

## APPLE CIDER FOOD SAFETY CONTROL WORKSHOP

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- **Efficacy of the *CiderSure 3500* Ultraviolet Light Unit in Apple Cider** – Dr. Randy Worobo, Cornell University
- **Research Findings on the Application of Warming and Freezing** – Imme Kersten, University of Minnesota
- **Multiple Hurdle Interventions Against *E. coli* O157:H7 in Apple Cider** – Dr. Steve Ingham, University of Wisconsin – Madison
- **Verifying Apple Cider Plant Sanitation and HACCP Programs: Choice of Indicator Bacteria and Testing Methods** – Megan Lang, Steven Ingham, & Barbara Ingham
- **Routes to Regulatory Clearance for New Intervention Processes** – Dr. Pat Hansen, FDA
- **Juice Warning Statement** – Geraldine June, FDA
- **Warning and Notice Statement: Labeling of Juice Products Small Entity Compliance Guide**

- ***Escherichia coli* O157:H7 in Apple Cider: A Quantitative Risk Assessment** – Dr. John Schaffner, Rutgers University
- **Promising Control Practices for Production of Safe Apple Cider** – Dr. Art Miller, FDA
- **CFSAN Management Perspective: Panel Discussion and Q's and A's**
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- **Continuing Research Needs: Panel Discussion** – Dr. Robert Beelman, Penn State University
- **Continuing Research Needs: Panel Discussion** – Mr. Jim Cranney, U.S. Apple Association
- **Continuing Research Needs: Panel Discussion** – Dr. Charles Seizer, NCFST
- **Continuing Intervention Needs of the Cider Industry: Central States Perspective** – Bob Tritten, Michigan State University Extension
- **Cider Industry Diversity** – Dr. John Tilden, Michigan Department of Agriculture
- **Continuing Research Needs: Panel Discussion** – Dr. Mary Wang, California Department of Health Services
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- **Apple Cider Thermal Pasteurization Equipment Recommendations** – AFDO
- **Efficacy of Sanitizing Agents for Pathogen Reduction in Cider Production** -- Michael Beck, Uncle John's Cider Mill, MI.
- **Recommended Good Manufacturing Practices Fresh Apple Juice** – Dr. Mark McLellan and Tracy Harris, Cornell University

**Other References Submitted to FDA  
(Not included – refer to the appropriate technical journal)**

- Buchanan, R. L., S. G. Edelson, K. Snipes, and G. Boyd, Inactivation of *Escherichia coli* O157:H7 in Apple Juice by Irradiation, Applied and Environmental Microbiology, Nov. 1998.
- Evrendilek, G. A., Q. H. Zhang, and E. R. Richter, Inactivation of *Escherichia coli* O157H7 and *Escherichia coli* 8739 in Apple Juice by Pulsed Electric Fields, Journal of Food Protection, Vol. 62, No. 7, 1999.
- Ingham, Steven and Heidi Ulias, Prior Storage Conditions Influence the Destruction of *Escherichia coli* O157:H7 during Heating of Apple Cider and Juice, Journal of Food Protection, Vol. 61, No. 4, 1998.
- Roering, A. M., J. B. Luchansky, A. M. Ihnot, S. E. Ansay, C. W. Kaspar, and S. C. Ingham, Comparative Survival of *Salmonella typhimurium* DT 104, *Listeria monocytogenes*, and *Escherichia coli* O157:H7 in Preservative-free Apple Cider and Simulated Gastric Fluid, International Journal of Food Microbiology 46, 1998–1999
- Sage, Jay and Steven Ingham, Evaluating Survival of *Escherichia coli* O157:H7 in Frozen and Thawed Apple Cider: Potential Use of a Hydrophobic Grid Membrane Filter–SD–39 Agar Method, Journal of Food Protection, Vol. 61, No. 4, 1998.

- Sapers, Gerald F., and Gilbert F. Simmons, Hydrogen Peroxide Disinfection of Minimally Processed Fruits and Vegetables, *Food Technology*, Vol. 52, No. 2, 1998
- Senkel, I. A, R. A. Henderson, B. Jolbitado, and J. Meng, Use of Hazard Analysis Critical Control Point and Alternative Treatments in the Production of Apple Cider, *Journal of Food Protection*, Vol. 62, No. 7, 1999
- Ulias, Heidi E. and Steven C. Ingham. Combination of Intervention Treatments Resulting in 5-Log – Unit Reductions in Numbers of *Escherichia coli* O157:H7 and *Salmonella typhimurium* DT104 Organisms in Apple Cider, *Applied and Environmental Microbiology*, May 1999.

## **Apple Cider Food Safety Control Workshop**

**July 15 - 16, 1999, Washington D.C.**

The Food and Drug Administration (FDA) has announced a workshop to present information regarding food safety controls for the apple cider industry. The discussion at the workshop will address issues regarding pathogen reduction interventions that research studies suggests can be effective for apple cider production, and methods that can be used to measure and validate such interventions. Results of research conducted by federal, state, private, and academic institutions will be presented. This workshop will provide an opportunity for industry representatives and other members of the public to discuss information regarding food safety control measures for the apple cider industry. Agency experts will be available to answer technical food safety questions.

- **Dates and Location:** The workshop will be held on Thursday, July 15, 1999, from 9 a.m. to 4:30 p.m., and Friday, July 16, 1999, from 9 a.m. to noon. The workshop will be held in conference room 705-A, HHS/Humphrey Building, 200 Independence Ave., SW., Washington, D.C. 20201.
- **Registration:** Interested persons are asked to register so sufficient materials and space can be assured. Registration for the workshop will be provided on a first come, first served basis. Persons interested in attending this workshop should by Friday, July 8, 1999, fax their name, title, firm name, address, telephone and fax numbers, and e-mail address to Darrell Schwalm, Center for Food Safety and Applied Nutrition (CFSAN) (HFS -625), Food and Drug Administration, 200 C. St. SW., Washington, DC 20204, 202-205-4040, FAX 202-205-4121 or e-mail "[dschwalm@bangate.fda.gov](mailto:dschwalm@bangate.fda.gov)". If special accommodations are needed due to a disability, please include this in the registration.
- **Written Materials:** Participants can request to have relevant materials distributed at the workshop. Submit written comments, written requests to distribute materials, and materials regarding relevant scientific studies to be distributed at the workshop to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Two copies of any comments and materials to be distributed are to be submitted, except that individuals may submit one copy. It is suggested that a copy also be sent to Darrell Schwalm. Participants are requested to bring to the workshop at least 50 copies of any written or published materials they wish to distribute.
- **Web Site Information:** Interested persons should note that additional information regarding the workshop will be posted on CFSAN's web site, "[www.cfsan.fda.gov](http://www.cfsan.fda.gov)" as it becomes available. Accordingly, such persons are encouraged to visit that web site on a regular basis until the workshop convenes.

7/12/99

**Apple Cider Food Safety Control Workshop**  
July 15 -16, 1999  
Hubert Humphrey Building (HHS), Room 705-A, Washington, DC

<b>Time</b>	<b>Subject</b>	<b>Presenter</b>
<b>Thursday, July 15</b>		
<b>Introduction and Background</b>		
9:00 - 9:15 am	● Purpose of the Workshop and Presentation Format	Dr. John Kvenberg, FDA
9:15 - 9:35 am	● Food Safety Hazards Associated with Apple Cider Processing	Dr. LeeAnne Jackson, FDA
9:35 - 10:00 am	● The Concepts of Performance Standards, Cumulative Steps, and Validation Studies	Dr. John Kvenberg, FDA
10:00 - 10:20 am	Audience Questions and Discussion	
<b>Food Safety Control Guidelines</b>		
10:20 - 10:35 am	● FDA's Good Agricultural Practices (GAP)	Michele Smith, FDA
10:35 - 10:55 am	● Apple Hill Quality Assurance Program and Guidelines	Dave Bolster, Barsotti's Orchard
10:55 - 11:15 am	● Citrus Juice Validated Practices	Peter Chaires, Florida Gift Fruit Shippers Assoc.
11:15 - 11:35	Audience Questions and Discussion	
11:35 - 12:40	<b>Lunch</b>	
12:40 - 1:00 pm	● USDA Extension Service Programs	Dr. Anne Bertinuson, USDA
<b>Pre-Pressing Apple Surface Control Measures</b>		
1:00 - 1:20 pm	● Summary of Research Findings on Washing, Brushing, Sanitizers	Dr. Gerald Sapers, USDA

- |                |   |                         |
|----------------|---|-------------------------|
| 1:20 – 1:40 pm | ● Comparison of Tree Picked and Dropped Fruit on Microflora | Dr. Bob Merker, FDA     |
| 1:40 – 2:00 pm | ● Research on the Use of Hot Water Systems                  | Dr. Suzanne Keller, FDA |
| 2:00 – 2:20 pm | ● Audience Questions and Discussion                         |                         |

**Post-Pressing Juice Control Measures**

- |                |   |                                      |
|----------------|---|--------------------------------------|
| 2:20 – 2:40 pm | ● Research Findings on UV Application                                 | Dr. Randy Worobo, Cornell University |
| 2:40 – 3:00 pm | ● Research Findings on the Application of Warming and Freezing cycles | Imme Kersten, U. of Minnesota        |
| 3:00 – 3:15 pm | <b>Break</b>  |                                      |
| 3:15 – 3:35 pm | ● Application of Warming and Freezing cycles – Continued              | Dr. Steven Ingham, U. of Wisconsin   |
| 3:35 – 3:55 pm | ● Q's & A's on Food Additive Requirements                             | Dr. Pat Hansen, FDA                  |
| 3:55 – 4:15 pm | ● Q's & A's Juice Labeling Requirements                               | Felica Satchell, FDA                 |
| 4:15 – 4:30 pm | Audience Questions and Discussion                                     |                                      |

**Friday, July 16**

**Risk Prevention**

- |                 |                                   |                           |
|-----------------|-----------------------------------|---------------------------|
| 9:00 – 9:20 am  | ● Quantitative Risk Assessment    | Dr. Don Shaffner, Rutgers |
| 9:20 – 9:40 am  | ● Promising Control Practices     | Dr. Art Miller, FDA       |
| 9:40 – 10:00 am | Audience Questions and Discussion |                           |

**Continuing Research Needs on  
Interventions - Panel Discussion**

10:00 - 11:00 am

- East Coast Perspective
- Central State Perspective
- West Coast Perspective
- Apple Industry Perspective
- MOFFETT Center
- FDA, CFSAN
- Dr. Robert Beelman, Penn State University
- Bob Tritten, Michigan State University Extension
- Dr. Mary Wang, CA Dept. of Health Services
- Jim Cranney, U.S. Apple Association
- Dr. Chuck Seizer, NCFST
- Dr. Bob Buchanan

11:00 - 11:30 am

Audience Questions and Discussion

11:30 - Noon

**Closing Summary**

Dr. John Kvenberg, FDA

7/15/99

**Apple Cider Workshop**  
July 15-16, 1999, Humphrey Bldg, Wash DC  
**Attendance List**

Asmindson, Roderick, FDA, ORA  
Baker, Ashley, Food Chem News  
Beelman, Robert, Penn State U  
Bertinuson, Dr. Anne, USDA  
Bohne, Keith, Drew Farms, MA Cider Guild & MA Fruit Growers Assoc  
Bolster, Dave, El Dorado Country Dept of Agric  
Brown, Dr. Gerry, U of Kentucky  
Buchanan, Dr. Robert, FDA, CFSAN  
Bush, Don, Canada Food Inspection Agency  
Chaires, Peter, Florida Gift Fruit Shippers Assoc.  
Colman, Matt, Ardens Garden, Atlanta, GA  
Cranney, Jim, US Apple Assoc, Alexandria, VA  
Crassweller, Dr. Robert, Penn State U  
Cruver, Dr. James, Salcor Corp.  
Darrell Schwalm, FDA, CFSAN  
Dougherty, Dr. Richard, Washington State U  
Duffy, Siobain, Rutgers  
El-Begearmi, Dr. Mahmoud, U of Maine Cooperative Extension  
Fanaselle, Wendy, FDA, Div of Cooperative Program  
Garcia, Guadalupe, FDA, ORA  
Hansen, Dr. Pat, FDA, CFSAN  
Harris, Linda, U of California at Davis  
Haxton, Robert, Iowa Dept of Inspections & Appeals  
Henderson, John, Canada, Ontario Ministry of Agric  
Hirsch, Diana Wright, U of Conn Cooperative Extension  
Hirst, Dr. Peter, Purdue U  
Horan, Chris, Con Agra Grocery Products, Fullerton, CA  
Humes, Lorraine, FDA, ORA  
Hunsucker, Jeff, FDA, ORA  
Ilunsucker, Jeff, FDA, Atlanta  
Ingham, Steven, U of Wisconsin  
Kautter, Don, FDA, CFSAN  
Keller, Susanne, FDA, MOFFETT  
Kersten, Imme, U of Minnesota  
Kirchner, Charles, Ohio Dept of Agric  
Kvenberg, John, FDA, CFSAN  
LaBorde, Dr. Luke, Penn State U  
Lockwood, Dr. David, U of Tenn, Extension  
Lyon, Jeanette, FDA, Div of Cooperative Programs  
Matthys, Allen, NFPA, Washington, DC

Merker, Dr. Robert, FDA, CFSAN  
Morris, Dr. William, U of Tenn. Extension  
Phelps, Kalmia, Virginia Tech  
Phillips, Christie, United Fresh Fruit & Vegetable Assoc, Alexandria, VA  
Podoski, Brett, FDA, CFSAN  
Richards, Frank, Hunt-Wesson Foods, Fullerton, CA  
Rickburg, Shelia, U of Maryland  
Robert Titten, Michigan State U Extension  
Rodeheaver, Dave, Delaware Div of Public Health  
Ronald, Pace, FDA, ORA  
Ruhnke, Gene, Salcor Corp.  
Rupert, John, Penn Dept of Agric  
Sanford, Tennessee Dept of Agric  
Sapers, Dr. Gerald, USDA  
Satchell, Felica, FDA, CFSAN  
Seizer, Dr. Charles, NCFST, Chicago, IL  
Shaffner, Dr. Don, Rutgers  
Shallo, Hilary, Praxair, Inc, Burr Ridge, IL  
Smiley, Robert, MA Fruit Growers Assoc  
Smith, Durward, U of Nebraska  
Smith, Michele, FDA, CFSAN  
Smith, Priscilla, Food Regulation Weekly  
Snodgrass, William, El Dorado Country Dept of Agric  
Soudah, Jane, FDA, ORA  
Steele, Zaire, Nutrition Labeling Watch  
Taylor, Kirk, El Dorado Country Dept of Agric  
Tierney, Paul, MA Dept of Public Health  
Tritten, Bob, Michigan State U Extension  
Walls, Dr. Isabel, NFPA, Washington, DC  
Wang, Mary, California Dept of Health Services  
Wasserman, Beth, Miller Reporting Company  
Worobo, Dr. Randy, Cornell U  
Yager, James, FDA, ORA National QA Systems  
Zinn, Leslie, Ardens Garden, Atlanta, GA

## APPLE CIDER FOOD SAFETY WORKSHOP

### INTRODUCTION

Dr. Art Miller, FDA

My name is Art Miller and I am with the Center for Food Safety and Applied Nutrition here at FDA. I wanted to quickly run through the program to give a blueprint of where we're going and what we hope to accomplish at this workshop. You should all have copies of your program in your workbooks.

This morning we will have some presentations from the FDA explaining why we are here, what the problem is with unpasteurized apple cider, and the current thinking on this issue by FDA. We will move into what you might call an "orchard to jug" discussion of interventions that may contribute to the solution of the problem. We will then discuss things like Good Agricultural Practices as currently applied.

This afternoon we will hear a talk from the USDA Extension point of view, and then we'll move into the plant with a discussion of a couple of promising food safety intervention technologies. We will close with a discussion of post-pressing juice control measures. We will also be having question and answer (Q & A) sessions along the way.

On Friday we will talk about quantitative risk assessment and try to pull some of the current thinking together about promising or best control practices. We will then try to finish with a roundtable discussion on regional issues. As I'm sure you all know, what's true in apple cider making on the East Coast is not necessarily true on the West Coast or the Midwest. We have tried to bring together a variety of speakers, each representing a different part of the United States. The workshop should be completed by noon tomorrow.

If you look at who's here, you will find some common orientations. Most people who are in the audience represent what I would call "extension interest." You as the conduit to the apple cider producers. Let me give you an idea of the demographics. There are a number of representatives of State government. We also have representatives from academic and trade associations, and a few actual apple cider producers.

The information that you're going to receive today and tomorrow, and the handouts that you have, will be important in your role as conduits. We invite you to transfer this information

to the people who really have the need to know, and that is those who are engaged in producing unpasteurized apple cider. That is, we hope that the information we share about FDA's current thinking, current technologies, promising future technologies will be taken and transferred back to the apple cider production folks in your regions and states.

## APPLE CIDER FOOD SAFETY WORKSHOP

### **PURPOSE OF THE WORKSHOP**

Dr. John Kvenberg, FDA

I thought it was very interesting when I saw a show of hands of who is represented here. We hope that today's conference will be one where we can initiate a dialogue to get to the next phase or the level where we need to be in food safety in the area of apple juice products.

Taking you back to recent history, I think that with respect to apples there was obviously a shaking event in apple juice that caused the initial concern in food safety about fresh juice products. As a piece of this history, we will be hearing today a lot about the work that was done on the science and technology front at the Food and Drug Administration. We will also hear about the interacting with regulators at the State level; the work with the producers, the industry itself; and, very importantly, the interactions with the scientist and academicians that are also involved in tackling these issues.

Issues related to microbial food safety are often in the news and at the forefront of the publics' concerns. I would like to suggest that we are in the best of times and in the worst of times. The resources that are being devoted to protecting the public health in the area of microbial hazards have never been as focused as they are now. We are on the point of the curve of making significant strides in reducing the risk to food-borne pathogens in the food supply.

With that increased focus comes change. It is recognized that cider and apple juice production has a history in the United States that goes back before the formation of the United States, into our colonial times. The aim of this conference today is to provide useful scientific information to interested parties in this audience to help you get to the point where we can collectively improve the safety of apple juice production in the United States.



# *Microbiological Hazards of Apple Juice/Cider*

LeeAnne Jackson, Ph.D.  
Science Policy Analyst

Center for Food Safety and  
Applied Nutrition



# *Microbiological Hazards of Apple Juice/Cider*

LeeAnne Jackson, Ph.D.  
Science Policy Analyst

Center for Food Safety and  
Applied Nutrition

FDA

## Outline

- ▶ Outbreaks associated with apple juice/cider
- ▶ Juice processing issues
- ▶ Characteristics of microorganisms

FDA

## Outbreaks associated with Apple Juice/Cider

- ▶ *Escherichia coli* O157:H7
- ▶ *Salmonella* Typhimurium
- ▶ *Cryptosporidium* sp.

FDA

## Apple Juice/Cider

### *Escherichia coli* O157:H7

- ▶ 1980 - Toronto, Canada
  - fresh apple juice
  - 13 or 14 children had bloody diarrhea and Hemolytic Uremic Syndrome (HUS)
- ▶ 1991 - Massachusetts
  - fresh pressed unpasteurized apple cider
  - 23 ill, 16 with bloody diarrhea, 4 with HUS
- ▶ 1996 - Connecticut
  - unpasteurized apple cider
  - 14 ill, 7 hospitalized, 3 with HUS

FDA

## Apple Juice/Cider

### *Escherichia coli* O157:H7 (cont'd)

- ▶ 1996 - Washington, California, Colorado, British Columbia
  - commercially produced unpasteurized apple juice
  - 70 ill, 14 with HUS, one death
- ▶ 1996 - Washington, Church function
  - unpasteurized apple cider
  - 6 ill

FDA

## Apple Juice/Cider

### *Salmonella* Typhimurium

- ▶ 1974 - New Jersey
  - 300 ill
  - cider made from drops from an orchard fertilized with manure

FDA

## Apple Juice/Cider

### *Cryptosporidium* sp.

- ▶ 1993 - Maine - Fair
  - unpasteurized apple cider
  - 160 primary and 53 secondary cases
  - apples from trees near a cow pasture
- ▶ 1996 - New York
  - unpasteurized apple cider
  - 20 confirmed and 11 suspected cases
  - cause unknown but postulated to be from well water used to rinse apples which was coliform-positive

FDA

## Juice Processing Issues

- ▶ Pressing/squeezing/grinding of fruits and vegetables
- ▶ Bruises / injury
- ▶ Transfer of microorganisms by insects

FDA

## Juice Processing Issues

Pressing/squeezing/grinding of fruits and vegetables

- ▶ Exterior contamination
- ▶ Interior contamination

FDA

## Juice Processing Issues

Bruises / injury

- ▶ Point of entry for pathogens
  - punctures
  - water

FDA

## Juice Processing Issues

### Transfer of microorganisms by insects

- ▶ Fruit flies transmission of *E. coli* O157:H7 from apple to apple

FDA

## Characteristics of Microorganisms

- ▶ Resistance to acid
- ▶ Resistance to preservatives
- ▶ Resistance to sanitizers
- ▶ Resistance to heat
- ▶ Resistance to other control methods

FDA

## Characteristics of Microorganisms

### Resistance to acid

- ▶ Some strains of *E. coli* O157:H7 have the ability to survive exposure to acidic conditions for extended periods.
- ▶ Can survive in refrigerated apple juice for most, if not all of the product's shelf life.

FDA

## Acid resistance of *E. coli* O157:H7

- ▶ Acid resistance enhanced by refrigeration
- ▶ Malic acid is one of the gentlest of the organic acids
- ▶ *E. coli* can be induced to increased acid tolerance by prior exposure to mild acid conditions
- ▶ Have potential for cross protection

FDA

## Characteristics of Microorganisms

### Resistance to preservatives

- ▶ Preservatives are ineffective against *Cryptosporidium*
- ▶ *E. coli* O157:H7 in apple cider
  - 0.1% sodium benzoate
  - 0.1% potassium sorbate

FDA

## Characteristics of Microorganisms

### Resistance to sanitizers

- ▶ Chlorine
- ▶ H<sub>2</sub>O<sub>2</sub>
- ▶ Peroxyacetic acid

FDA

## Characteristics of Microorganisms

### Resistance to heat

- ▶ Storage conditions may influence pathogen destruction
- ▶ Survival of *E. coli* O157:H7 is enhanced by lowering storage temperature

FDA

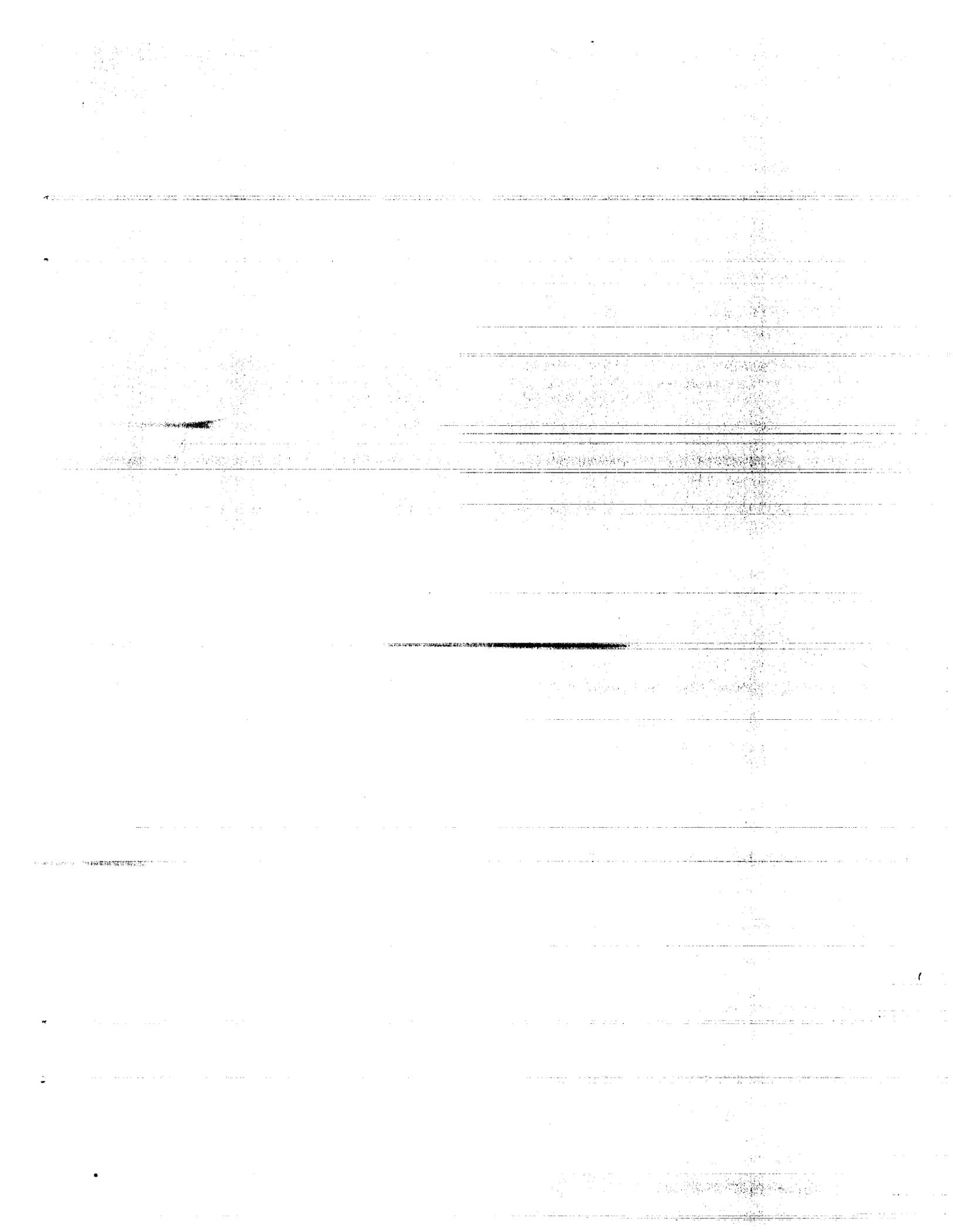
## Characteristics of Microorganisms

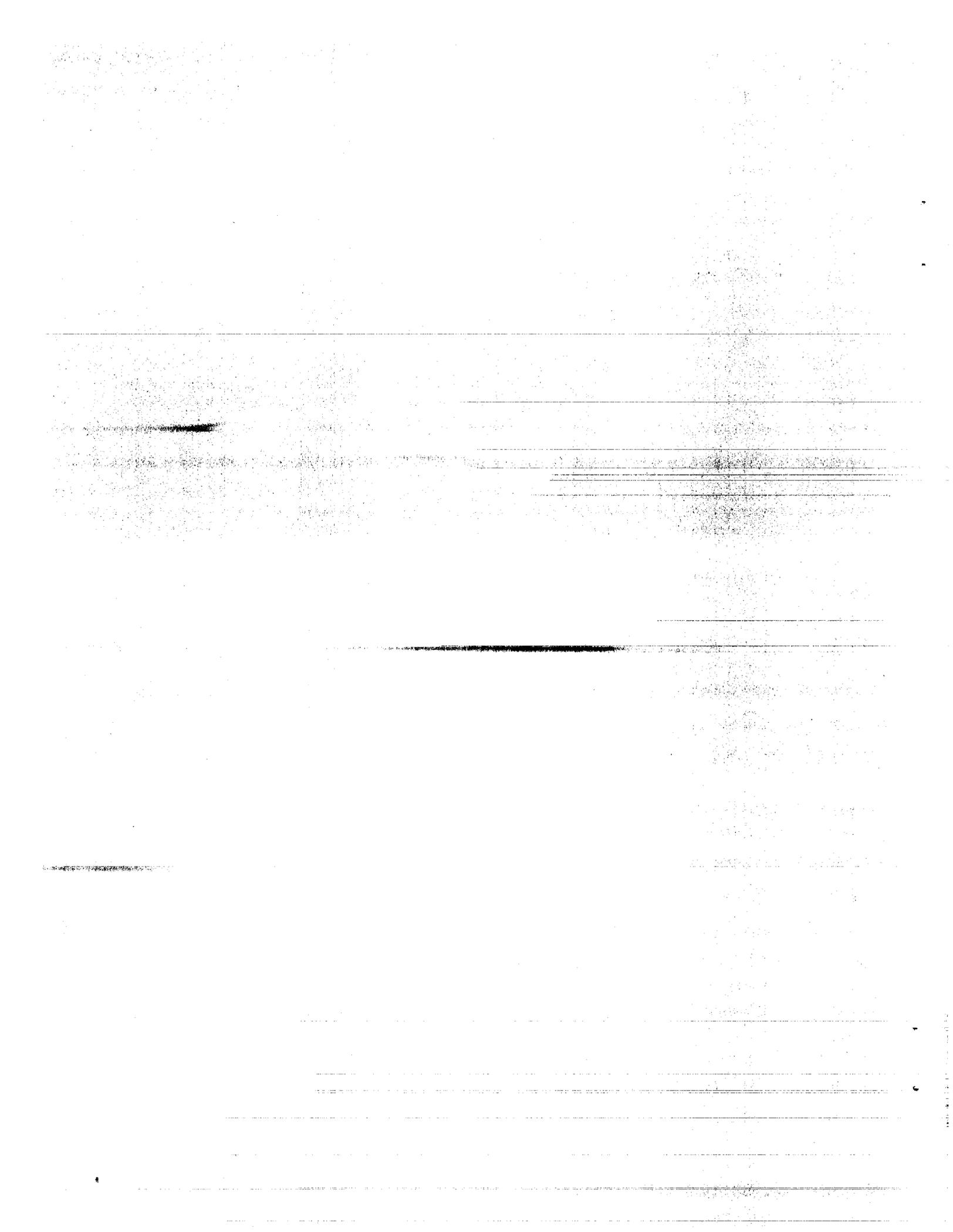
### Resistance to other control methods

- ▶ High Hydrostatic Pressure
- ▶ Microwaves
- ▶ Irradiation
- ▶ Pulsed-light

FDA







**THE CONCEPTS of  
PERFORMANCE STANDARDS,  
CUMULATIVE STEPS AND  
VALIDATION STUDIES**

**Dr. John Kvenberg,  
Acting Director, Office of Field Programs  
July 15, 1999**



**THE CONCEPTS of  
PERFORMANCE STANDARDS,  
CUMULATIVE STEPS AND  
VALIDATION STUDIES**

**Dr. John Kvenberg,  
Acting Director, Office of Field Programs  
July 15, 1999**

**Performance Standards —  
Background**

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- **A control measure must prevent, eliminate or reduce a hazard to acceptable levels**
- **A performance standard sets the criteria for “acceptable reduction”**
- **Applied to individual control measures or to a series of control measures**

## Performance Standards

- Performance standards define level of acceptable hazard reduction
- Have created need for scientific studies
- Issues in designing validation studies:
  - Laboratory studies vs In-plant validation
  - Pathogens vs surrogates
  - Other study design considerations (e.g. individual control vs entire process evaluation)

## Performance Standard for Juice — Warning Statement Rule

- Fresh juice industry:
  - No control measures to *prevent* a pathogen hazard from occurring – raw agricultural product
  - No control measures to *eliminate* a pathogen – no kill step
- Have to *reduce* hazards to an acceptable level

## **What is a 5 Log Reduction Performance Standard?**

- **Reduction in number of microorganisms by a factor of 100,000 fold (from 100,000 to 1 organism)**
- **Reduction of risk to less than 1 in 100,000**

## **Advantages of a Performance Standard**

- **Gives industry flexibility -- use different control measures**
- **Shift away from a “command and control” approach**
- **Disadvantage -- validation more complicated:**
  - individual controls only partially effective
  - can use different combinations of controls

## **How Does a Manufacturer Achieve 5 Log Reduction?**

- **Use of control measures shown to be effective**
- **Use of a single control measures alone or in combination with other measures**
- **Combination results in a cumulative reduction**

## **Which Control Measures are Effective?**

- **Sources of Information:**
  - Scientific literature
  - Federal and state agencies
  - Industry associations
  - Data generated at the facility or by a consultant
- **FDA Technical Workshop proceedings for citrus processing**

## **Which Control Measures Can Be Counted as Cumulative?**

- **A measure that has been shown to be effective**
- **A measure that the processor can verify has been effectively applied to every lot**

## **How Effective are Control Measures?**

- **Effectiveness of Citrus Fruit Industry Control Measures (APPROXIMATE REDUCTIONS):**
  - Culling -- 0.6 to 1.0 log reduction
  - Cleaning, washing, brushing, and sanitizing -- 2.5 log reduction
  - Hot waxing -- 1.0 log reduction
  - Hot dip or steam tunnel -- 5+ log reduction
  - Pinpoint juice extraction -- 1.2 to 1.9 log reduction

## **Validation Study Design**

- **Study design not specified by FDA**
- **Options include:**
  - In-plant studies using surrogate microorganisms
  - Pilot plant studies
  - Laboratory studies using pathogens
- **Laboratory studies need in-plant confirmation that controls are applied**

## **Validating 5 Log Reduction**

- **Processors may contract with a private laboratory:**
  - use laboratory to test a simulated process using a know pathogen or pertinent microorganism
  - conduct tests on a simulated process using surrogates
- **Processors may conduct their own studies:**
  - conduct studies in-plant using a surrogate microorganism

## **What are Pertinent Microorganisms?**

- **Most resistant illness-causing microbe**
- **Ability to survive the specific treatment being tested**
- **Examples include:**
  - *E. coli* O157:H7
  - *Salmonella* sp.
  - *Listeria monocytogenes*

## **What are Surrogate Microorganisms?**

- **Any non-pathogenic microbe that is acid-resistant and heat-resistant**
- **Has other relevant characteristics**
- **Should have GRAS status**
- **Examples include:**
  - food grade lactic acid bacteria
  - *Klebsiella pneumoniae* which is naturally occurring

## **Validation Studies**

- **Assess whether the hazard analysis and controls are working:**
  - all hazards have been identified, and
  - the control measures being used are effective.

## **Microbial Testing and the Initial Validation**

- **Purpose of Validation:**
  - Demonstrate that control measures selected as critical are effective
  - Demonstrate that proper control limits are applied
  - Confirm that CCP's are sufficient to control identified hazards and reduce the microbial levels appropriately

## **Verification Audits**

- **Purpose is to assess whether preventive measures have been applied as designed**
- **Audits based upon control records**

## **FDA's Role in Validation Studies**

- **Provides for self-validation by processor**
- **FDA's role is auditing validation studies**
- **FDA needs baseline data on effectiveness of various control measures and critical limits**
- **Requires shift from regulatory samples to research**

## **Validation Studies**

- **Types of Validation Activities:**
  - Review documents and scientific literature
  - Challenge studies
  - Product testing

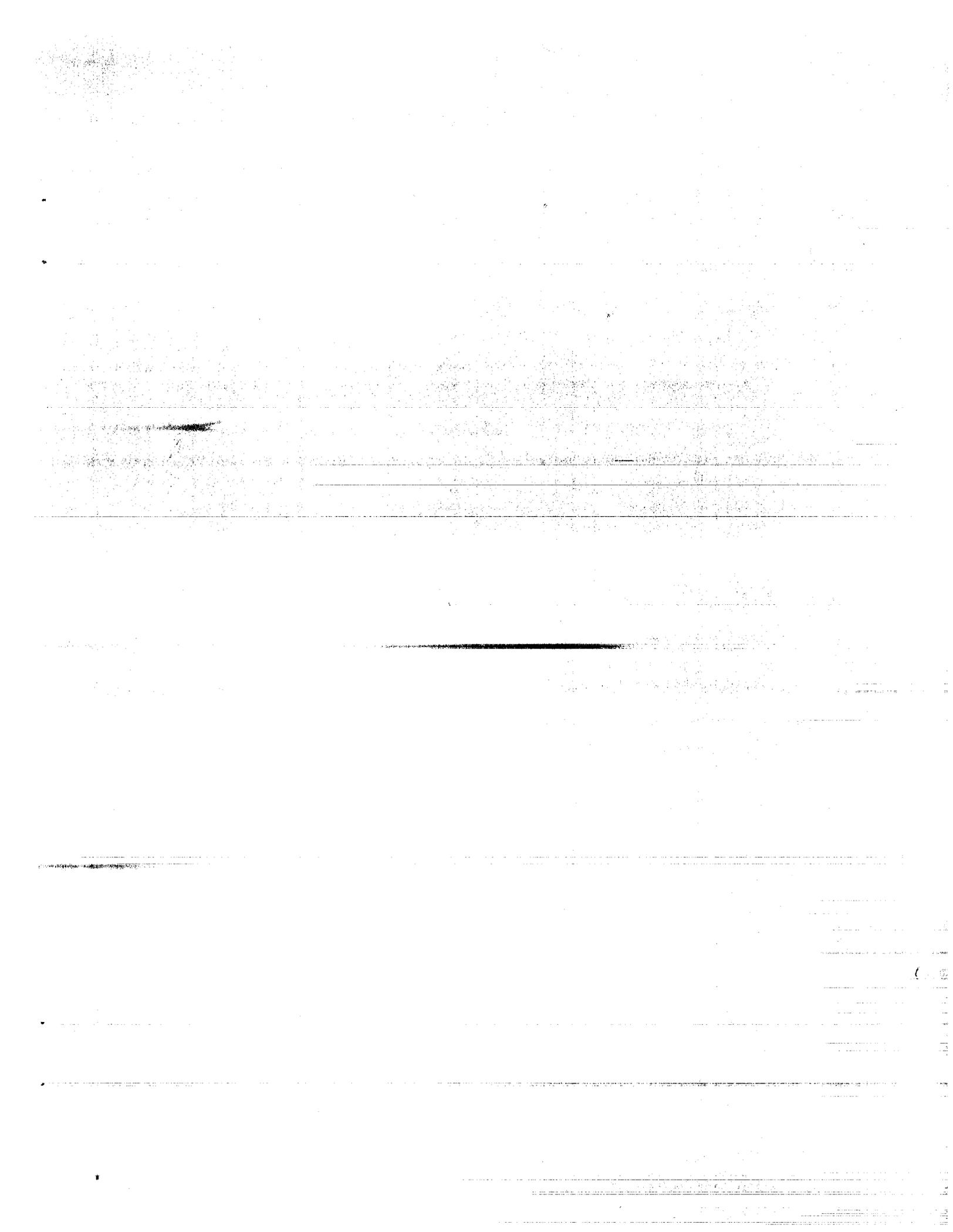
## **Using Validating Data**

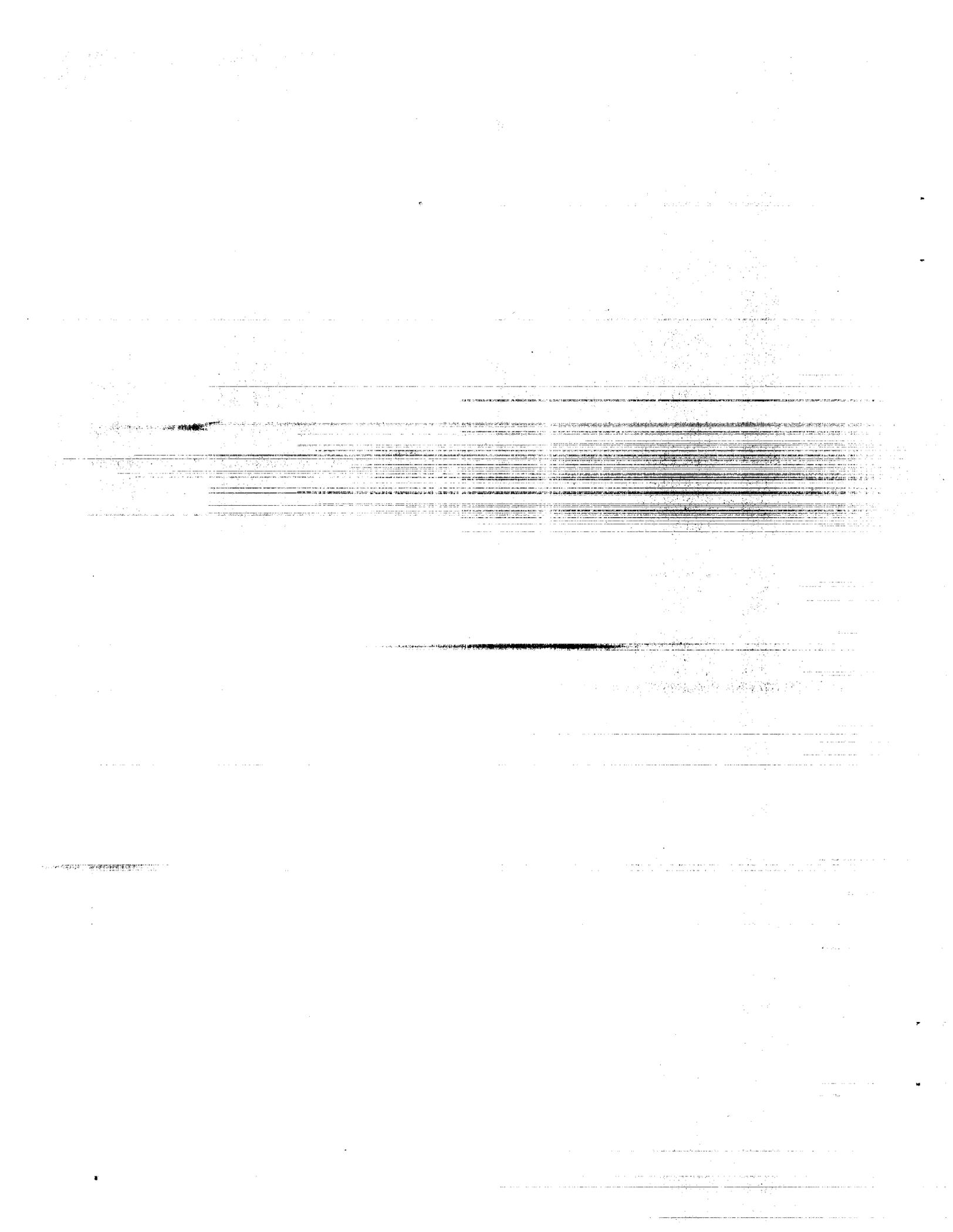
- **Processors may rely upon scientific studies and validations conducted by others including:**
  - ingredient suppliers
  - equipment and chemical providers
  - academia and government agencies
- **Processors may rely upon ‘standard’ controls that utilize equivalent procedures and limits**

## **Microbial Testing and Verification**

- **Microbial testing not currently required but encouraged by FDA**
- **Microbial testing can help:**
  - keep management informed on safety issues
  - evaluate sanitation & cleaning
  - evaluate incoming ingredients
  - provide data for annual validations
  - provide data for customer reviews Microbial testing not required but







# NACMCF Recommendations on Fresh Juice

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April 9, 1997

Prepared for  
Food and Drug Administration, Center for Food Safety and Applied Nutrition

by  
National Advisory Committee on Microbiological Criteria for Foods



The Fresh Produce Subcommittee (FPS) of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF--the Committee) met in a drafting session the morning of December 18, 1996 to consider the safety of all juices in light of the information and discussion provided during the December 16 and 17, 1996, open public meeting on Current Science and Technology on Fresh Juices. The FPS risk conclusions were based on documented outbreaks of illness associated with consumption of contaminated juices. These data were presented and discussed during the open public meeting.

Many aspects of juice production affect pathogen control: agricultural practices; product handling; equipment used in harvesting and processing; growing location, including produce obtained from below ground (carrots), on ground (e.g., drops), or from trees; pH; acidulants; method of processing; degree of animal contact; refrigeration; packaging; and the distribution system. In determining the best control mechanisms it is important to remember that the conditions for microbial survival differ from those for growth.

