient to destroy pathogens

Labeling - Not Ready to Eat Products

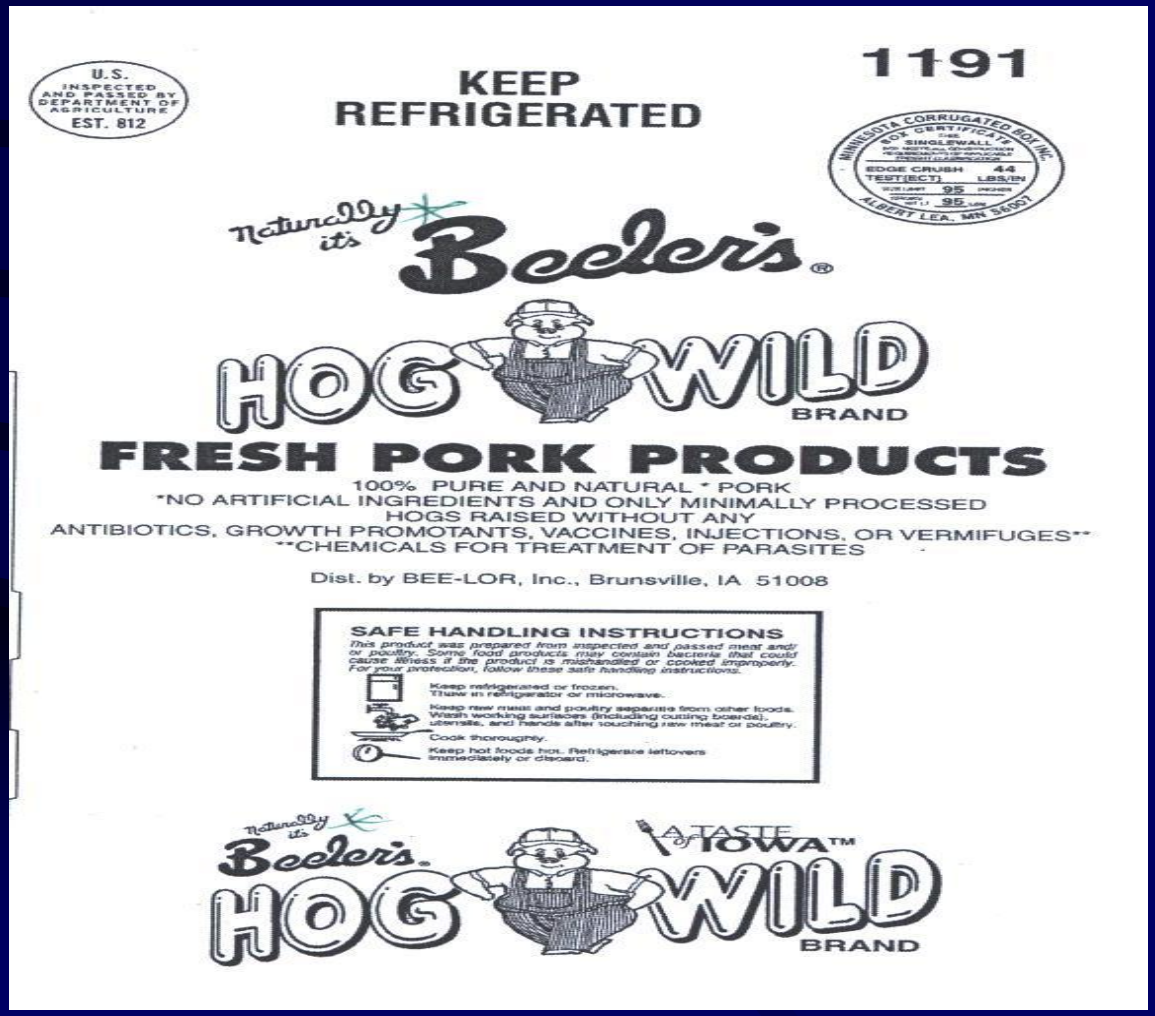
- Terms required on principal display panel displayed in a prominent manner in product name, in a starburst or elsewhere on principal display panel
  - Uncooked
  - Ready to cook
  - Cook before eating
  - Cook and serve
  - Needs to be fully cooked
- Safe handling instructions are recommended

Product Labeled "Natural"

Processing-related meaning (FSIS Policy Memo 055):