NACMCF conclusions:

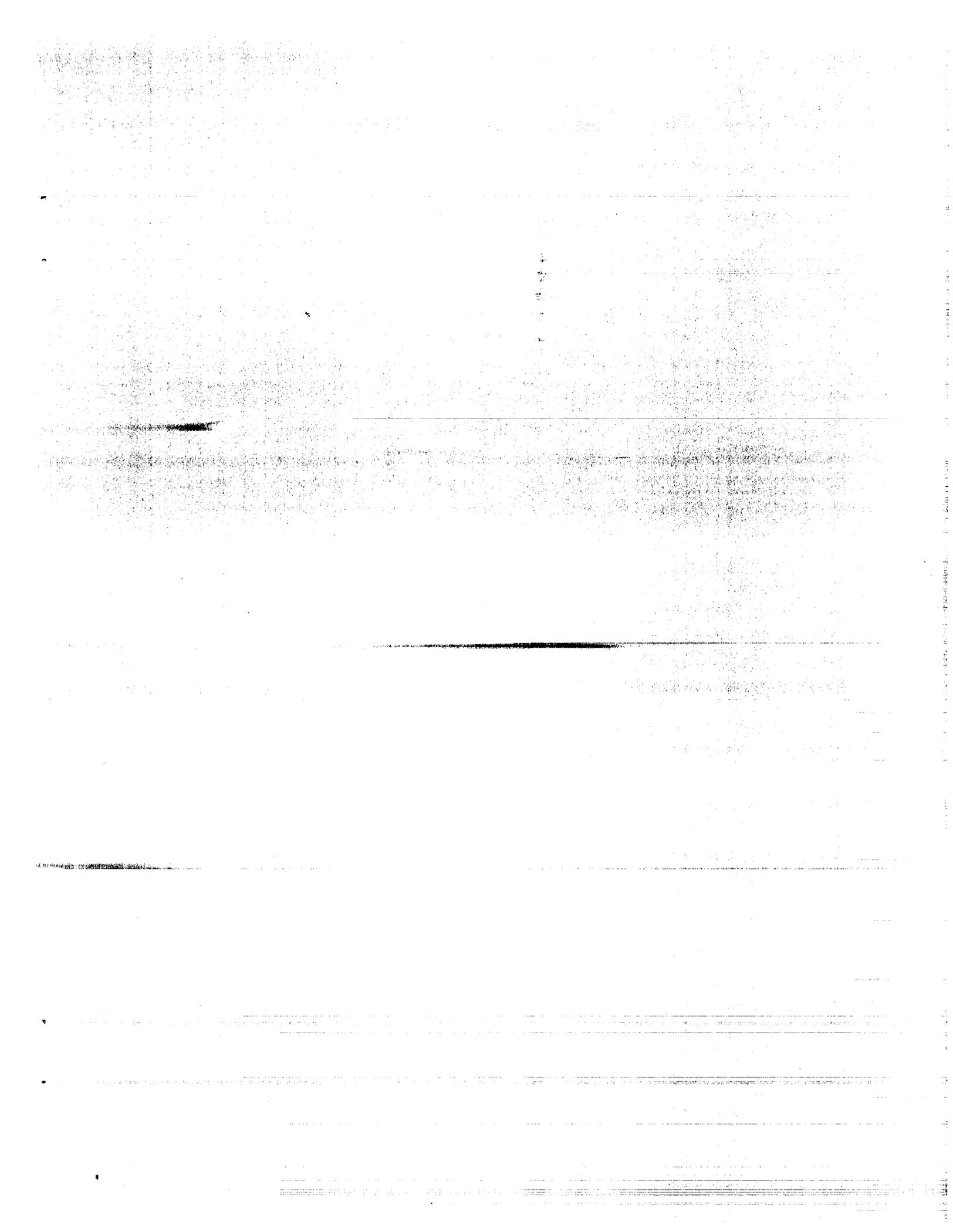
1. The Committee concludes that while the risks associated with specific juices vary, there are safety concerns associated with juices, especially unpasteurized juices.
2. The Committee concludes that the history of public health problems associated with fresh juices indicates a need for active safety interventions.
3. The Committee concludes that, for some fruit, intervention may be limited to surface treatment, but for others, additional interventions may be required.
4. The Committee recommends the use of safety performance criteria instead of mandating the use of a specific intervention technology. In the absence of specific pathogen-product associations, the committee recommends the use of *Escherichia coli* O157:H7 or *Listeria monocytogenes* as the target organisms, as appropriate.
5. The Committee believes that a tolerable level of risk may be achieved by requiring an intervention(s) that has been validated to achieve a cumulative 5 log reduction in the target pathogen(s) or a reduction in yearly risk of illness to less than  $10^{-3}$ , assuming consumption of 100 ml of juice daily.
6. The Committee believes that Hazard Analysis Critical Control Points (HACCP) and safety performance criteria form the general conceptual framework needed to assure the safety of juices. Control measures should be based on a thorough hazard analysis. Validation of the process must be an integral part of this framework.
7. The Committee recommends mandatory HACCP for all juice products. Implicit in this recommendation is that plants have implemented and are strictly adhering to industry GMPs.

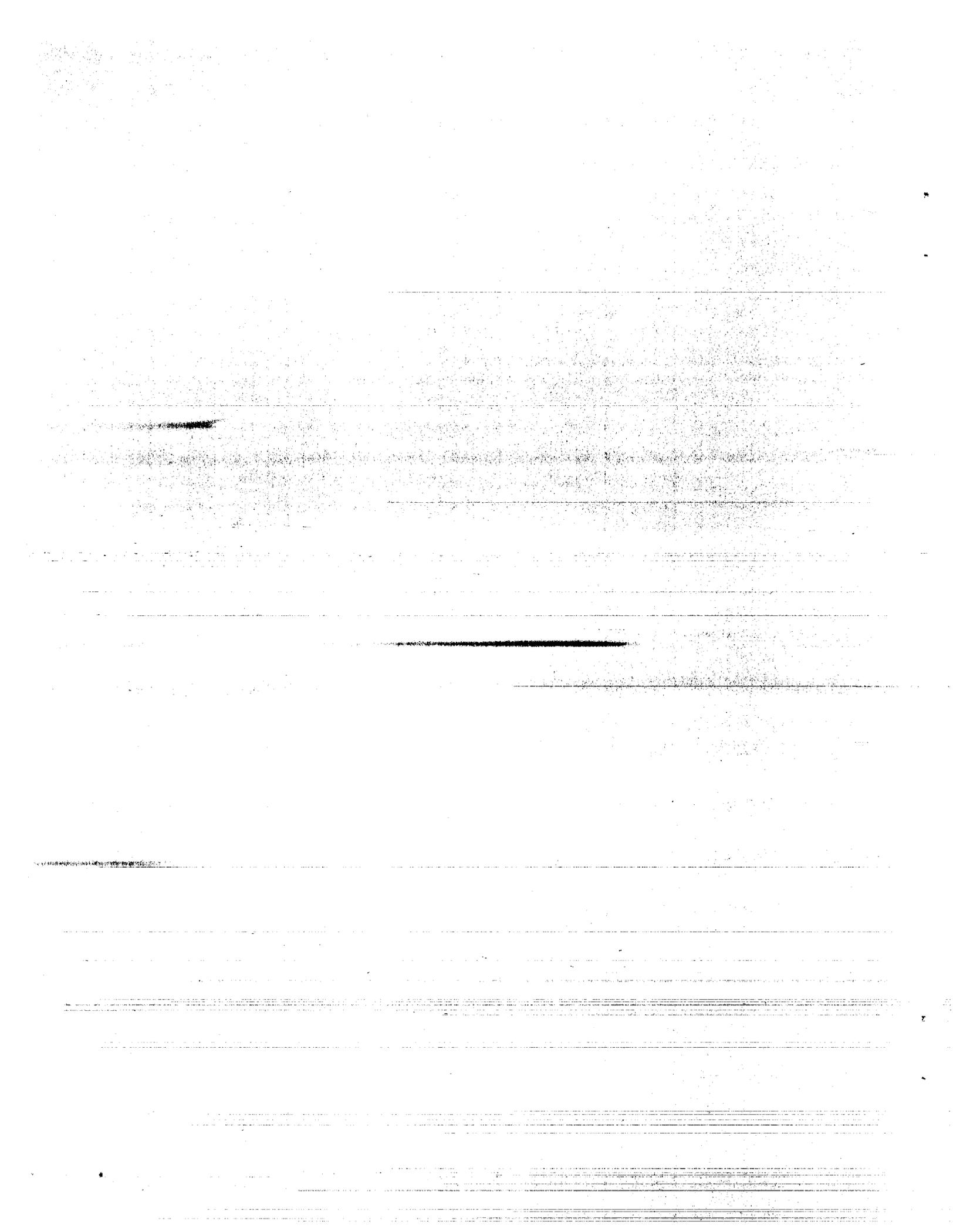
8. The Committee recommends industry education programs addressing basic food microbiology, the principles of cleaning and sanitizing equipment, GMPs, and HACCP.
9. The Committee recommends further study in the following areas:
  - Research on the efficacy of new technologies and intervention strategies for safety.
  - Research on the contamination, survival and growth of pathogens on produce with or without breaks in skin, areas of rot, and within the core.
  - Research on how produce becomes contaminated with human pathogens including the relevant microbial ecology during production and processing of juice. In particular, there is an urgent need for these types of studies on *E. coli* O157:H7 in apple juice.
  - Baseline studies on the incidence of human pathogens on fruits and vegetables, particularly those used in juice processing.
  - Research on labeling information needed for consumer understanding and choice of safer juices and juice products.

On the basis of all the testimony presented at the December 16 and 17, 1996 public meeting, the members agreed that there is a need to understand the differences among all juice and juice products, e.g. citrus vs. other. A significant problem identified by the Committee is that consumers presently do not have a means to clearly differentiate between unpasteurized and pasteurized products. Terms used to refer to juice products do not always have universal meanings, e.g. the term "cider" is perceived to be an unpasteurized product whereas the term "juice" is often perceived to be pasteurized.

Traditional heat treatments given to juices and juice products have been designed to achieve shelf stability, to remove water (concentration) or other quality-related factors. These treatments, commonly referred to as pasteurization, are greatly in excess of a process needed to inactivate foodborne pathogens.

Because of the lack of sufficient data to evaluate the effectiveness of labeling statements for safety interventions or to inform consumer choice, the Committee could not strongly endorse labeling as an interim safety measure.





# Apple Cider Food Safety Workshop

FDA's Good Agricultural Practices

Dr. Michelle A. Smith

July 15, 1999



Apple Cider Food Safety  
Workshop

FDA's Good Agricultural Practices

Dr. Michelle A. Smith

July 15, 1999

Guide to Minimize Microbial  
Food Safety Hazards for Fresh  
Fruits and Vegetables

(The Guide)

## The Guide

- Broadscope - practices common to the growing and packing of most fresh produce
- Guidance only - no new requirements
- Risk reduction, not elimination

## Fresh Produce

### Scope:

- Fruits and vegetables likely to be sold in an unprocessed or minimally processed (raw) form
- Likely to be consumed without a microbiologically lethal treatment
- Maybe intact or cut during harvest
- Includes “fresh-cut” and other specialty products

## Use Of The Guide

- Increase awareness of common microbial hazards for fresh produce
- Useful when practices recommended to minimize hazards are adapted to specific operations
  - Assess individual operations
  - Institute appropriate cost effective practices

## Table of Contents

- Water
- Manure and Municipal Biosolids
- Worker Health and Hygiene
- Sanitary Facilities
- Field/Packing Facility Sanitation
- Transportation
- Traceback

## Water

- Water quality dictates the potential for contamination
  - May be a direct source of contamination or
  - May spread pathogens in the field or packinghouse
- Surviving pathogens on produce may cause illness

## Water Quality

Needs vary with how and when water is used

- Degree of contact
- Time until harvest
- Crop characteristics

## Processing Water

- “Safe and Sanitary” meets microbiological standards for drinking water
- If water is recycled, follow GMPs to maintain water quality
- Water use should not contribute to food safety concerns

## Consider Antimicrobials

Useful in processing water for

- Reducing pathogens on the surface of produce and
- Reducing build-up of pathogens in processing water

## Manure and Biosolids

- Beneficial fertilizer and soil amendment
- Significant potential source of human pathogens
  - *E. coli* O157:H7
  - *Salmonella*
  - *Cryptosporidium*

## Manure and Biosolids

Growers should follow GAPs for handling animal manure or biosolids to minimize microbial hazards

## Manure

GAPs to minimize microbial hazards

- Treatments to reduce pathogens
- Maximize time between application and harvest

## Personal Health and Hygiene

- Establish a worker training program
  - Teach basic sanitation and hygiene
  - Follow-up sessions may be needed
- Become familiar with disease signs and symptoms
- Provide protection from lesions

## Field Sanitation

- Keep harvest and packing equipment as clean as practicable
- Keep harvest containers clean
- Assign responsibility for equipment to person in charge

## Packing Facility Sanitation

- Keep equipment as clean as practicable
- Clean packing areas at end of each day
- Maintain cooling system in working order
- Clean product storage areas regularly

## Pest Control

- Establish a pest control system
- Maintain the grounds in good condition
- Monitor and maintain facilities regularly
- Block access of pests into facility
- Use a pest control log

## Accountability

- Once GAPs and GMPs are in place, ensure the process is working
- Comprehensive and coordinated effort throughout production and distribution
- Assign responsibility for specific tasks
- Follow-up on the process

## Traceback

The ability to identify the source of a product

- Cannot prevent initial outbreak
- Important compliment to GAPs and GMPs
- Limit economic and public health impact
- Information may help identify/eliminate hazards

## For more information

<http://www.fda.gov>

<http://vm.cfsan.fda.gov>

## The Guide at a Glance

### *The Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables In Brief*

This *Guide* provides general, broad-based voluntary guidance that may be applied, as appropriate, to individual operations

#### **The Guide**

- Is intended to assist domestic and foreign growers, packers, and shippers of unprocessed or minimally processed (raw) fresh fruits and vegetables by increasing awareness of potential hazards and providing suggestions for practices to minimize these hazards
- Covers agricultural and postharvest water uses, manure and biosolids, worker health and hygiene, field and facility sanitation, transportation, and traceback.
- Does not impose any new requirements or supercede existing laws or regulations
- Will be most effective when used to evaluate individual operations and to institute good agricultural and good manufacturing practices (GAPs and GMPs) appropriate to the individual operations

#### **Basic Principles include**

- Prevention of microbial contamination of fresh produce is favored over reliance on corrective actions once contamination has occurred
- Accountability at all levels of the agricultural and packing environments is important to a successful food safety program

#### **Water**

Wherever water comes into contact with fresh produce, its quality dictates the potential for pathogen contamination

#### *Agricultural Water*

- Identify source and distribution of water used.
- Be aware of current and historical use of land
- Review existing practices and conditions to identify potential sources of contamination. Consider practices that will protect water quality
- Maintain wells in good working condition
- Consider practices to minimize contact of the edible portion of fresh produce with contaminated irrigation water. Where water quality is good, risk is low regardless of irrigation method

#### *Processing Water*

- Follow GMPs to ensure water quality is adequate at the start of and throughout all processes
- Maintain water quality, such as by periodic testing for microbial contamination, changing water regularly, and cleaning and sanitizing water contact surfaces
- Antimicrobial chemicals may help minimize the potential for microbial contamination to be spread by processing water; levels of antimicrobial chemicals should be routinely monitored and recorded to ensure they are maintained at appropriate levels
- As organic material and microbial load increase, the effectiveness of many antimicrobial chemicals will decrease. Filtering recirculating water or scooping organic material from tanks may help reduce the build-up of organic materials

### Cooling Operations

- Maintain temperatures that promote optimum produce quality and minimize pathogen growth
- Keep air cooling and chilling equipment clean and sanitary
- Keep water and ice clean and sanitary
- Manufacture, transport, and store ice under sanitary conditions

### **Manure and Municipal Biosolids**

**Properly treated manure or biosolids can be an effective and safe fertilizer.**

- If manure is used as a fertilizer, it should be managed to minimize microbial hazards
- Federal regulations address the requirements for use of biosolids in the U.S.. Some states also have specific requirements for the use of biosolids. Foreign growers should follow these or similar requirements

### Manure

- Use treatments to reduce pathogens in manure and other organic materials. Treatments may be active (e.g., composting) or passive (e.g., aging)
- Manure treatment and storage sites close to fresh produce fields increase the risk of contamination
- Consider factors such as slope and rainfall and the likelihood of runoff into fresh produce production areas
- Use barriers or physical containment to secure storage and treatment sites
- Protect treated manure from being re-contaminated
- When purchasing treated manure, get information about the method of treatment
- Maximize the time between application of manure to production areas and harvest
- Use of raw manure on produce during the growing season is not recommended

### Animal Feces

**While not possible to exclude all animal life from fresh produce production areas, many field programs include elements to protect crops from animal damage.**

- Domestic animals should be excluded from fields and orchards during the growing and harvesting season
- Follow GAPs to ensure animal waste from adjacent fields, pastures, or waste storage facilities does not contaminate fresh produce production areas. Where necessary, consider physical barriers such as ditches, mounds, grass/sod waterways, diversion berms, and vegetative buffer areas
- Control of wild animal populations may be difficult or restricted by animal protection requirements. However, to the extent feasible, where high concentrations of wildlife are a concern, consider practices to deter or redirect wildlife to areas where crops are not destined for fresh produce markets

### **Worker Health and Hygiene**

**Infected employees who work with fresh produce increase the risk of transmitting foodborne illness.**

- Train employees to follow good hygienic practices
- Establish a training program directed towards health and hygiene – include basics such as proper handwashing techniques and the importance of using toilet facilities
- Become familiar with typical signs and symptoms of infectious diseases

- Offer protection to workers with cuts or lesions on parts of the body that may make contact with fresh produce
- If employees wear gloves, be sure the gloves are used properly and do not become a vehicle for spreading pathogens
- Customer-pick and road-side produce operations should promote good hygienic practices with customers – encourage handwashing, provide toilets that are well equipped, clean, and sanitary and encourage washing fresh produce before consumption

#### Sanitary Facilities

- Poor management of human and other wastes in the field or packing facility increases the risk of contaminating fresh produce.
- Be familiar with laws and regulations that apply to field and facility sanitation practices
- Toilet facilities should be accessible to workers, properly located, and well supplied
- Keep toilets, handwashing stations, and water containers clean and sanitary
- Use caution when servicing portable toilets to prevent leakage into a field
- Have a plan for containment in the event of waste spillage

#### **Field Sanitation**

**Fresh produce may become contaminated during pre-harvest and harvest activities from contact with soil, fertilizers, water, workers, and harvesting equipment.**

- Clean harvest storage facilities and containers or bins prior to use
- Take care not to contaminate fresh produce that is washed, cooled, or packaged
- Use harvesting and packing equipment appropriately and keep as clean as practicable
- Assign responsibility for equipment to the person in charge

#### **Packing Facility**

**Maintain packing facilities in good condition to reduce the potential for microbial contamination.**

- Remove as much dirt as practicable outside of packing facility
- Clean pallets, containers, or bins before use; discard damaged containers
- Keep packing equipment, packing areas, and storage areas clean
- Store empty containers in a way that protects them from contamination

#### Pest Control

- Establish and maintain a pest control program
- Block access of pests into enclosed facilities
- Maintain a pest control log

#### **Transportation**

**Proper transport of fresh produce will help reduce the potential for microbial contamination.**

- Good hygienic and sanitation practices should be used when loading, unloading, and inspecting fresh produce
- Inspect transportation vehicles for cleanliness, odors, obvious dirt and debris before loading
- Maintain proper transport temperatures
- Load produce to minimize physical damage

## Traceback

**The ability to identify the source of a product can serve as an important complement to good agricultural and management practices.**

- Develop procedures to track produce containers from the farm, to the packer, distributor, and retailer
- Documentation should indicate the source of the product and other information, such as date of harvest, farm identification, and who handled the produce
- Growers, packers and shippers should partner with transporters, distributors and retailers to develop technologies to facilitate the traceback process

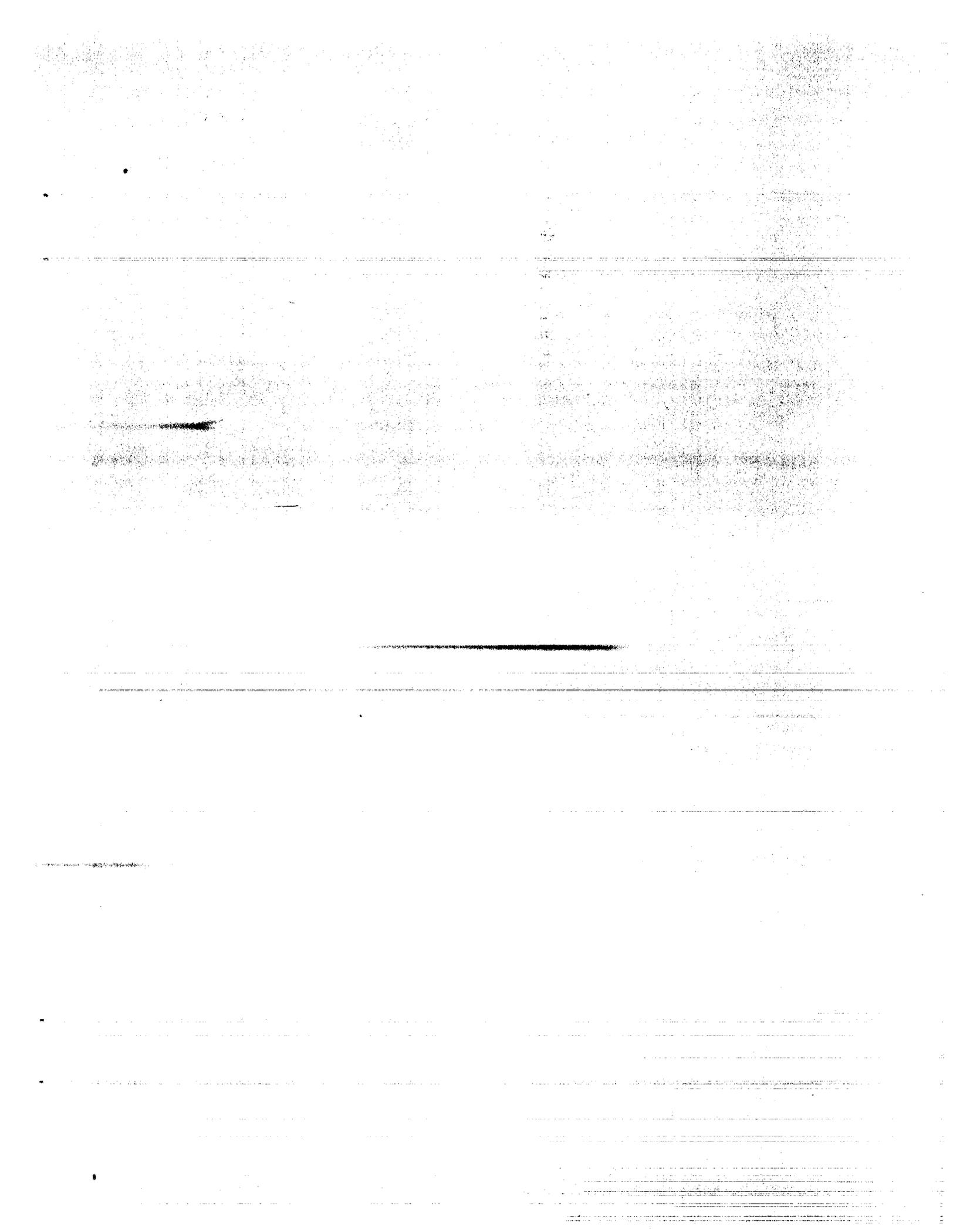
**Once good agricultural and management practices are in place, ensure that the process is working correctly. Without accountability, the best efforts to minimize microbial contamination are subject to failure.**

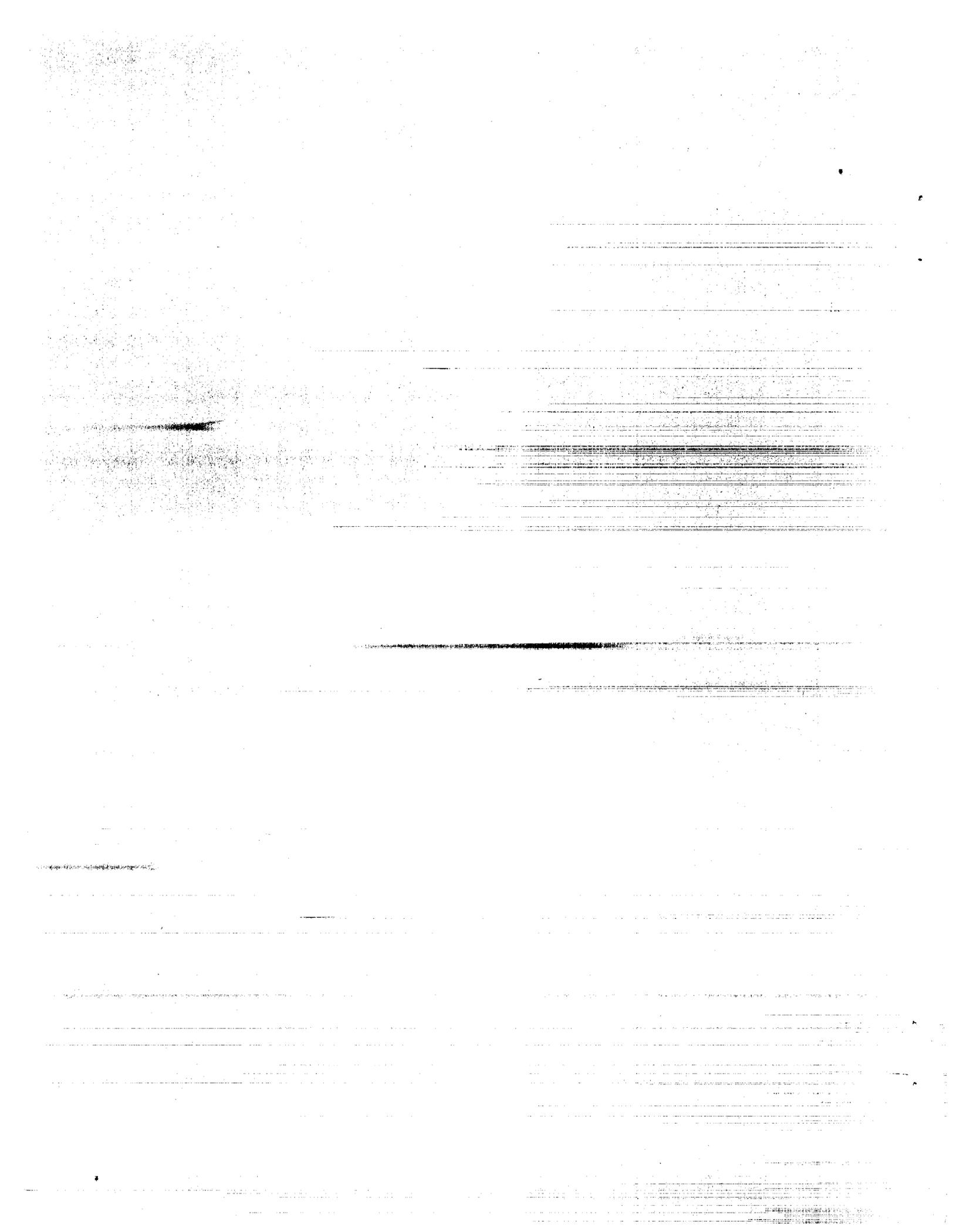
Copies of the *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, October 1998, are available from:

Food Safety Initiative Staff (HFS-32)  
U.S. Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, DC 20204

(Tel) 202-260-8920

Or on the Internet at:  
<http://www.fda.gov>







**EL DORADO COUNTY**  
**DEPARTMENT OF AGRICULTURE**  
**WEIGHTS AND MEASURES**

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**Bill Snodgrass**  
Agricultural Commissioner  
Sealer of Weights and Measures

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Placerville, CA 95667  
(530)621-5520  
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**APPLE CIDER FOOD SAFETY CONTROL WORKSHOP**  
**JULY 15-16, 1999**  
**APPLE HILL QUALITY ASSURANCE PROGRAM AND GUIDELINES**

Dave Bolster  
Senior Agricultural Biologist

**BACKGROUND**

The Apple Hill Growers Association was created in 1964 to promote Direct Marketing of their agricultural products. It was so successful that now over ½ million people annually come to Apple Hill to buy a box of apples, an apple pie and fresh apple juice/cider. Apple Hill developed a positive marketing image by providing fresh, wholesome and healthy products that the public could not buy in the supermarket. Fresh apple juice/cider is an important part of the reason people come to Apple Hill each year. Any negative publicity about apples would have a negative impact on their products because of the reputation for quality and high profile.

When E.coli 0157 H:7 was found in fresh apple juice in 1996 Apple Hill Juice/Cider Processors were concerned about what impact this would have on their product. Apple Hill Juice/Cider Processors had always produced a quality product, **not using grounders**, to make their fresh apple juice/cider. To insure that they were producing a safe product they asked the California Health Department and the FDA to inspect their facilities and advise them on how they could improve their present operations. As a result the Apple Hill Juice/Cider Quality Assurance Plan (AHQAP) was developed in cooperation government health agencies. The plan met the food safety requirements of FDA and the small cider mills could afford the improvements without putting them out of business. In addition the QAP provided the Apple Hill Processors something **POSITIVE** to give public when they asked about their product safety. As a result of the AHQAP retail sales of fresh apple juice/cider were not hit nearly as hard during the 1997 Apple Hill season as other areas.

## **APPLE HILL QUALITY ASSURANCE PLAN**

The AHQAP is a comprehensive, integrated program of voluntary guidelines for apple production and juice/cider processing that enhance the safety and quality of unpasteurized apple juice/cider from “bloom to bottle”. The plan was developed using a Hazard Analysis Critical Control Point (HACCP)- based approach. The following are the Essential Elements of the Plan.

### **ADMINISTRATIVE GUIDELINES**

- 1) Processors must develop and implement an individual Quality Assurance Plan (QAP).
- 2) Designate a manager, employee or employees as the official quality control supervisor(s) for in-house processing.
- 3) Establish and maintain a record keeping system from “bloom to bottle”.
- 4) Processors must maintain identification of fruit from “field to bottle”.
- 5) Purchase apples only from growers who provide a “grower agreement” stating the fruit was produced and harvested using cultural and production practices that minimize the potential for microbial contamination.
- 6) Purchase apples from commercial packing houses that meet commercial “peeler grade” standards (“U.S. 1” Processing Grade).

### **APPLE PRODUCTION GUIDELINES**

- 7) Employ cultural, production, and harvesting practices that minimize the potential for microbial contamination of apples in the orchard.  
*These practices include, but are not limited to:*
  - a) Field Sanitation: Provide toilet and hand washing facilities that meet federal and state standards for quantity and accessibility.
  - b) Livestock Grazing: Do not allow livestock to graze in orchards.
  - c) Livestock Fertilizers: Do not use livestock fertilizers or biosolids as a nutrient source for apple trees.
  - d) Harvest: Supervise the harvesting process to ensure that only tree-picked apples are placed into bins or field containers.
- 8) Meet applicable standards for water quality and agricultural practices.
- 9) Place fruit received into cold storage or into an enclosed area until used for processing.

### **JUICE/CIDER PROCESSING**

- 10) Follow GENERAL SANITARY GUIDELINES for unpasteurized apple juice/cider production and processing.
- 11) Follow daily plant Sanitary Operating Procedures (SOP's).
- 12) Use only tree-picked fruit for juice/cider processing.
- 13) Apples used in processing meet or exceed the minimum standards for “U.S. Cider” grade as specified in the “U.S. Standards for Grades of Apples for Processing”.
- 14) Prior to processing, grade, inspect and wash all apples.
- 15) Use water in the processing facility that meets drinking water standards.
- 16) Wash apples in water containing an approved anti-microbial agent in which the levels are

monitored at appropriate intervals. Rinse apples with potable water before grinding and pressing.

- 17) Establish and conduct a pest control program.
- 18) Place juice/cider into refrigeration until final distribution to the consumer.
- 19) Conduct an environmental monitoring program in the processing facility to verify sanitation.

### **TRAINING**

- 20) Establish a training program that addresses:
  - a) General sanitation practices in the processing plant and in the field.
  - b) Personal hygiene practices in the processing plant and in the field.
  - c) Cultural and harvest practices in the orchard.

### **PRODUCT LABELING**

- 21) The label, "fresh unpasteurized" will be placed on the caps of all fresh juice/cider containers.

### **PROGRAM VERIFICATION**

- 22) Verification of compliance with the QAP will be monitored by staff from the El Dorado County Department of Agriculture in cooperation with the California Department of Health Services, the U.S. Food and Drug Administration, and the El Dorado County Department of Environmental Health.
- 23) Processors who are in compliance with the AHQAP are entitled to use the program's official seal.

### **SUMMARY**

What has made the AHQAP successful? There were a number of elements, but the most important one was cooperation between industry and government. Other elements were:

1. The plan was voluntary.
2. Industry took pride of ownership of the plan.
3. State Health and the FDA were willing to set aside their enforcement role and advise the industry on what they could do to improve juice/cider safety.
4. The local Department of Agriculture was able to act as a facilitator.

More was gained through cooperation (carrot) as industry saw they had something to gain and were not simply complying with another government regulation (hammer). Regulations have a role in insuring product safety but they should not be the entire program.

Attachment: Apple Hill Quality Assurance Plan Flier



**Fresh Unpasteurized  
Apple Juice / Cider  
Quality Assurance Plan**

*Developed by the Association of  
Apple Producers of the Apple Hill  
Quality Assurance Plan  
in cooperation with:*

*The Dorado County  
Department of Agriculture*

*The Dorado County Department  
of Environmental Management  
Division of Environmental Health*

*California Department of  
Food and Agriculture*

*California Department of  
Health Services*

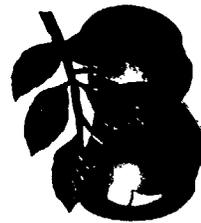
*University of California  
Cooperative Extension*

*U.S. Food and Drug Administration*

*More information about the Apple Hill®  
Quality Assurance Plan is available on the  
internet at [www.tasteldorado.com](http://www.tasteldorado.com)*

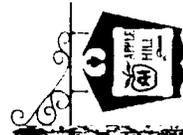


**Quality Assurance Plan**



Apple Hill®  
P.O. Box 494  
Carmine, CA  
95709

[www.applehill.com](http://www.applehill.com)

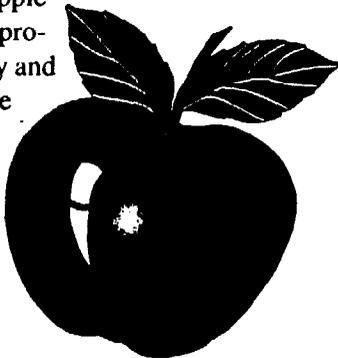


**Fresh  
Unpasteurized  
Apple Juice/Cider  
Quality  
Assurance Plan  
from Apple Hill®**



# Apple Hill® Fresh Unpasteurized Apple Juice/Cider Quality Assurance Plan

The Apple Hill Juice/Cider Quality Assurance Plan (AHQAP) is a comprehensive, integrated program of voluntary guidelines for apple production and juice/cider processing that enhance the safety and quality of unpasteurized apple juice/cider from “bloom to bottle”. The plan was developed using a Hazard Analysis Critical Control Point (HACCP) - based approach.



## Essential Elements

### Administrative Guidelines...

- 1) Processors must develop and implement an individual Quality Assurance Plan (QAP).
- 2) Designate a manager, employee or employees as the official quality control supervisor(s) for in-house processing.
- 3) Establish and maintain a record keeping system from “bloom to bottle”.
- 4) Processors must maintain identification of fruit from “field to bottle”.
- 5) Purchase apples only from growers who provide a “grower agreement” stating the fruit was produced and harvested using cultural and production practices that minimize the potential for microbial contamination.
- 6) Purchase apples from commercial packing houses that meet commercial “peeler grade” standards (“U.S. 1” Processing Grade).

### Apple Production Guidelines...

- 7) Employ cultural, production, and harvesting practices that minimize the potential for microbial contamination of apples in the orchard.

*These practices include, but are not limited to:*

- a) Field Sanitation: Provide toilet and hand washing facilities that meet federal and state standards for quantity and accessibility.
  - b) Livestock Grazing: Do not allow livestock to graze in orchards.
  - c) Livestock Fertilizers: Do not use livestock fertilizers or biosolids as a nutrient source for apple trees.
  - d) Harvest: Supervise the harvesting process to ensure that only tree-picked apples are placed into bins or field containers.
- 8) Meet applicable standards for water quality and agricultural practices.
  - 9) Place fruit received into cold storage or into an enclosed area until used for processing.

### Juice/Cider Processing...

- 10) Follow GENERAL SANITARY GUIDELINES for unpasteurized apple juice/cider production and processing.
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- 13) Apples used in processing meet or exceed the minimum standards for “U.S. Cider” grade as specified in the “U.S. Standards for Grades of Apples for Processing”.
- 14) Prior to processing, grade, inspect and wash all apples.

- 15) Use water in the processing facility that meets drinking water standards.
- 16) Wash apples in water containing an approved anti-microbial agent in which the levels are monitored at appropriate intervals. Rinse apples with potable water before grinding and pressing.
- 17) Establish and conduct a pest control program.
- 18) Place juice/cider into refrigeration until final distribution to the consumer.
- 19) Conduct an environmental monitoring program in the processing facility to verify sanitation.

### Training...

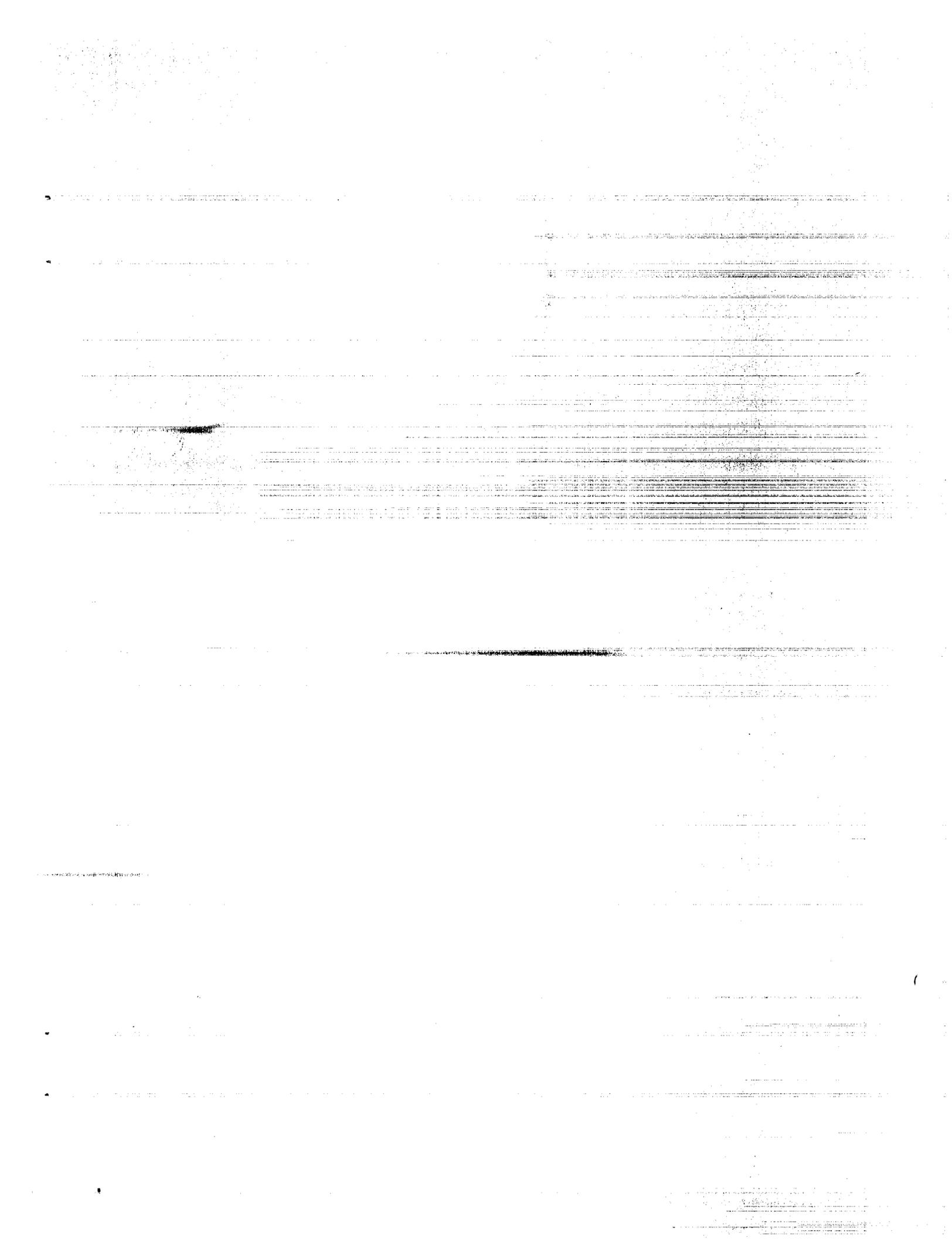
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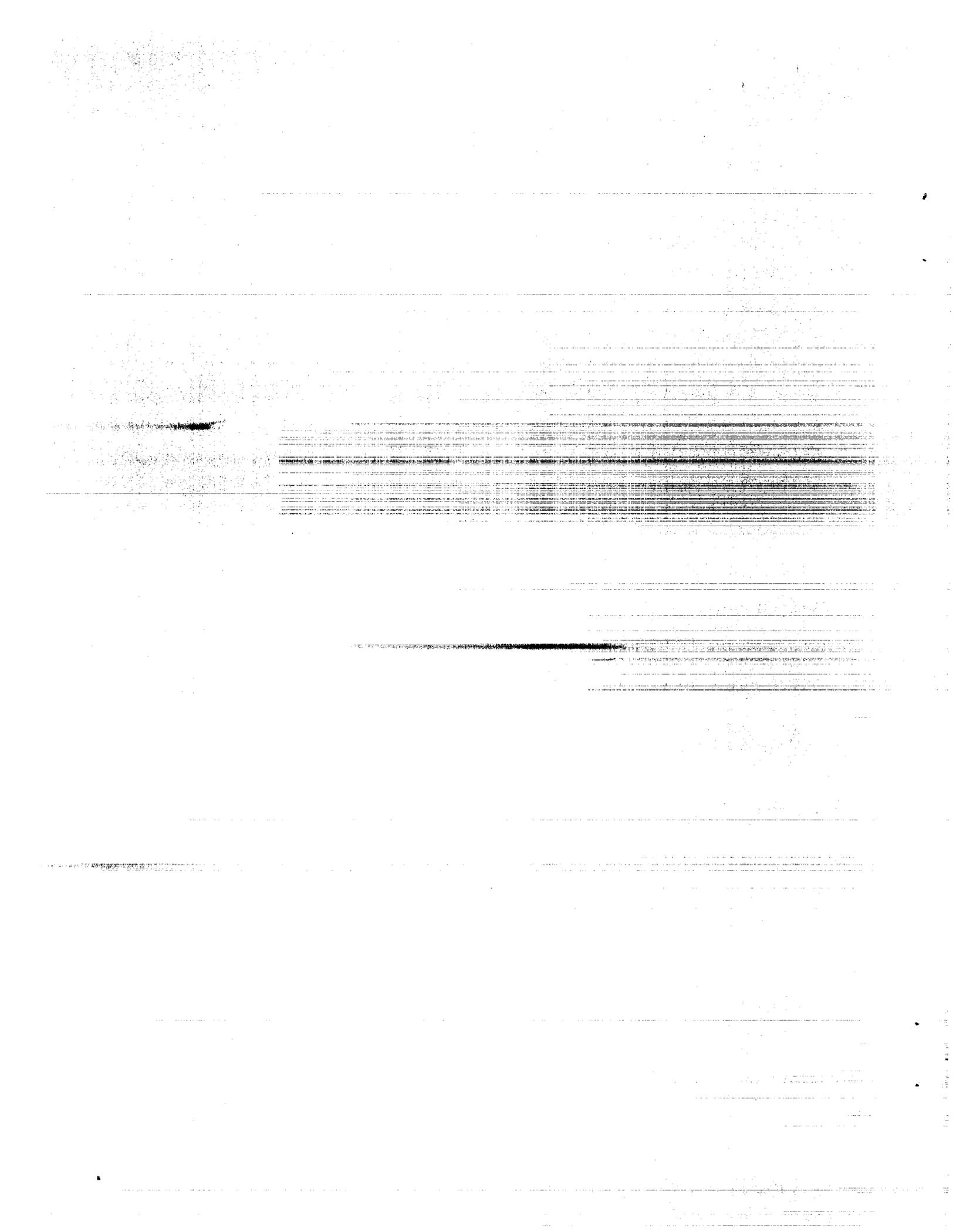
### Product Labeling...

- 21) The label, “fresh unpasteurized” will be placed on the caps of all fresh juice/cider containers.

### Program Verification...

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- 23) Processors who are in compliance with the AHQAP are entitled to use the program's official seal.





**APPLE CIDER FOOD SAFETY CONTROL WORKSHOP**

**JULY 15 & 16**

**J. PETER CHAIRES**

**ACTING CHAIRMAN - AMERICAN FRESH JUICE COUNCIL**

**ASSOCIATE VICE PRESIDENT - FLORIDA GIFT FRUIT  
SHIPPERS ASSOCIATION**

**"CITRUS JUICE VALIDATION PRACTICES"**



## I. INTRODUCTION

### A. FGFS

- B. AFJC To promote the value and development of a safe fresh juice industry through education, communication and the continuous improvement of GMP's.

## II. EFFORTS TO DATE:

- A. Focused on compliance with Warning Label Regulation. Finalized on July 8, 1998.

- B. Warning is quite strong – Warning: This product has not been pasteurized and therefore may contain harmful bacteria that can cause severe illness in children, the elderly and persons with weakened immune systems.

Strong push to help producers keep label off product.

### C. Display options:

Point of Sale or on Package

### D. Exemptions

1. Product sold for consumption on this site.
2. Juice processed in a manner to produce a 5-log reduction or whatever is equal to or greater than the final HACCP rule in the pertinent microorganism for period equal to its shelf life.

### E. Effective Dates:

1. September 8, 1998 for all juices other than citrus.
2. Initially November 5, 1998, but extended to July 8, 1999 for citrus juice producers requesting the time and agreeing to develop a 5-log (and agree to certain parameters).

## II IT IS AFJC AND INDUSTRY'S HOPE THAT COMPLIANCE WITH THE WARNING LABEL RULE – WILL PROVIDE A LAUNCHING PLATFORM INTO SOLID HACCP PLANS.

## IV WHAT HAS THE INDUSTRY (AFJC) BEEN DOING?

### A. Practical Changes:

### B. Division in Approaches:

1. LARGER SCALE: \* Continuous Production \* Distribution

Private labs and validation

Some – more proprietary due to intense competition.

Some use of cumulative reduction concept. Some with a beginning to end measure.

2. SMALLER SCALE: \* Retail / Grocers \* Roadside stands & shops

Forced to work cooperatively

Corporate validation concept

FCJTF –

Attempted interstate effort

Great level of cooperation

Not intended to validate existing techniques – but rather to work within knowledge of what small plants are doing and can do.

Focus on cumulative reduction with traditional set-ups – with additional research for enhanced results and unique situations.

Consolidation of scientific and technical expertise. Some of this was used by larger scale plants.

3. FORMAL CHANGES:

Improved knowledge and use of SSOP's and GMP's across country

Knowledge sharing within industry

Active land-grant and extensive programs. (Education, workshops)

Cross-commodity exchange of technology and ideas

Widespread HACCP application.

4. GENERAL TREATMENT PROGRAMS – CITRUS

OBJECTIVE

5 log reduction of microorganisms in fresh squeezed citrus juice

Target organisms are E. coli O517:H7 and salmonella spp.

Appropriate surrogate can be used.

Cumulative log reduction can be used.

#### TRADITIONAL TREATMENTS

Chemical cleaning

Mechanical cleaning

Grading / culling

FMC Extraction

External sanitizer treatment

#### CHEMICAL CLEANING

Various fruit cleaners have been used on the brushwasher, e.g.:

Phosphoric acid / anionic cleaner

Chlorine

Cholorine dioxide

Alkaline cleaners

Other soaps

#### SOME ALKALINE CLEANERS ARE PROVING VERY EFFECTIVE, SUCH AS FMC'S 395 CLEANER

Foaming

2.5 – 3.0 logs ( 30 seconds p # 11.5 – 12)

No phenyls

#### MECHANICAL CLEANING

Brushwashing with soap / cleaner

Log reduction may need to be determined for specific application, due to variance

in dwell time and concentration of cleaner

#### GRADING CULLING

If aggressive and diligent, does provide a log reduction

Somewhat unique to each application, though some general research is available.

#### EXTRACTION

Individual and corporate validation of FMC 5-head machine. FDOC research of most common smaller units.

Conservative 1.1 – 1.9 logs

#### EXTERNAL TREATMENTS

Phosphoric Acid / Anionic cleaner / sanitation

Chlorine

Chlorine dioxide

Peroxyacetic acid

Iodophor

Ozone

Note: Actual sanitizers are more effective at preventing cross contamination

#### 5. SMALL SCALE PRODUCERS (Cumulative)

(Must have minimally addressed)

Fruit purchasing and / or harvesting standards

Fruit grading

Fruit cleaning (brush wash, rinse)

Surface treatment

Chemical: chlorine, SOPP (sodium orthophenylphanate), acid cleaner, alkaline cleaner)

Heat (pasteurize the peel only)

UV

Sanitary storage – if short term - hold prior to extraction

Extraction

Research conducted on most widely used equipment

In some instances – juice treatment (thermal, UV treatment).

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**Example of log reduction scenario – from FCJTF:**

Brush washing, SOPP soaping, rinsing 3.5.log +/- .4

High alkaline wax application, with heat dry.

(Also tested alkaline cleans.) 1.1 log

Extraction with FMC or Juice Tree technology 1.0 log (conservative)

5.6 log

Options: Other Sanitizers, heat.

Ex. Hot water immersion: 176° = 1 minute 5 log

158° = 2 minute

Hot water spray or steam

190°F - 200°F, 30 – 60 seconds 5 log reduction

Note: Surface thermal treatments are highly effective – but must be integrated into a program of solid GMP's, SSOP's and/or HACCP – to maintain effectiveness and minimize or remove a chance of contamination.

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## V. LARGE SCALE - FRESH PLANT EXAMPLES

### A. Albritton Fruit Company

Use a combination of traditional methods

- Chemical washing or brushwasher (FMC fruit clean 395 for 30 seconds)
- Fruit surface acic anionic sanitizer
- Aggressive culling
- FMC 5-head extractor

Achieved and independently verified >5 log.

### B. The Fresh Juice Company

- Use a combination of traditional methods
- A certified organic plant

No phosphoric acid sanitizer / wash

Use citrus acid and chlorine and chlorine dioxide

- Steps:
  - Two brush wash steps
  - Two grading steps (zero tolerance)
  - Sanitizer spray 83 seconds, 46 nozzles
- Achieved an independently verified > 7 log.
- Well documented HACCP, SSOP's & GMP's

### C. Steam Applications: (such as Sun Orchard)

Clean, graded fruit enters steam tunnel

Time / Temperature: 30 seconds @ 190° F

Fruit surface temp reaches 155° F

Following steam, a cool 50 ppm chlorinated rinse

Remainder of log reduction from: wash, sanitize, extraction

Concept initiated by FDOC

## VI INFO SHARED AT PUBLIC MEETINGS – AVAILABLE ON NET

In plant testing for surrogates

Outside testing – process duplication in labs or university settings – pilot processes

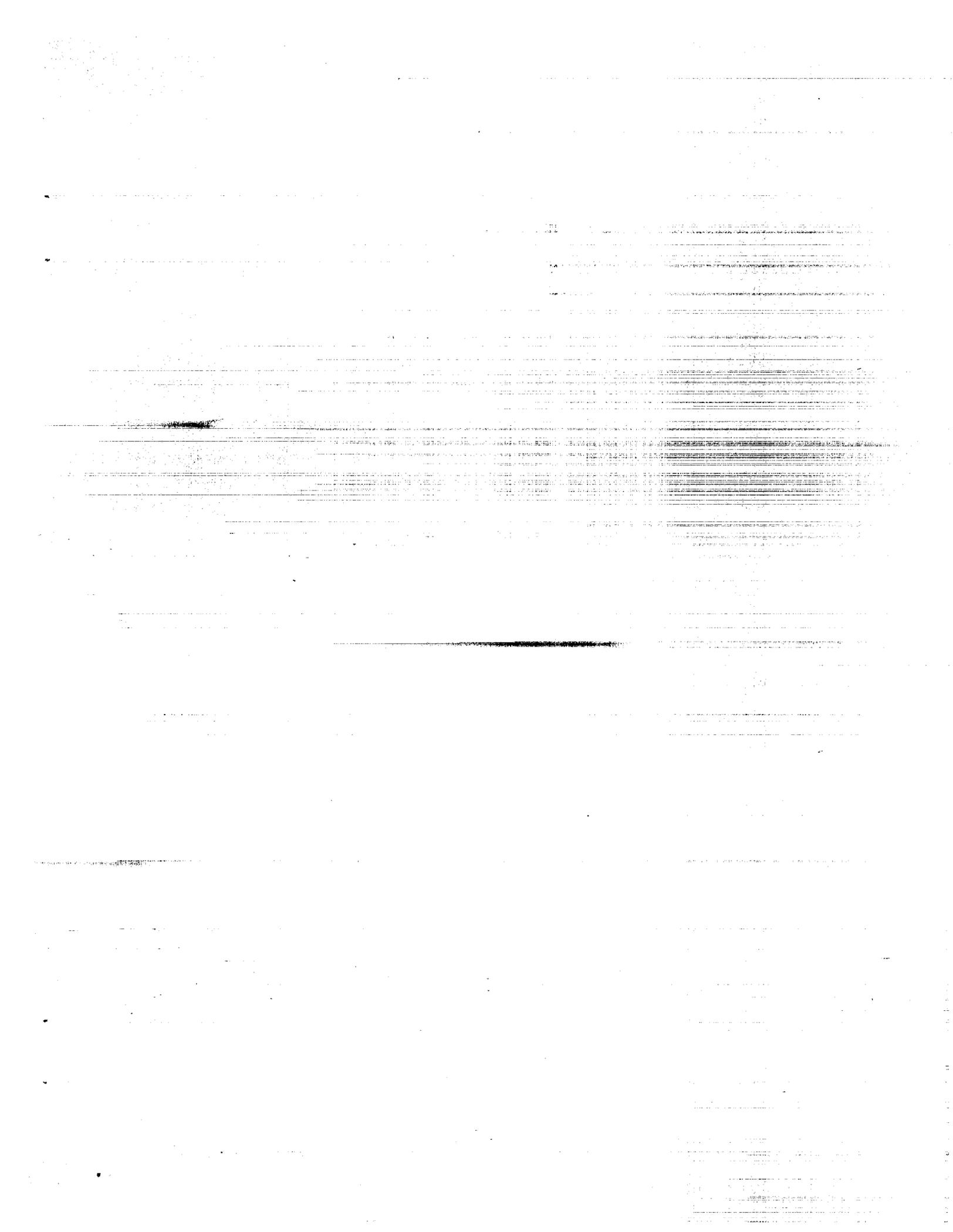
FDA surrogate research.

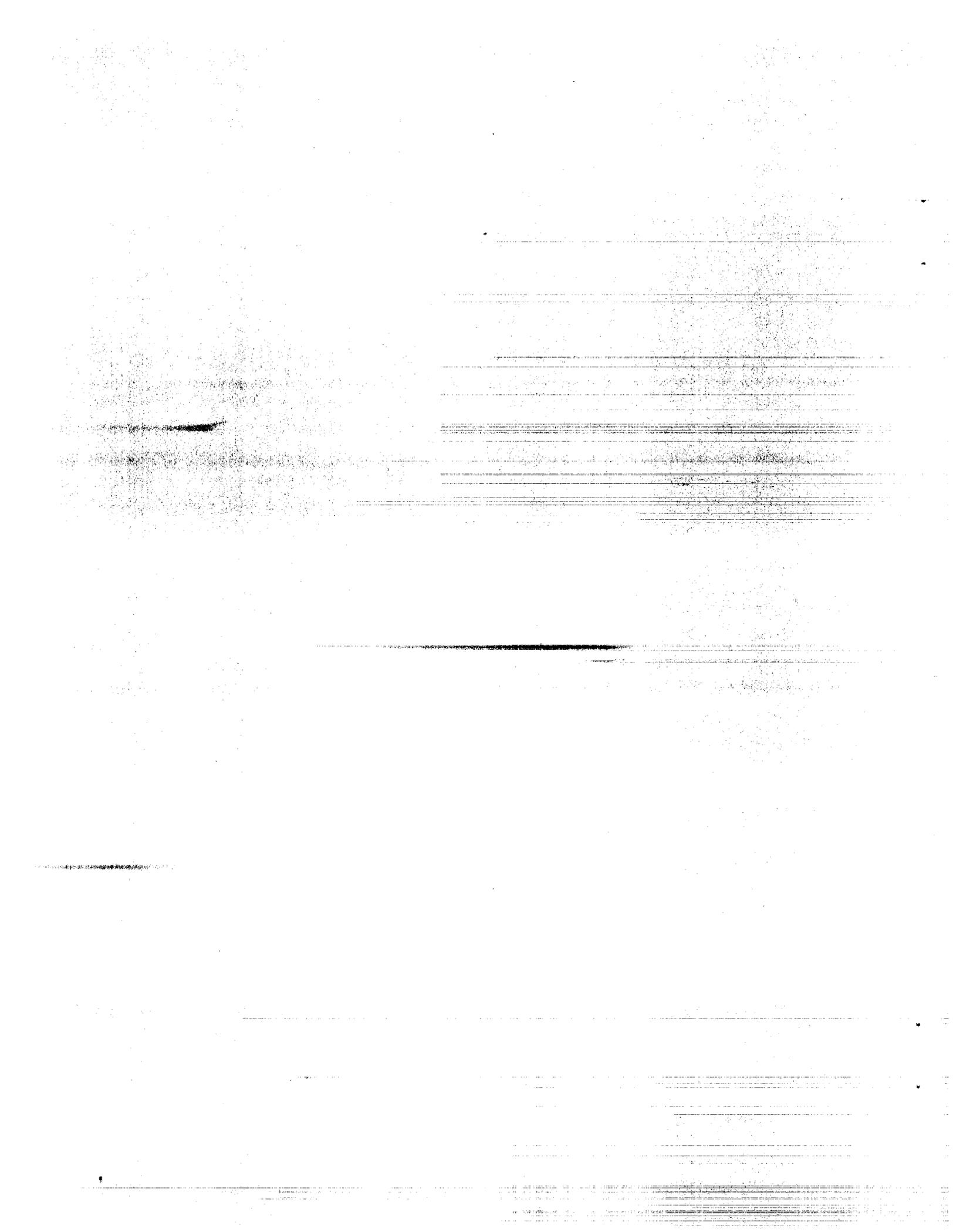
Chemical applications and use of ORP technology

## VII RESEARCH STILL NEEDED:

- Sanitizer research should include – all fruit types – Cleaning and grading of raw fruit most important to preventative measure – Most effective for each fruit type.
- The sanitizers effect on fruit and equipment, residue in product and overall safety.
- Sanitizer usage including effective concentrations, duration of exposure and temperature.
- Based on the use of certain types of sanitizers, what will be the subsequent type of frequency of tests for the pathogenic bacteria?
- Based on results on this research, what corrective action, criteria and procedures need to be implemented?
- Research the microbiological environment surrounding the growing and cultivation of each type of raw fruit and vegetable used to make fresh unpasteurized juice. This review would need to be specific and address existing assumptions which have proven to be inaccurate (such as: pH and acid levels) and what conditions impact the survival, growth or destruction of the Salmonella and E. coli 0157:H7 bacteria.
- Develop further extensive research on the ecology of Salmonella and E. coli 0157:H7 in the field and in the processing plant.
- Develop scientific performance information on the acceptable levels of coliform, mold, yeast, and E. coli. Take new test methods into consideration.
- Develop, validate, and implement improved detection methods for rapid testing of low levels of Salmonella and E. coli 0157:H7.

- Provide prevention techniques for long term control, reduction, and elimination of E. coli and Salmonella by developing new methods to prevent initial colonization, new methods to reduce or eliminate contaminants before harvest, new disinfection methods, surface decontamination, alternative disinfection methods and biofilm control.
- Explore the practicality of package sensors that will allow the industry to alert consumers of inappropriately stored or contaminated product.
- Public meeting for FDA and USDA to share information generated to date.





**ASSOCIATION OF FOOD AND DRUG OFFICIALS**  
**REQUIREMENTS AND RECOMMENDATIONS FOR APPLE CIDER PROCESSING**  
**OPERATIONS**

May 26, 1999

Because fresh, or unpasteurized apple cider has been linked to numerous foodborne illness outbreaks, the Association of Food and Drug Officials believes that pasteurization, or an equivalent process, is the only scientifically valid way to ensure the safety of apple cider. Since it may be unreasonable to expect that all apple cider processors will choose to pasteurize their products, the following requirements and recommendations for apple cider processing operations have been developed to significantly reduce the possibility that apple cider will be involved in future foodborne illness outbreaks.

**Definitions**

**Dropped Apples:** Apples that have contacted the ground in any manner in the orchard, storage cooler, pressing room or any other area. Where prudent precautions have not been taken to maintain separation of tree-picked and dropped apples, all apples shall be considered to be dropped apples.

**Must:** Term used to state mandatory requirements.

**Pasteurized:** Apple cider which has been produced by a method that includes a processing step (typically a heat process) which has been shown to effectively reduce the pathogenic microbial population in the resulting product to a level that does not contribute to foodborne illness.

Nothing contained in this definition shall be construed as barring any other process as may be demonstrated to be equally effective.

**Shall:** Term used to state mandatory requirements.

**Should:** Term used to state recommended or advisory procedures or identify recommended equipment.

**Tree-Picked Apples:** Apples which have been picked directly from the tree and segregated under sanitary conditions from dropped apples.

**Unpasteurized:** Apple cider which has been produced by methods that do not include a heat processing step which has been shown to reduce the pathogenic microbial population of the resulting product to a level that does not contribute to foodborne illness.

**General**

The use of a Hazard Analysis Critical Control Point (HACCP) program is strongly recommended.

## **Facility Requirements**

Cider processing and other food-processing operations must be located in a separate, enclosed room or building. The food processing room must have impervious walls and ceilings, and the floors must be continuous concrete or other equally impervious and cleanable material with adequate floor drains.

Walls and ceilings should be light colored for easier cleaning and to provide better lighting on all work surfaces.

The processing facility must be adequately screened to eliminate insect and rodent entry. Cold storage door plastic curtains are effective where entrance is by forklift. During the cider processing season, overhead garage door openings can be framed in with temporary screened panels and a walk-in door provided. Temporary screens should be constructed in a manner which allows the garage doors to be closed whenever desired.

Completely enclosed toilet facilities must be provided and should be conveniently located near the work area. The lavatory must have hot and cold running water and soap for hand washing. In addition, there must be a suitable hand drying device or disposable towels and covered trash containers. A sign must be placed in the bathroom reminding employees to wash their hands after using the lavatory.

Adequate lighting must be provided. All lights over exposed food areas must be shielded to prevent pieces of glass from getting into food in the event of bulb or tube breakage.

Grounds and buildings surrounding the cider operation must be free of conditions which may result in contamination of the product. This includes improperly stored equipment or spray materials, litter, waste, uncut weeds and grass, and other rodent or pest harborage.

Disposal of all wash and waste water shall be through an approved sanitary sewage disposal system that is sized, constructed, maintained and operated according to law.

Equipment, utensils, chemicals and supplies not used in food processing must be stored in an area clearly separated from those used in food processing.

Cleaning chemicals, such as Clean-in-Place (CIP) chemicals, must be stored separately from pesticides or other non-processing chemicals.

Hot and cold potable, running water must be available in all processing areas. Sufficient volume and water pressure must be available to dislodge particles of fruit and film from all surfaces. A high pressure washer is highly recommended.

If well water is used, it must be tested by a certified lab at least annually to meet potability standards. The test should be done within two months prior to the commencement of seasonal apple cider operations.

The use of insecticides and rodenticides is permitted only under such precautions and restrictions as will prevent the contamination of food or packaging material with illegal residues. If used within the processing area, precautions must be taken to protect all raw ingredients and packaging materials. After spraying and before commencement of any food processing operation, all food contact surfaces must be thoroughly cleaned and sanitized.

## **Equipment**

All food contact surfaces must be constructed of food-grade materials which are safe, durable, corrosion-resistant, non-absorbent, and can be easily cleaned and sanitized. Copper, copper alloys and galvanized metals must not be used in contact with apple cider.

All food contact equipment and supplies (examples: racks, cloths) must be stored off the floor in a well-ventilated location which minimizes the potential for contamination.

All tubing carrying cider must be approved for food use and all plastic tubing should be transparent. Tubing must be protected from abrasion or breakage and easily replaced. If the tubing passes through spaces that are not readily accessible, the tubing should be one piece and easily cleaned. Tubing should be as continuous as possible with couplings kept to a minimum. Periodic disassembling, cleaning and sanitizing of tubing, clamps, couplings and connections must be performed. Tubing must be positioned so that no pockets of liquid remain when the tubing is rinsed (self-draining). Tubing must be cleaned and sanitized at least after each day's run and prior to use following extended interruption.

## **Employees**

Competent supervisory personnel must be assigned the responsibility of supervising the overall sanitation of the facility.

To prevent contamination of food products, all persons working in the processing and filling areas must wear clean outer garments, maintain a high degree of personal cleanliness, and conform to hygienic practices while on duty. Hands must be washed thoroughly before starting work, after each absence from the working area, between operations and any other time when they have become soiled. All insecure jewelry shall be removed. Hair restraints (hairnets, headbands, caps, etc.) must be worn. If gloves are used, they must be designed for food handling operations. Whenever personnel change from non-food contact or cleaning operation to food contact operation, the individual must replace gloves or wash hands thoroughly before resuming food contact operations.

Tobacco in any form must not be used in rooms where food or food ingredients are processed, handled or stored.

A person who has diarrhea or is a carrier of a communicable disease that can be transmitted by food is prohibited from working with cider apples or in the processing area.

## **Harvesting**

Steps can be taken in the orchard to minimize microbial contamination of apples. Where possible orchards should be fenced in order to restrict or eliminate animal grazing in the orchard. If orchards are frequented by large flocks of starlings or other roosting birds, soiled fruit should not be used in unpasteurized cider. Care should be taken during collection to prevent the contact of damaged apples with wholesome fruit.

Eliminate to the extent possible animal droppings and manure in the orchard. Unpasteurized apple cider must not be made from apples of orchards fertilized with human or animal wastes.

Dropped apples must not be used for the production of unpasteurized cider.

Good hygienic practices should be used by those collecting apples and toilet and hand washing facilities should be readily accessible to field workers.

Know the quality of the apples from which you will be making your cider. More contaminated apples coming into your process will require more stringent inspection and cleaning to make safe cider. The use of written contract specifications is highly recommended for cider producers who purchase cider apples.

Clean containers must be used to harvest and transport apples. Containers should be properly maintained and inspected continually throughout the season.

### **Receiving**

If cider apples are purchased, accurate records should be kept of incoming lots which identify the date of purchase and source of apples used to produce each lot of cider. Accurate records can limit product recalls and producer liability in the event of an outbreak.

Processing apples should be kept in cold storage, as close to 32° F as possible, or in an enclosed area, free of flies, other insects, rodents and other pests. Lower temperatures extend product shelf-life considerably.

Animals (cats, birds, dogs, wild animals, etc.) are prohibited from processing and storage areas of the building.

Apple containers should be inspected upon receipt and before apples are used to assure the containers are free of visible filth which may contaminate the apples.

### **Inspection**

All apples must be inspected before or during washing and brushing. Only intact, sound apples shall be used. Wormy, decayed or rotten fruit must be discarded before entering the washing step. Only intact, sound tree-picked fruit shall be used in the production of unpasteurized apple cider. Damaged fruit (i.e. hail damage, etc.) may be used as long as such damage does not negatively impact the microbiological quality of the fruit; otherwise, damaged fruit must be discarded before entering the washing step.

Fruit should be dry-dumped for inspection to prevent heavily soiled apples from spreading contamination via wash water.

If a flume is used, flume water must be of potable quality. Additionally, potable water or its equivalent must be used as a final rinse prior to pressing.

If field crates are floated in flume water, pressure washing the bottoms of crates before submerging them in flume water is recommended.

### **Washing and Brushing**

Apples must be thoroughly washed and cleaned (free of visible filth and debris) before crushing. This can be accomplished as part of the grading operation if there is no storage or holding time between grading and pressing.

Use of a food grade detergent and sanitizer in accordance with the manufacturer's label

specifications to further reduce biological contamination is recommended.

### **Crushing and Pressing**

Crushing and pressing equipment must be cleaned prior to start-up and cleaned and sanitized at the end of each day of operation at a minimum.

Equipment must be dismantled or disassembled at least daily to insure adequate cleaning and sanitizing. Do not rinse equipment after sanitizing. All equipment must be air-dried.

Press cloths must be specifically designed for cider production, made of durable materials and be replaced frequently. During processing, the cloths must be handled in a sanitary manner, which includes hanging the cloths on a line or placing them in a clean container off the floor between runs. At the end of each day's operation, all press cloths must be washed, rinsed, dipped in sanitizing solution, and dried. The cloths may be dried by spreading them on a clean line in a well ventilated and screened area away from flies and vermin. If a washing machine is used, it must be dedicated solely for the cloths and not for personal and work clothing.

Press racks must be made of food-grade plastic or hardwood which has been maintained free of excessive cracks or crevices. Poorly maintained equipment can be impossible to clean and sanitize adequately.

Keep press racks off the floor at all times. At the end of each day, all used press racks must be washed, sanitized, and allowed to dry.

Pressed pomace must be properly disposed of immediately. Pomace residue must not be left overnight in the processing area. Pomace residue removal helps control insects and rodents on the property.

### **Processing Options**

If additives (e.g., sodium benzoate and potassium sorbate) are used, care must be taken to assure they are used in accordance with good manufacturing practices and as specified in Title 21 of the Code of Federal Regulations. Studies have shown a combination of both additives at 0.1% each to be most effective in controlling *E.coli O157:H7*.

Fresh cider is typically not pasteurized but recent data has shown that heating cider for only 6 seconds at 160°F eliminates *E. coli* contamination.

### **After Pressing**

Thermal or ultraviolet pasteurization is recommended as is the use of microbiological testing procedures on production batches to identify sanitation failures or product contamination. In order to guarantee that the pasteurization equipment you plan to purchase, or have already purchased, incorporates those design features necessary to insure your cider has been properly pasteurized, it is recommended that you submit a schematic of the pasteurizer to the regulatory authority for review (see addendum titled "Apple Cider - Thermal Pasteurization Equipment Recommendations). While end product testing may not be a complete assurance that the cider is free of pathogens, indicator organisms such as coliforms or generic *E coli* may help determine if adequate and consistent sanitation is being practiced. Testing may also play a role in HACCP plan verification and establishes a quality history.

Cider must be bottled in new containers and caps which have been properly stored to be free of dust, debris, and insects. Containers must be stored in their original closed plastic bags and inverted with the open tops down to avoid environmental contamination. Inspect containers carefully before filling and/or sanitize them thoroughly. Refilling used consumer containers risks contamination of filling equipment and cider and can take place only in a manner approved by the regulatory authority.

### Labeling

Containers must be properly labeled with the following information:

- Product identity -- Apple Cider
- Ingredients (if additives are used)
- Name, address, city, state, and zip code of manufacturer, packer or distributor
- Net quantity

Nutritional labeling, as identified in Title 21, Part 101 of the Code of Federal Regulations (21 CFR 101) may also be required.

The statement, "**IMPORTANT, Must be Kept Refrigerated,**" should appear on the label, as well as, meaningful coding which identifies the packing period.

In most cases, federal regulations require warning statements on labels of packaged juice products that have not been processed in a manner that will produce a reduction in pathogenic microorganisms to an acceptable level. The required warning statement, identified in 21 CFR 101.17 (g), reads as follows:

**WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.**

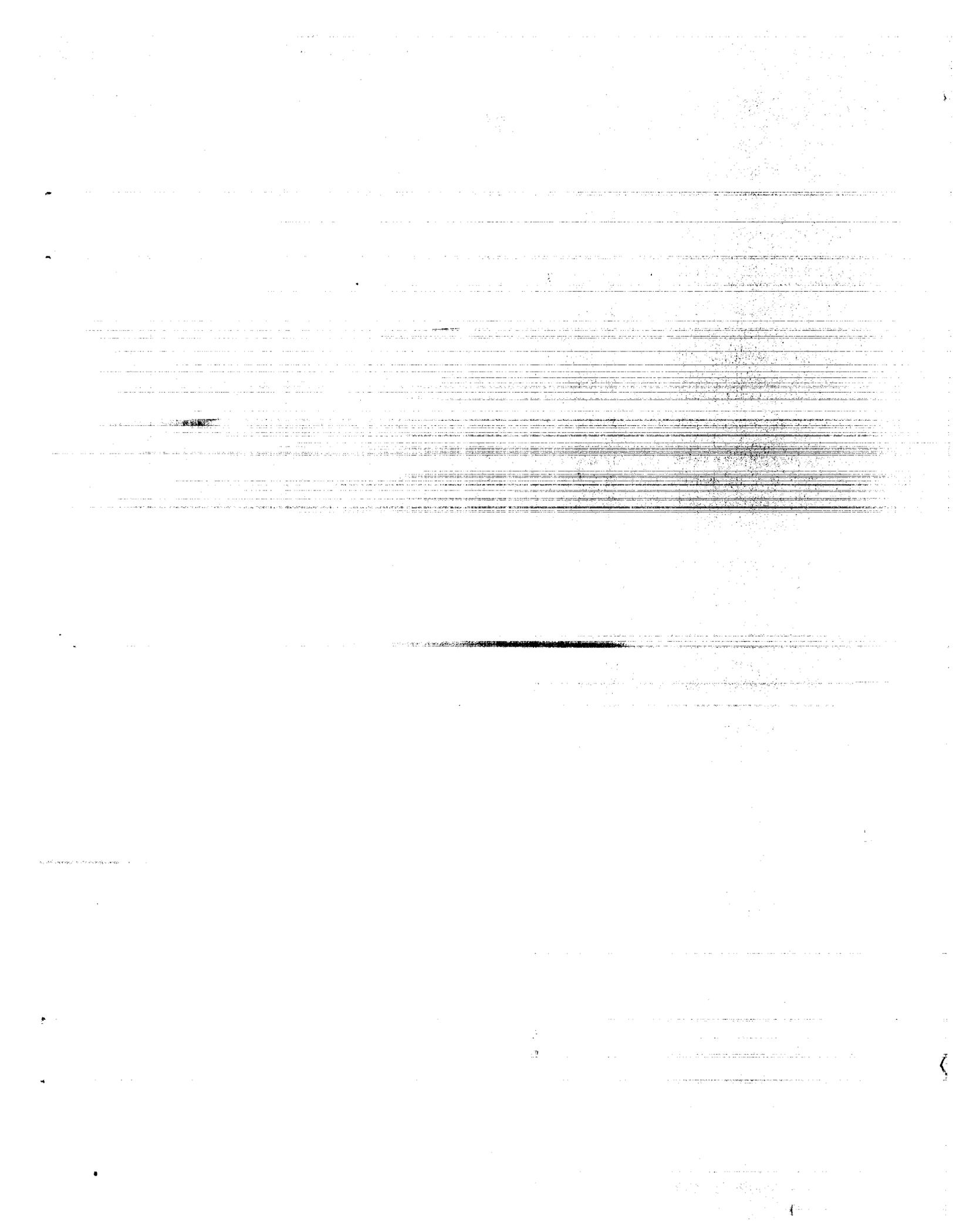
Those operators who produce apple cider that has not been processed in a manner that will produce a reduction in pathogenic microorganism to an acceptable level, but do not fall within the requirements of 21 CFR 101.17 (g), are encouraged to implement such a labeling program to inform at-risk consumers of the hazards that may be associated with such products.

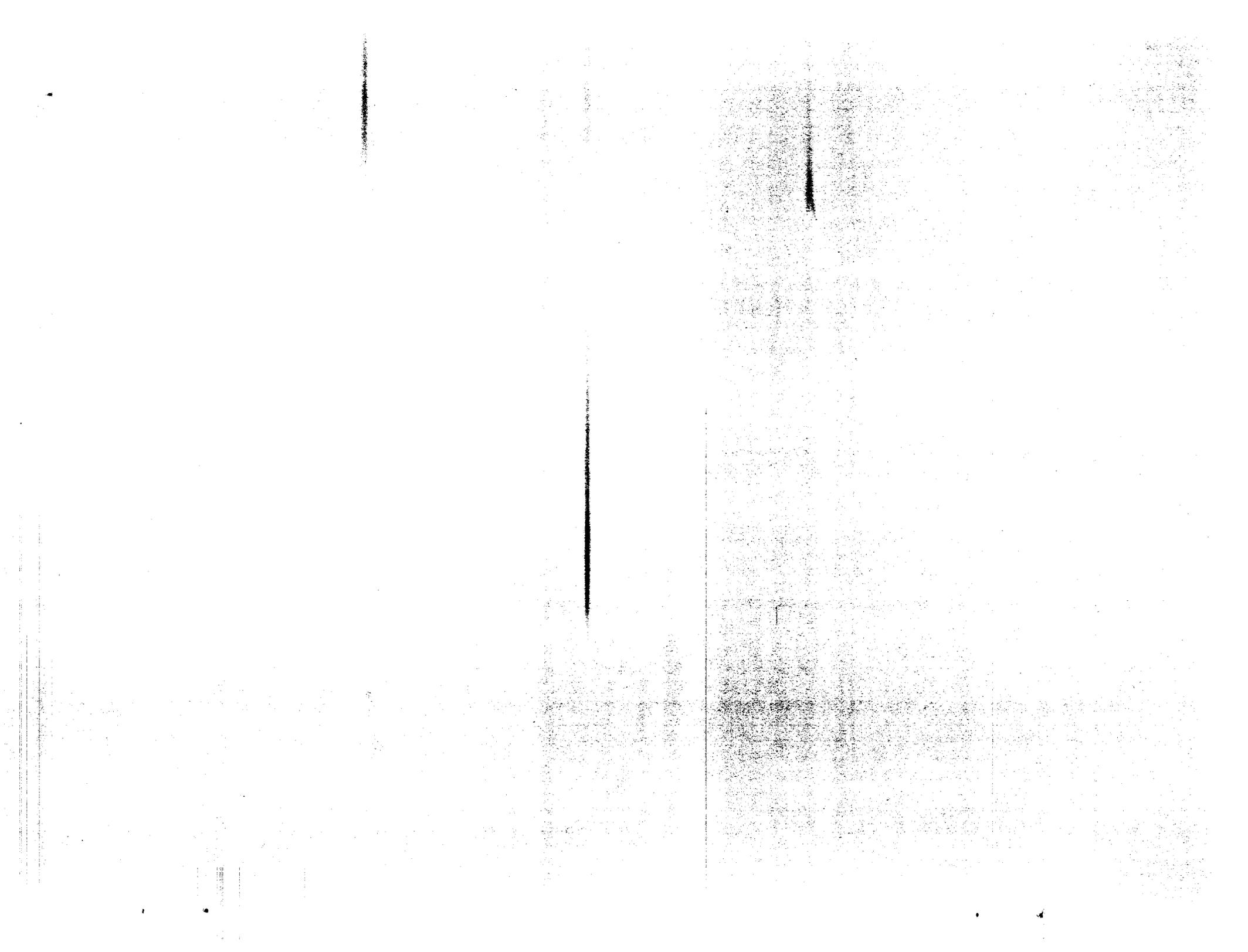
### Off-season

During the off-season, press racks and cloths should be stored so that birds, animals, insects, etc. are unable to come in contact with them. Thoroughly clean, sanitize, dry, and wrap racks and cloths before storage.

**While none of the foregoing requirements and recommendations can guarantee pathogen-free cider, their implementation will serve to greatly reduce the possibility that your cider will be involved in a foodborne disease outbreak.**

**These guidelines are based on currently available scientific information and will be revised and updated as researchers learn more about pathogens of concern in cider and their control.**





## Extramural Food Safety Research and Education Funded by USDA

*Dr. Anne Bertinuson, Cooperative State Research, Education, and Extension Service*

Food Safety responsibilities at USDA fall under several main divisions, or mission areas, of the agency. The Research, Education, and Economics mission area houses both the Agricultural Research Service (ARS) and the Cooperative State Research, Education, and Extension Service (CSREES).

### **The Agricultural Research Service**

As the principal in-house research component of USDA, ARS provides the scientific expertise needed to support the work of most of the Department's action and regulatory agencies and other Federal agencies, such as the Food and Drug Administration, the Environmental Protection Agency, some components within the Department of Defense, and the Department of the Interior. The USDA action and regulatory agencies served by ARS include Agricultural Marketing Service, Animal and Plant Health Inspection Service, Farm Services Agency, Food and Nutrition Service, Food Safety and Inspection Service, Foreign Agricultural Service, Grain Inspection, Packers & Stockyards Administration, and Natural Resources Conservation Service. ARS employs about 1,900 scientists, and owns and manages nearly 3,000 laboratory and office buildings and about 400,000 acres of land in support of its research mission carried out at over 100 domestic and foreign locations. ARS scientists communicate research results and transfer new technologies from the agency to other scientists, institutions of higher education, producers, product and process developers, consumers, and other end users through publications; conferences, workshops, and consultations; and cooperative agreements and patent licenses. The Agricultural Research Magazine is a great way to learn about current ARS research, and the magazine and other news and information from ARS are available at:

<http://www.ars.usda.gov/is/>

### **CSREES**

CSREES, an agency which merges the former Extension Service and Cooperative Research Service, works in partnership with the Land-Grant University system, which includes the Cooperative Extension Service. Work supported by CSREES is extramural, because the research and extension efforts are carried out by State employees at these universities, rather than CSREES itself. Under this Federal-State partnership, research and extension at the Land-Grants are supported in part through federal formula, base, and grant funds to these universities. Research directly related to cider production has been performed at Land-Grant institutions.

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Example:

ENHANCING FOOD SAFETY THROUGH CONTROL OF FOODBORNE DISEASE  
AGENTS

INVESTIGATOR: Pierson, M. D.; Flick, G. J.; Hackney, C. R.

PERFORMING INSTITUTION: FOOD SCIENCE AND TECHNOLOGY  
VIRGINIA POLYTECHNIC INSTITUTE, BLACKSBURG, VIRGINIA 24061

OBJECTIVES: Develop or improve methods for control of elimination of pathogens, for example *E. coli* O157:H7, *Salmonella*, and *Listeria* in foods.

The effectiveness of a combination wash treatment as a control for *E. coli* O157:H7 on apples was tested. Whole blemish free intact apples of uniform size were inoculated with 100 CFU *E. coli* O157:H7 per cm<sup>2</sup> and allowed to air dry. Apples were then immersed in the treatment solutions. The temperature of the treatment solutions was 25 C. The apples were held at 15 C. The treatments tested were chlorine (200 ppm, pH 5), acetic acid (5%), acetic acid followed by hydrogen peroxide (3%), a commercial phosphate fruit wash (Decco APL Keen 246), Tsunami 100 C and water. The treatments were applied for two minutes. For those treatments that involved two chemicals the total treatment time was two minutes. The treated apples were massaged in 100 ml .1% sodium lauryl sulfate and plated sorbitol MacConkey and TSA with 1% pyruvic acid to recover injured and noninjured cells of *E. coli* O157:H7. All the treatments were significantly different than water. Chlorine was the least effective treatment. The acetic acid wash was significantly different from the other treatments. The wash treatments did not adversely effect the organoleptic qualities of the apples. Apple cider processors indicated in a survey that most do not wash apples. The results of this study would indicate that most processors would benefit from washing the apples prior to cider processing.

PUBLICATION:

Wright, J.R., Sumner, S.S., Hackney, C.R., and Pierson, M.D. 1998.

Reduction of *E. coli* O157:H7 on apples using acetic acid, hydrogen, peroxide, and phosphoric acid wash treatments. *J. Food Prot.* 61(Sup:A):38.

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### **The Competitive Grant Process**

Another important mechanism to support research, education, and extension, is a competitive grant process. In a Request for Proposals (RFP), the agency describes a research or extension need, sometimes in very specific detail, and requests proposals to address the problem. Merit review of the proposals selects the best work for funding. These RFPS can be targeted to high priority areas, and some competitions are open to all institutions (not restricted to Land-Grants).

In writing the RFPS, CSREES staff use input from stakeholders and other federal agencies, such as FDA, to decide on research and extension priorities.

### **Transferring Research Results to the Public**

Research funded under any of these mechanisms is transferred to the public in similar way to ARS research: publications, conferences, and workshops. The Cooperative Extension Service, at State and local levels, uses USDA research results in education, technology transfer, and information dissemination. In addition, anyone can access the Current Research Information System (CRIS) to learn about research funded by USDA, including CSREES. CRIS is the USDA's documentation and reporting system for ongoing and recently completed research projects in agriculture, food and nutrition, and forestry. The project summaries given in this paper were taken from CRIS. The CRIS home page is:

<http://cristel.nal.usda.gov:8080/>

Major programs of CSREES which fund food safety research and education:

#### **I. The National Research Initiative Competitive Grants Program (NRICGP)**

<http://www.reeusda.gov/nri/>

The NRICGP supports a spectrum of research ranging from basic, fundamental questions relevant to agriculture in the broad sense to research that bridges the basic and applied sciences and results in practical outcomes. Competition is open to scientists at all academic institutions, Federal research agencies, private and industrial organizations, and those individuals qualified but not affiliated with one of the aforementioned organizations.

The NRICGP Food Safety Program for fiscal year 1999 requested research on: " a) identification of sources and reservoirs of pathogenic organisms and their toxins in food, animal feed and the environment; b) determination of the levels of microbial contamination in finished food products; c) identification of farm-based production practices that contribute to increased prevalence of foodborne pathogens; and d) identification of potential sites of contamination in the processing, transportation, retail setting, and consumer use of food products. In addition, a special new program, "Epidemiological Approaches for Food Safety" requested research on " a) identification of sources and reservoirs of pathogenic organisms and their toxins in food, animal feed and the environment; b) determination of the levels of microbial contamination in finished food products; c) identification of farm-based production practices that contribute to increased prevalence of foodborne pathogens; and d) identification of potential sites of contamination in the processing, transportation, retail setting, and consumer use of food products"

In past years, NRI has funded research directly relevant to cider production.

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**Example:**

**INTEGRATED POSTHARVEST STRATEGIES TO ASSURE SAFETY/QUALITY/  
PROFITABILITY OF APPLE CIDER PRODUCTION**

**INVESTIGATOR:** Jensen, H. H.; Reitmeier, C.; Gleason, M.; Glatz, B.; Nikolov, Z.

**PERFORMING INSTITUTION:** CENTER FOR AGRIC & RURAL DEV  
IOWA STATE UNIVERSITY AMES, IOWA 50011

**OBJECTIVES:** This project is designed to address the needs of apple orchards and processors who face new food safety and environmental regulations. The objectives are to evaluate the technical efficacy and economic effectiveness of various methods of controlling food safety hazards in apple and apple cider production. The technologies of pasteurization, apple sanitizer treatments, and irradiation are investigated with respect to control of food safety, effect on food quality, and costs. Alternative contracting mechanisms, the use of HACCP, and costs and benefits are considered for the agricultural system.

**APPROACH:** The project takes a systems approach to solving related problems of cider safety, environmental stewardship, and the regulatory environment to maintain the economic viability of smaller commercial apple producers and processors. First, the use of pasteurization, sanitizing treatments and electron beam irradiation is evaluated in terms of effectiveness in eradicating E.coli O157:H7. Next, the technical feasibility for selected methods is developed for prototype grower-processor systems for the alternative technologies. Third, we measure the economic impact in terms of costs and benefits of various technologies and incentive mechanisms for reducing the risk of E.coli in apple cider and in stored apples. An economic optimization model will be used to evaluate the relative merits and drawbacks of the alternative postharvest strategies for smaller producers. Processing and distribution systems for pooling of product, organizing processing to achieve larger scale of operation, and contracting mechanisms will be considered.

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## **II Special Research Grants Program, Food Safety Research**

<http://www.reeusda.gov/pas/programs/foodsafety/fsrgrants.htm>

The purpose of this grant program is to support problem-solving food safety research that addresses National emerging issues in food safety. The program for FY 1999 will focus on conducting qualitative and quantitative risk assessments of ready-to-eat foods; the scientific basis for critical control points, critical limits, and process capability in assuring food safety; and ensuring the safety of imported and domestic fruits and vegetables.

In fiscal year 1998, this program funded two projects on the safety of fresh juice/cider.

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INVESTIGATOR: Worobo, R. W.

PERFORMING INSTITUTION:  
FOOD SCIENCE AND TECHNOLOGY  
N Y AGRICULTURAL EXPT STATION  
GENEVA, NEW YORK 14456

NONTHERMAL PROCESSING ALTERNATIVES TO ENSURE THE SAFETY OF APPLE CIDER

OBJECTIVES: Our goals are to investigate ultraviolet irradiation, sulfur dioxide and dimethyl dicarbonate as potential nonthermal processes that will achieve a 5-log reduction of E.coli O157:H7 in apple cider.