- Contains no artificial ingredients
- Is only minimally processed
  - Fresh meat and poultry automatically qualify
- Negative labeling *vis a vis* livestock and poultry raised without antibiotics/hormones
  - Approval relies upon testimonials and affidavits provided by producer

All Natural Product (PM 55)



Niman Ranch
Jambon Label Front - Part # F1010-1
09.20.04
Niman Ranch Contact: Judy Wu, judyw@nimanranch.com, 510-500-1624

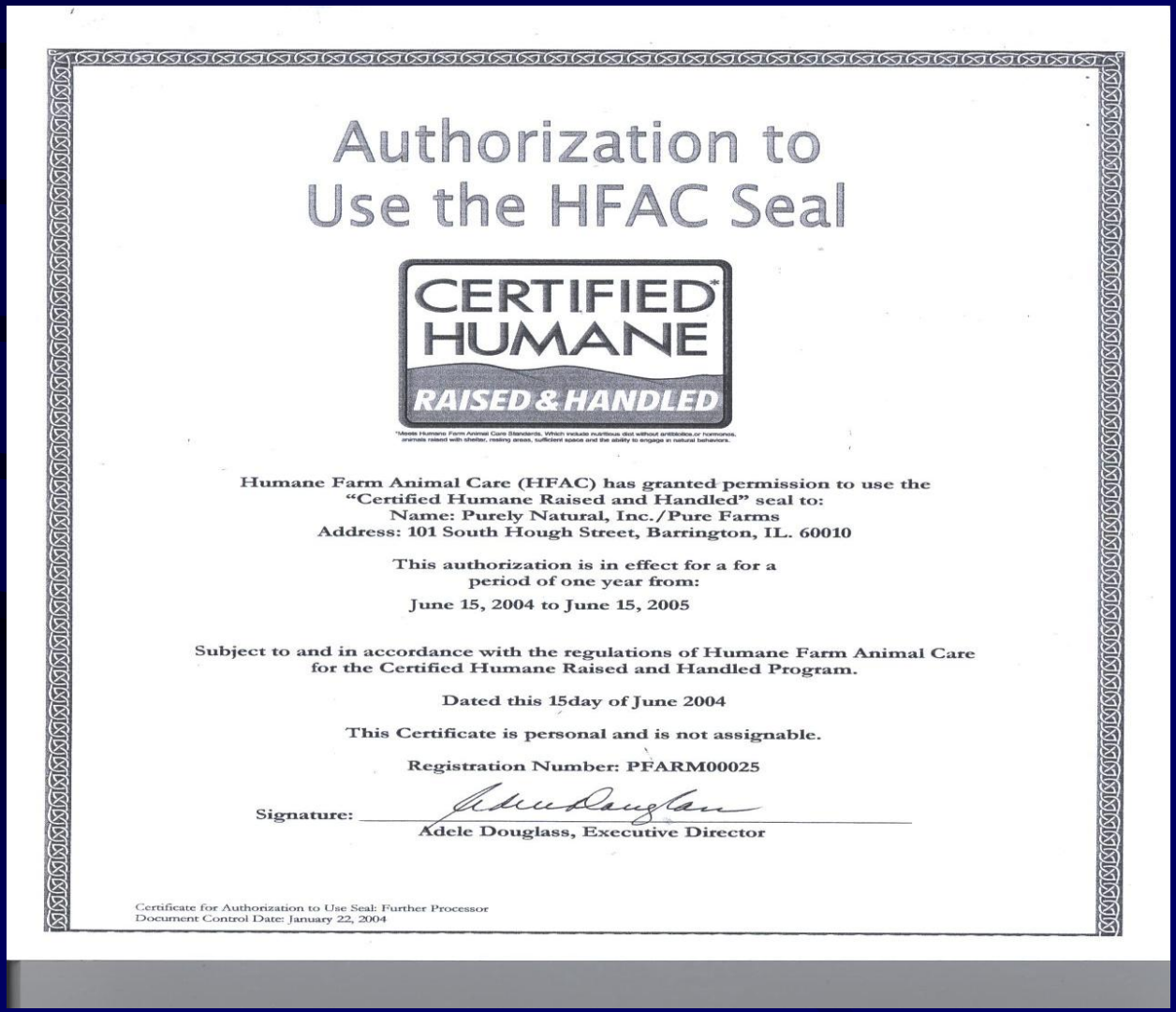
Red = 485c

Beige = 4525c

Blue = 2755c

Green = 350c

Certified Humane (fee for service)



Authorization to Use the HFAC Seal

CERTIFIED HUMANE
RAISED & HANDLED

*Meets Humane Farm Animal Care Standards. Which include nutritious diet without antibiotics or hormones, animals raised with shelter, resting areas, sufficient space and the ability to engage in natural behaviors.

Humane Farm Animal Care (HFAC) has granted permission to use the "Certified Humane Raised and Handled" seal to:
Name: Purely Natural, Inc./Pure Farms
Address: 101 South Hough Street, Barrington, IL. 60010

This authorization is in effect for a for a period of one year from:
June 15, 2004 to June 15, 2005

Subject to and in accordance with the regulations of Humane Farm Animal Care for the Certified Humane Raised and Handled Program.

Dated this 15day of June 2004

This Certificate is personal and is not assignable.

Registration Number: PFARM00025

Signature: _____
Adele Douglass, Executive Director

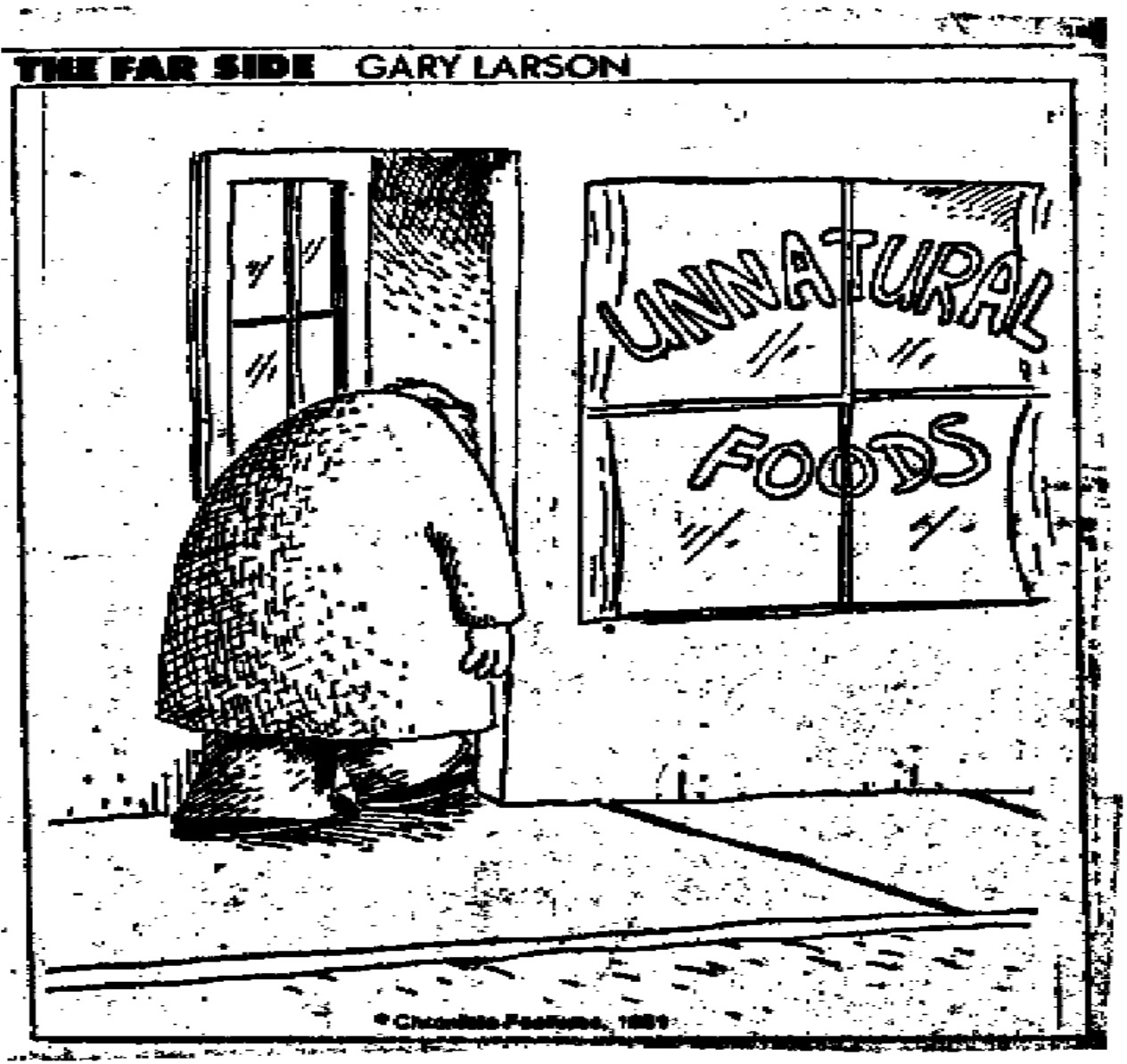
Certificate for Authorization to Use Seal: Further Processor
Document Control Date: January 22, 2004