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ALTERNATIVE PROCESSING TECHNIQUES FOR FRESH JUICES

INVESTIGATOR: Golden, D. and Sumner, S.

PERFORMING INSTITUTION:  
UNIVERSITY OF TENNESSEE  
AGRICULTURAL EXPERIMENT STATION  
KNOXVILLE, TN

OBJECTIVES: This proposal addresses methods to reduce or eliminate the pathogens E. coli O157:H7, Salmonella and Cryptosporidium parvum in apple cider and orange, grape and cranberry juices, by treatments involving UV light and ozone, alone or in combination.

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### **III Food Safety and Quality National Initiative**

<http://www.reeusda.gov/pas/programs/foodsafety/index.htm>

The Food Safety and Quality National Initiative Program focuses on reducing the incidence of foodborne illness through improving safe food handling practices, improving processes that safeguard the food supply, and improving the understanding of food-related risks. Competitive grants are awarded annually through the Food Safety and Quality National Initiative Program to support the development of food safety education programs at land-grant colleges and universities in the Cooperative Extension System. The awards increase Cooperative Extension's ability to deliver high-quality educational programs in food safety to a wide variety of consumers

and industry groups. Nationwide, projects funded through the Food Safety and Quality National Initiative Program provide education and training in safe food selection and preparation, food sanitation and storage, food preservation (canning, drying, freezing), safe food handling, seafood safety, aquaculture, pesticide residues in foods, biotechnology, and food irradiation. Funded projects also address the use of Hazard Analysis and Critical Control Point concepts in assuring the safety of the food supply.

In fiscal year 1999, one part of the RFP called for proposals on Hazard Analysis and Critical Control Points (HACCP) model development, training, and education in four targeted areas. Included are minimizing microbial food safety hazards for fresh fruits and Vegetables, and HACCP "train the trainer" programs using currently available models, curricula, and materials the development of HACCP "train the trainer" programs using currently available models developed for HACCP. Projects focused on developing or adapting existing HACCP models for use in emerging areas and/or for new target audiences will also be supported.

In fiscal year 1997, a project directly related to cider processors was funded by this program.

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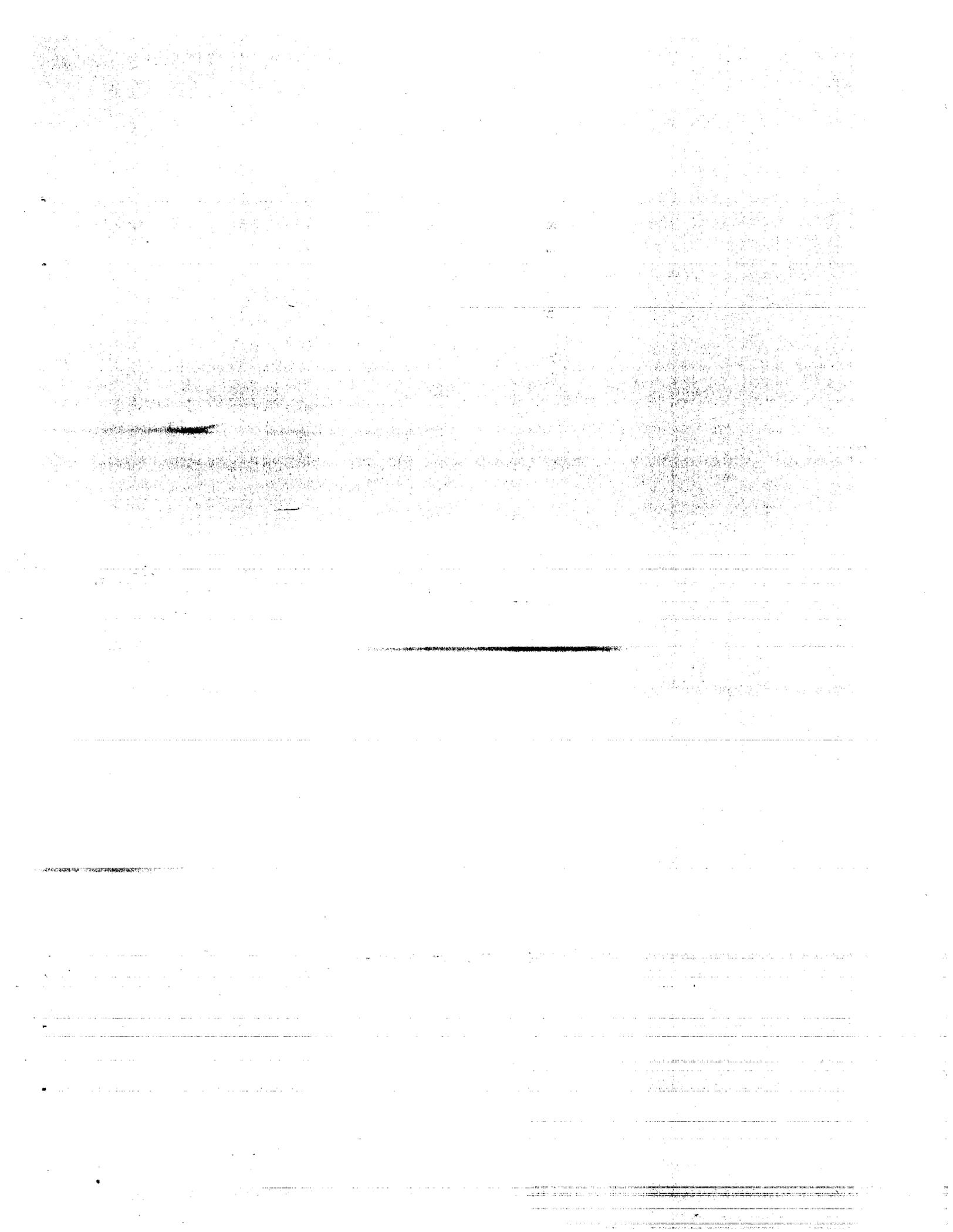
#### HACCP IMPLEMENTATION

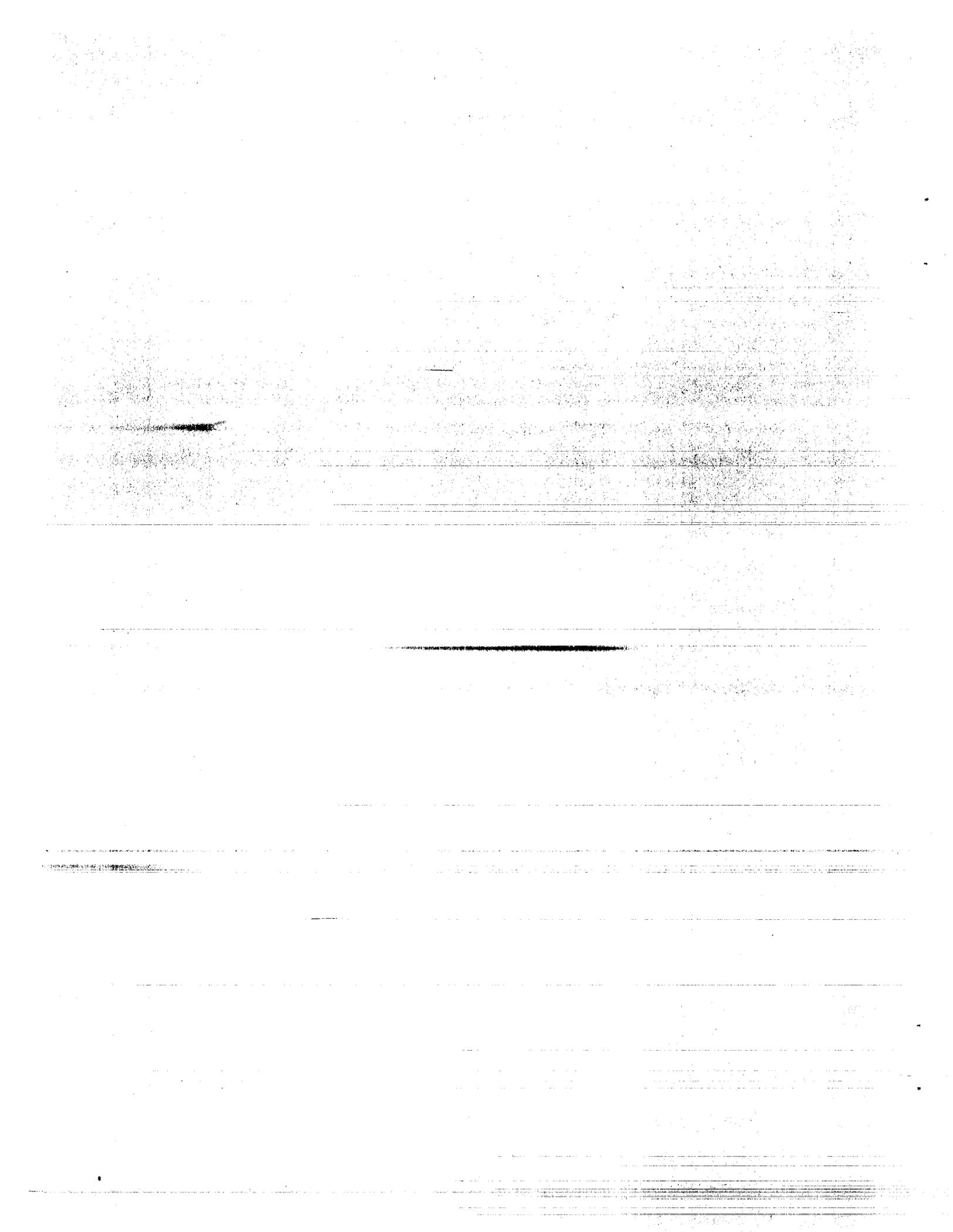
INVESTIGATOR: Sumner, S.

PERFORMING INSTITUTION: FOOD SCIENCE AND TECHNOLOGY  
VIRGINIA POLYTECHNIC INSTITUTE, BLACKSBURG, VIRGINIA 24061

OBJECTIVES: Develop model HACCP plans, conduct HACCP workshops, and a pilot HACCP implementation program for small to medium food processors, including cider producers.

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# Research on Decontamination of Apples by Washing with Detergents and Sanitizing Agents

Gerald M. Sapers, Ph.D.  
Eastern Regional Research Center, Agricultural Research Service  
U.S. Department of Agriculture  
600 E. Mermaid Lane, Wyndmoor, PA 19038  
[gsapers@arserrc.gov](mailto:gsapers@arserrc.gov)

- I. Introduction (S-1)
  - A. Overview of research on microbiological safety of fruits and vegetables at Eastern Regional Research Center (S-2).
  - B. Research objectives (S-3).
    1. Compare effectiveness of conventional and experimental washing/sanitizing agents.
    2. Determine efficacy of promising washing treatments applied in commercial brush washer.
    3. Identify factors limiting efficacy of washing.
- II. Comparison of Commercial and Experimental Washing Agents in Laboratory Studies
  - A. Methodology (S-4)
    1. Apples inoculated by immersion in suspension of non-pathogenic *E. coli* to give 10,000-100,000 CFU/g.
    2. Inoculated apples washed by immersion in solution of cleaning or sanitizing agent at 20° or 50°C with agitation for 1 min (S-5).
      - a. 200 ppm chlorine as sodium hypochlorite (pH 6.5).
      - b. Acidic and alkaline detergent formulations.
      - c. Trisodium phosphate.
      - d. Peroxyacetic acid formulations.
    3. Washed apples and inoculated controls homogenized and plated on BHIA for enumeration of surviving bacteria.
  - B. Effectiveness of commercial washing and sanitizing agents (S-6).
    1. Commercial washing agents and chlorine (sodium hypochlorite, at pH 6.5) achieve 1-2 log reduction (90-99%).
    2. Small improvement (less than 1 log) if solutions applied at 50°C.
  - C. Efficacy of hydrogen peroxide in decontaminating apples (S-7).
    1. 5% hydrogen peroxide at 50°C superior to conventional agents.

2. Combinations of hydrogen peroxide and conventional agents can achieve 3-4 log reductions (99.9-99.99%) on inoculated apple halves.
3. Population reductions of approx. 3 logs (99.9%) can be obtained with whole apples.

### III. Washing Trials in a Commercial Cider Mill (Placerville, California)

- A. Methodology (S-9)
  1. Apples inoculated on day before trials.
  2. Apples held 15 min in dump tank, then washed in flatbed brush washer, ground, and pressed.
  3. Most promising washing formulations compared.
  4. Bacterial population on apples and in cider determined.
- B. Efficacy of washing treatments (S-10).
  1. No reduction in dump tank.
  2. None of washing treatments achieved even 1 log reduction (90%) in bacterial population.
- C. Cross-contamination.
  1. No cross contamination in dump tank.
  2. Major cross contamination in hammermill or press.

### IV. Factors Limiting Efficacy of Washing (laboratory studies)

- A. *E. coli* attaches to apple surface within 24 hr and cannot be rinsed off with water (S-11).
- B. *E. coli* in inaccessible stem and calyx regions survives wash (S-12).
- C. *E. coli* in skin punctures can grow in puncture and survive wash (S-13).
- D. *E. coli* in contaminated water (drench water, dump tank, flume?) might infiltrate through calyx into apple core under suitable conditions (S-14-Photo).

### V. New Approaches (S-15)

- A. Targeted scrubbing/pressure washing, sonication.
- B. Targeted abrasion, peeling/coring.
- C. Surface pasteurization.
- D. Combination treatments (hurdle principle) – novel agents.
- E. Defect detection and sorting.

### VI. Conclusions (S-16)

- A. Commercial washing formulations tested and 200 ppm Cl<sub>2</sub> (pH 6.5) cannot reduce bacterial population on apples by more than 1-2 logs (90-99%) when apples are washed in laboratory by immersion in solution.

- B. Hydrogen peroxide solutions can reduce bacterial population on apples by 3 logs (99.9%) when apples are washed in laboratory by immersion.
- C. Washing apples in a flatbed washer will not reduce bacterial population on apples, even with effective anti-microbial agents.
- D. Efficacy of population reduction by washing may be limited by bacterial adhesion to apple surface, attachment in inaccessible areas of apple (calyx and core), presence in punctures, and infiltration within apple core.

**Research on Decontamination of Apples by Washing  
with Detergents and Sanitizing Agents**

**Gerald M. Sapers**

**Eastern Regional Research Center  
Agricultural Research Service  
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**Research on Microbiological Safety of Fruits and  
Vegetables at Eastern Regional Research Center,  
ARS, USDA**

**Environmental sources of microbial contamination**

**State of microbial contaminants on produce**

- **Microbial ecology**
- **Factors affecting resistance to anti-microbial treatments**

**Interventions to improve microbiological safety**

- **Exclusion of contaminated produce**
- **Decontamination by washing or other means**
- **Suppression of bacterial growth**

**Commodities currently under investigation**

- **Apples**
- **Potatoes**
- **Fresh-cut fruits and vegetables**
- **Sprouts**

## **Research Objectives**

- A. Compare effectiveness of conventional and experimental washing/sanitizing agents.**
- B. Determine efficacy of promising washing treatments applied in commercial brush washer.**
- C. Identify factors limiting efficacy of washing.**

## Methodology for Comparison of Commercial and Experimental Washing Agents

- Apples – unwaxed Golden Delicious: whole, punctured, or cut in half.
- Inoculation – 5 min in suspension of *E. coli* ATCC 25922 (non-pathogenic) to give  $10^4$ - $10^5$  CFU/g.
- Washing – 1 min in washing solution at 20° or 50°C with agitation on shaker; then drained and rinsed.
- Microbiological evaluation – composites (6-8 apples) homogenized, diluted, and plated on BHIA.

### Characteristics of Commercial Sanitizing Washes for Apples

<u>Code</u>	<u>Composition tested</u>	<b>Concentration</b>	
		<u>(%)</u>	<u>pH</u>
A	Acid anionic surfactant	1	2.4
B	Acid soap	5	3.4
C	Phosphoric acid + surfactant	1	2.1
D	Phosphoric acid + surfactant	1-2	1.7-1.8
E	Phosphoric acid + surfactant	1.6	1.9
F	Citric acid + surfactant	3.2	2.3
G	NaOH + surfactant	0.66-1	11.9-12.2
H	Trisodium phosphate	1-8	11.8-12.4
I	Surfactant	1	9.3
J	Peracetic acid + H <sub>2</sub> O <sub>2</sub> + acetic acid	0.01-0.1	3.3-3.9

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**Effect of Commercial Sanitizing Agents on *E. coli* (ATCC 25922) in  
Inoculated Golden Delicious Apple Halves<sup>a</sup>**

<b>Composition of Sanitizing Agent in Wash<sup>b</sup></b>	<b>Concn Tested</b>	<b>pH</b>	<b>Log10 Reduction</b>
Cl <sub>2</sub> (pH 6.5)	200 ppm	6.5	2.07±0.31
Surfactant	1%	9.3	0.98±0.07
Phosphoric acid + surfactant	1%	1.7	1.90±0.11
Phosphoric acid + surfactant at 50°C	1%	1.7	2.61±0.11
Trisodium phosphate	4%	12.4	2.36±0.08
Trisodium phosphate at 50°C	4%	12.4	2.45±0.08
Peracetic acid + H <sub>2</sub> O <sub>2</sub> + acetic acid	1000 ppm	3.3	2.05±0.48
Peracetic acid + H <sub>2</sub> O <sub>2</sub> + acetic acid at 50°C	1000 ppm	3.3	2.58±0.22

---

<sup>a</sup>Apples halves immersed 5 min in *E. coli* inoculum containing  $2.0 \times 10^7$  cfu/mL.

<sup>b</sup>Washed for 1 min.

**Efficacy of Washes Containing Hydrogen Peroxide and Commercial Sanitizing Agents For Decontamination of Golden Delicious Apple Halves Inoculated with *E. coli* (ATCC 25922)<sup>a</sup>**

<u>Washing Treatment<sup>b</sup></u>	<u>Log<sub>10</sub> Reduction</u>
200 ppm Cl <sub>2</sub> (pH 6.5)	2.01±0.17
5% H <sub>2</sub> O <sub>2</sub>	3.39±0.39
5% H <sub>2</sub> O <sub>2</sub> at 50°C	3.82±0.82
5% H <sub>2</sub> O <sub>2</sub> + 1% Surfactant	3.22±0.20
5% H <sub>2</sub> O <sub>2</sub> + 1% H <sub>3</sub> PO <sub>4</sub> /surfactant	3.27±0.21
5% H <sub>2</sub> O <sub>2</sub> + 1% H <sub>3</sub> PO <sub>4</sub> /surfactant at 50°C	4.20±0.56
5% H <sub>2</sub> O <sub>2</sub> + 2% Trisodium phosphate	3.27±0.29
5% H <sub>2</sub> O <sub>2</sub> + 2% Trisodium phosphate at 50°C	3.55±1.67 <sup>c</sup>

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<sup>a</sup>Apples halves immersed 5 min in *E. coli* inoculum containing  $2.0 \times 10^7$  cfu/mL.

<sup>b</sup>Washed for 1 min.

<sup>c</sup>Variable response due to decomposition of heated alkaline H<sub>2</sub>O<sub>2</sub>.

**Efficacy of Washes Containing Hydrogen Peroxide and Commercial  
Sanitizing Agent in Decontaminating Whole Golden Delicious  
Apples Inoculated with *E. coli* (ATCC 25922)<sup>a</sup>**

<u>Treatment<sup>b</sup></u>	<u>n</u>	<u>Log<sub>10</sub> Reduction<sup>c</sup></u>
5% H <sub>2</sub> O <sub>2</sub> at 50°C	2	2.67±0.10
5% H <sub>2</sub> O <sub>2</sub> + 1% Sanitizer C at 50°C	2	2.82±0.11
1% Sanitizer C at 50°C	2	1.53±0.33

<sup>a</sup>For each treatment, 9 whole apples inoculated by immersion for 5 min in 3L diluted *E. coli* inoculum containing approx.  $1.3 \times 10^7$  CFU/mL.

<sup>b</sup>1 min wash.

<sup>c</sup>Based on log<sub>10</sub>(CFU/g) of corresponding inoculated controls (mean=4.16±0.17); data from BHIA plate counts.

## **Methodology for Washing Trials in Placerville Cider Mill**

**Apples – unwaxed Golden Delicious (inoculated) and Fuji (not inoculated).**

**Inoculation – 20 lb portions of Golden Delicious apples immersed 5 min in suspension of *E. coli* K-12 (non-pathogenic) to give 10<sup>5</sup> CFU/g. Apples held overnight at 10°C before washing.**

**Cider mill unit operations:**

**Dump tank – 40 lb Golden Delicious apples (inoculated) mixed with ~250 lb Fuji apples (not inoculated) in 350 gal water at 20°C for 15 min.**

**Brush washer – sprayed with wash solution at 20° or 50°C during 25 sec transit over brushes, then rinsed with water on exit conveyor.**

**Hammermill**

**Press**

**Cider collection tank**

**Microbiological evaluation – duplicate 6-apple samples (Golden Delicious and Fuji) obtained before and after inoculation, after dump tank, and after brush washer; samples homogenized in 1 gal blender. Samples of dump tank water and cider also obtained. Samples diluted and plated on BHIA containing streptomycin (20mg/L).**

**Decontamination of Apples Inoculated with *E. coli* (Strain K12) with Sanitizing Washes in a Flat-Bed Brush Washer**

<u>Treatment<sup>b</sup></u>	<i>E. coli</i> (log <sub>10</sub> CFU/g) <sup>a</sup>				
	<u>Before Dump Tank</u>	<u>After Dump Tank</u>	<u>After Brush Washer</u>	<u>In Cider<sup>c</sup></u>	<u>In Dump Tank Water<sup>c</sup></u>
Water, 20C	5.49±0.09	4.92±0.37	4.81±0.26	3.83±0.15	0.00
Water, 50C	5.49±0.09	5.03±0.15	4.59±0.08	3.73±0.15	0.00
200 ppm Cl <sub>2</sub> , 20C	5.87±0.07	5.45±0.05	5.64±0.23	4.30±0.10	0.00
Cross Contam.	0.69	0.00	0.50	3.07±0.03	--
5% H <sub>2</sub> O <sub>2</sub> , 22C	5.87±0.07	5.46±0.40	5.27±0.09	3.83±0.05	0.00
5% H <sub>2</sub> O <sub>2</sub> , 54C	5.87±0.07	5.54±0.31	5.49±0.10	4.30±0.60	0.00

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<sup>a</sup>Mean of 2 determinations ± SD.

<sup>b</sup>200 ppm Cl<sub>2</sub> prepared from sodium hypochlorite adjusted to pH 6.4 with citric acid.

<sup>c</sup>Log<sub>10</sub> CFU/mL.

**Attachment of *E. coli* (ATCC 25922) to apple surfaces at 20°C**

Time after inoculation (hr)	Log <sub>10</sub> CFU/g <sup>a</sup>	
	Inoculated control	After wash
0.5	4.35 <sup>bc</sup>	3.38 <sup>d*</sup>
24	4.80 <sup>b</sup>	4.33 <sup>bc*</sup>
48	4.06 <sup>c</sup>	4.65 <sup>b</sup>
72	4.18 <sup>bc</sup>	3.88 <sup>cd</sup>

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<sup>a</sup>Mean of duplicate trials.

<sup>b-d</sup>Within the same column, means with no letter in common are significantly different ( $p < 0.05$ ) by Bonferroni LSD.

\*Log<sub>10</sub>CFU/g reduction significant at  $p < 0.01$ ) by ANOVA.

**Distribution of *E. coli* (ATCC 25922) on surface of inoculated apples  
before and after washing with 5% H<sub>2</sub>O<sub>2</sub> at 50°C**

<u>Location</u>	<u>Log<sub>10</sub>(CFU/cm<sup>2</sup>)<sup>a</sup></u>	
	<u>Inoculated</u>	<u>Washed<sup>b</sup></u>
Skin on wedges	4.77 <sup>d</sup>	2.05 <sup>d</sup>
Skin at calyx end of core	7.26 <sup>c</sup>	5.20 <sup>c</sup>
Skin on stem end of core	6.63 <sup>c</sup>	5.06 <sup>c</sup>

<sup>a</sup>24 h after inoculation; based on calculated surface area of skin.

<sup>b</sup>Washed 1 min in 5% H<sub>2</sub>O<sub>2</sub> at 50°C.

<sup>c-d</sup>Within the same column, means with no letter in common are significantly different ( $p < 0.05$ ) by Bonferroni LSD.

**Growth of *E. coli* in Punctures on Inoculated  
Golden Delicious Apples**

<u>No. of punctures</u>	<u>Inoculum strength (log<sub>10</sub>CFU/mL)</u>	<u>Log<sub>10</sub>CFU/g<sup>a</sup></u>		
		<u>Time after inoculation (hr)</u>		
		<u>0.5</u>	<u>24</u>	<u>48</u>
4 <sup>b</sup>	7.24	4.85	6.03	ND <sup>d</sup>
1 <sup>c</sup>	6.40	3.53	4.85	4.96
1	6.37	4.42	5.09	5.24

---

<sup>a</sup>Based on weight of whole apple; mean of duplicate trials.

<sup>b</sup>Four 1-cm deep punctures made with sterile nail on opposite sides of apple.

<sup>c</sup>Single 1-cm deep puncture made with sterile nail 2-3 cm from stem.

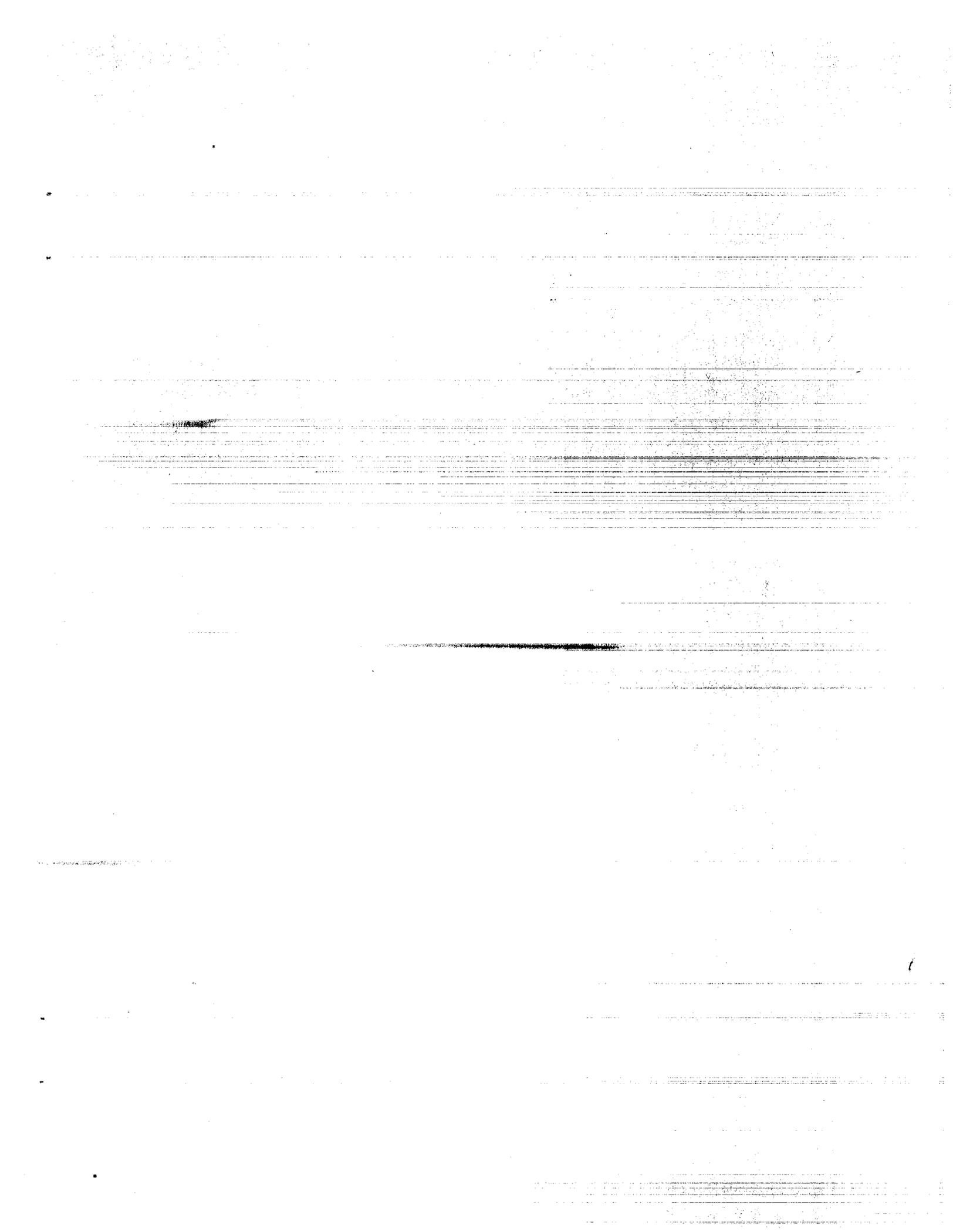
<sup>d</sup>ND=not determined.

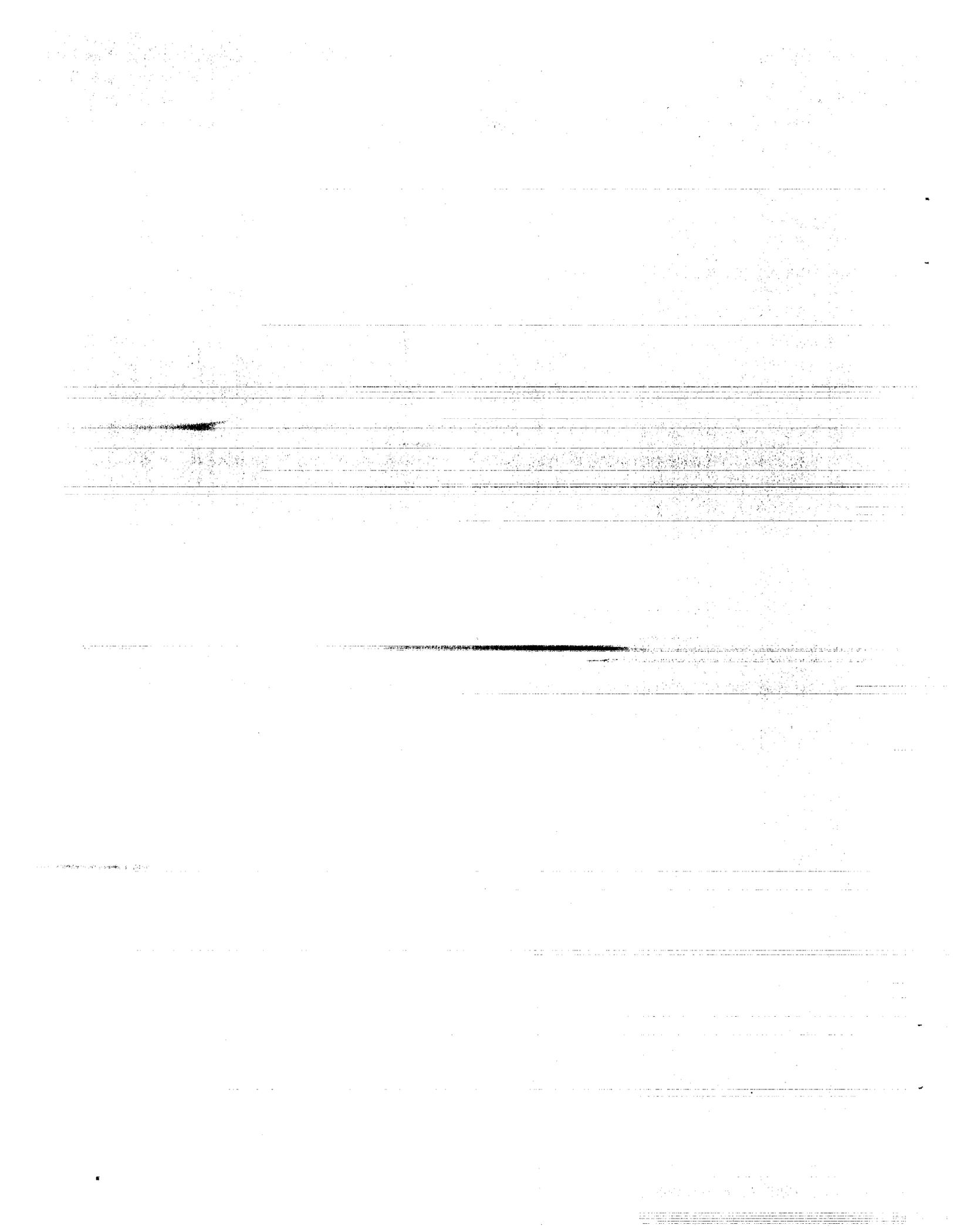
## **New Approaches to Produce Decontamination**

- **Targeted scrubbing/pressure washing, sonication**
- **Removal of contaminated surface by targeted abrasion, peeling, or coring**
- **Surface pasteurization with hot water or steam**
- **Combination treatments, novel anti-microbial agents, gas-phase treatments**
- **Defect detection and sorting**

## Conclusions

1. Commercial washing formulations tested and 200 ppm  $\text{Cl}_2$  (pH 6.5) cannot reduce bacterial population on apples by more than 1-2 logs (90-99%) when apples are washed in laboratory by immersion in solution.
2. Hydrogen peroxide solutions can reduce bacterial population on apples by 3 logs (99.9%) when apples are washed in laboratory by immersion.
3. Washing apples in a flatbed washer will not reduce bacterial population on apples, even with effective anti-microbial agents. This is probably due to short exposure and ineffective brushing.
4. Efficacy of population reduction by washing may be limited by bacterial adhesion to apple surface, attachment in inaccessible areas of apple (calyx and core), presence in punctures, and infiltration within apple core.





# Apple Cider Production:

Input Apples - Tree Picked vs.  
Dropped Apples

- What we know
- What we don't know
- Why we should take precautions

Robert I. Merker

FDA/CFSAN



## Apple Cider Production:

### Input Apples - Tree Picked vs. Dropped Apples

- What we know
- What we don't know
- Why we should take precautions

Robert I. Merker  
FDA/CFSAN

## The Problem

Apple Cider / Apple Juice Outbreaks -  
primarily contamination with *E. coli*  
O157:H7, some contamination with  
*Cryptosporidium*, *Salmonella* spp.

- Association of dropped apples as  
contamination source in at least one  
instance. No unequivocal data to support  
or refute assertion.
- Therefore, presumption that input apples  
were source of contamination.

## The Problem [continued]

In recent outbreaks, contamination usually only present in one batch or a limited number of batches.

Difficult to discriminate between contamination on apples pre-harvest, or contamination of apples during harvest.

Probability of finding *E. coli* O157:H7 or *Salmonella* on apples too low.

## Questions:

1. Are tree picked apples less likely to be contaminated with pathogens than dropped apples?
2. What are the likely sources of contamination with pathogenic microbes?

## Potential Sources of Contamination

- Will vary among different regions, where microbial ecology may vary, but the following general observations may be made.
  - Field contamination \* likely to be reflected in higher numbers of microbes in dropped apples.
    - soil microbes, microbes from contaminated water supplies, microbes from nearby domesticated and wild animals, and insects.
    - contamination in harvesting process -hand washing, other precautions.
  - In-Plant Contamination
  - Post-Processing Contamination

## Are dropped apples more likely to be contaminated?

- Presumption would be yes due to contact with agricultural environment on ground.
- Dingman, DW [Connecticut Agricultural Experiment Station, New Haven 06504] 1999. Prevalence of *Escherichia coli* in apple cider manufactured in Connecticut. *J. Food Prot.* 62(6): 567-73.

## Conclusions of Recent Study

- Samples from 11 cider mills
- samples from 6 were positive for *E. coli* at least once during production year. 4% of samples contained *E. coli*.
- *E. coli* found only in samples produced in mid-late October to January only.
  - Found in cider samples produced from October- to-December.
    - No correlation of Brix, decrease in acidity to *E. coli* presence.
- *E. coli* found in samples produced from both dropped apples and tree picked apples. NOT O157:H7.

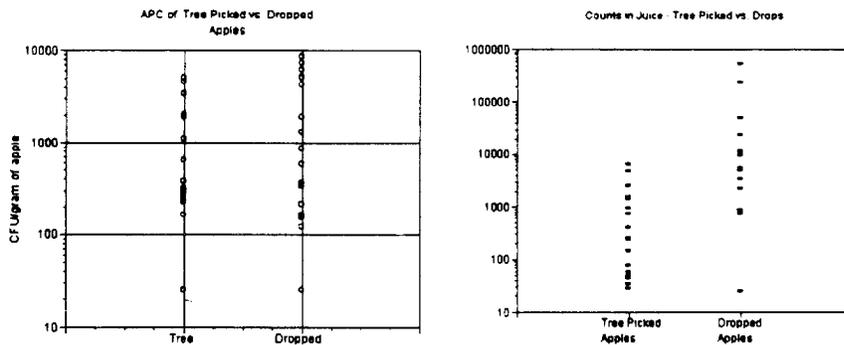
## A Study in Progress

- Apple Hill - 1998-2000:
  - An FDA Cooperative Research Project with El Dorado County California, National Center for Food Science and Technology, University of California, Davis, and USDA.
  - Tree Picked vs. dropped apples
    - No *E. coli* or coliforms detected in apple and cider samples during October to December period.

## Data Currently Available

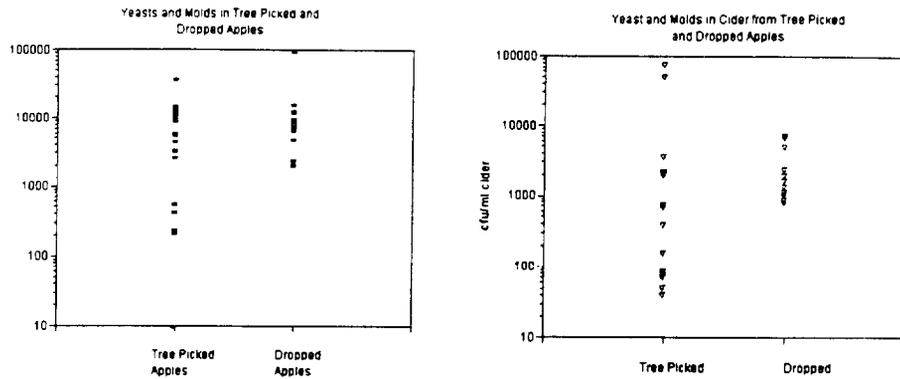
- **Granny Smith Data:** reasonably complete - immediate data on fresh samples only.
  - Significant increases in mean APC and yeasts and molds in dropped apples and cider from dropped apples.
- **Lauren Jackson - FDA/CFSAN/DFPP**
  - Patulin found at significant levels in cider produced from dropped Golden Delicious apples, but not detected in cider from tree-picked Golden Delicious or Granny Smith apples.

## APC in Granny Smith Apples and Juice



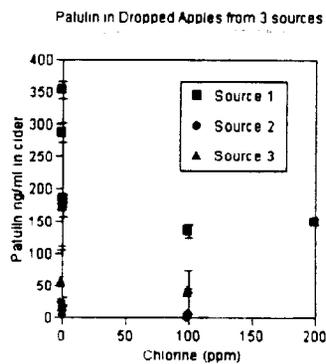
Conclusion: dropped apples may harbor more bacteria, which may get transmitted to the cider

## Yeasts and Molds on Apples and in Cider



Dropped apples appear to harbor more yeasts and molds, which may increase yeasts and molds in juice

## Patulin in Cider Produced from Dropped Golden Delicious Apples 1998 season



- Mycotoxin produced primarily by *Penicillium expansum* - apple rot mold.

- Mutagenic, toxic effects in rodents. Should be no more than 50ng/g in apple products.

- No detectable patulin in cider produced from tree picked apples or dropped Granny Smith Apples

## Plans for 1999 Season relative to natural flora on apples

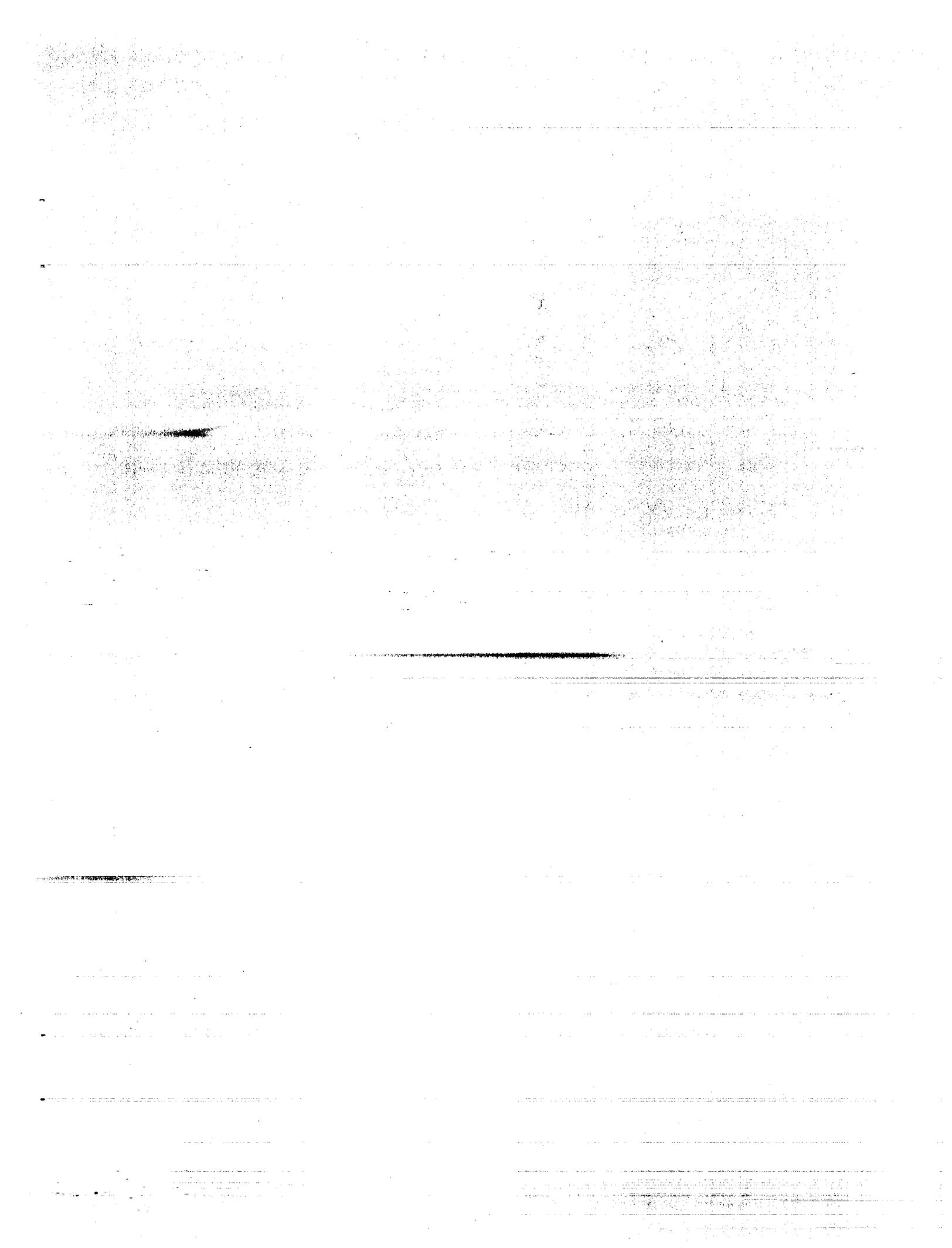
- Determine levels of natural flora on and in apples.
- How do different quality levels, dropped apples, affect on microbial population in cider.