FREE FARMED
AMERICAN HUMANE
ASSOCIATION
MONITORED™

Certified Humane, Free Farm

AMERICAN HUMANE ASSOCIATION

MONITORED

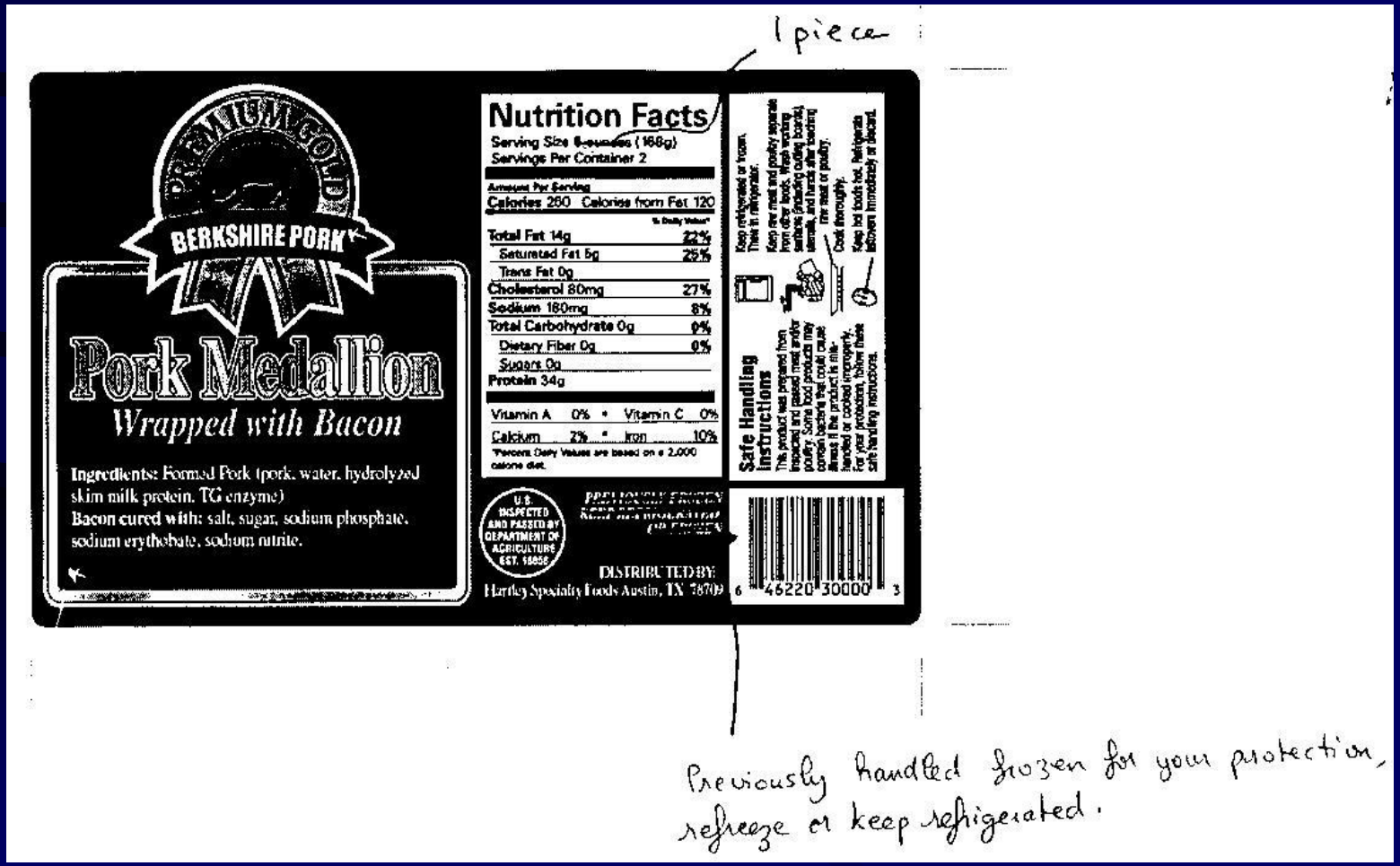

THE FAR SIDE GARY LARSON
UNNATURAL
FOODS

Animal Raising/Production/ Processing Technology Claims

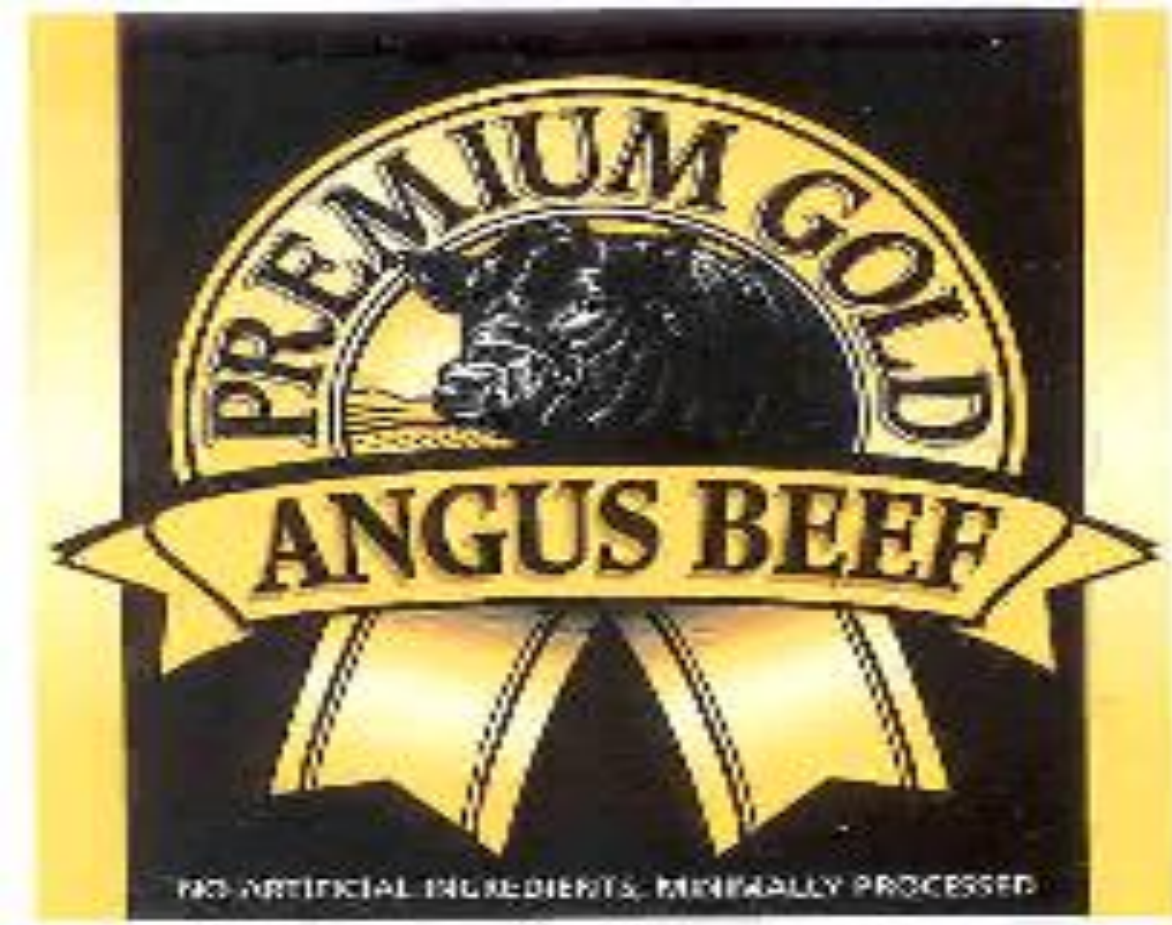
- No Hormones Added
- No Antibiotics Administered
- Free-Range/Free Roaming/Meadow Raised
- Natural
- Humanely Raised (e.g., cage-free)/Humanely Slaughtered
- Breed (e.g., Certified Angus)
- Process Verified


COUNTY FAIR
THEY LOOK WEIRDER EVERY SUMMER! WHO KNOWS WHAT CRAZY CHEMICALS THEY'RE BEING RAISED ON!