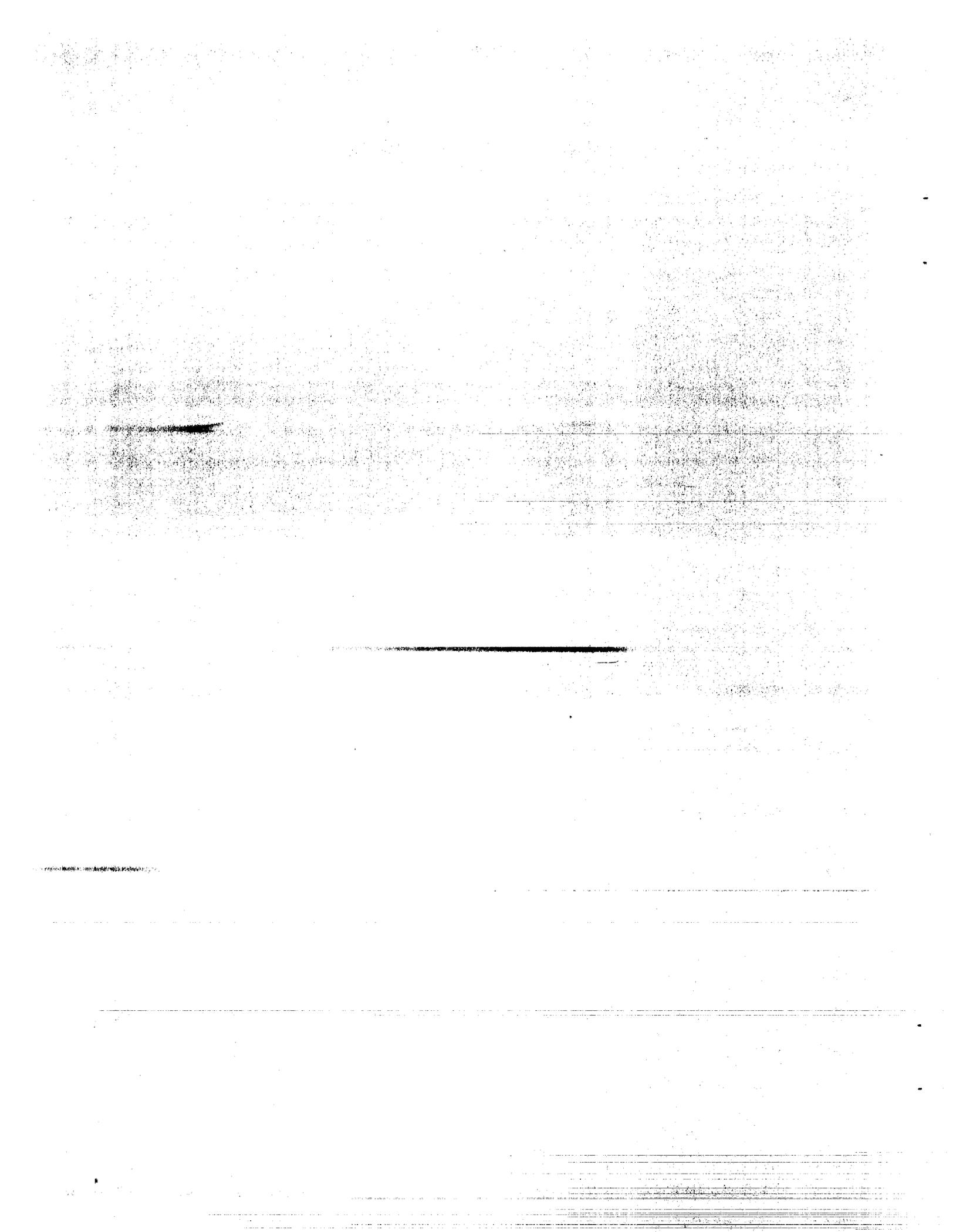
## General Conclusions

- The emergence of *Escherichia coli* O157:H7, some *Salmonella* spp. and *Cryptosporidium* and their association with outbreaks caused by contaminated apple cider has increased the need for information and improved safety practices in apple cider production.
- Dropped apples have been associated with cider contaminated by pathogens, but no direct evidence of dropped apples as the source of contamination.
- In some regions, generic *E. coli* contamination may occur only during specific portions of the growing season and may be associated with both tree-picked and dropped apples.

## Conclusions

- The Apple Hill project has shown the following:
  - Patulin was detected only in dropped Golden Delicious apples, not in tree-picked Golden Delicious apples or in Granny Smith apples .
    - Detection of patulin alone would be sufficient reason for avoiding use of dropped apples from more susceptible varieties .
  - APC and Yeast and Mold levels in dropped apples are higher than those for tree picked apples.
- Therefore the exclusion of dropped apples should yield a higher quality and safer product.





# Surface heat treatment of apples used for cider production

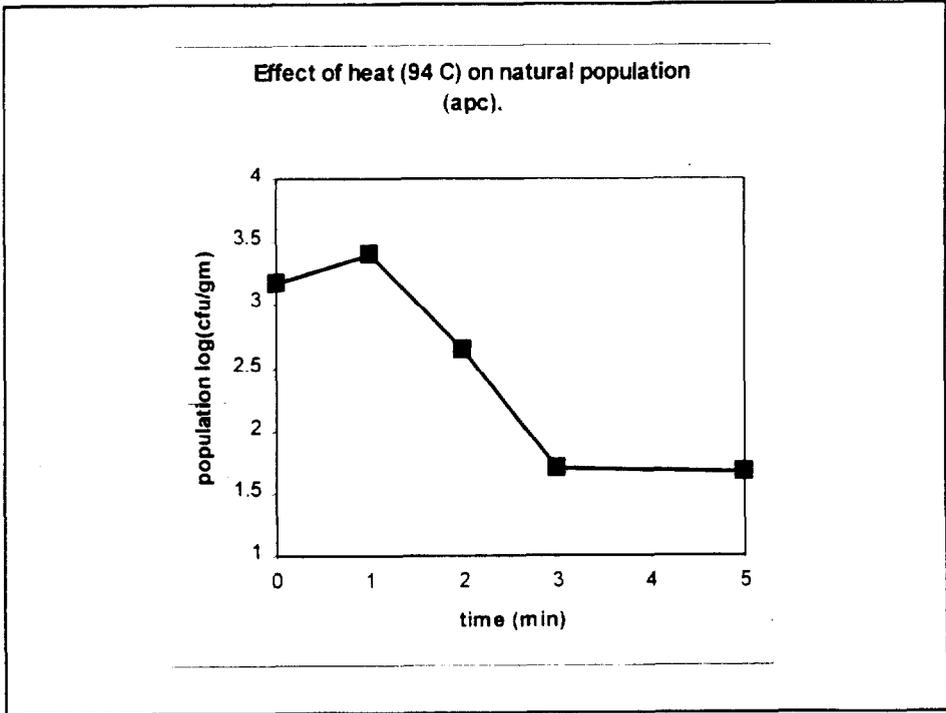
S. E. Keller



Surface heat treatment of apples  
used for cider production

S. E. Keller

Carla Bator  
Stuart Chirtel  
Robert Merker  
Kirk Taylor  
Dave Bolster  
Hsu Ling Tau  
Valerie Davis  
Greg Fleischman



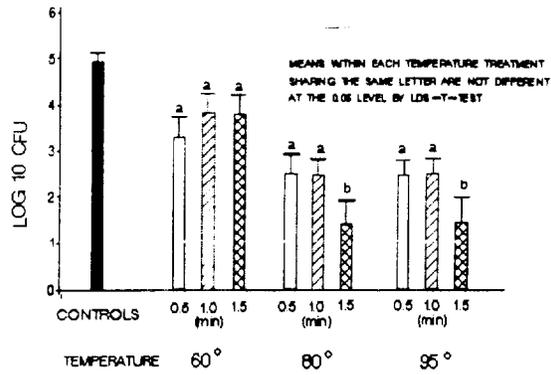
### Cultures used for inoculation:

*E. coli* O157:H7 str<sup>r</sup>,  
from ATCC 35150  
*E. coli* K12 str<sup>r</sup>,  
ATCC 35695

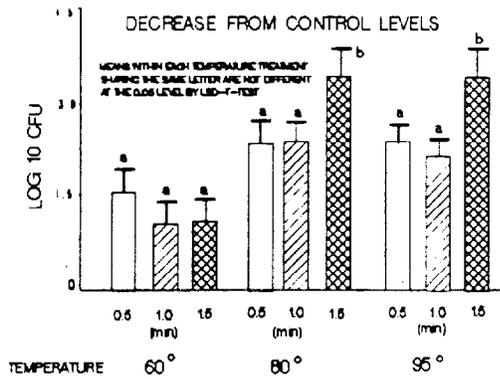
### Surface Heat Treatment

1. Inoculation of apples
  - a. Overnight (stationary),  
BHI + 0.75% glucose, 35°C
  - b. Five minute immersion, followed by  
air drying
  - c. Refrigerated overnight
2. Immersion in hot water bath
3. Air dried and cooled in bacteriological hood
4. Individual apples macerated in blender  
with diluent for ~ 1 min

THE EFFECTS OF TIME AND TEMPERATURE  
ON E.coli 0157:H7 COUNTS IN APPLES



THE EFFECTS OF TIME AND TEMPERATURE  
ON E.coli 0157:H7 COUNTS IN APPLES  
DECREASE FROM CONTROL LEVELS



## Heat treatment, skin sections

Inoculate apples as before

Heat treated at 94°C @ 30, 60, and 90sec

Aseptically cut 2 skin squares (3 x 3 cm) per apple

Composite 6 skin squares from 3 apples

## Counts/composite before treatment

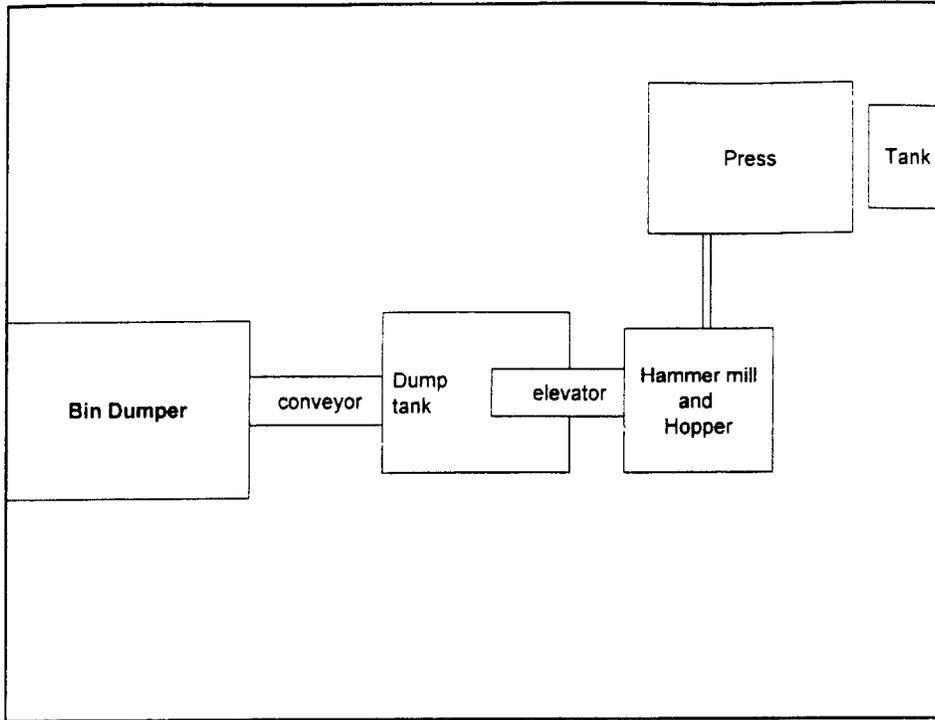
3.51 ± 0.34 (54 cm<sup>2</sup>)

## Counts/composite after treatment

None detected

## Procedure for Placerville Surface Heating Experiments:

1. Inoculated with overnight culture of  
*E. coli* K-12 (MC4100)
2. Hold apples overnight
3. Enumerate *E. coli* on apples prior to use  
4 composites, 6 apples/composite
4. Treat for two time periods at three temperatures  
in the “troph-o-matic”
5. Remove apples after treatment and enumerate  
surviving *E. coli*



Placerville results:

190-212°F (87.8-100°C)

<u>Before</u>	<u>After</u>	<u>ΔLog</u>
5.09	3.08	2.01

180-190°F (82.2-87.8°C)

<u>Before</u>	<u>After</u>	<u>ΔLog</u>
4.78	3.47	1.31

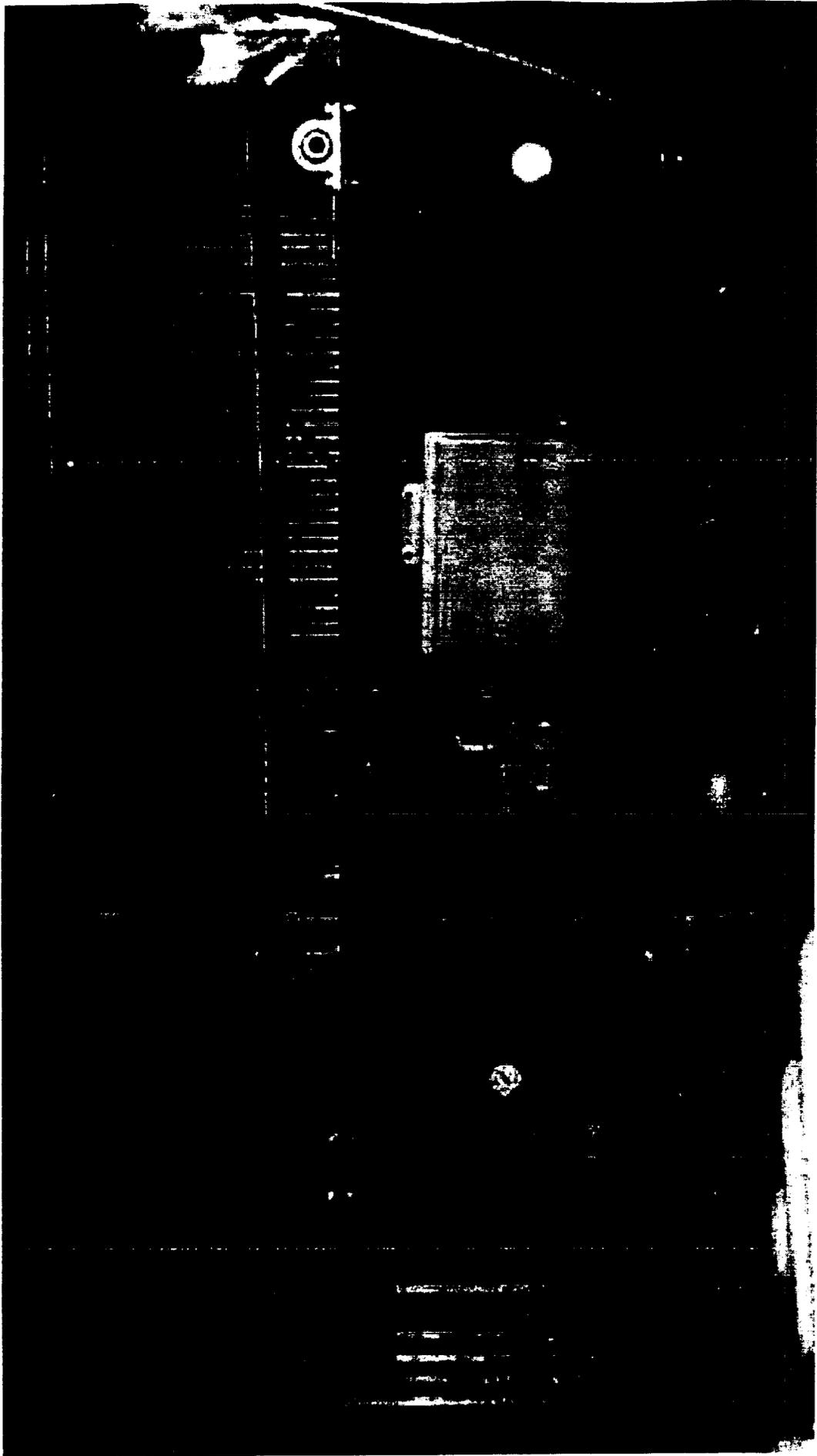
165-175°F (73.9-79.4°C)

<u>Before</u>	<u>After</u>	<u>ΔLog</u>
5.18	4.04	1.14

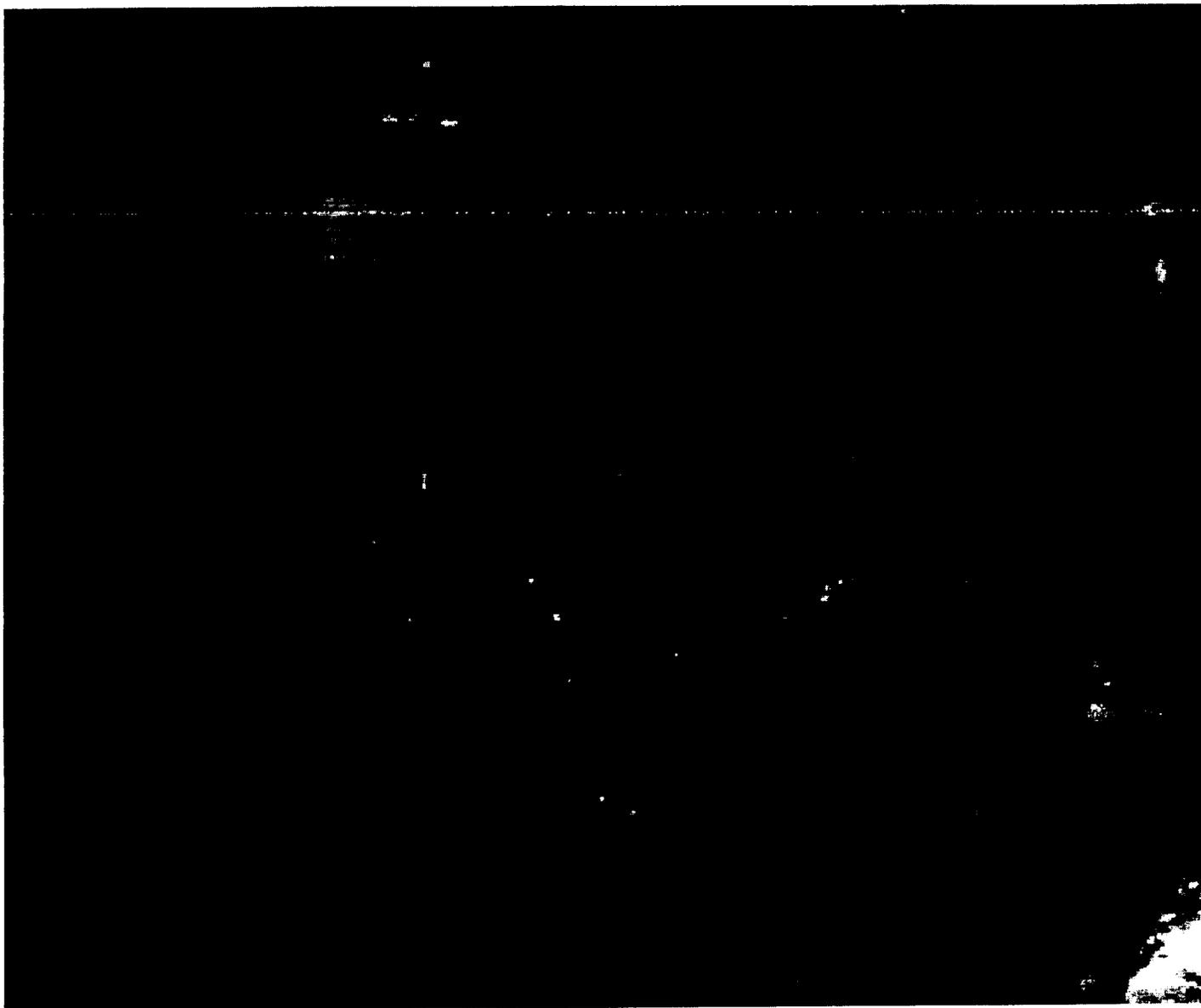
## Summary:

1. Surface heat treatment of natural populations resulted in a ~ 1.5 log drop in apc
2. Laboratory studies with *E. coli* O157:H7, surface heat treatment resulted in a ~ 3 log drop
3. Examination of skin sections after surface heat treatment found no detectable *E. coli* (laboratory data)
4. Pilot plant surface heat treatment with a surrogate (*E. coli* K-12) resulted in a ~ 2 log drop

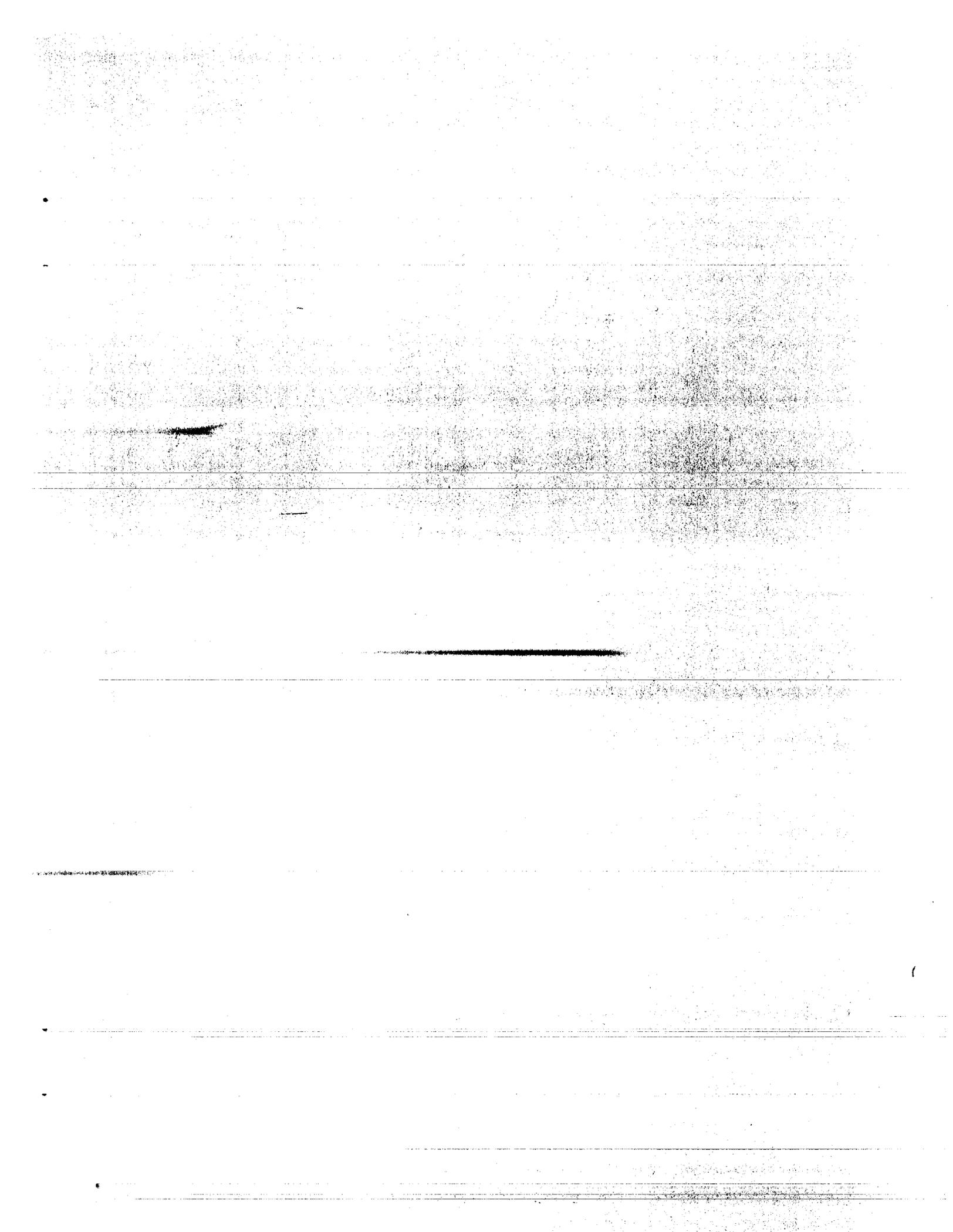












# Efficacy of the *CiderSure* 3500 Ultraviolet Light Unit in Apple Cider

Randy W. Worobo  
Department of Food Science & Technology  
Cornell University

## **Background**

Within the past 10 years, fresh, unpasteurized apple cider has been responsible for foodborne illness outbreaks across the United States and Canada. The microorganism responsible for these outbreaks is *Escherichia coli* O157:H7. In an attempt to curtail the incidence of foodborne illness associated with the consumption of fresh apple cider, recommendations for processing apple cider prior to consumption were made. Unfortunately, the sole processing technique available prior to one year ago was thermal pasteurization. This single processing alternative restricted a large proportion of apple cider producers by the cost, space restrictions, taste defects or complexity of operation. In response to the processing limitations, alternative processes such as ultraviolet (UV) light were investigated.

Extensive research on the application of ultraviolet light yielded a production model based on ultraviolet light for the treatment of apple cider. The production model is essentially ultraviolet lamps exposing a thin film of apple cider. The flow rate is controlled by a computer interface that reads the ultraviolet penetration every 20 milliseconds using ultraviolet sensors. Depending on the UV intensity at that point in time, the computer controls the pump automatically to increase or decrease the flow rate to achieve a 5-log reduction for the cider passing through the unit at that point in time.

Apple cider composed of different varieties, solids content and darkness were used to test the *CiderSure* unit. Changes in all these variables are compensated for by the unit and ensures a 5-log or greater reduction in the pertinent pathogen, *E. coli* O157:H7. A production unit of the *CiderSure* was used to test the efficacy against three different strains of *E. coli* O157:H7 which included ATCC 43889, 933 and 43895. All three pathogenic strains were inoculated into various blends and variations of apple cider and passed through the *CiderSure* unit with numerous repetitions. All three strains of *E. coli* O157:H7 showed the same UV sensitivity/resistance with no statistical difference between repetitions or strains.

A nonpathogenic surrogate microorganism, *E. coli* ATCC 25922, was selected with the same UV sensitivity/resistance as the three pathogenic strains of *E. coli* O157:H7. Numerous strains of microorganisms were tested and it was observed that there are differences in the response to ultraviolet light. Since ATCC 25922 showed almost identical UV sensitivity, it was used as the surrogate microorganism to test additional production units and for the validation of each unit to ensure its compliance with the required 5-log reduction.

All of the testing up until this point was carried out in a microbiology laboratory at Cornell University to prevent the potential environmental contamination. The FDA/USDA test cider mill in the Apple Hill region allowed for the examination of the efficacy of the *CiderSure* unit in a typical cider mill production setting. With the cooperation of various federal and state government agencies, Cornell University and FPE Inc., the *CiderSure* model was tested for its effectiveness in an apple cider production setting.

The following are the results obtained from the testing carried out at Cornell University and in the FDA/USDA test cider mill in Placerville, California.

### **Methodology**

Apple cider was prepared from a variety of blends of different apple varieties, as well as different degrees of filtration.

The various samples of apple cider was inoculated with an overnight culture of *E. coli* ATCC 25922 grown in Tryptic Soy Broth (TSB). The inoculated apple cider was then passed through the *CiderSure* unit. Samples for microbiological analysis was taken before and after processing.

For all the microbiological analysis, the samples were serially diluted in 0.1% peptone and plated onto appropriate media. *E. coli* ATCC 25922 was enumerated on tryptic soy agar and incubated at 35°C overnight. The plates were counted the following day. Total plate count was performed using plate count agar and incubating at 22°C for 2 days. Yeast and mold were enumerated using acidified Potatoe Dextrose Agar (pH 3.5) or YM petri-film and incubated for 4 days before enumerating.

### **Results**

**TABLE 1**

Ultraviolet light eradication of *E. coli* O157:H7 strains in apple cider.

Target Microorganism	Single pass log number reduction
<i>Escherichia coli</i> O157:H7 ATCC 43889	6.12 ±0.36
<i>Escherichia coli</i> O157:H7 ATCC 43895	5.83 ±0.11
<i>Escherichia coli</i> O157:H7 ATCC 933	5.87 ±0.11

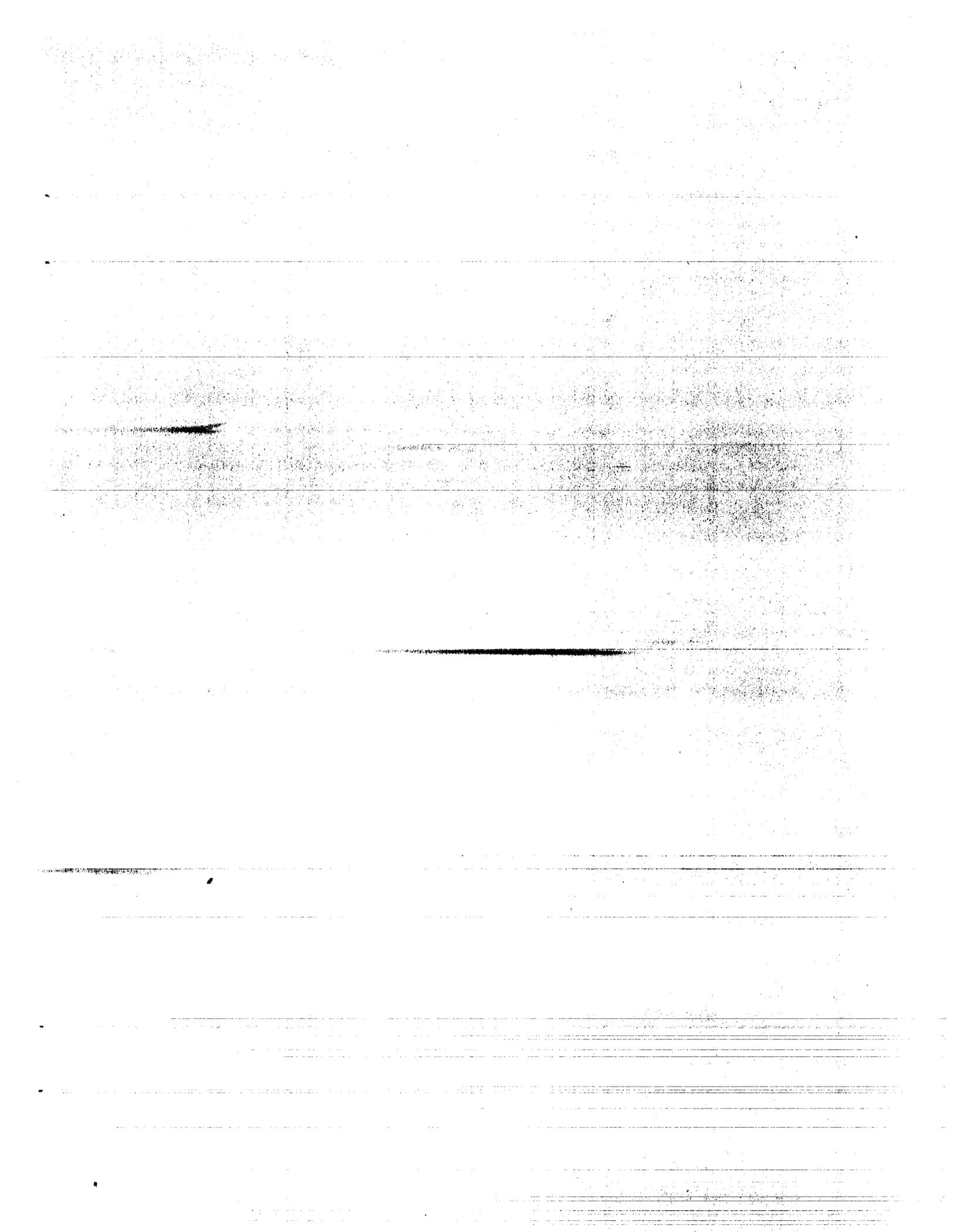
### **Conclusions**

The results from the test cider mill confirmed the existing data that has been obtained from extensive laboratory research at Cornell University. The large volume inoculated apple cider runs reconfirmed the ability to achieve a 5-log reduction of *E. coli* ATCC 25922 with the *CiderSure* 3500. The surrogate microorganism *E. coli* ATCC 25922 showed a greater than 5-log reduction consistently throughout the processing run.

The *CiderSure* UV unit is programmed to automatically compensate for differences that may exist in apple ciders such as total solids and color. Increased solid content and darker color due to extended storage of apples decreases the UV penetration through the apple cider but the calibration curve programmed into the computer interface of the unit ensures that all the apple cider achieves the appropriate UV exposure to achieve a 5-log reduction.

The original work was performed in a contained biosafety microbiology laboratory at Cornell University using *E. coli* O157:H7 strains. The identification of a surrogate organism allows for each of the *CiderSure* units to be validated for its ability to achieve a 5-log reduction in the surrogate organism prior to being placed in an actual apple cider mill. The experiments conducted in the FDA/USDA test cider mill allowed for the confirmation that the *CiderSure* UV units were capable of achieving a 5-log reduction in the surrogate microorganism in a typical apple cider mill and production setting. Since the FDA/USDA apple cider mill will eventually be returned to a commercial production cider mill, it was not possible to use pathogenic strains of *E. coli* O157:H7.





# Research Findings on the Application of Warming and Freezing

Imme W. Kersten, Dr. Sita R. Tatini,  
Kaushik Subramanian





## Research Findings on the Application of Warming and Freezing

Imme W. Kersten, Dr. Sita R. Tatini,  
Kaushik Subramanian

### Increased research devoted to finding alternatives to pasteurization

- ⇒ isostatic high pressure
- ⇒ pulsed electric field
- ⇒ filtration
- ⇒ ozone
- ⇒ UV light
- ⇒ **Freeze/thawing**



### Freeze/thawing as a viable method

⇒ little start-up capital compared to pasteurization

⇒ minimal to no nutritional loss

⇒ possibly no change in sensory characteristics  
i.e taste, smell, appearance



### Contradictory

⇒ generally thought of as a method of preservation

⇒ presence of sugar as a cryoprotective agent

### Supportive

⇒ high acid, presence of preservative



Test tube experiments (10ml)

⇒ test tubes inoculated with each strain ( $10^6$  CFU/ml target level)

- frozen @  $-16.8^{\circ}\text{C}$ , removed on a weekly basis, thawed in a room temperature water bath, enumerated and held @  $4^{\circ}\text{C}$  until gone



⇒ test tubes frozen for 4 and 7 days, thawed, heated to  $50^{\circ}\text{C}$

⇒ test tubes subjected to 2 and 3 freeze/thaw cycles, then held @  $4^{\circ}\text{C}$  until gone



## Methods

### Preparation of inoculated cider

Four strains of verotoxigenic *Escherichia coli*

OD (O157:H7)

933(O157:H7)

406(O22:H6)

O104:H21



### Fresh, unpasteurized, non-autoclaved cider

⇒ 5 Minnesota Orchards

⇒ 2 produce cider without sodium benzoate

⇒ pH range from 3.1 to 3.6 (early on in the season)

⇒ coliforms range from <10/ml to 50/ml

⇒ no *E. coli* detected



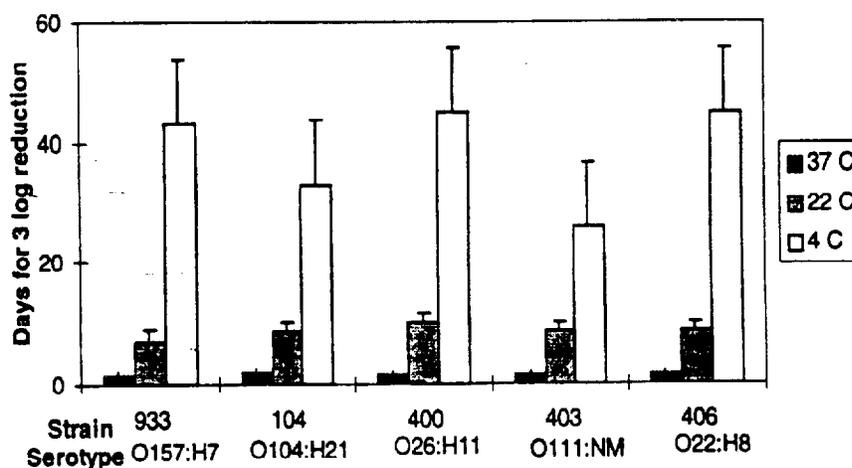
## Large container experiments

⇒ similar experiment as with test tubes but with gallons and 1/2 gallons this time

⇒ also gallons and 1/2 gallons were inoculated with cells grown at a lower pH of 5.2

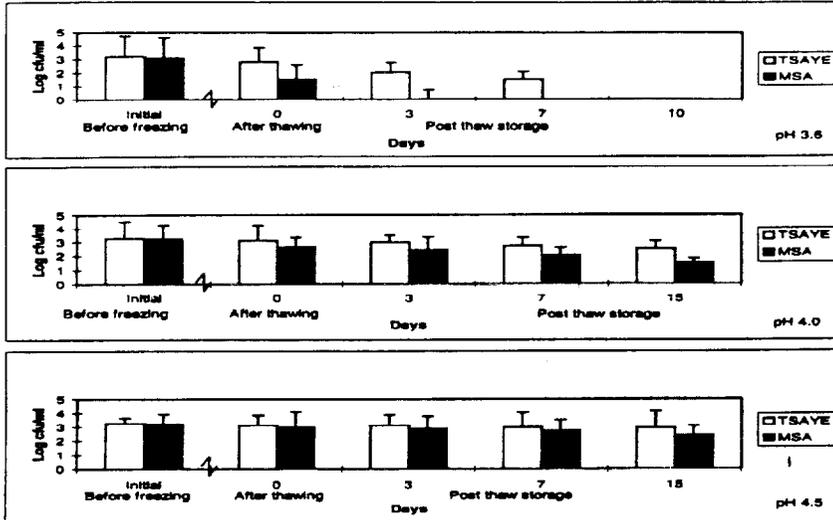


## Survival of VTEC in Apple Juice of pH 3.4 at 4, 22, and 37°C



Kaushik Subramanian M.S. Thesis

### Influence of pH of apple cider on survival of freeze-thawed VTEC OD during storage at 4°C



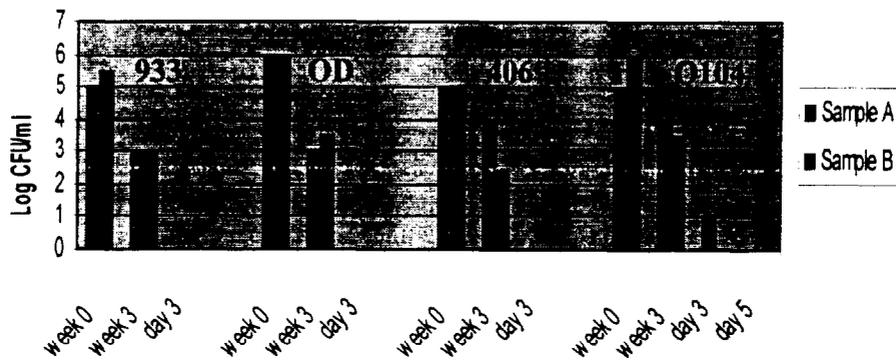
Kaushik Subramanian M.S. Thesis

### Influence of frozen storage (-16.8°C) at varying lengths of time on strain 933 in test tubes

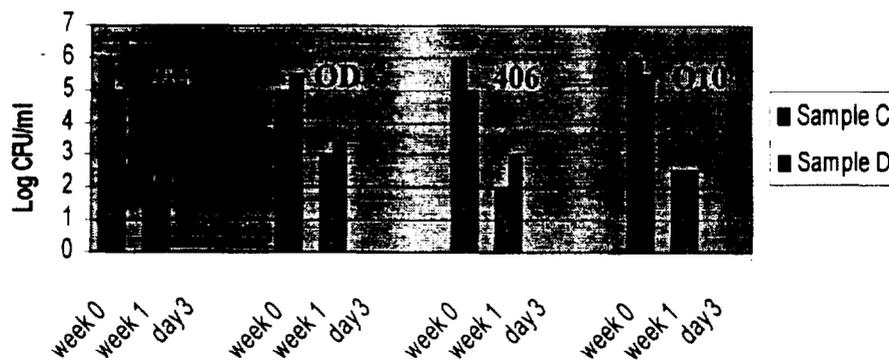
933(O157:H7)



Influence of frozen storage ( $-16.8^{\circ}\text{C}$ ), defrosting and holding at  $4^{\circ}\text{C}$  on verotoxigenic *Escherichia coli* in unpasteurized apple cider **containing no preservative** – test tubes



Influence of frozen storage ( $-16.8^{\circ}\text{C}$ ), defrosting and holding at  $4^{\circ}\text{C}$  on survival of verotoxigenic *Escherichia coli* in unpasteurized apple cider **containing sodium benzoate** – test tubes



Applying heat (50°C) to cider which had been frozen

- ⇒ freeze 7 days and then heat
  - almost 5 log with sodium benzoate
  - 4 log without preservative
- ⇒ hold for 1 or 2 days
- ⇒ raise temperature to 55°C



Use of 3 freeze/thaw cycles

- ⇒ with benzoate, 2 days holding = 6 days total
- ⇒ without benzoate, 8 days holding = 12 days total

Time is shortened but....

- ⇒ energy expense
- ⇒ cycle time changes with larger sizes



Influence of frozen storage (-16.8°C) followed by thawing and holding @ 4°C on destruction of verotoxigenic *Escherichia coli* in unpasteurized apple cider **without preservative**

Source	Size	Strain	Length of time for 5 log destruction
--------	------	--------	--------------------------------------

E <sub>1</sub>	1 gallon	933/406	2 wks, 13 days
	1 gallon	OD/O104	2 wks, 13 days
A	1 gallon	933/406	4 wks, 5 days
	1 gallon	OD/O104	4 wks, 5 days
	1/2 gallon	all strains	4 wks, 7 days
	1/2 gallon	all strains	4 wks, 5 days



Influence of 1 week frozen storage (-16.8°C) followed by thawing and holding @ 4°C on destruction of verotoxigenic *Escherichia coli* in unpasteurized apple cider **with sodium benzoate**

Source	Size	Strain	Length of time @ 4°C for 5 log destruction
--------	------	--------	--

E <sub>2</sub>	1 gallon	933/406	9 days
	1 gallon	OD/O104	9 days
	1/2 gallon	all strains	9 days
	1/2 gallon	all strains	14 days
	1/2 gallon	all strains	14 days
C	1 gallon	933/406	3 days
	1 gallon	933/406	7 days
	1 gallon	OD/O104	3 days
	1 gallon	OD/O104	7 days



Influence of 1 week frozen storage (-16.8°C) followed by thawing and holding @ 4°C on destruction of verotoxigenic *Escherichia coli* in unpasteurized apple cider **with sodium benzoate** (cells grown at pH 5.2)

Source	Size	Strain	Length of time @ 4°C for 5 log death
D	1 gallon	933/406	1 day
	1 gallon	933/406	1 day
	1 gallon	OD/O104	1 day
	1 gallon	OD/O104	1 day
C	1/2 gallon	all strains	1 day
	1/2 gallon	all strains	4 days
E <sub>2</sub>	1/2 gallon	all strains	3 days



### Conclusion

⇒ sodium benzoate contributes to death of injured cells

⇒ behavior of *E.coli* in test tubes versus larger containers is not alike

⇒ cause of variability is unknown



### Possible Explanations

⇒ variation in test tube versus gallon/ 1/2 gallon

- slow freezing/slow defrosting thought of as most damaging
- gallons/ 1/2 gallons are slow/slow
- test tubes are fast/fast



⇒ Distribution of liquid water to ice?

⇒ Size and number of crystals formed?

- high cooling rates = small internal ice crystals
- slower cooling rates = external ice crystals leading to dehydration



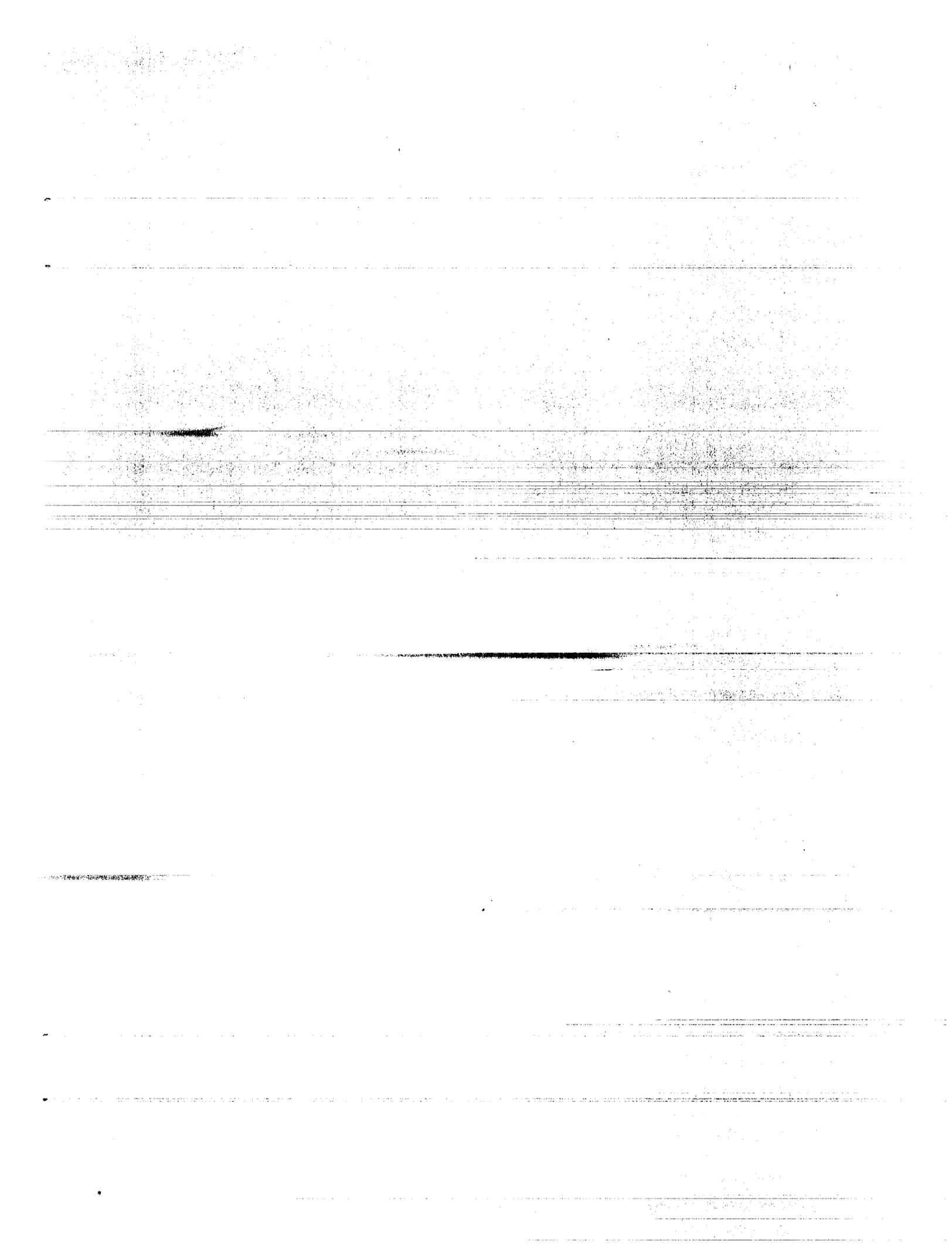
⇒ Freezing point of different apple cider?

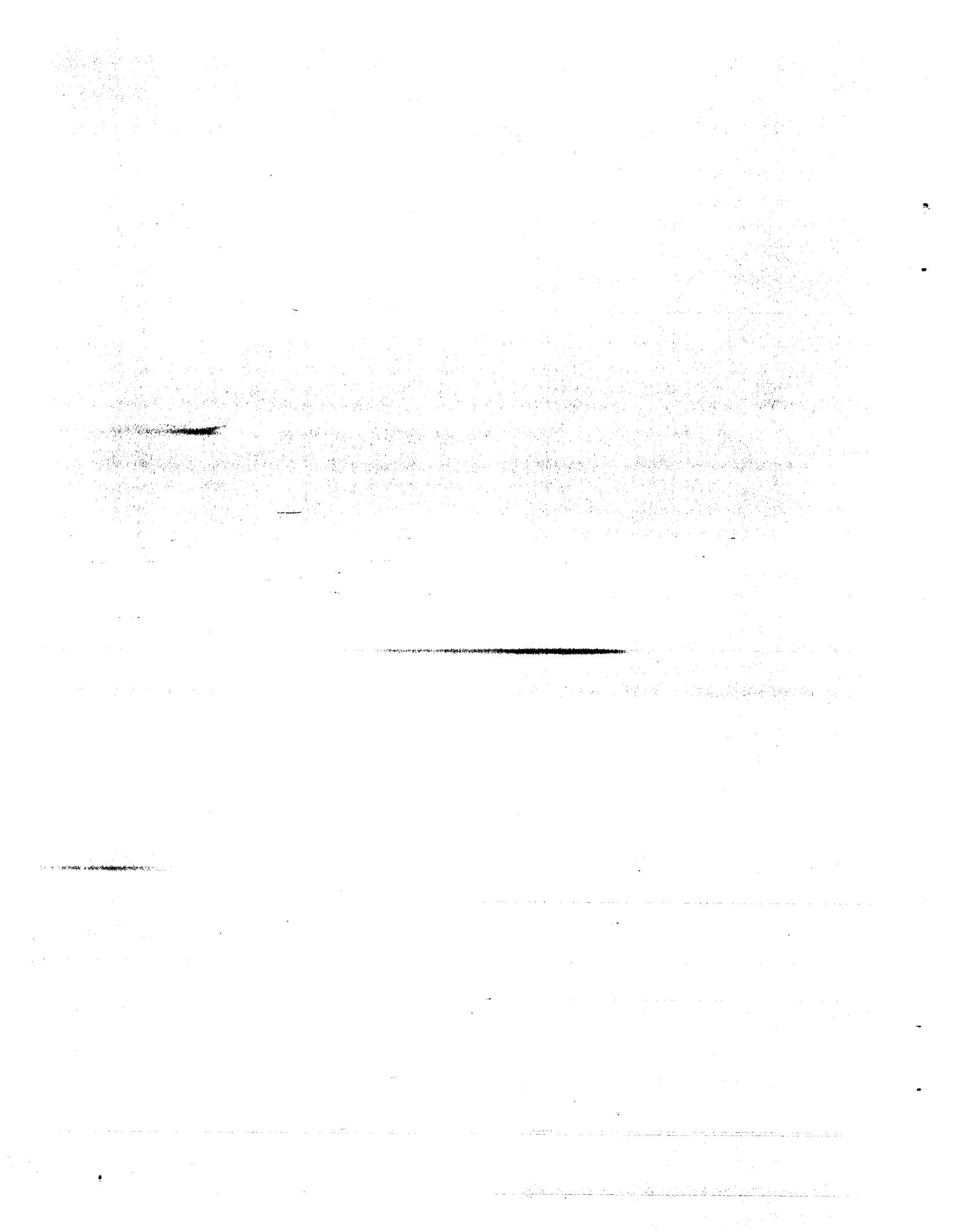
⇒ Distribution of pectin and pulp in the test tubes?

- variation among orchards
- may be protective



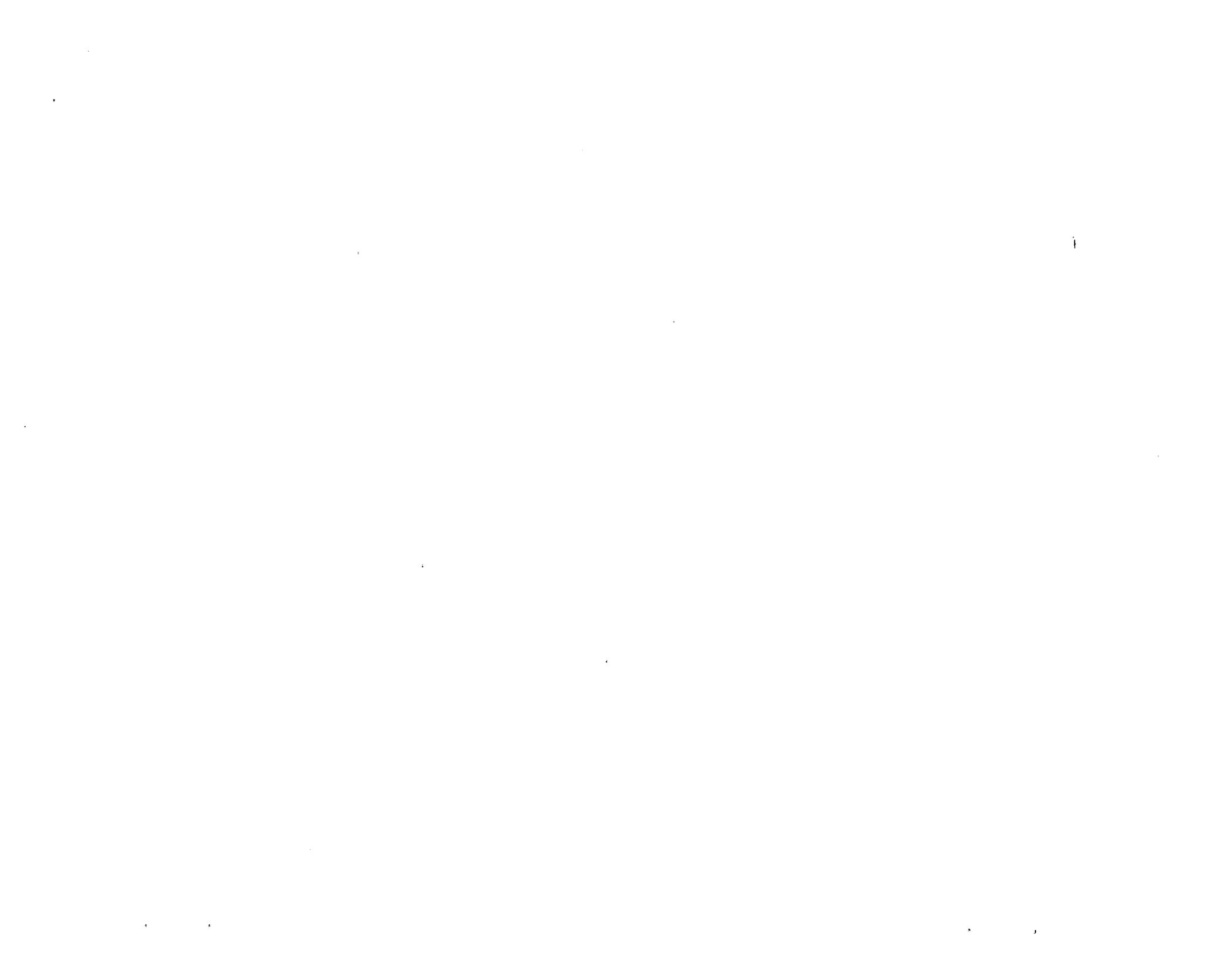
More research needs to be conducted in various container sizes, involve cider with different pH's, from different times of the season and from orchards in diverse agricultural areas.





Multiple Hurdle Interventions  
Against  
*E. coli* O157:H7 in Apple Cider

Steve Ingham  
University of Wisconsin-Madison



Multiple Hurdle Interventions  
Against  
*E. coli* O157:H7 in Apple Cider

Steve Ingham  
University of Wisconsin-Madison

Wisconsin's Cider Safety  
Extension Team

- Teryl Roper - growers
- Steve Ingham - processors
- Barbara Ingham - consumers

## Apple Cider/*E. coli* O157:H7 Research Topics

- Lethality of freeze/thaw treatment
- Multiple hurdle interventions
- Other pathogens of concern
- Useful indicator organisms

## Lethality of Freeze/Thaw against *E. coli* O157:H7 in Apple Cider

- pH 3.5 cider, 10 ml/bottle, heat-sterilized
- two test strains
- -20° C, 24 h to freeze
- thaw at 4°C, 23°C, or 10 sec in microwave
- 0.69 - 3.43 log kill (TSA plating)
- 1.39 - 5.64 log kill (SMA plating)

## A New Intervention Paradigm

- Organic acids more lethal at warm temperatures
- Immediate refrigeration is NOT best for cider safety
- Short-term storage at 25 - 45°C to kill pathogens

## Multiple Hurdle Protocol # 1

- Heat-sterilized ciders; pH 3.3, 3.7, 4.1
- 7-log, “cocktail” inoculum
- enumeration of survivors by plating
- freeze/thaw
- sorbic acid = SA (0.1%)
- short-term storage at 4, 25, or 35°C

5-log kill of *E. coli* O157:H7 in  
pH 3.3 Cider

- 6h at 35°C
- Freeze/thaw  
4.0 ml, -20°C for 48 h, then 4°C for 4 h

5-log kill of *E. coli* O157:H7 in  
pH 3.7 Cider

- 6 h at 4°C + freeze/thaw
- 2 h at 25°C + freeze/thaw
- 1 h at 35°C + freeze/thaw
- 6 h at 35°C
- 0.1% SA + 12 h at 25°C

## 5-log kill of *E. coli* O157:H7 in pH 4.1 Cider

- 6 h at 35°C + freeze/thaw
- 0.1% SA + 12 h at 25°C + freeze/thaw
- 0.1% SA + 4 h at 35°C + freeze/thaw
- 0.1% SA + 6 h at 35°C

## Taste Panels

- 6 h at 35°C preferred over pasteurized
- freeze/thaw preferred over pasteurized
- 6 h at 35 C + freeze/thaw preferred over pasteurized

## Taste Panels

- 0.1% SA + 6 h at 35 C  
NOT preferred over pasteurized
- 0.1% SA + 6 h at 35 C + freeze/thaw  
NOT preferred over pasteurized

## Multiple Hurdle Protocol # 2

- Irradiation-sterilized ciders (3), pH adjusted to 3.3, 3.5, 3.7, 3.9, 4.1
- Potassium sorbate = SA (0.05, 0.1%)  
sodium benzoate = BA (0.05, 0.1%)
- Short-term storage at 5, 15, 25 35, 45°C
- Freeze/thaw
- Growth/no growth broth assay for 5-log kill

Protocol #2:

5-log Kill of *E. coli* O157:H7

- pH 3.3 + 0.1% SA or BA + 6 h at 35°C
- pH 3.3 - 3.7 + 0.1% SA or BA + 6 h at 45°C
- pH 3.9 + 0.1% BA + 6 h at 45°C
- pH 3.3 + 0.1% BA + 4 h at 25°C + freeze/thaw
- pH 3.3 + 0.1% SA + 12 h at 25°C + freeze/thaw

Protocol #2:

5-log Kill of *E. coli* O157:H7

- pH 3.3 + 0.1% SA + 4 h at 35°C + freeze/thaw
- pH 3.3 + 0.1% BA + 2 h at 35°C + freeze/thaw
- pH 3.3 + 0.05% SA or BA + 6 h at 35°C + freeze/thaw
- pH 3.7 - 4.1 + 0.1% BA + 4 h at 45°C + freeze/thaw

## Other Bacterial Pathogens of Possible Concern in Apple Cider

- *Salmonella typhimurium* DT104: intermediate survival in unpasteurized cider; will not survive treatments that are effective against *E. coli* O157:H7
- *Listeria monocytogenes*: poor survival in unpasteurized cider; not an appropriate target pathogen

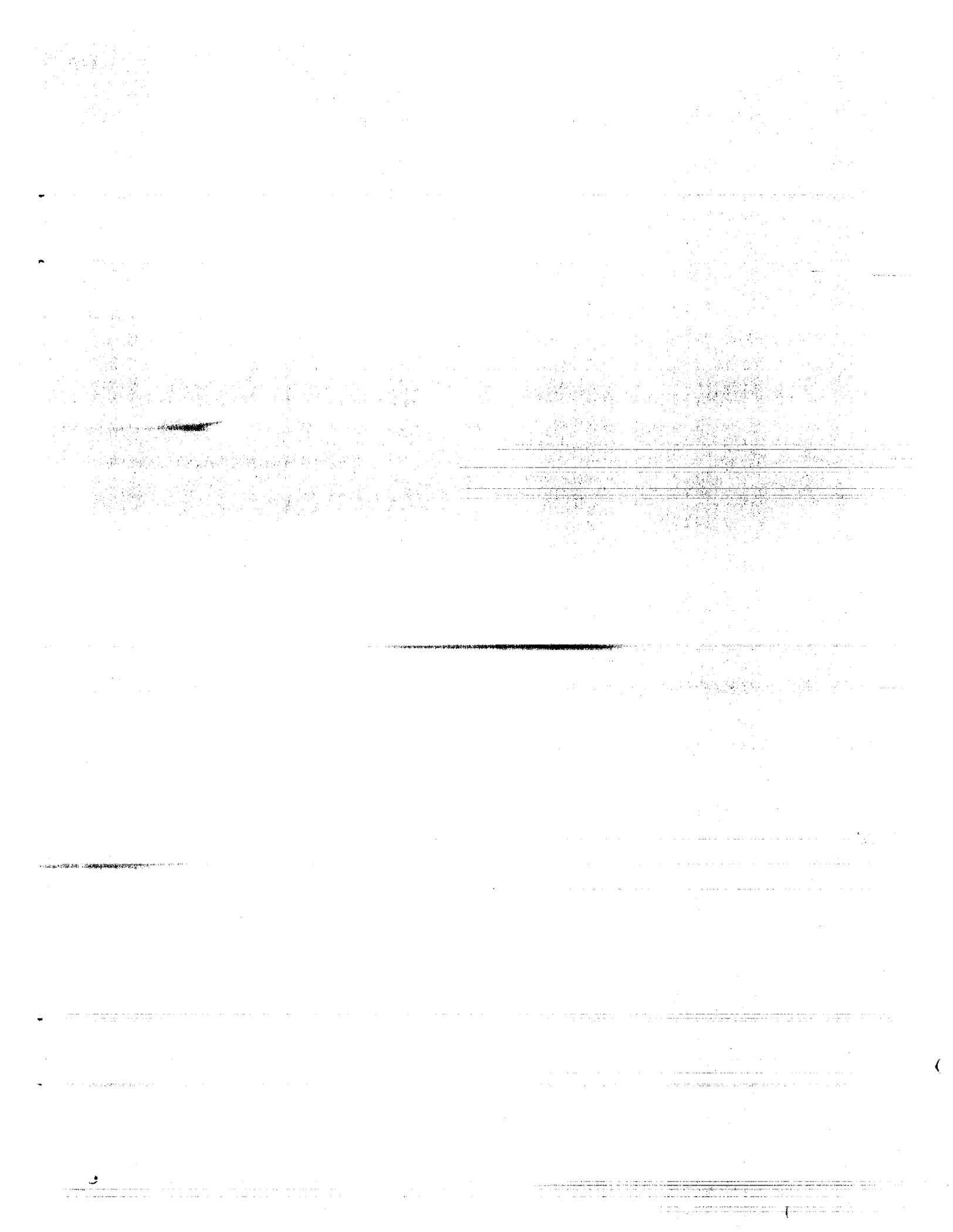
## Potential Indicator Organisms for Evaluating Sanitation

- Generic *E. coli*: survives well in refrigerated cider
- Coliforms: more prevalent, but problem with possible non-fecal origin
- *Enterococcus* spp.: survive poorly in refrigerated cider

## Testing for Indicator Organisms

- Drop apples more likely to contain generic *E. coli*; apple rinse testing may be useful
- Wash water can become a contamination step; testing here is appropriate
- Test cider quickly; neutralize or dilute it before testing
- Coliform kits vary widely in performance







**Verifying Apple Cider Plant Sanitation and HACCP Programs:  
Choice of Indicator Bacteria and Testing Methods**

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**Key Words: Coliforms, Enterococci, Apple Cider**

**Short Title: Indicator Bacteria in Apple Cider**

## ABSTRACT

The objectives of this study were: 1) to evaluate the survival of coliforms, *E. coli*, and enterococci in refrigerated apple cider, 2) to develop simple and inexpensive presumptive methods for detection of these bacteria, 3) to perform a field survey to determine the prevalence of these bacteria on apples and in apple cider, and 4) based on our results, to recommend the most useful of these three indicator groups for use in verifying apple cider processing plant sanitation and HACCP programs. Eight of 10 coliform strains (five *E. coli*, one *Enterobacter aerogenes*, and two *Klebsiella* spp.) inoculated into preservative-free apple cider (pH 3.4, 13.3° Brix) survived well at 4°C for 6d ( $\leq 3.0 \log_{10}$  CFU/ml decrease). Of 21 enterococci strains (*Enterococcus faecalis*, *E. faecium*, and *E. durans*), only two *E. durans* and three *E. faecium* strains survived well. Simple broth-based colorimetric methods were developed which detected the presence of ca. 10 cells of coliforms or enterococci. In three field studies, samples of unwashed apples (“drops” and picked), washed apples, and freshly pressed cider were presumptively analyzed for total coliforms, *E. coli*, and enterococci using qualitative and/or quantitative methods. Drop apples were more likely than picked apples to be contaminated with *E. coli* (26.7% vs. 0%) and enterococci (20% vs. 0%). Washing had little effect on coliform populations, and in one field study was associated with increased numbers. Total coliform populations in cider ranged from  $< 1$  CFU/ml to  $> 738$  MPN/ml, depending on the enumeration method used and the sample origin. *E. coli* was not recovered from washed apples or cider, but enterococci were present on 13% of washed apple samples. The qualitative coliform method successfully detected these bacteria on apples and in cider. Based on its exclusively fecal origin, good survival in apple cider, and association with drop

apples, we conclude that *E. coli* is the most useful organism for verifying apple cider sanitation and HACCP programs.

In response to recent illness outbreaks linked to unpasteurized apple juice or cider contaminated with pathogenic microorganisms (1,2,3), the United States Food & Drug Administration (FDA) has proposed mandatory adoption of the Hazard Analysis Critical Control Point (HACCP) system by juice processors. The proposed regulations require that a sanitation Standard Operating Procedure (SOP) be written and implemented. Mandatory monitoring and record-keeping of sanitation performance are also specified. In addition, the proposed regulations require that the implemented HACCP system effect a 100,000-fold reduction in the risk of contamination by a target pathogenic microorganism (4). For apple cider, here defined as the unfermented pulp-containing juice made from chopped and pressed apples, the logical target pathogen is *Escherichia coli* O157:H7. Numerous researchers have described the exceptional survival of this bacterium in acidic apple beverages (8,12). One way in which *E. coli* O157:H7 is believed to contaminate apple cider is as a result of making cider from “windfall” or “drop” apples which have contacted animal feces.

Analyses for coliform bacteria, *Escherichia coli*, or enterococci may be useful for verifying sanitation and HACCP program performance in apple cider processing plants. However, survival of these bacteria in cider may be poor. The relatively small number of *E. coli* O157:H7 outbreaks involving apple cider suggest that directly testing apple cider for the presence of this pathogen is unlikely to be useful. Quantitative or qualitative testing of apple cider for bacterial groups associated with fecal contamination, hereafter referred to as “indicator bacteria,” would be more useful in monitoring sanitation and verifying that intervention steps such as a “no use of drops” policy, washing treatments, or pasteurization were functioning as expected within a HACCP system.

The coliform bacteria, *E. coli*, and enterococci are each potential groups of indicator bacteria in apple cider processing operations. Each of these groups has characteristics which recommend their use. The coliform group is comprised of bacteria in the genera *Escherichia*, *Enterobacter*, *Citrobacter*, and *Klebsiella*, that ferment lactose and produce gas during 48 h aerobic incubation at 37°C (6). Coliform numbers have long been used by water utilities and the dairy industry to indicate fecal contamination (water) and general sanitary conditions (dairy products) (6). However, coliforms can be found on vegetation that has not been contaminated by feces; thus their presence in cider may not necessarily indicate that fecal contamination has occurred. A further drawback of testing apple cider for coliform bacteria is that some analytical techniques yield falsely high levels (11).

As an alternative to enumerating all coliform bacteria, the presence and/or numbers of only *E. coli* can be used to indicate fecal contamination of foods. This species is exclusively of fecal origin, and thus its presence indicates fecal contamination. In some cases, relatively expensive and/or time-consuming procedures are necessary to differentiate *E. coli* from other coliform bacteria. However, methods are also available which combine enumeration of coliforms and of *E. coli*. Although *E. coli* O157:H7 would not be detected by several generic *E. coli* methods, the presence of generic *E. coli* would indicate that fecal contamination had occurred, possibly involving *E. coli* O157:H7, and that appropriate prevention or intervention steps should be implemented.

Enterococci (*Enterococcus* spp.) are prevalent in human and animal feces, but also may colonize vegetation or other non-fecal surfaces (6). Compared to the coliform group, enterococci tend to survive better in refrigerated foods (5,10). The major drawbacks of using

enterococci as the indicator group for apple cider are its potential non-fecal origin and that the food industry has not traditionally analyzed foods for enterococci.

Apart from the inherent ramifications of using coliforms, *E. coli*, and enterococci as indicator bacteria, many of Wisconsin's apple cider-makers lack both training and the facilities necessary to perform bacterial indicator group testing. Currently, most cider-makers would need to ship samples, under refrigeration, to a testing laboratory for analysis. Conceivably, one day could elapse between sample collection and testing, and therefore it is desirable that indicator bacteria for cider processing plant HACCP or sanitation testing survive refrigerated storage in apple cider. Alternatively, cider processors could evaluate cider themselves if easy-to-use inexpensive methods were designed for their use.

The present study compared the survival of several coliform and enterococci strains in refrigerated, pH 3.4, preservative-free apple cider. In addition, simple qualitative tests for coliforms and enterococci were developed for analyzing apples and cider. After determining that coliform bacteria, notably including *E. coli*, survived better than enterococci, 30 samples each of unwashed apples, washed apples, and freshly pressed apple cider were obtained from commercial cider-making operations and analyzed quantitatively for presumptive coliforms and *E. coli* using commercially available kits. Samples were also analyzed using the previously developed simple qualitative analyses for presumptive coliforms and enterococci. All methods were evaluated for potential use by cider processing plant personnel having only rudimentary facilities and little or no microbiology training.

## MATERIALS AND METHODS

Preparation of inocula for challenge study Coliforms isolated from beef carcasses, enterococci isolated from retail Swiss-type cheese (9), and coliform and enterococci strains from the American Type Culture Collection (ATCC; Manassas, VA) and the Centers for Disease Control and Prevention (CDC; Atlanta, GA) were used in apple cider challenge studies. From frozen stock cultures, each coliform or *Enterococcus* strain was streaked on Trypticase Soy Agar (TSA; Becton Dickinson, Cockeysville, MD) or Brain Heart Infusion Agar (BHIA; Difco Laboratories, Detroit, MI) and incubated for 18h at 37°C. A loopful of cells was then transferred to each of two tubes containing 10 ml of Trypticase Soy Broth (coliforms; TSB; Becton Dickinson) or Brain Heart Infusion (enterococci; BHI; Difco) and incubated 18h at 37°C. Finally, 0.1 ml of this culture was transferred to 50 ml BHI or TSB and incubated 18h at 37°C. Cell populations in the final cultures were determined by dilution in 0.1% (w/v) peptone (Difco) and inoculation of duplicate Petrifilm™ Coliform Count films (3M; St. Paul, MN) for coliforms or spread-planting in duplicate on Kanamycin Esculin Azide agar (KEA; Oxoid, Ogdensburg, NY) for enterococci. Petrifilms™ were incubated 24h and KEA plates were incubated 48h at 37°C, colonies were counted, and the log<sub>10</sub> CFU/ml for each culture was calculated.

Apple cider for challenge study Preservative-free apple cider (pH 3.4, 13.3° Brix) was purchased at a local market in November, 1997, dispensed 15 ml per jar (30 ml Nalgene™ jars, Fisher Scientific, Itasca, IL), and immediately frozen at -18°C. Indigenous lactic acid

bacteria and enterococci were enumerated by dilution in 0.1% (w/v) peptone (Difco) and duplicate spread-plating on MRS agar (Oxoid) and KEA agar, respectively. Plates were incubated 48h at 37°C, and colonies were then counted and log<sub>10</sub> CFU/ml calculated. Frozen apple cider was thawed at 4°C for 24h when needed for experiments.

Challenge study inoculation, storage, and analysis Apple cider (15 ml) was inoculated by adding 0.1 ml of a given coliform or enterococci culture to result in 6.0 - 7.0 log CFU/ml. The inoculum was dispersed in the cider by swirling the closed jar, and the inoculated cider samples were then returned to 4°C storage. The inoculum cell numbers in the cider were determined after inoculation ( $\leq 2$  h), and after 2, 4, and 6d of 4°C storage. Coliforms and enterococci were enumerated in duplicate on Petrifilm™ Coliform films and KEA agar plates, as previously described. For each inoculum organism, the mean and range for CFU/ml were calculated for each sampling time.

Development of simple qualitative methods Ten coliform strains (Table 1) and 12 selected enterococci from the laboratory culture collection were grown under the same conditions as in the challenge study, diluted in Butterfield's phosphate diluent (Fisher Scientific, Itasca, IL), and then 0.1 ml of the appropriate dilution was inoculated into 9.0 ml of either Violet Red Bile Broth (VRBB; coliforms) or Kanamycin Esculin Azide Broth (KEAB; enterococci) to give inoculum levels of 3 - 15 CFU. Tubes of VRBB and KEAB were incubated for 24h at 37°C (coliforms) or 42°C (enterococci). The VRBB consisted of (per liter): 3 g yeast extract (Difco Laboratories, Detroit, MI), 7 g Peptone (Difco), 1.5 g Bile Salts No. 3 (Difco), 10 g

lactose (Difco), 5 g sodium chloride (VWR Scientific, Norwood, OH), 0.03 g neutral red (Sigma), and 0.002 g crystal violet (Sigma). The appearance of a purple precipitate, followed by yellow coloration due to alkaline reversion indicated the presence of presumptive coliforms. The KEAB consisted of (per liter): 20 g tryptone (Difco), 5 g yeast extract (Difco), 5 g sodium chloride (VWR), 1 g sodium citrate (Sigma), 1 g esculin (Sigma), 0.5 g ferric ammonium citrate (Sigma), 0.15 g sodium azide (Sigma) and 20 mg kanamycin sulphate (Oxoid, Ogdensburg, NY). The appearance of a black color (resulting from esculin hydrolysis) indicated the presence of presumptive enterococci. Inocula were enumerated using Coliform Petrifilms™ and KEA (Oxoid) spread-plates as described for the challenge study. The VRBB and KEAB methods were then tested for ability to recover cells from apple cider as follows: 0.1 ml of appropriately diluted culture (ca.  $10^6$  CFU/ml) was inoculated into 15 ml apple cider, incubated for 24h at 4°C, and then 0.1 ml of inoculated cider was transferred into 9.0 ml of either VRBB or KEAB. Enumeration of inocula, incubation of VRBB and KEAB, and interpretation of results were done as in the preceding experiment.

Apple and cider field study samples Levels of indicator bacteria were determined for drop apples, picked apples, washed apples, and freshly made apple cider. Three visits to commercial cider processors were made in mid-September, late September, and mid-October, 1998. At each visit, 5 drop apples, 5 apples from trees, and 10 washed apples were aseptically collected using Whirl-Pak™ bags (Nasco, Fort Atkinson, WI). Ten cider samples were also collected, either from the cider press or from a refrigerated storage tank, filling either sterile 30 ml Nalgene™ jars (Fisher) or 50 ml plastic conical-tip centrifuge tubes (Falcon brand,

Fisher). Cider and apple samples were placed in insulated boxes which contained frozen cooler packs, transported to the laboratory, and placed in a 4°C refrigerator. Analyses were conducted within 8-12h of sample collection.

Sample preparation Cider samples were prepared and analyzed first in order to minimize exposure of bacteria to cider acidity. One sample of cider was analyzed for pH and °Brix, and the amount of 0.1 N NaOH needed to neutralize 5.0 ml of cider (pH 6.5 - 7.5) was determined. For each of the other cider samples, 5.0 ml was aseptically neutralized for Petrifilms™ (coliform and *E. coli*) analysis according to the manufacturer's recommendation. The remainder of each sample was analyzed using other methods for which neutralization was determined to be unnecessary. Drop apples, picked apples, or washed apples were prepared for analysis by adding 99 ml of Butterfield's phosphate diluent (Fisher) to the sample bag, the bag was then re-sealed, and the contents were vigorously shaken for 30s. The diluent used to rinse the apples was then analyzed for total coliforms, *E. coli*, and enterococci.

Microbiological analyses Cider and diluent samples were diluted as necessary in Butterfield's phosphate diluent and then quantitatively analyzed for presumptive coliforms and presumptive *E. coli* using the Petrifilm™ Coliform films, Petrifilm™ *E. coli* films, Simplate™ Normal Counting Range (Idexx Laboratories, Westbrook ME) and Reveal BioPlate™ (Neogen, Lansing, MI) methods. For each analytical method, the manufacturer's written instructions were followed. For a given sample dilution, a single test was conducted using each method. In addition, samples were qualitatively tested for presumptive coliforms by making  $10^{-2}$

dilutions of sample in VRBB and KEAB, incubating at 37°C and 42°C, respectively, and interpreting results as previously described.

Statistical analysis For each combination of field study, sample type and analytical method, the prevalence of presumptive coliforms, *E. coli*, or enterococci was determined (% of samples containing the given indicator bacteria group). For quantitative tests, the mean of log CFU/ml and log MPN/ml were calculated for cider samples, and the mean of log CFU and log MPN were calculated for each apple sample. When CFU or MPN exceeded a counting limit of “x”, the value assigned for calculation of means was “x + 1”. When CFU or MPN were below a detection limit “y”, the value assigned was “y - 1” except when y = 1, in which case the value assigned was 0.1. The 2-sample t-test (Minitab Release 8 software, Minitab Inc., State College, PA) was used to compare analytical methods for a given sample type and to compare sample types analyzed by a given method. A significance level of 5% was used for these analyses.

## RESULTS AND DISCUSSION

In general, the coliform strains tested survived well during 6d storage in 4°C apple cider (Table 1). Eight of the 10 strains decreased in numbers by < 3.0 log CFU/ml during 6d storage. One strain each of *Enterobacter cloacae* and *Citrobacter amalonaticus* did not survive 2d (> 5.0 log CFU/ml decrease). These results suggest that coliforms generally can survive well in refrigerated apple cider, but some species and/or strains are acid-sensitive and will rapidly die. Further, the results indicate that apple cider coliform testing should be done

as rapidly as possible, particularly if initial cell populations are small. For example, if the original number of coliforms in the cider had been 1.0 log CFU/ml, only five of the strains tested would have been detected after 2d of refrigeration. All five *E. coli* strains tested (two typical strains obtained from ATCC and three atypical strains obtained from beef carcasses) were among those surviving well in refrigerated apple cider. This finding, along with the potential non-fecal origin of coliform bacteria, suggests that *E. coli* testing would be more useful than total coliform testing for indicating fecal contamination of cider apples.

In contrast to the generally good survival of coliforms in refrigerated apple cider, all but five of the 21 enterococci strains tested failed to survive well during 6d storage (decreased  $\geq 3.0$  log CFU/ml) (Table 2). In fact, nine of the 21 strains were not detectable after 2d storage. These nine strains included all four *E. faecalis* and five of 15 *E. faecium* strains tested. After 6d of storage, an additional three *E. faecium* strains were not detectable. Three *E. faecium* strains and both *E. durans* strains tested, all originally isolated (9) from retail Swiss-type cheese [typical pH of 5.6 (7)], survived well during 6d storage (decreased  $\leq 3.0$  log CFU/ml). The 100-fold greater acidity in cider was clearly lethal to most of the Swiss cheese strains tested. These results show that although acid-tolerance varies substantially within the genus, the enterococci are not a suitable indicator group for evaluating fecal contamination of apple cider. However, the documented ability of enterococci to survive refrigerated storage in less acidic foods (5,10) suggests that enterococci enumeration may be an appropriate method for assessing the sanitary status of apples before pressing releases the acidic juice. This possibility was investigated in the subsequent three field studies. The challenge study allowed us to conclude that, of the indicator bacteria that can be associated

with fecal contamination, coliforms, in general, and *E. coli*, in particular, are more likely than enterococci to survive in apple cider.

The simple broth-based methods designed for cider processors were able to detect a calculated inoculum of 3 - 15 CFU for all but one coliform strain and all enterococci strains. The coliform strain which was incapable of growth in VRBB was re-tested using 100-fold more cells in the inoculum and again failed to grow in VRBB. Because the VRBB and KEAB methods consistently detected very low numbers of cells, they were considered potentially useful for detecting coliforms and enterococci on the surface of apples. When the VRBB and KEAB methods were tested using inoculated apple cider, only one coliform strain and one enterococci strain were not detected. Based on these results, the VRBB and KEAB methods were also considered potentially useful for analyzing apple cider.

To determine the prevalence of presumptive coliforms, presumptive *E. coli*, and presumptive enterococci on drop apples, picked apples, washed apples and apple cider, a series of field studies was conducted. During the field studies, several analytical methods were compared and evaluated for possible use by apple cider processors. Presumptive coliform bacteria were detected in 0 to 100% of the drop apples from a given field study, with the analytical method being a major source of variability (Table 3). In general, presumptive coliforms were found more often on drop apples from the first two field studies than on drop apples from the final field study. The last field study occurred after a killing frost and the lower prevalence of presumptive coliform bacteria may have been the result of cold-induced death of bacteria or reduced bird, insect, and mammal activity in the orchard. Presumptive coliform bacteria were detected less often on picked apples, with analytical methods again

being a major determinant of prevalence. The prevalence of presumptive coliform bacteria on washed apples remained low (relative to prevalence on picked apples) for samples from the first and third field studies, but increased on samples from the second field study. This difference probably reflects the fact that apples from the first and third field studies were washed in a batch system which used chlorinated water, while apples from the second field study were washed in a continuous system, which appeared to involve considerable recirculation of wash water. Quantitative results (Table 4) showed that the batch-washing system had no consistent effect on presumptive coliform concentrations, and that the continuous washing system actually resulted in an increase in presumptive coliform populations on washed apples relative to picked apples.

The only samples found to contain presumptive *E. coli* were drop apples from the first field study (Table 3). The Reveal Bioplate™ method, which defined presumptive *E. coli* cells as those which grew and exhibited beta-glucuronidase activity, detected presumptive *E. coli* on two of five drop apples at levels of 216 and 2,807 MPN/apple and on one picked apple at 5,830 MPN/apple. The Petrifilm™ method, which defined presumptive *E. coli* cells as those which grew, produced gas, and exhibited beta-glucuronidase activity, detected presumptive *E. coli* on only one of five drop apples at 1,400 CFU/apple. Three drop apples and one picked apple from the second field study contained presumptive enterococci. Furthermore, three washed apples from the second field study also contained presumptive enterococci. Because the KEA broth method was qualitative, the numbers of enterococci on apples could not be determined.

Results of quantitative testing for presumptive coliforms often showed significant differences in mean numbers between drop apples and picked apples (Table 4), although results varied with the enumeration method used. This result, along with the presumptive *E. coli*-positive drop apples described previously, highlights the importance of not using drop apples to make cider. The levels of presumptive coliforms in cider were comparable to those reported by Silk *et al.* (11). However, mean presumptive coliform numbers in cider varied significantly depending on the analytical method used. Both the Reveal Bioplate™ and Simplate™ methods defined presumptive coliforms as cells that grew and exhibited beta-galactosidase activity (pink color in medium wells). However, the Reveal Bioplate™ method yielded the highest mean values on drop apple and cider samples from all three field studies and for picked apples and washed apple samples from one field study each. This finding may be the result of differences in the selectivity of the media used in the two methods. The Petrifilm™ method defined presumptive coliforms as those cells which grew and produced gas (red colony with one or more adjoining bubble). For all sample types, the Petrifilm™ method detected numerous non-gas producing bacteria (red colonies with no adjoining bubble; Table 4). With the exception of cider samples from one field study, the mean log CFU of these bacteria was always greater than the mean log MPN obtained using the Simplate™ method. Similarly, with the exception of cider samples from two field studies, the mean log CFU of these non-gas producing bacteria was always higher than the mean log MPN for presumptive coliforms obtained using the Reveal Bioplate™ method. Because lactose is the fermentable carbohydrate present in the Petrifilm™ medium, it is possible that at least some of these

organisms would have been defined as presumptive coliforms by the Simplate™ and Reveal Bioplate™ methods.

None of the quantitative coliform methods presented clear advantages for use by apple cider processors. Both the Simplate™ and Reveal Bioplate™ methods required dilution of the sample, using this dilution to rehydrate the test medium, pouring the rehydrated medium onto a multiwell holder, and draining off excess medium prior to incubation. Examination of incubated multiwell holders was straightforward. The Reveal Bioplate™ medium was difficult to rehydrate, and aseptically opening the Reveal Bioplate™ medium bottle was difficult due to excessively adhering seals. The Petrifilm™ method also required pipeting and some experience in inoculating the films. Counting colonies on incubated Petrifilms™ was not as simple as examining the medium wells in the Simplate™ and Reveal Bioplate™ methods, but rapidly became easier with experience. To avoid confusion for inexperienced users, the Petrifilm™ manufacturer provided pictures of typical colonies and overly crowded films. The Petrifilm™ *E. coli* films allow enumeration of both presumptive coliforms and presumptive *E. coli*, as do the Simplate™ and Reveal Bioplate™ methods. A potential advantage of the Petrifilm™ method is that the use of an ultraviolet lamp is not needed for detecting presumptive *E. coli*. Only a single pipette transfer was required for the simple broth-based coliform and enterococci detection methods. Evaluating the incubated tubes was generally quicker than evaluating the incubated Petrifilm™ films or the Simplate™ and Reveal Bioplate™ multiwell holders. One weakness of the qualitative methods is that they provide no information about the extent of contamination. It is notable that the percentage of samples for which the VRBB method detected presumptive coliforms was comparable to that obtained

using the Reveal Bioplate™ method, which most often detected presumptive coliforms in all sample types (Table 3).

In summary, the results of this study show that drop apples can be highly contaminated with presumptive coliform bacteria and possibly with presumptive *E. coli* and presumptive enterococci. Cider should not be made from drop apples. Recirculation of wash water should also be avoided as it may increase the prevalence of contamination by any fecal bacteria present. We conclude that *E. coli* is the most useful indicator organism for the apple cider industry. We base this conclusion on 1) the exclusively fecal origin of this species, 2) the generally good survival of this species in refrigerated apple cider compared to other coliforms and enterococci, 3) the association of *E. coli* with drop apples, and 4) the greater selectivity of available *E. coli* testing methods compared to those for coliforms.

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Table 1. Survival of coliform bacteria in preservative-free apple cider (pH 3.4, 13.3° Brix) stored at 4°C. Values are mean log CFU/ml (n = 2) with range (difference between two trials) in parentheses.

Species	Strain	Decrease in log CFU/ml		
		2d	4d	6d
<i>Escherichia</i>				
<i>coli</i>	ATCC 4351	1.5 (±0.05)	1.8 (±0.2)	2.6 (±0.0)
	ATCC 25922	1.5 (±0.0)	2.0 (±0.0)	1.7 (±0.05)
	SCI <sup>a</sup> 2	0.1 (±0.0)	0.3 (±0.05)	0.3 (±0.1)
	SCI 3	1.0 (±0.0)	1.2 (±0.1)	1.2 (±0.1)
	SCI 8	0.9 (±0.05)	1.2 (±0.15)	2.2 (±0.8)
<i>Enterobacter</i>				
<i>aerogenes</i>	ATCC 13048	1.5 (±0.1)	1.6 (±0.05)	2.0 (±0.0)
	<i>cloacae</i>	ATCC 29893	5.3 <sup>b</sup> (±0.05)	5.3 <sup>b</sup> (±0.05)
<i>Klebsiella</i>				
<i>pneumoniae</i>	ATCC 141	0.5 (±0.15)	1.0 (±0.05)	1.2 (±0.15)
	ATCC 29016	1.8 (±0.0)	2.2 (±0.1)	2.5 (±0.15)
<i>Citrobacter</i>				
<i>amalonaticus</i>	ATCC 24505	5.7 <sup>b</sup> (±0.05)	5.7 <sup>b</sup> (±0.05)	5.7 <sup>b</sup> (±0.05)

<sup>a</sup>Isolates with SCI designation were obtained from beef carcasses.

<sup>b</sup>No surviving cells detected (< 1 log<sub>10</sub> CFU/ml)

Table 2. Survival of enterococci in preservative-free apple cider (pH 3.4, 13.3° Brix) stored at 4°C. Values are mean log CFU/ml (n = 2) with range (difference between two trials) in parentheses. Species and biotype designations obtained using the API 20 Strep system (bioMerieux Vitek, Hazelwood, MO).