Breed Claim (Pork)



Breed Claim


PREMIUM GOLD
ANGUS BEEF
NO ARTIFICIAL INGREDIENTS. MINIMALLY PROCESSED
BLUE RIBBON

Agricultural Marketing Service (AMS) Regulations

AMS serves, in part, to promote the marketing of meat and poultry products

Market-driven rules/programs:

- **National Organic Program (organic certification)**
- **Commodity Quality Grading (Meat, Poultry, Eggs, Dairy and other products)**
- **Certification/Verified Production Controls**
- **Country of Origin Labeling at Retail (2002 Farm Bill)**

NO COPY AREA

NO COPY AREA

NO COPY AREA

NO COPY AREA

California Grown Fresh

Family Owned Since 1939

Foster Farms

15 Piece
5 Wings, 5 Drumsticks
& 5 Thighs

100% NATURAL* CHICKEN • 99% FAT FREE

USDA A GRADE

NO COPY AREA

Organic Foods Production Act of 1990

- Required USDA to develop national standards for organically produced agricultural products
  - to assure consumers such products meet consistent standards
  - to facilitate commerce in organically produced fresh and processed food

"Organic" Regulations

- Proposed rule published December 1997
- Established criteria for the organic products of agricultural commodities including meat and poultry
- Over 200,000 comments received -- irradiation/biotech/sludge were big issues
- Re-proposed in March 13, 2000
- Final Rule December 21, 2000 (65 FR 80548)

-- Effective February 21, 2001 (April 21, 2001)

-- Effective implementation April 20, 2002 - October 21, 2002

Overview of the Organic Rules

OFPA 1990/National Organic Program (AMS)

→ NOSB

- Organic production and handling
- Labeling and marketing
  information/compliance/testing/fees
- Certification/recordkeeping/accreditation
- State organic programs


Shelton's
Organic
CHICKEN PIE
100% ORGANIC INGREDIENTS
Certified Organic Chicken Meat Blended With
Organic Vegetables & Creamy Gravy,
Topped With Organic Whole-Wheat Flour Crust
INSPECTED U.S.
NET WEIGHT 9 OZ (255 g)
KEEP FROZEN

Sheltons Organic CHICKEN PIE

100% ORGANIC INGREDIENTS

Nutrition Facts

Serving Size 1 pie (255 g)
Servings Per Container 1

Amount Per Serving	
Calories 0	Calories From Fat 0
	% Daily Value*
Total Fat 0 g	0%
Saturated Fat 0 g	0%
Cholesterol 0 mg	0%
Sodium 0 mg	0%
Total Carbohydrate 0 g	0%
Dietary Fiber 0 g	
Sugars 0 g	
Protein 0 g	

FPO

Not a significant source of dietary fiber, sugar, vitamin A, vitamin C, calcium and iron.

*Percent Daily Values are based on a 2000 calorie diet.

We at Sheltons have been making chicken pies for over 30 years and we've been making these chicken pies with 100% certified organic ingredients because of the organic ingredients used. We produce 3 types of genetically modified organisms, which were unsure for many customers. Please look at the ingredients listing and you will see there are many stuff, artificial ingredients, because we don't use them. We use natural and organic ingredients certified organic, all the meat is free range chicken, but that's how. We do not use any genetically modified organisms.

- 30 years experience in pie manufacturing.
- 100% Certified organic ingredients.
- Genetically Modified Organisms (GMO) free.
- Kitchen recipe ingredients, no chemistry nor ingredients.
- Free of preservatives.
- Great home made taste.

Cooking Instructions: Preheat your oven to 400 degrees. Remove the frozen pie from the FPO. Bake on your oven's cookie sheet, on the middle shelf of your oven. Bake until golden brown. (approximately 1 hour).