Species/Biotype	Strain	Decrease in log CFU/ml		
		2d	4d	6d
<i>E. faecium</i> 1	115 <sup>a</sup>	1.2 (±0.3)	2.0 (±0.3)	7.0 (±0.0)
	116	0.5 (±0.5)	1.5 (±0.45)	7.0 (±0.0)
	128	7.2(±0.05)	7.4 <sup>b</sup> (±0.0)	7.4 <sup>b</sup> (±0.0)
	129	0.7 (±0.0)	1.5 (±0.25)	2.5 (±0.5)
	130	2.0 (±0.2)	2.5 (±0.2)	3.0 (±0.35)
	142	2.6 (±2.6)	6.1 <sup>b</sup> (±0.05)	6.1 <sup>b</sup> (±0.05)
	143	5.9 <sup>b</sup> (±0.25)	5.9 <sup>b</sup> (±0.25)	5.9 <sup>b</sup> (±0.25)
	144	1.6 (±0.1)	2.8 (±0.0)	2.0 (±0.5)
	145	7.0 <sup>b</sup> (±0.0)	7.0 <sup>b</sup> (±0.0)	7.0 <sup>b</sup> (±0.0)
	148	2.1 (±0.35)	2.8 (±0.1)	3.6 (±0.2)
	149	1.9 (±0.05)	2.3 (±0.2)	2.4 (±0.1)
	150	6.1 <sup>b</sup> (±0.35)	6.1 <sup>b</sup> (±0.35)	6.1 <sup>b</sup> (±0.35)
	CDC-1916-77	6.5 <sup>b</sup> (±0.05)	6.5 <sup>b</sup> (±0.05)	6.5 <sup>b</sup> (±0.05)
<i>E. faecium</i> 2	101	1.2 (±0.25)	2.0 (±0.05)	7.0 <sup>b</sup> (±0.05)
	135	2.8 (±0.2)	3.4 (±0.2)	4.0 (±0.15)
<i>E. faecalis</i> 1	124	7.2 <sup>b</sup> (±0.1)	7.2 <sup>b</sup> (±0.1)	7.2 <sup>b</sup> (±0.1)

<i>E. faecalis</i>	2	ATCC 19848	5.8 <sup>b</sup> ( $\pm 0.1$ )	5.8 <sup>b</sup> ( $\pm 0.1$ )	5.8 <sup>b</sup> ( $\pm 0.1$ )
		42	6.8 <sup>b</sup> ( $\pm 0.0$ )	6.8 <sup>b</sup> ( $\pm 0.0$ )	6.8 <sup>b</sup> ( $\pm 0.0$ )
		48	6.8 <sup>b</sup> ( $\pm 0.0$ )	6.8 <sup>b</sup> ( $\pm 0.0$ )	6.8 <sup>b</sup> ( $\pm 0.0$ )
<i>E. durans</i>	2	146	2.1 ( $\pm 0.35$ )	3.0 ( $\pm 0.7$ )	3.0 ( $\pm 0.15$ )
		164	1.9 ( $\pm 0.05$ )	2.2 ( $\pm 0.1$ )	2.4 ( $\pm 0.15$ )

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<sup>a</sup>Strain designations without letter prefixes were obtained from retail Swiss-type cheese.

<sup>b</sup>No surviving cells detected ( $< 1 \log_{10}$  CFU/ml)

Table 3. Prevalence of presumptive coliforms, presumptive *Escherichia coli*, and presumptive enterococci on drop apples, picked apples, washed apples, and preservative-free, unpasteurized apple cider from three field studies. Methods for presumptive coliform analysis were Violet Red Bile broth (VRBB), Petrifilm™ Coliform film (PFC), Reveal™ (R), and Simplate™ (S). Methods for presumptive *E. coli* analysis were Petrifilm™ *E. coli* film (PFE), Reveal™ (R), and Simplate™ (S). Presumptive enterococci were detected using Kanamycin Esculin Azide broth (KEAB).

Field Study #	Sample Type	Coliforms	% samples positive for presumptive							
			Method Used				<i>E. coli</i>			Enterococci
	n <sup>a</sup>	VRBB	PFC	R	S	PFE	R	S	KEAB	
1	Drop Apples	5	60	40	80	60	20	40	0	0
1	Picked Apples	5	0	0	80	0	0	0	0	0
1	Washed Apples	10	0	10	20	40	0	0	0	10
1	Cider	10	100	0	90	60	0	0	0	0
2	Drop Apples	5	100	60	100	80	0	0	0	60
2	Picked Apples	5	40	0	0	0	0	0	0	0
2	Washed Apples	10	100	70	50	30	0	0	0	30
2	Cider	10	0	20	40	10	0	0	0	0
3	Drop Apples	5	40	0	80	0	0	0	0	0
3	Picked Apples	5	60	0	0	20	0	0	0	0

<b>3 Washed Apples</b>	10	30	0	10	0	0	0	0	0
<b>3 Cider</b>	10	30	10	100	20	0	0	0	0

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<sup>a</sup> Number of samples analyzed.

Table 4. Comparison of mean presumptive coliform bacteria populations on drop apples, picked apples, washed apples, and in apple cider as determined by Petrifilm™ Coliform (PFC), Simplate™, and Reveal Bioplate™ methods in three field studies. For comparison, non-gas producing cells enumerated by PFC are listed (ng-PFC). Values are means of log CFU (PFC) or log MPN (R,S) per apple or per ml of cider.

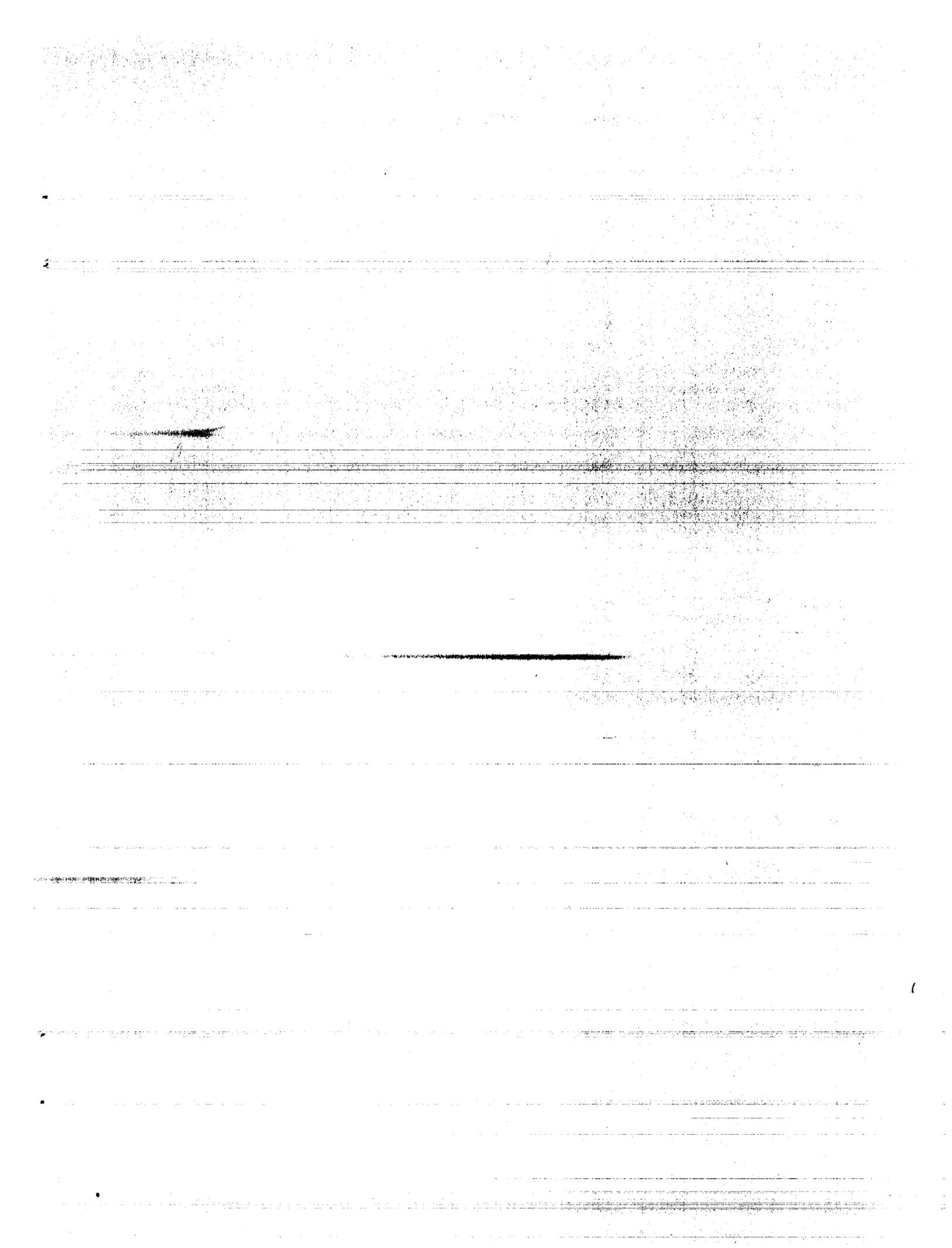
Field Study	Mean log populations of presumptive coliforms					
	Sample Type	n <sup>a</sup>	ng-PFC	PFC	S	R
1	Drop Apples	5	4.3 (A <sup>b</sup> , 1 <sup>c</sup> )	2.2 (B,1)	3.1 (B,C,1)	4.1 (C,1)
	Picked Apples	5	3.8 (A,1,2)	2.1 (B,1)	ND <sup>d</sup>	3.0 (C,1,2)
	Washed Apples	10	3.3 (A,2)	ND	2.5 (B,1)	2.4 (B,2)
	Cider	10	1.8 (A)	ND	0.8 (B)	2.9 (C)
2	Drop Apples	5	4.8 (A,1)	ND	2.8 (B,1)	4.4 (B)
	Picked Apples	5	2.9 (2)	ND	ND	ND
	Washed Apples	10	3.6 (A,2)	2.3 (B)	2.3 (B,1)	2.3 (B)
	Cider	10	-0.1 (A)	-0.1 (A)	0.0 (B)	0.5 (B)
3	Drop Apples	5	4.2 (A,1)	ND	ND	2.9 (B,1)
	Picked Apples	5	3.8 (A,1)	ND	2.1 (B)	ND
	Washed Apples	10	3.5 (A,1)	ND	ND	2.4 (B,2)
	Cider	10	4.0 (A)	0.1 (B)	0.1 (B)	2.6 (C)

<sup>a</sup> Number of samples analyzed.

<sup>b</sup>Different capital letters in a given row indicate a significant difference ( $P < 0.05$ ) between enumeration methods.

<sup>c</sup> For a given field study, different numbers indicate a significant difference ( $P < 0.05$ ) between values for two different sample types.

<sup>d</sup> ND = none detected (for Petrifilm™ methods :  $< 99$  CFU/apple or  $< 1$  CFU/ml cider; for Simplate™ and Reveal Bioplate™ methods:  $< 198$  MPN/apple or  $< 2$  MPN/ml cider).



***ROUTES TO REGULATORY CLEARANCE FOR  
NEW INTERVENTION PROCESSES***

**Patricia A . Hansen, Ph.D.  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition (CFSAN)  
Office of Premarket Approval**



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NEW INTERVENTION PROCESSES***

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- Legal framework
  - ◆ Which agency?
  - ◆ What procedures for which types of technology?
- Science-based safety decisions
  - ◆ Questions that must be answered
  - ◆ Data and information that can provide answers
- Examples





## *FDA Regulatory Procedures*

- Goal - protecting of public health
- Endpoint - reaching decisions based on sound science
  - Chemical analyses
  - Nutrient analyses
  - Microbiological analyses
  - In vitro, animal, clinical or other testing
  - Quantitative arguments and/or modeling
  - Scientific literature
- Boundaries - reaching decisions within the legal framework



## *Scope of FDA's premarket approval authority*

The potential scope of FDA's premarket approval requirements is broad:

\*\*\*Any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use)\*\*\*

- FD&C Act, section 201(s), definition of a "food additive"



*Scope of FDA's  
premarket approval authority*

**Certain classes of substances are explicitly excluded from FDA premarket approval:**

- Pesticide chemicals in or on, or used in production, storage, or transport of any raw agricultural commodity\*
- Substances "generally recognized as safe" (GRAS)\*\*
- Prior-sanctioned substances
- Dietary ingredients intended for use in dietary supplements\*\*

\*EPA registration required

\*\* optional FDA notification process



*Scope of FDA's  
premarket approval authority*

**In certain cases, FDA has authority to exercise discretion ...**

Food-contact materials meeting certain criteria - Threshold of Regulation Policy

**In still other cases, FDA has no authority to exercise discretion...**

Sources of radiation



## *New Interventions*

Use of a source of radiation?

Equipment with food-contact surfaces?

Already covered in FDA regulations or by previous exemption?

If not, does it appear to meet the criteria for an exemption under the Threshold of Regulation Policy?

Antimicrobial chemical added to food or wash water?

Pesticide chemical?

Already covered in FDA regulations?

If not, has it otherwise been determined to be GRAS under the proposed conditions of use?

Situation unclear? Other special circumstances?



## *Premarket Approval - Roles and Responsibilities*

- Sponsor/Petitioner is responsible for establishing the safety of the request
- FDA is responsible for
  - conducting a full and fair evaluation of the data and information
  - issuing a regulation if agency scientists conclude the requested use is safe
- FDA is not legally permitted to consider possible benefits.



## *What is involved in the premarket approval process?*

- **Submission of a petition containing the data and other information necessary to establish safety**
- **Screening of the submission against the criteria for filing**
  - file/don't file decision
  - letter to submitter
- **If filed**
  - Federal Register filing notice prepared



## *Data Requirements*

- Identity
- Conditions of proposed use
- Intended technical effect
- Method for determining "quantity"
- Data and information establishing safety
- Information regarding potential effects on the environment (NEPA)

*FD&C Act (Section 409) and 21 CFR 171*



## *Safety Standard*

“Safety requires proof of a reasonable certainty that no harm will result from the proposed use ... It does not - and cannot - require proof beyond any possible doubt that no harm will result under any conceivable circumstance.”

H. Rept. 2284, 85th Cong., 2d sess. 4 (1958)



## *Safety - General Areas that Must be Addressed*

- Toxicological considerations
- Nutritional considerations
- Microbiological considerations



## *Toxicological Considerations*

- **What kinds of chemical changes can occur?**
- **In what amounts?**
- **Are the products of these changes likely to be toxic in the amounts consumed?**



## *Nutritional Considerations*

- **Is the food a significant source of particular nutrients? Which ones?**
- **Does the proposed treatment result in nutrient losses?**
- **Are the losses significant in the context of the daily diet?**



## ***Microbiological Considerations***

- **Is the intended technical effect is microbiological? Are the proposed use conditions adequate?**
- **Is the treatment "substerilizing"? If so, can pathogens such as *C. botulinum* grow and produce toxin?**



## ***Premarket Approval Procedures - Technical review***

- **FDA scientists review data and evaluate petitioner's safety argument; document findings**
- **FDA communicates with petitioner to resolve any questions and/or additional data needs**
- **If necessary - further FDA review, documentation**
- **FDA staff reach a scientific conclusion and make a recommendation**



*What happens after FDA's technical review is complete?*

- **FDA prepares a draft decision document**
  - discussion of scientific basis for FDA's decision and any policy considerations
  - actual text that will appear in the CFR
- **FDA reviews the draft decision document**
  - technical
  - policy
  - legal
- **The Government Printing Office publishes the decision (final rule) in the Federal Register**



*Other Regulatory Routes -  
Food-Contact Materials*

- **Threshold of Regulation Policy**
- **FDA's policy for food-contact materials in cases where dietary exposure to components is v.v. low and certain additional criteria are met**
  - FDA can legally exempt v. low level migrants from regulation
  - "V. v. low " dietary exposure level and additional criteria based on safety evaluation of many hundreds of compounds
- **If all relevant criteria are met, FDA exempts from the requirement of a regulation (21 CFR 170.39)**



## *TOR Requests*

### **Data Requirements:**

- Chemical composition
- Technical effect
- Conditions of use
- Statement of basis for request
- Data enabling FDA to estimate dietary concentration
- Literature search

### **Criteria:**

- Dietary concentration less than 0.5 ppb
- No evidence of carcinogenicity



## *Purpose of TOR Policy*

- To direct FDA's limited resources to situations of highest potential public health risk
- To reduce the time needed to reach certain regulatory decisions

**No rulemaking, FDA responds by letter**



## *Other Regulatory Routes - GRAS Substances*

- GRAS Proposal - April 17, 1997
- Clarify criteria for GRAS status
- Eliminate rulemaking for GRAS substances
  - Eliminate old GRAS petition process,
  - Establish new GRAS notification procedure



## *What is GRAS?*

### Two Criteria:

- Technical (Safety)  
"reasonable certainty of no harm"
- Common Knowledge (General Recognition) -  
General Availability  
General Acceptance

Both criteria elements must be met



## *Proposed GRAS Notification Procedure*

- Optional
- If used, informs FDA of a notifier's GRAS determination -
  - must discuss basis for the determination
  - must include supporting information - but less detailed information than required in old GRAS petition process
- Rulemaking not required - FDA responds by letter
- FDA is currently using procedure, fine-tuning details before issuing a final version



## *Past Example - Pulsed Light*

Broadband (200-1100 nm) pulsed light to treat food

- Use of a source of radiation? YES
- Covered by an existing regulation? NO - not at the time

Premarket approval by FDA was required

- FDA provided guidance



## *Pulsed Light - Information*

- **Identity** - Xenon flashlamps
- **Conditions of use** - Short pulses (no longer than 2 msec)  
12 Joules/cm<sup>2</sup> cumulative maximum  
All food types
- **Technical Effect** - Reduce microorganisms on food surfaces
- **Quantitative method** - Photodetectors and associated equipment
- **Safety Information** - **Analytical data**  
**Quantitative arguments**  
**Microbiological data**  
**Published literature**
- **Environmental assessment**



## *Pulsed Light - FDA Conclusions*

- **Toxicological** - Types and amounts of photoproducts pose no safety problems
- **Nutritional** - No significant reduction in nutrients, no problems related to nutritional quality
- **Microbiological** -
  - Treatment can be effective in reducing the numbers of microorganisms on food surfaces
  - Treated foods will be at least as safe - from a microbiological standpoint - as untreated foods currently marketed



### *Current Example - UV Treatment of Juice*

- Use of a source of radiation? YES
- Is this use already covered by an existing regulation? NO
  - high intensities needed for significant pathogen reduction in juice
  - the existing regulation limits use of uv to low intensity

Higher intensity uses will require premarket approval

*Current status - a petition from California Day Fresh is under "expedited" (priority) review at FDA*



### *Past Example - Pulsed Electric Fields*

**High voltage pulses to treat liquid or pumpable foods**

- Use of certain food-contact surfaces under "new" conditions
- Potential for affecting characteristics of treated foods

**Dialogue between FDA and sponsor**

**Sponsor - responsible for establishing that**

- dietary exposure to any migrants would be negligible
- the technology would not pose other significant safety issues.

**FDA - responsible for a full and fair evaluation of the sponsor's argument and reaching a decision**



## ***Pulsed Electric Fields - Submission***

- **Assessment of possible electrochemical changes  
calculations, scientific literature**
- **Assessment of effect on vitamin levels  
analytical data**
- **Assessment of possible migration of electrode  
materials and other components into food  
analytical data, calculations**
- **Microbiological data**



## ***Pulsed Electric Fields - Conclusions***

- Significant microbial reductions can be achieved
- **Sponsor's assessment: Electrochemical changes, vitamin reductions, and migration of electrode components to food would be negligible - data and calculations to support**
- **FDA's evaluation: Data and calculations showed that significant negative effects on treated foods were unlikely**

**FDA CONCLUDED THAT UNDER CONDITIONS PROPOSED,  
PREMARKET APPROVAL WAS NOT REQUIRED -  
RESPONDED BY LETTER**



## *Chemical XYZ*

- **Direct addition of a chemical substance? YES**
- **Is the substance “prior sanctioned”?**
  - YES - premarket approval by FDA not required
  - NO - go on to next question...
- **Is the substance a “pesticide chemical”?**
  - Is cider/juice itself treated, chemical applied to wash water, or apples directly treated in a cider mill or similar facility? - NO ... Go on to next question
  - Are apples treated at another stage (i.e., when legally considered “raw agricultural commodities” or RAC's)? - YES ... See EPA
- **If you're not sure - ASK FDA**



## *Chemical XYZ*

- **Is there already a food additive regulation that covers the proposed use ? (See 21 CFR Part 172)**
  - YES - premarket approval by FDA not required
  - NO - go on to next question...
- **Is there already a GRAS listing that covers the proposed use? (See 21 CFR Parts 182 and 184)**
  - YES - premarket approval by FDA not required
  - NO - go on to next question...
- **Apart from any listings, is the substance GRAS under the proposed conditions of use???**



***Current Example - High Hydrostatic Pressure***

- Use of radiation source?      NO
- Addition of an antimicrobial chemical?      NO
- Food-contact surfaces?      YES
  
- Components of food-contact surfaces already covered by FDA's regulations or by a previous exemption under TOR?
- Do they appear to meet TOR criteria?
- Any special conditions of use?





## **For Additional Information...**

● Visit our website - <http://vm.cfsan.fda.gov>

- ◆ Click on “Food Additives and Premarket Approval”

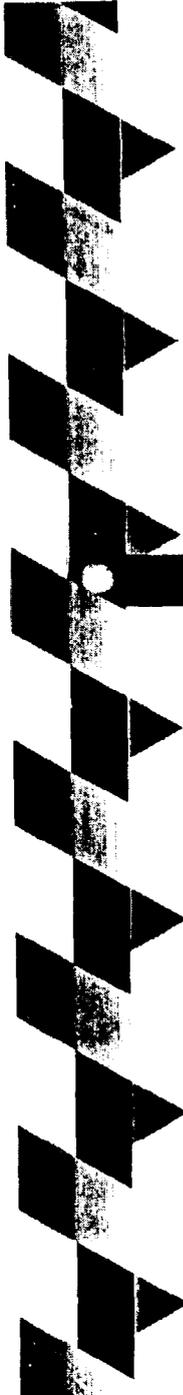
● Or call one of our contactpersons -

- ◆ Expedited Review - Robert Martin, Ph.D., 202-418-3074
- ◆ TOR - Mitchell Cheeseman, Ph.D., 202-418-3083 or Edward Machuga, Ph.D., 202-418-3085
- ◆ GRAS Notices - Linda Kahl, Ph.D., 202-418-3101
- ◆ FDA or EPA? - Mark Hepp, Ph.D., 202-418-3098

Patricia Hansen, Ph.D., 202-418-3093 or -3090







# Food and Drug Administration

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Juice Warning Statement





## Food and Drug Administration

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### Juice Warning Statement



## Juice Warning Statement

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### • Final Rule -

~ Published July 8, 1998 - 63 FR 37030

~ Effective Date

– September 8, 1998 for Apple juice/cider

– November 5, 1998 for all other juices



## Juice Warning Statement

- Final Rule -

- ~ Requires that fruit and vegetable juice products that have not been pasteurized or otherwise processed to achieve a 5-log reduction bear a warning statement.



## Juice Warning Statement

- “Juice” means -

- ~ The aqueous liquid expressed or extracted from one or more fruits or vegetables
- ~ A puree of the edible portions of the fruit or vegetable that is used as a beverage
- ~ Any concentrate of such liquids or purees

## Juice Warning Statement

- What products must bear the warning statement?

- ≈ Any juice or beverage containing juice that has not been processed to achieve at least a 5-log reduction in the pertinent microorganism for the shelf life of the product when stored under normal and moderate abuse conditions.

## Juice Warning Statement

- 5-log Reduction -

- ≈ Reduces the number of microorganisms by 100,000-fold
- ≈ Can be accomplished by a single control measure such as pasteurization
- ≈ Can be accomplished by a combination of control measures that have a cumulative effect of 100,000-fold reduction



## Juice Warning Statement

### • Control Measures

- ≈ Discarding blemished, bruised or broken fruit/vegetable
- ≈ Culling and washing fruit/vegetable
- ≈ Pasteurization
- ≈ UV light
- ≈ Ultra High Pressure
- ≈ Electromagnetic Pulse



## Juice Warning Statement

### • Pertinent Microorganism

- ≈ Most resistant foodborne illness-causing bacteria that is reasonably likely to occur in the particular juice
- ≈ Examples
  - *E. coli* 0157:H7
  - *L. monocytogenes*

## Juice Warning Statement

- What products are exempt from the warning statement?
  - ~ Untreated juice products sold in retail stores, intended for immediate consumption, and that are not pre-packaged -  
e.g., products sold by the glass in restaurants

## Juice Warning Statement

- Juice ingredients that are to be used solely in the manufacture of other foods, relabeled, or repackaged before sale to retail consumers need not bear the warning statement on the product label provided the information is disclosed in documents accompanying the product, e.g., invoices, bills of lading.



## Juice Warning Statement

- Placement and Prominence of Warning Statement in Labeling -
  - ≈ On sign, placard, counter card, etc. at point where juice product is displayed
  - ≈ In type size no less than one-fourth inch



## Juice Warning Statement

- The Warning Statement may appear in labeling until -
  - ≈ September 8, 1999 for Apple juice/cider
  - ≈ November 5, 1999 for all other juices



## Juice Warning Statement

- ⊙ Who is responsible for providing the signs, placards, or counter cards?
  - ≈ The manufacturer or distributor is responsible for producing the label
  - ≈ The retailer is responsible for displaying the label

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U.S. Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Food Labeling  
September 18, 1998

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## Guidance for Industry

# Warning and Notice Statement: Labeling of Juice Products Small Entity Compliance Guide <sup>(1)</sup>

### SUMMARY

There recently have been outbreaks of foodborne illness associated with the consumption of some juice products contaminated with harmful bacteria. Beginning September 8, 1998, for apple juice and apple cider and November 5, 1998, for all other juice products, FDA is requiring labeling with a warning statement those fruit and vegetable juice products (i.e., juices and beverages containing juice) that have not been pasteurized (i.e., heat treated) or treated in another way capable of preventing, reducing, or eliminating harmful bacteria by 100,000 fold. This reduction in bacteria is referred to as "a 5-log reduction."

Products required to bear the statement must be labeled with the following statement:

**WARNING:** This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

Manufacturers can apply the warning statement directly on the product or, for a limited time, on signs and placards. Apple juice and apple cider manufacturers may provide the required warning statement on signs or placards in letters at least 1/4 inch in height, rather than on the labels of their products, until September 8, 1999. Manufacturers of all other juice products may provide the warning statement on signs and placards until November 5, 1999. After these dates, the warning statement must appear on the label, i.e., on the container of the products.

### QUESTIONS AND ANSWERS

#### COVERAGE

1. Question: What is the definition of "juice" for the purposes of the warning statement regulation?

Answer: For purposes of this regulation, juice means the aqueous liquid expressed or extracted from one or more fruits or vegetables (e.g., apple juice, apple cider, orange juice, and carrot juice); a puree of the edible portions of the fruit or vegetable that is used as a beverage (e.g., banana puree or peach puree); or any concentrate of such liquids or purees (e.g., grape juice concentrate or grapefruit juice concentrate).

2. Question: What products are required to bear the warning statement?

Answer: Any juice or beverage containing juice (i.e., any "juice product") that has not been processed in a manner capable of achieving at least a 5-log reduction in the pertinent microorganism (i.e., any "untreated juice product") for the shelf life of the product when stored under normal and moderate abuse conditions must bear the warning statement.

3. Question: If a juice product is not 100 percent juice but contains a mixture of juice and other ingredients, is the finished product required to have the warning statement?

Answer: Juice that has not been treated must bear the warning statement. If the finished beverage is treated, the individual juice ingredients would not have to be treated. Similarly, if each individual juice ingredient has been treated the finished beverage need not be treated.

4. Question: Must untreated juice products that are to be used as ingredients bear the warning statement?

Answer: If the juice ingredient is not for distribution to retail consumers and is used solely in the manufacture of other foods, or is to be labeled, or repackaged before sale to retail consumers, it does not have to bear the warning statement *provided* that the lack of processing to achieve the 5-log reduction is disclosed in documents (e.g. invoices, bills of lading) that accompany the ingredient.

5. Question: Are untreated juice products that are sold in retail establishments required to bear the warning statement?

Answer: If untreated juice products are sold in package form, they are required to bear the warning statement. However, untreated juice products sold in retail establishments, i.e., restaurants, delis, some grocery stores, and roadside stands, that are intended for immediate consumption and are not pre-packaged do not require warning statements.

6. Question: What juice products are not required to bear a warning statement?

Answer: Packaged juice products that have been processed in a manner to achieve, at a minimum, a 5-log reduction in the pertinent microorganism. Heat pasteurization is one process that will achieve a 5-log reduction.

7. Question: If a juice processor has strong GMP's and a strong HACCP system in place, does he have to place a warning statement on his juice products?

Answer: The warning label regulation specifies that the juice product must be processed in a manner to achieve a 5-log reduction. Therefore, only if the system in place achieves a 5-log reduction are the juice products exempted from the warning statement requirement.

8. Question: Are products other than beverages that contain juice required to bear the warning statement? For example, is a sherbet containing a fruit puree that has not been processed to achieve the 5-log reduction required to bear the statement?

Answer: No. The regulation applies only to juices and beverages containing juice. A fruit puree is included in the definition of juice because it may be used in beverages. However, if sherbet contains the puree, even if the puree is not processed to achieve a 5-log reduction, the sherbet is not required to bear the warning statement because it is not a beverage or a juice.

9. Question: Are citrus oils required to bear the warning statement?

Answer: No. Citrus oils do not fit the definition of juice because they are not aqueous liquids.

### **THE 5-LOG REDUCTION**

10. Question: What is a 5-log reduction?

Answer: A 5-log reduction means a reduction in the number of microorganisms by 100,000-fold. For example, if a juice product contained 100,000 pertinent microorganisms, a 5-log reduction would reduce the number of pertinent microorganisms to 1.

11. Question: How does a juice manufacturer achieve a 5-log reduction without pasteurizing the product?

Answer: A manufacturer can achieve a 5-log reduction by using control measures that have been shown to be effective in reducing the number of microorganisms. A processor can use one control measure that has been shown to reduce the pertinent microorganism by at least 100,000-fold (e.g., pasteurization), or a combination of control measures that have a cumulative effect of a 100,000-fold reduction.

12. Question: What steps in the processing of juice may a manufacturer consider in determining control measures to achieve a 5-log reduction?

Answer: The control measures used to achieve a 5-log reduction may include any measure at the farming, harvesting, or processing phases over which the processor has control and which are effective in reducing the number of pertinent microorganisms.

13. Question: How can a manufacturer determine whether a process achieves a 5-log reduction?

Answer: A processor can conduct its own studies to validate the effectiveness of its process or rely upon scientific studies conducted by others (e.g., researchers, states, etc.). Validation studies may include (1) tests of the control measure with a known level of the pertinent microorganism in a controlled experimental setting which is similar to a production setting, or (2) tests with a surrogate microorganism in an experimental or process setting. Manufacturers of equipment or sanitizers that can be used to control harmful microorganisms may test the control measure they are recommending and supply the validation information to the processor.

14. Question: If I have information from validation studies done by others (e.g., researchers, states, etc.), do I have to do anything else to show that my process is validated?

Answer: Yes. A processor must show that the validated control measure is being used in the same manner as it was used in the validation study. For example, any machinery should be used in the same manner or any sanitizer at the same concentration as used in the validation study.

15. Question: What does "pertinent microorganism" mean?

Answer: The pertinent microorganism is the most resistant (i.e., most resistant to being killed by the specific treatment under consideration) foodborne pathogenic (i.e., illness-causing) microorganism that is reasonably likely to occur in a particular juice. Pathogenic microorganisms can be introduced into juice both within and outside the processing plant environment, including before, during, and after harvesting. A pathogenic microorganism that

is likely to occur in a juice is one that, based on the evidence provided by experience, illness data, scientific reports, and other information, has a reasonable possibility of occurring in the particular juice if appropriate controls to protect against its occurrence are not put in place.

16. Question: What does "surrogate microorganism" mean?

Answer: A surrogate microorganism is any non-pathogenic microorganism that has acid-tolerance, heat resistance, or other relevant characteristics similar to pertinent microorganisms. Food-grade lactic acid bacteria that have GRAS (generally recognized as safe) status are a possible option if their characteristics are similar to the pertinent microorganisms.

17. Question: What are some examples of pertinent microorganisms?

Answer: For many juice manufacturers, the most pertinent microorganism will be *E. coli* O157:H7 or *Listeria monocytogenes*. *E. coli* O157:H7 is known to be unusually acid resistant and *L. monocytogenes* is relatively heat resistant. Other microorganisms may be pertinent if they are known to be reasonably likely to occur in a particular juice product or process.

#### WARNING STATEMENT

18. Question: What is the required warning statement for packaged juice products that have not been pasteurized or otherwise processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present?

Answer: **WARNING:** This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

19. Question: Where must the warning statement be placed on the label?

Answer: The statement must appear either on the information panel (the label panel immediately to the right of the principal display panel) or on the principal display panel (that part of the label most likely to be seen by the consumer at the time of purchase, generally the front of the package).

20. Question: How should the warning statement appear on a label?

Answer: The statement must appear on the label prominently, conspicuously, and must appear in a minimum type size of one-sixteenth inch. The statement must appear in a box set off by hairlines. The word "warning" must appear in bold capital letters. For example:

**WARNING:** This product has not been pasteurized and, therefore, may contain harmful bacteria that may cause serious illness in children, the elderly, and persons with weakened immune systems.

21. Question: Can manufacturers use signs or placards instead of changing their labels?

Answer: Yes temporarily. Manufacturers may provide the warning statement on signs or placards, until September 8, 1999, for apple juice and apple cider and until November 5, 1999, for all other juices.

22. Question: How should the warning statement appear on signs or placards?

Answer: The statement should appear prominently and conspicuously in letters that are legible in a minimum type size of one-fourth inch.

23. Question: Where must signs or placard be placed?

Answer: The sign or placard must be placed at the point of purchase of the juice product. Point of purchase means at the place where the product is displayed, e.g., on the outside of the refrigerated case or on a shelf inside the case.

24. Question: Must the warning statement on signs be printed in professionally set type?

Answer: The regulation does not address how the sign must be printed. Therefore, the sign can be done by any means, including written by hand, as long as the statement is legible and the letters are at least one-fourth inch in height.

## **COMPLIANCE**

25. Question: When must warning statements appear on covered products?

Answer: The warning statement must be available to consumers at point of purchase by September 8, 1998, for apple juice and apple cider, and by November 5, 1998, for other juice products. The warning statement may appear either on the labels of covered products or on signs and placards displayed with the products until September 8, 1999 for apple juice and apple cider, and until November 5, 1999, for other juice products. After these dates, the warning statement must appear on the labels of the packaged products.

26. Question: Is it the manufacturer or retailer who is responsible for providing the signs or placards?

Answer: Both share responsibility. The firm identified as the manufacturer or distributor of the product is responsible for producing the label. A firm may decide to provide signs instead of changing their labels to add the warning statement. If a firm decides not to use the label but to provide a sign, the retailer must display the sign with the product because failing to do so would constitute misbranding of the product, which is a violation of the Federal Food, Drug, and Cosmetic Act.

27. Question: How will FDA determine whether juice that is sold after the effective dates of the rule is properly labeled?

Answer: FDA may conduct inspections at juice firms that do not provide warning labels or signs and that do not pasteurize. FDA would identify the control measures that are used to reduce pathogens and review any scientific data that the firms provide to show that their process provides a 5-log reduction and, therefore, does not require the warning statement.

## **MISCELLANEOUS**

28. Question: Can a juice product that has been heat treated to pasteurize the product be labeled "fresh?"

Answer: No. The term "fresh" implies that a food is raw and unprocessed. Juice products that have been pasteurized are processed and, therefore, can not be labeled "fresh."

29. Question: If juice products, themselves, have been treated to achieve the 5-log reduction in ways other than heat pasteurization (e.g., high pressure treatment, sodium benzoate etc.), can they be labeled "fresh?"

Answer: No. Juice products that have been preserved or otherwise processed are not unprocessed and, therefore, cannot be labeled "fresh."

30. Question: FDA encouraged voluntary warning label statement in a *Federal Register* notice in 1997. Must a manufacturer who uses a warning statement on a juice product that has different wording than the statement in the regulation have to change the labels?

Answer: A manufacturer may continue to label their products using the advice provided in FDA's August 28, 1997 notice until the label inventory is depleted. Any applicable labels printed after July 7, 1998 must use the exact warning statement as noted above in #20.

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**Footnote:**

1. The Food and Drug Administration (FDA) has prepared this guide in accordance with section 212 of the Small Business Regulatory Fairness Act (P.L. 104-121). This guidance document restates in plain language the legal requirements set forth in the current regulation for the labeling of juice products that have not been processed to prevent, reduce, or eliminate harmful bacteria. Any statement in this guidance document that goes beyond merely restating the applicable legal requirements represents the agency's current thinking on this subject. The regulation is binding and has the force and effect of law; however, this guidance document does not, itself, create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

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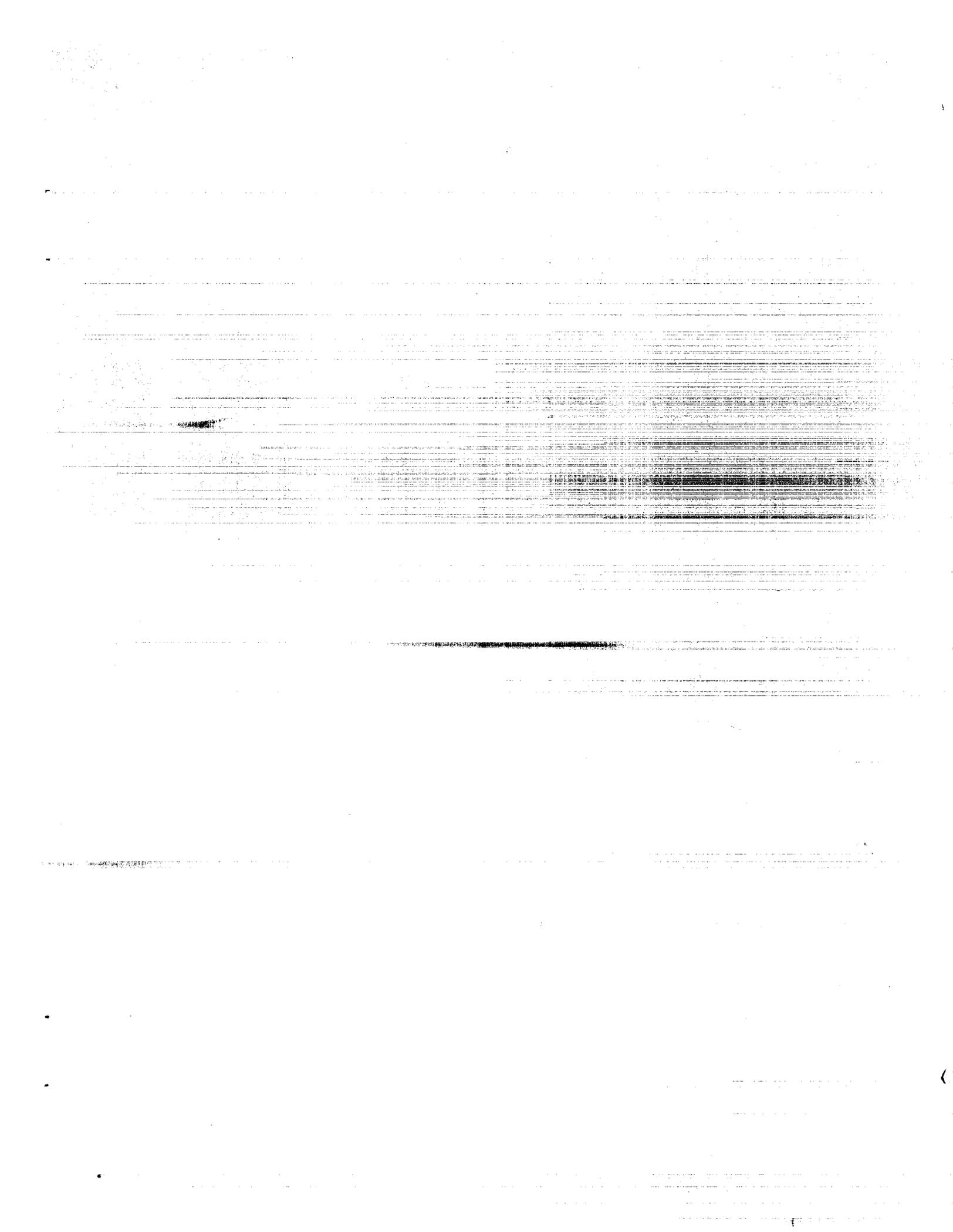
(Tel) 202-205-5099

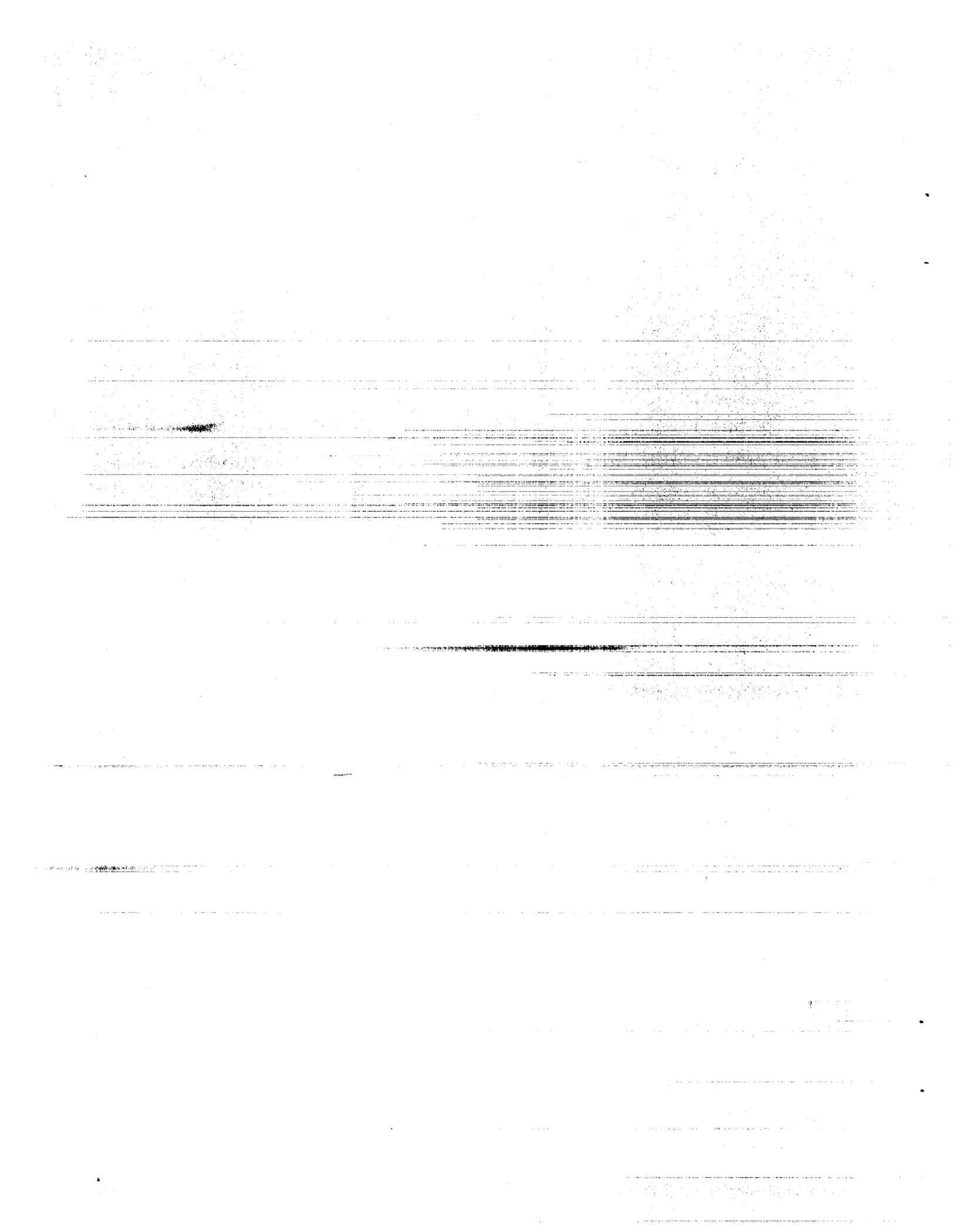
(Internet) <http://www.cfsan.fda.gov/~dms/guidance.html>

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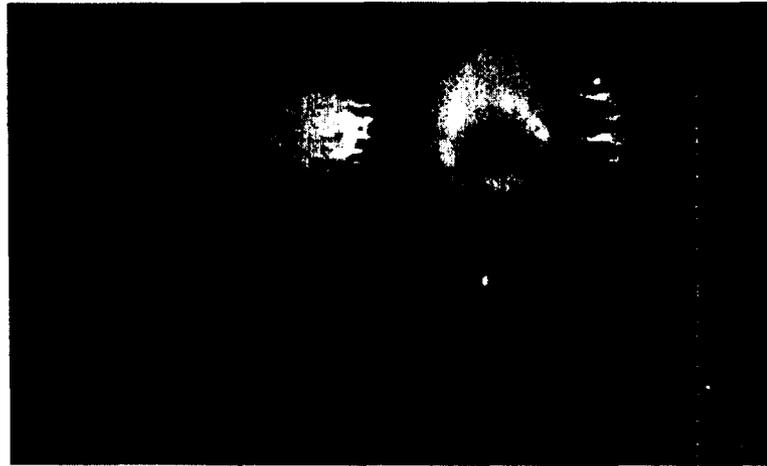
**Home**

Hypertext updated by xxz/ear/dms 1998-OCT-09





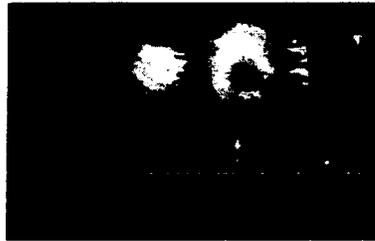
# *Escherichia coli* O157:H7 in Apple Cider: A Quantitative Risk Assessment



Don Schaffner, PhD  
Siobain Duffy  
Food Risk Analysis Initiative  
Rutgers University



## *Escherichia coli* O157:H7 in Apple Cider: A Quantitative Risk Assessment

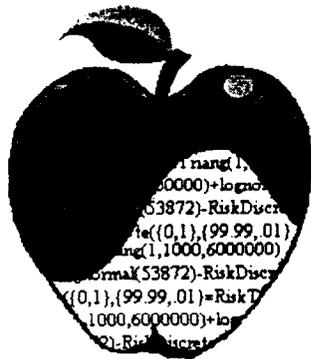


Don Schaffner, PhD  
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Rutgers University

## What is QRA?

- A blend of published scientific literature, and expert opinion linked together by computer simulation
- An organized warehouse of data collected on a certain topic
- A summary of the influence of specific factors on the overall safety of a product
- A science-based, cost-effective way to estimate risk

## Why QRA?



- Quantitative results
- Combines data from many different labs, experiments
- Incorporates variability and uncertainty
- Customizable for individual producer's needs
- QRA can help to identify HACCP Critical Control Points

## What can be part of a QRA?



- Pre-harvest conditions
  - manure, animal contamination, drops, fruit fly transmission, cultivars
- Processing
  - flume water, washing, brushing, equipment contamination, pasteurization, human and storage bin contamination
- Storage Conditions
  - preservatives, temperature, freeze/thaw cycles, time to sale

## The end results of a QRA

- Conceptual framework for thinking about the problem
- Dynamic model of a particular food processing and storage system
- Sensitivity analysis, i.e. what factors are important
- Avenues of future research

How many apples in the orchard?