Certified Organic by:
California Certified
Organic Farmers

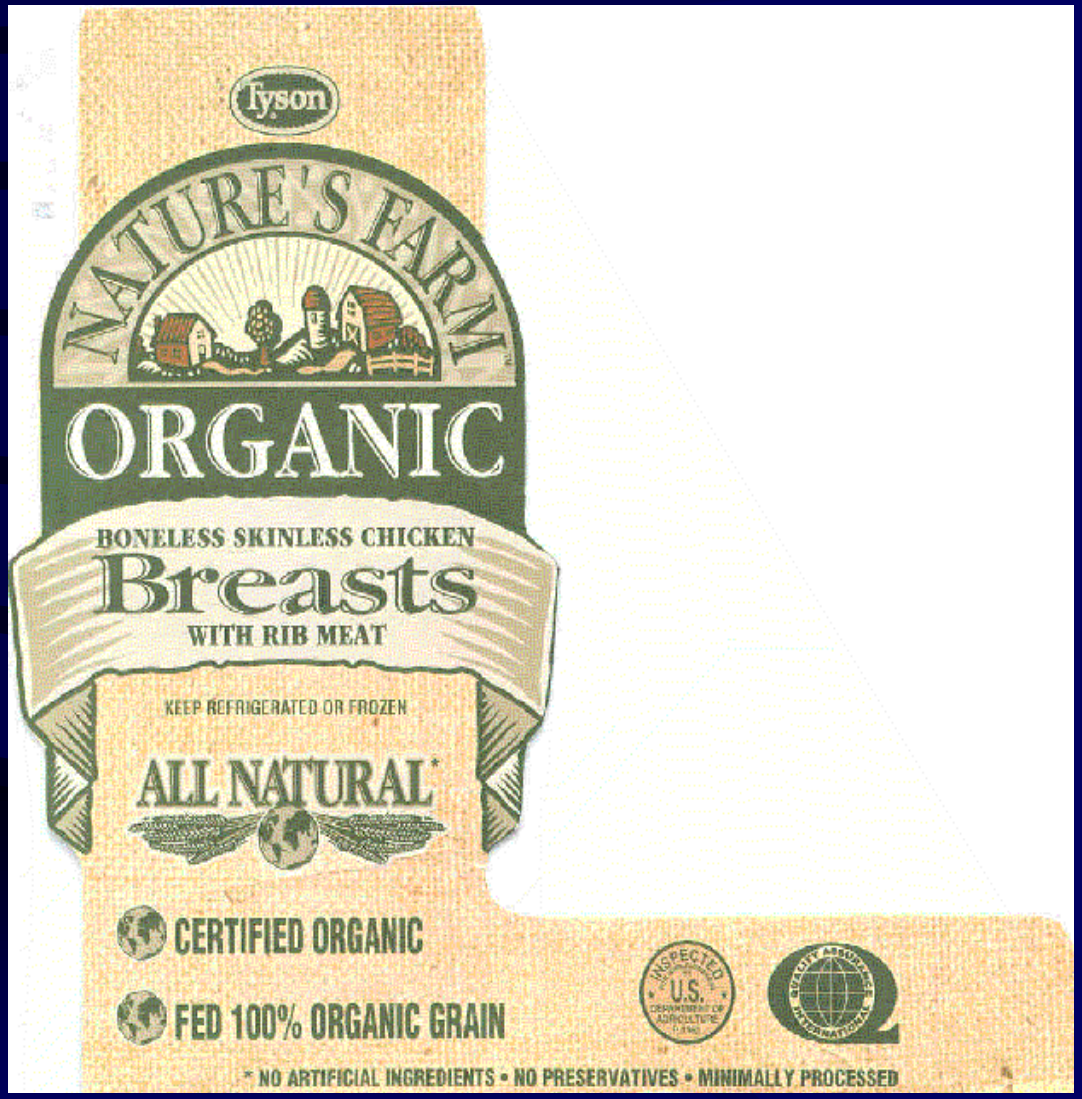
Fill ing Ingredients: Organic chicken broth, organic chicken meat, water, organic peas, organic carrots, organic potatoes, organic potato starch, sea salt, organic spices, organic dehydrated onion and organic dehydrated celery.

Crust Ingredients: Organic Whole Wheat flour, water, organic butter and sea salt.

Distributed by
Sheltons,
Premium Poultry since 1924
Petaluma, CA 94952
(800) 541-1833 • www.sheltons.com

FPO

0 48481 16800 0

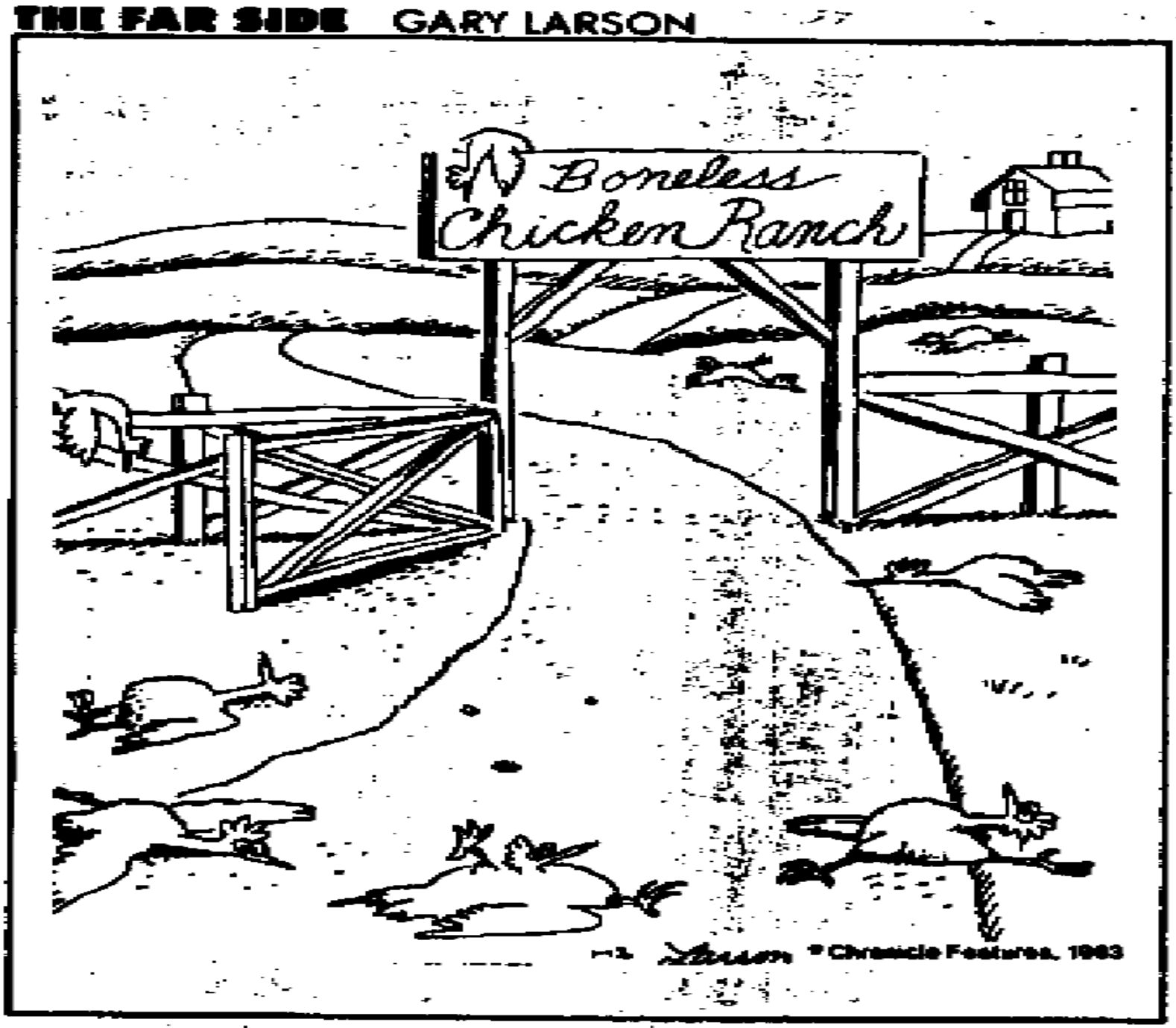

Tyson
NATURE'S FARM
ORGANIC
BONELESS SKINLESS CHICKEN
Breasts
WITH RIB MEAT
KEEP REFRIGERATED OR FROZEN
ALL NATURAL*
CERTIFIED ORGANIC
FED 100% ORGANIC GRAIN
INSPECTED U.S.
* NO ARTIFICIAL INGREDIENTS • NO PRESERVATIVES • MINIMALLY PROCESSED

Labeling Terms: Meat

- " 'Meat': muscle that is skeletal, or in the tongue, diaphragm, heart or esophagus…" (9 CFR 301.2)
- Includes product recovered from "advanced" meat recovery systems (AMRS) machinery
- "Meat" does not include spinal cord, central nervous system (CNS) tissue, or mechanically separated (species) (i.e., mechanically separated beef)

Definition of Meat and BSE Issues

- January 12, 2004 regulations in response to positive finding of BSE
- “Beef” does not include spinal cord or CNS tissue
- “Beef” from cattle 30 months of age or older can not contain Specific Risk Materials (SRMs), i.e., skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia
- Tonsils from all cattle are already prohibited (inedible)
- Small intestines from all cattle prohibited (inedible)
- “Mechanically separated beef” is inedible


THE FAR SIDE GARY LARSON
Boneless Chicken Ranch
© Chronicle Features, 1983