How many apples/boxes?

Orchard near landfill or ocean?

Is the orchard managed with animal waste?

How many apples are processed in a single batch?

How many gallons are produced in a single batch?

Number of cows in orchard in previous month

Number of deer in orchard in previous month

Number of dogs in orchard in previous month

Number of horses in orchard in previous month

Number of pigs in orchard in previous month

Number of sheep in orchard in previous month

What % sheep manure do you use?

What concentration of Chlorine do you use in your wash water? (in ppm)

Do you recycle your farm water?

What % of your processing equipment is made of stainless steel?

What % of your processing equipment is made of wood?

Do you wash UV or heat pasteurize or irradiate with a dose of 1.8 kGy or greater?

Do you use 1% Sodium Benzoate, 1% Potassium Sorbate, or both?

Is the order held in refrigeration conditions or room temperature?

Does the order undergo a heat stress step?

The holding temperature?

How many hours do you hold it there?

pH of the order?

Which sanitizer do you use?

Do you clean your equipment daily?

number of E coli O157:H7 in a gallon of order in legs

Model

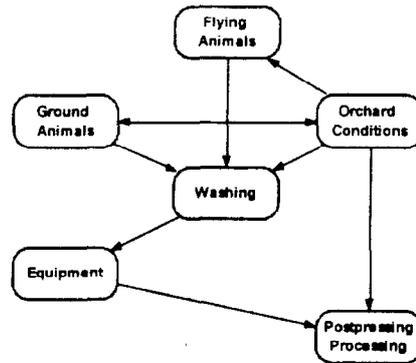
## The User Interface

pull down menus  
hidden model  
result button

Calc

## The Modules

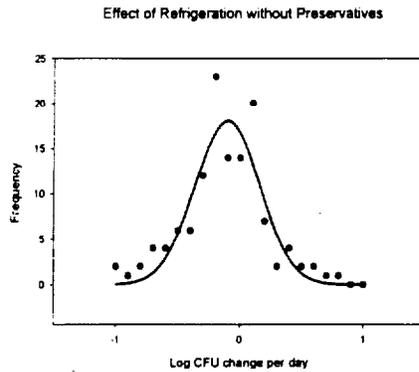
- Birds contaminate tree-picked apples
- Animals in the orchard influence CFUs on drops
- Flume water, chlorine rinses vary the pre-pressing microbial counts
- Use of sanitizers on equipment control O157
- Pasteurization, freeze-thaw and preservatives all reduce bacterial counts



## A look under the hood, part 1

- Refrigeration (4-8 °C) of cider contaminated with *E. coli* O157:H7
    - Decreases (and occasionally increases) in O157 counts per day from all papers
    - Summarized as a histogram
    - Fit with a statistical distribution
- D.W. Dingman, *J.Food Protect.* **62**, 567 (1999).
- L. Garland-Miller, C.W. Kaspar, *J.Food Protect.* **57**, 460 (1994).
- G.J. Leyer, L.-L. Wang, E.A. Johnson, *Appl. Environ. Microbiol.* **61**, 3752 (1995).
- A.M. Roering, et al., *Int. J. Food Microbiol.* **46**, 263 (1999).
- T. Zhao, M.P. Doyle, R.E. Besser, *Appl. Environ. Microbiol.* **59**, 2526 (1993).

## A look under the hood, part 1



- Uses Excel and Bestfit software programs
- Distribution describes the log change occurring in a single day
- Change per day is simulated over the shelf life of the cider

## A look under the hood, part 2

- Freeze-Thaw Cycles

- Uljas and Ingham (JFP, 5/99)
- Polynomial regression (SAS) to create model
- freeze/thaw, holding temperature, time and pH on log reduction of O157:H7

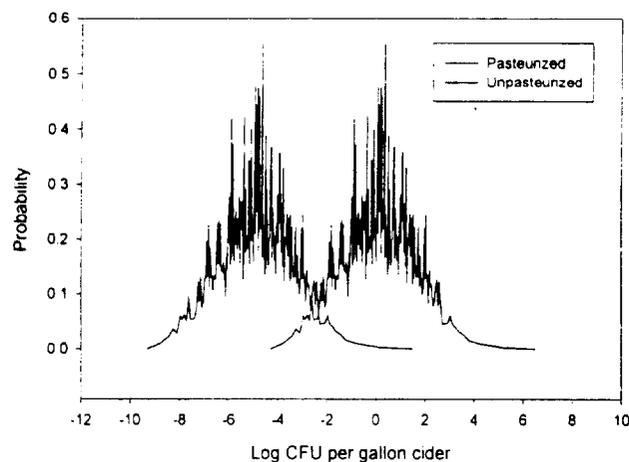
Variable	Parameter	P value
INTERCEPT	69.59985789	0.0036
TEMP	-0.04081142	0.0003
PH	-44.94493941	0.0007
HOURS	-0.36421373	0.0011
PH <sup>2</sup>	6.77622727	0.0002
HOURS <sup>2</sup>	0.01875504	0.0317

$$R^2 = 0.8914$$

## Simulation

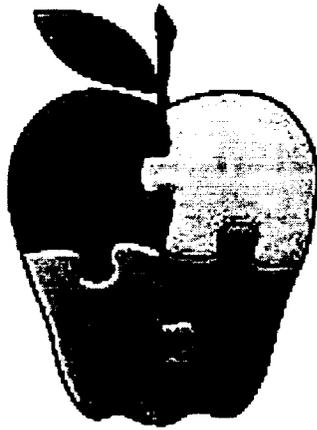
- Analytica uses Monte Carlo simulation to run a user-defined number of iterations on the conditions specified
- Graphical output or statistics on CFU *E. coli* O157:H7 on day of sale in a gallon of cider
- Can be run by any person who could download the free Analytica reader and our simulation

Effect of pasteurization, all other processing steps held constant\*



\*Assuming birds infected with O157:H7, animal manure used, no chlorine rinse, No freeze-thaw cycle, no preservative used, no cleaning or sanitizing of equipment

## Future Research



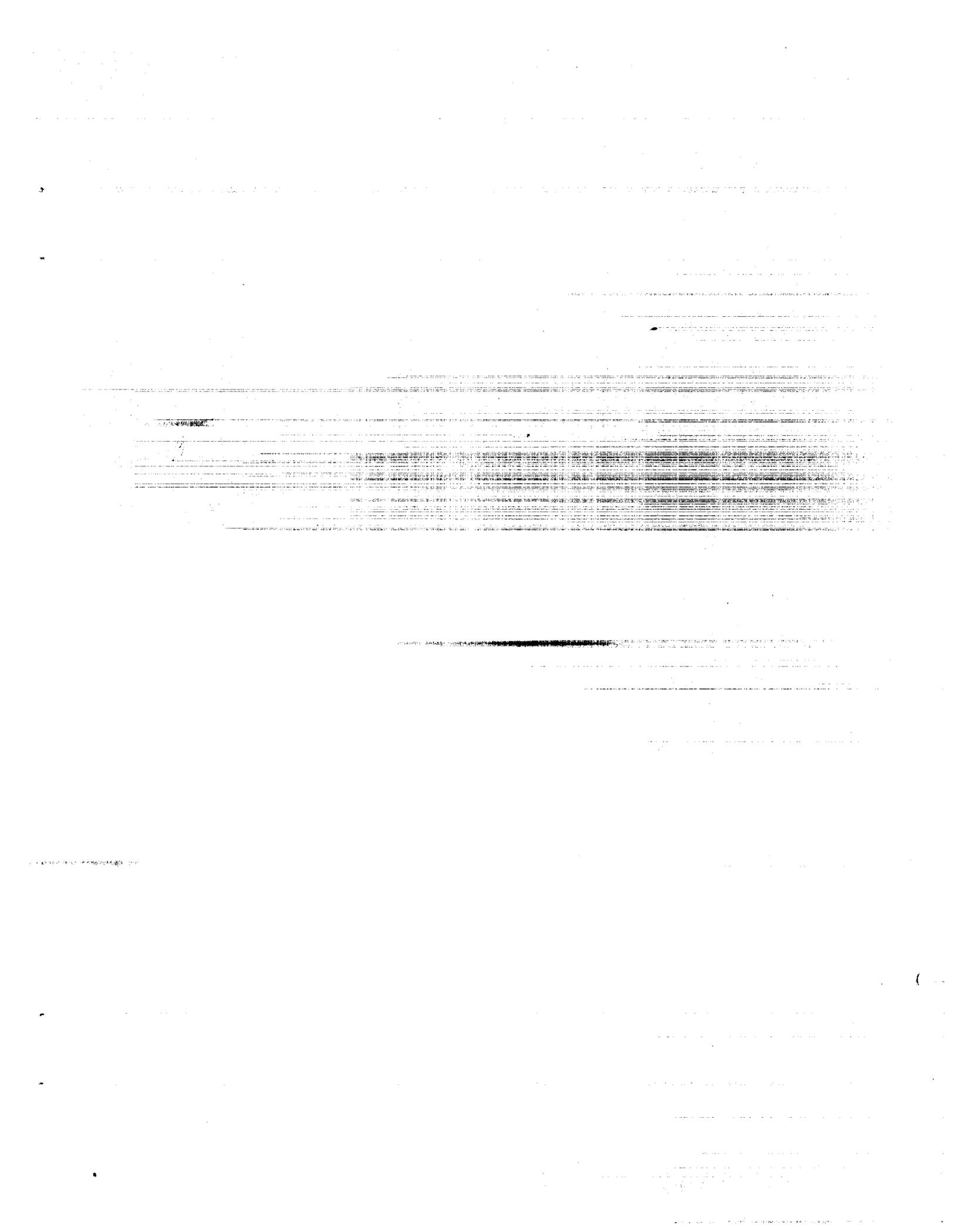
- Real-life studies to ascertain realistic levels of contamination
- More accurate distributions for all variables, as more data are collected
- Validation?

## Summary

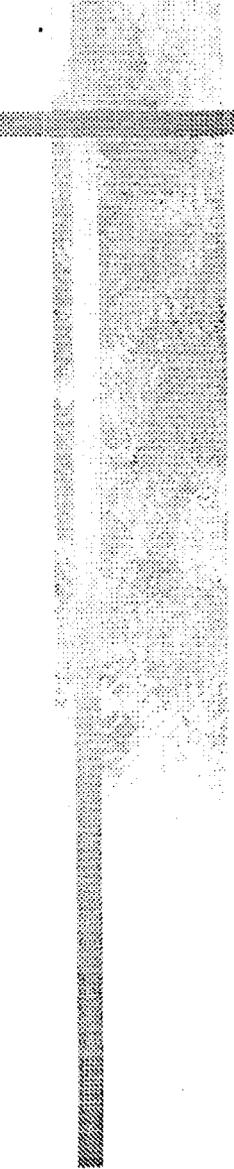
- A risk assessment is only as good as the data it models
  - O157: H7 in cow manure vs.
  - Brushing of apples
- This risk assessment is a good start, but it's only the first step
  - Peer review
  - More data, better data

“All models are  
wrong... but some  
are useful.”

- G. Cox







**Food and Drug Administration**

**PROMISING CONTROL PRACTICES FOR  
PRODUCTION OF SAFE APPLE CIDER**

**ARTHUR J. MILLER, Ph.D.**

**Center For Food Safety and Applied Nutrition  
Washington, DC**



## **Food and Drug Administration**

### **PROMISING CONTROL PRACTICES FOR PRODUCTION OF SAFE APPLE CIDER**

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Washington, DC**

## **Points to Cover**

- ✓ **Sources of contamination**
- ✓ **Mitigation approaches**
- ✓ **How does it add up?  
Can it?**
- ✓ **Research needs**
- ✓ **Research partnerships**



## **Minimizing Microbial Hazards and Risks: An Orchard to Jug Approach**

- Animals**
- Water**
- Harvest/Transport**
- Processing /Storage**
- Workers**

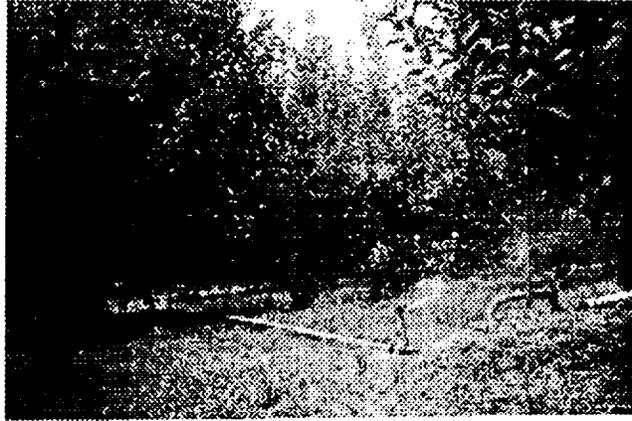


## **Animals as a Source of Microbial Hazards**

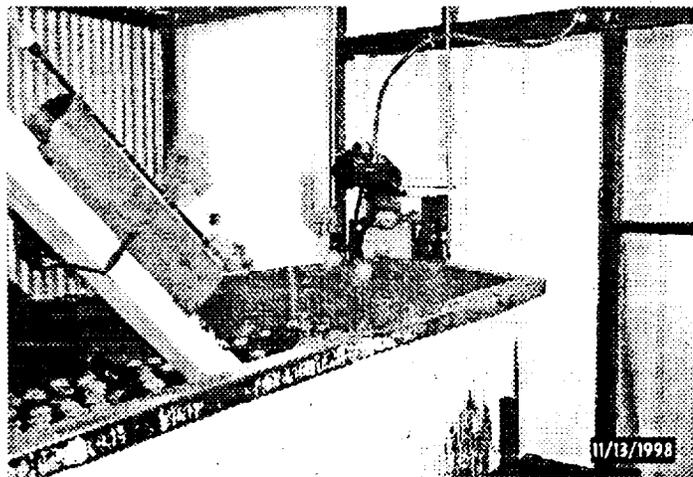
- Animal/human manure**
- Insects/rodents (?)**
- Damaged fruit?**
- Avoidance practices**
  - No manure fertilizer**
  - No animals in orchards**
  - No dropped apples (2 log)**
  - Minimum fruit grade**



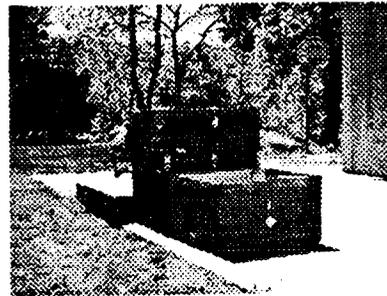
## **Water as a Source of Microbial Hazards Irrigation Water**



## **Water as a Source of Microbial Hazards Processing Water**



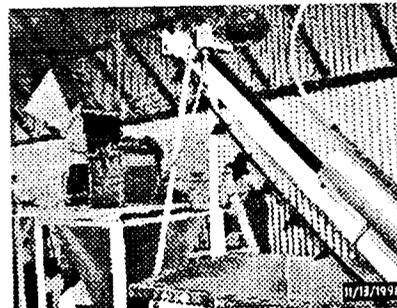
## **Harvesting/Transportation/ Storage as Sources of Microbial Hazards**



## **Processing as a Source of Microbial Hazards**

**Must conclude that this  
is a significant source**

- Literature
- Airborne microorganisms
- Irregularities between apple and cider microbial loads



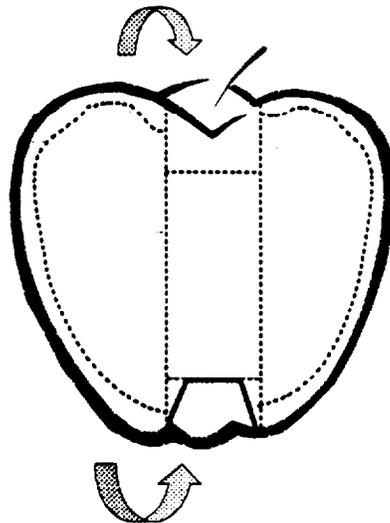
## Fruit Cleaning

- **Dump Tanks?**
- **Brush Washing**
- **Chemical treatments**  
( $<3$  log surface)
- **Hot water/steam**  
( $<3$  log surface)



## Internalization of Bacteria

- **Bacteria can enter by:**
  - Natural route
  - Immersion in wash water.
- **Mechanism:**
  - Stem
  - Calyx
  - Punctures
  - Bruises



## **Milling as a Contamination Source?**



## **Pressing as a Contamination Source?**



## **Post-Pressing/Packing Interventions**

- **UV**
- **Freezing**
- **Pulsed Electric Fields**
- **High Pressure**
- **Irradiation**
- **Refrigeration**
- **Membranes**
- **Preservatives**
- **Bright light**



## **Workers as Contamination Sources**

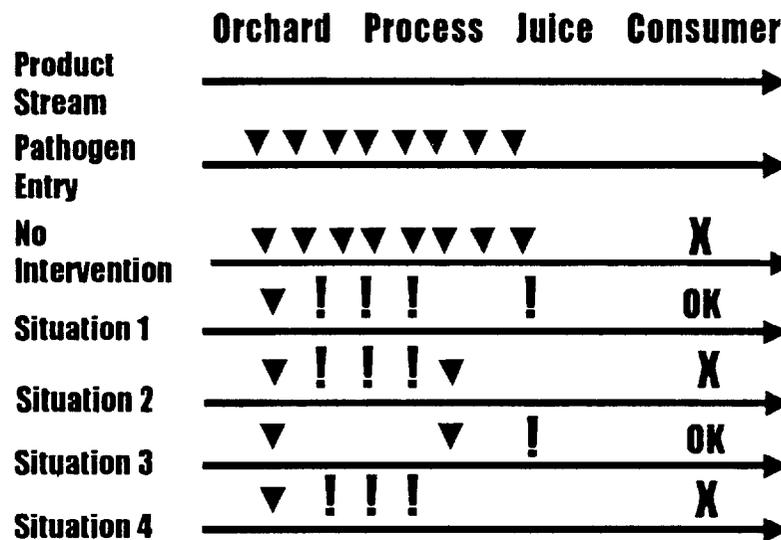
- **Healthy**
- **Practice good hygiene**
  - wash hands
  - gloves
- **Trained**
  - task
  - sanitation
  - hygiene



## What Will it Take to Achieve 5D? Assumptions

- **Contamination**
  - In-coming fruit is contaminated and internal, and additional contamination occurs during processing
    - Relative contribution from each source is unknown
- **Mitigation**
  - Efforts most effective if applied post-contamination
  - Efforts can be cumulative
  - Multiple interventions reduce cross-contamination and lower microbial loads entering processing plant

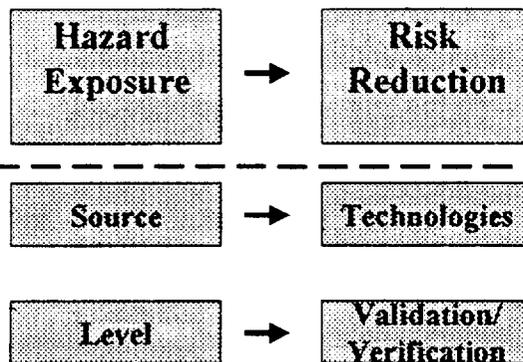
## Rationale



## **Conclusion About Application of Interventions**

**If we assume that contamination occurs within apples and during processing, then we must conclude that interventions applied after juice expression will have maximum public health benefit.**

## **Research Needs**



## **Research Needs -- Exposure**

- **Apples**
  - Quantitative levels of naturally occurring surface vs internal contamination
- **Processing**
  - Quantitative levels of contamination introduced by cider making process

## **Research Needs - Risk Reduction**

- **Intervention Technologies**
  - Pathogen reduction efficacy
  - Where to target intervention technologies?
  - Is the additive/cumulative risk reduction approach valid?
- **Validation**
  - Best approach to perform a validation study
  - Surrogates: Validity? Which? Application? Sampling?
- **Verification How?**

## Who's Conducting Research?

- **States**
  - **Universities**
  - **Governments**
- **Federal Agencies**
  - **USDA**
    - **ARS**
    - **CSREES**
  - **FDA**
- **Industry/Associations  
/Consortia**



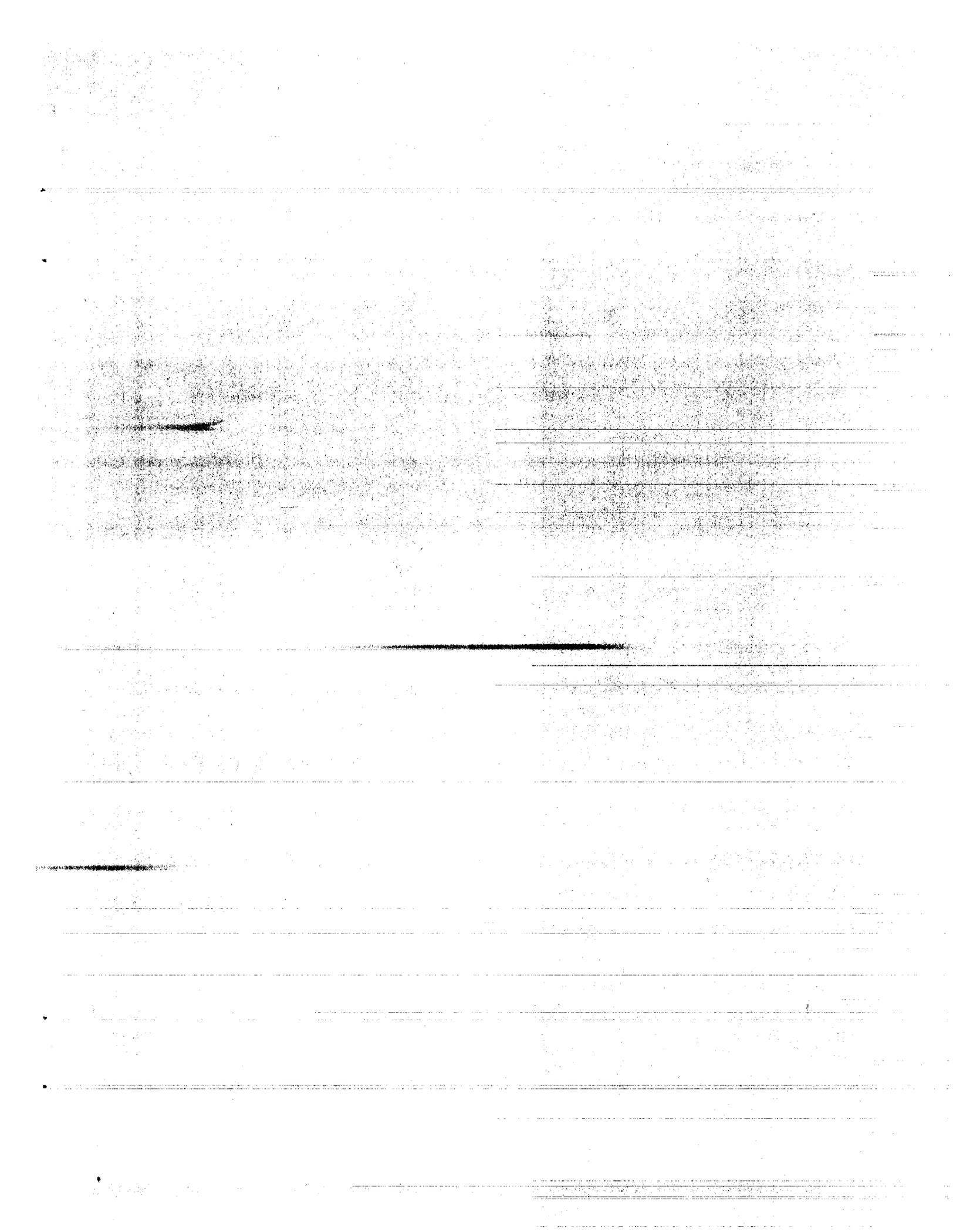
## Placerville Partnership

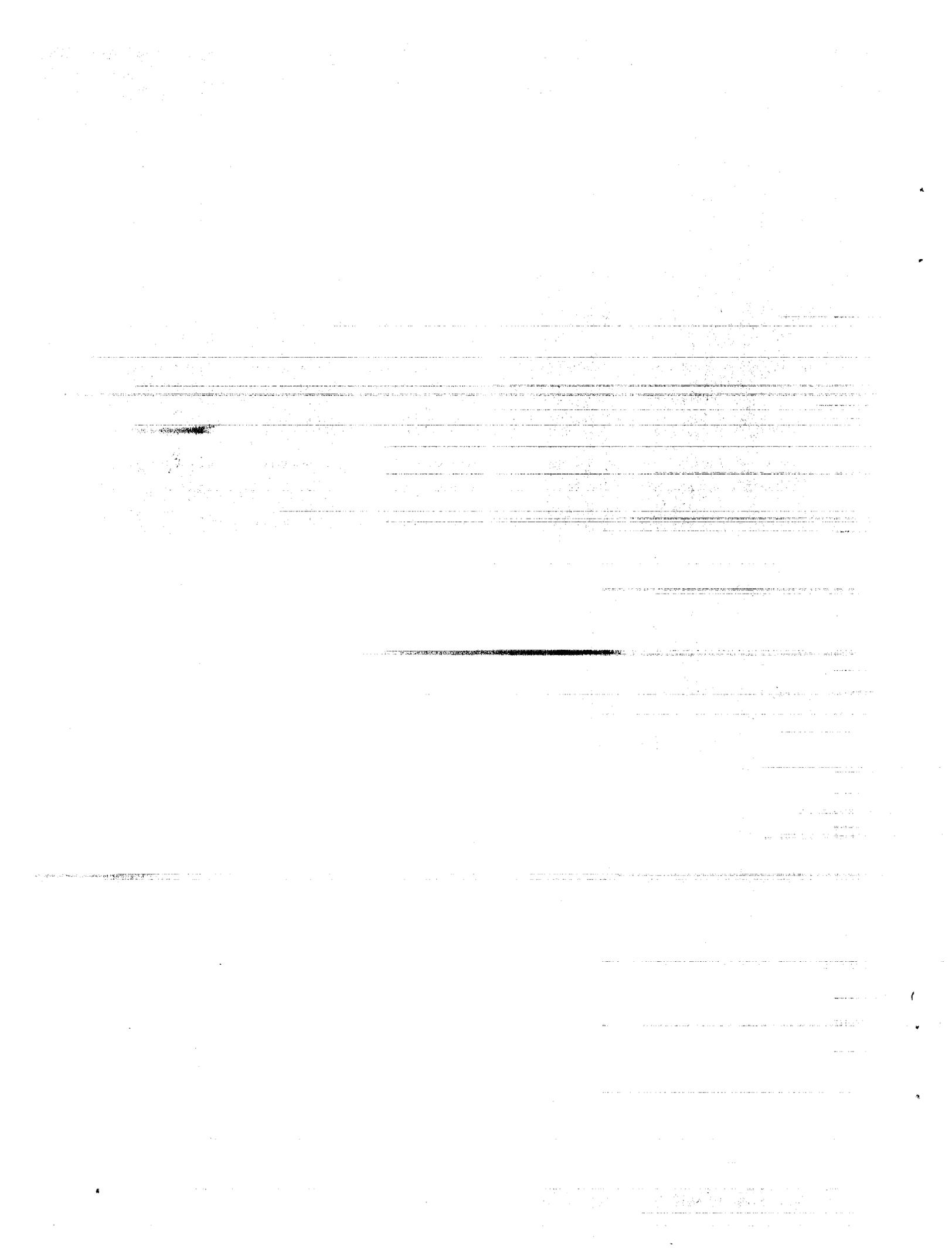
- **FDA**
- **USDA-ARS**
- **El Dorado County**
- **Apple Hill Growers**
- **State of California**
  - **Dept of Health Services**
  - **Univ Cal Davis**
- **Nat'l Center for Food Safety & Technology**



## **Points Covered**

- ✓ **Sources of contamination**
- ✓ **Mitigation approaches**
- ✓ **How does it add up? Can it?**
- ✓ **Research needs**
- ✓ **Research partnerships**





## **CFSAN Management Perspective – Panel Discussion and Q's & A's**

### **Apple Cider Safety**

FDA/CFSAN Panel: Dr. Bob Buchanan, Dr. John Kvenberg, Mr. Joe Bacca

(Excerpts from the Transcript)

MR. SCHWALM: The object of today's presentations is to wrap things up, and to talk about what our future needs, issues, and concerns. There have been a number of people at the workshop who have talked about "really needing to do this and really needing to do that." The next session is a panel of FDA/CFSAN managers who will provide an opportunity to get on the table concerns, issues, and directions as to where we want to go.

The panel consists of Dr. John Kvenberg who is the head of CFSAN's HACCP effort, and Dr. Bob Buchanan, who is CFSAN's science advisor and research coordinator. We also have Mr. Joe Bacca, who is our new Director of the Office of Field Programs and is very much involved in the interaction between our food safety programs in the Center and the field. The objective is to have an open discussion between the workshop participants and the panel.

DR. BUCHANAN: Let me begin by cautioning that since we are in the process of developing the final form of the juice HACCP regulation, there are certain restrictions on what we're allowed to talk about in public during that process. In particular, what we can't do is in any way talk to you about what will be in the final regulation.

MR. SANFORD: Sanford from Tennessee. I've worked with FDA for quite some number of years and have nothing but the highest regard and respect for a lot of the individuals I've worked with. I'm in the field, and I'm a mill grading officer. I'm one of those guys who is trying to make apple juice like milk. I get accused of this every day. All I'm trying to do is make it safe. I was asked to assess it, okay?

I want to address some issues, and really I'm just expressing some thoughts and issues. I work with some of the best academicians that I've ever worked with here at the University of Tennessee. They've worked with me. We've worked hand-in-hand with these folks.

Pasteurization -- we have some of the top experts in fluid, beverage, continuous flow pasteurization within 300 yards of this building here in Washington D.C. Sure, they are experts in milk pasteurization, but some, if not all, of the components are going to be the same. As of

this morning at 8 o'clock, they have never been contacted for any assistance in evaluating apple cider pasteurization equipment.

I have people that I deal with in my state that are being sold, as I expressed yesterday, junk by equipment companies and the cider processors are told that it's pasteurization equipment. I have nothing to stand on when I inspect this equipment. I can handle a vat pasteurizer, I can handle continuous flow, high temperature/short time, high heat, aseptic, UHT, any of those, work with them, understand them.

But I can not get someone from FDA to tell me what pasteurization requirements should be applied to apple juice. I have yet to see that. So that's one area that we really need to leap tall buildings in a single bound. And, again, there are FDA people readily available who have the required knowledge, whether it's all of the components or merely part of the components. I know because they trained me.

Sanitation inspections – this is another area that I'm running into great difficulty, and it's not only with State inspectors, it's also with FDA investigators, and no disrespect intended. These people's wagons are full. They may do a blood bank today, they may do a cosmetic manufacturer tomorrow, and they may do a food processor the next day.

I'm asked to do a public health safety assessment of an apple juice processor. I go in, and I come out with three sheets of significant public health safety concerns. I'll just go over a few common findings.

- Construction of the water supply, no water samples to verify a safe water supply -- I'm talking about the processing, the in-plant water;
- Product contact surfaces, non-food grade PVC, soft copper, galvanized;
- Hydraulic fluid pumps for product with no sanitary seals -- they're brass;
- Product vats that are half of a fuel tank off of a B-29 bomber, aluminum, that I can take and rub my hand and get spikes;
- Lead soldered joints and rusty crushers -- I'm talking about rusty as can be; and
- Lack of cleaners, sanitizers, construction degreaser for construction equipment, and bleaches.

We talked about steam in process, but no one has addressed the issue of safe steam. I find steam that may be killing the organisms, but it may also be applying toxic chemicals from

the descaler to the steam. We find cooling water in direct contact with product from cooling towers that's unprotected. We weren't told about Salmonella.

So I go in and I document this, and then I find out that FDA investigators have been there just previous, and their comments, and I've got copies of this, "No objectionable violations were found." I really have a problem with that. These people, they've not been properly trained. This is a very, very significant problem. These are my two concerns.

MR. BACCA: Can you give us, provide the examples that you've provided here and give me some list or something, and I'll take it up with ORA.

MR. SANFORD: Absolutely.

MR. BACCA: If we can provide training, we certainly will. And I think if we're missing some obvious GMP problems that you're aware of, then we have to start looking for those things.

MR. SANFORD: I have taken it up with the district person there who has been fully cooperative. I have actually been asked to put on some training, and have done that, with some of the investigators. I have full support at the top, but in between there's some insult factors, because at no time--there's a law written somewhere -- at no time can a State official train an FDA inspector to do anything, if you know what I'm saying. And we need to move beyond that, we need to move forward.

MR. BACCA: In response to your other comment, I think we are moving toward specialization, where food people do food work. While food people do food work, the food people may not necessarily do only apple juice, but we generally try and keep them focused in one area. And hopefully by doing more of that we can better address your concerns.

There's a limit to the number of people. That's our big limiting factor, and especially if we're going to be doing inspections out of our resident offices. If they're not near a big city or a district office, it creates a problem. But I'll certainly take those concerns up with ORA management and see what we can do.

DR. BUCHANAN: Yes, and I do want to add that most cider producers did not think of themselves as food processors. Most of them feel that they were agricultural activities. But I want to make it very clear is that as far as FDA is concerned, these are food processing operations, and as such fall under the Good Manufacturing Practices that are required of any food processing operation, and so they will be inspected on that basis.

MR. SANFORD: One additional question, if I may. Do all product contact surfaces, in your opinion, from the crusher on where we actually have juice, have to be safe?

DR. KVENBERG: Yes. We would go to our existing regulations under GMPs, under Part 110, referring to food contact surface information, and that's pretty clear. We should be focusing on the cleanability aspects. It's clearly something that's known, and how to do it.

DR. MATTHYS: Is there a reason we did not cover Part 110 requirements here at this particular session. There isn't even a copy of 110 in the documents here, and that should have been provided to the participants. It's a requirement that we all have to meet.

DR. MILLER: This meeting was designed to talk about mitigation strategies. It was the assumption that basic sanitation things are being done right. The question is, what can we do to provide even better food safety controls?

DR. CRASSWELLER: Rob Crassweller, Penn State University. The big question when I go back is going to be, what happens if a local grower produces 5,000 or even less than 5,000 gallons and he keeps it all within a two-county region? What jurisdiction does FDA have over that individual as far as Federal rules and regulations on safety? Can you come in and shut him down?

DR. KVENBERG: This goes to the legal question of what is FDA's jurisdiction, and I don't think we're prepared to answer the discussion on this particular issue at this point in time. As a general rule, the Food, Drug and Cosmetic Act gives FDA the authority to regulate interstate commerce, and there's a policy that we apply to determine when the requirements of the FD&C Act are applicable. We are just not prepared to talk about that in the context of juice because we're in the middle of rulemaking, and this is one of the issues that Dr. Buchanan warned you that we really couldn't comment on this, but I know that is a sensitive issue. I think it's quite valuable that you bring up this issue at this workshop as a concern.

DR. HIRST: I have a question concerning the proposed HACCP rule. It sounds like there will be some kind of HACCP rule in some form. What time frame do you have in mind? When will it be finalized?

DR. KVENBERG: I can't predict exactly. We have a proposed rule and we are currently reviewing the comments and addressing the issue in response to the comments that we have received. We are actively in that process now. I can't give you a time frame for when the rule will become final.

I might explain the process it has to go through once it is out of the Center. First it has to go through the department level at the Food and Drug Administration, through the Department of Health and Human Services, and then on through to the Office of Management and Budget. That's how rules are made. It's following the normal course, as other regulations do.

DR. BUCHANAN: To follow the process further, once it clears the Office of Management and Budget and it is signed by the President, then I believe there's a 30-day period during which we can not implement the rule in order to give Congress the opportunity to look at it.

DR. KVENBERG: Then, not to make it more complicated, there will be an effective date of the rule that will provide for its implementation. So it wouldn't be effective immediately. Further, we stated in the proposed rule that we would stagger the effective dates for large, small, and very small businesses. This would, again, stretch out the time frame for full enforcement implementation, if and when the rule becomes final.

DR. HIRST: So, I'd be pretty safe in assuming there's not likely to be a HACCP rule to cover us for this coming cider season.

DR. KVENBERG: That's what I'm saying, yes. That is a logical extension of what I said.

MR. TAYLOR: Kirk Taylor, El Dorado. One of the backbones of a HACCP program is identifying critical points and establishing critical limits. Do we have enough scientific information to establish these points and limits for the cider industry?

DR. BUCHANAN: I think that part of the last talk provided some thinking on how you would go about identifying where your critical control points are. And remember, a critical control point is not only where the hazard occurs, but it's the step that you have identified for controlling that hazard. And there are different options for controlling hazards. That's the purpose of this conference. Different controls and critical limits are being explored by different people.

So, it's hard to give a single answer, but what we are looking for in any HACCP program is the degree of control that will be achieved. This will require that the control steps that are needed have been identified, and that these controls are being applied. So, yes, you're going to have to have critical control points.

MS. HUMES: Lorraine Humes, FDA. There is a seafood HACCP hazards guide published. How specific is that, in comparing it to what might come out for the apple industry, as far as control points?

DR. KVENBERG: Your specific question is, are we going to have a hazard guide on juice products? My answer to that is yes. That is, in my opinion, we need to have a processors' guide in order to provide information as to likely hazards and information on corresponding controls for juice. When and how we accomplish this has not been decided.

DR. BUCHANAN: One of the commitments FDA has made under the Food Safety Initiative is not only to do research, do risk assessment, et cetera, but to make sure that the knowledge that's generated and the information that's needed by everybody is disseminated to them in a form that's useful. So we have a very active program now, and a very good team to put together the information and get it out by different means to the people that need it.

DR. SAPERS: Gerry Sapers, USDA. One of our preliminary conclusions concerns the possibility that apples might be contaminated internally. If this is the case, it would be necessary to intervene with controls applied to the juice, which presumably means some form of pasteurization. Have you considered the implications of this with regard to fresh cut or fresh market apples? That is, is there a significant risk of internalization of *E. coli* or other pathogens? It seems to me that hazards could be present in apples intended for other purposes as well as cider.

DR. BUCHANAN: Let me answer your question. You have raised several different points that need to be addressed. One is that the basis for any of our guidance and for our regulation is sound science. If a specific commodity is known to have a specific problem, control of that hazard must be addressed in the development of any kind of guidance or regulation. As we consider the issues associated with juices, we know that apples and oranges are not the same, and that we must bring to bear the best science we have in looking at those differences.

Another point to emphasize is that the first part of HACCP is the hazard analysis, and that this is where you bring your best science to bear to identify the problem. The hazard analysis part is specifically designed to be on a plant-by-plant basis because we know that no two processing plants are the same. Every processor needs to be able to identify where they think

their hazards are and then make sure that they have the appropriate controls to intervene at that point.

Right now, with the scientific knowledge that we have on potential internalization of bacteria and other microorganisms in apple products, we would have to work with the assumption that internalization of microorganism within the intact food is a reality or certainly within the realm of possibility.

MR. HAXTON: Bob Haxton, Iowa. You may have already answered this question, but let me ask it again anyway. Does the FDA regulation requiring warning labels for juice apply to manufacturers who are involved solely in intrastate commerce, and how do you define intrastate or interstate commerce? Are warning labels required when the manufacturer is only processing for sale at the mill store?

DR. KVENBERG: The question, as I understand it, goes to the labeling rule and how far does it reach. In essence does the rule apply to the retail unit and does it go right down to local distribution level? I'm not the legal expert on that rule, but it is my understanding that it does apply.

MR. TAYLOR: Mr. Kirt Talyor, California. In the proposed regulation there was some exemption for firms that produce less than 40,000 gallons. What type of exemption will be in the final rule?

DR. BUCHANAN: We have received numerous comments about that part of the proposal. We are actively reviewing those comments and evaluating whether to keep that, but beyond that, we can't really say.

MR. BUSH: Don Bush from Canada. What is the rationale behind the 5 log reduction? Why not six or seven?

DR. BUCHANAN: The rationale for the 5 D, which was articulated in the proposed regulation and which is being reevaluated, was based on the likely degree of contamination expected on fruit and in juice. The 5 D level resulted from the public meeting on juice that occurred almost two years ago. The information from the public meeting was then reviewed by the National Advisory Committee for Microbiological Criteria for Food (NACMCF) and they established the 5 D. Their recommendation was passed on to the Food and Drug Administration as a means of assuring safety while at the same time attempting to maintain the unpasteurized character of juices.

This is another subject in the proposed regulations that we received numerous comments on regarding both the extent of the reduction – 3, 5, 7, 12, etcetera logs -- and also where you start that process of counting. That is now being deliberated by the agency in making the final rule.

MS. ZINN: I'm Leslie Zinn, Ardens Garden. We are a juice processor in Atlanta. My concern is that the large outbreak that spurred all of this rule making to take place involved some negligent manufacturing practices. Further, several of the outbreaks that occurred previous to that large outbreak also included some very poor manufacturing processes. Although it has come to light that juice can carry pathogens and it is a possibility that contaminated juice can make some people sick, the risk seems to be extremely low.

As a processor of fresh juice, we don't have a problem with complying with GMP's. But, I am very concerned with this most recent outbreak that just took place involving citrus, that we're going to be forced into pasteurizing. It's not a cost issue. It's an issue that this is the niche of the market that we serve and this is what our customers want, and I'm afraid that we're going to be denied that opportunity to provide a fresh product, period.

DR. KVENBERG: I totally understand your remarks and your concern regarding the current situation that is unfolding. This outbreak is under investigation so we just cannot comment on it or how it may affect the specific rulemaking process that we are undergoing at this time. I guess my only comment is, we hear your concerns.

MR. BACCA: And let me say something with respect to the outbreaks that have occurred. When we have conducted inspections, it has not been obvious what the failure was that led to the contamination. When we had found the cause and we have been absolutely sure that it was the cause, it has taken an awful lot of digging. So, in general, the problem is not something that's right out there in front of everybody to look at.

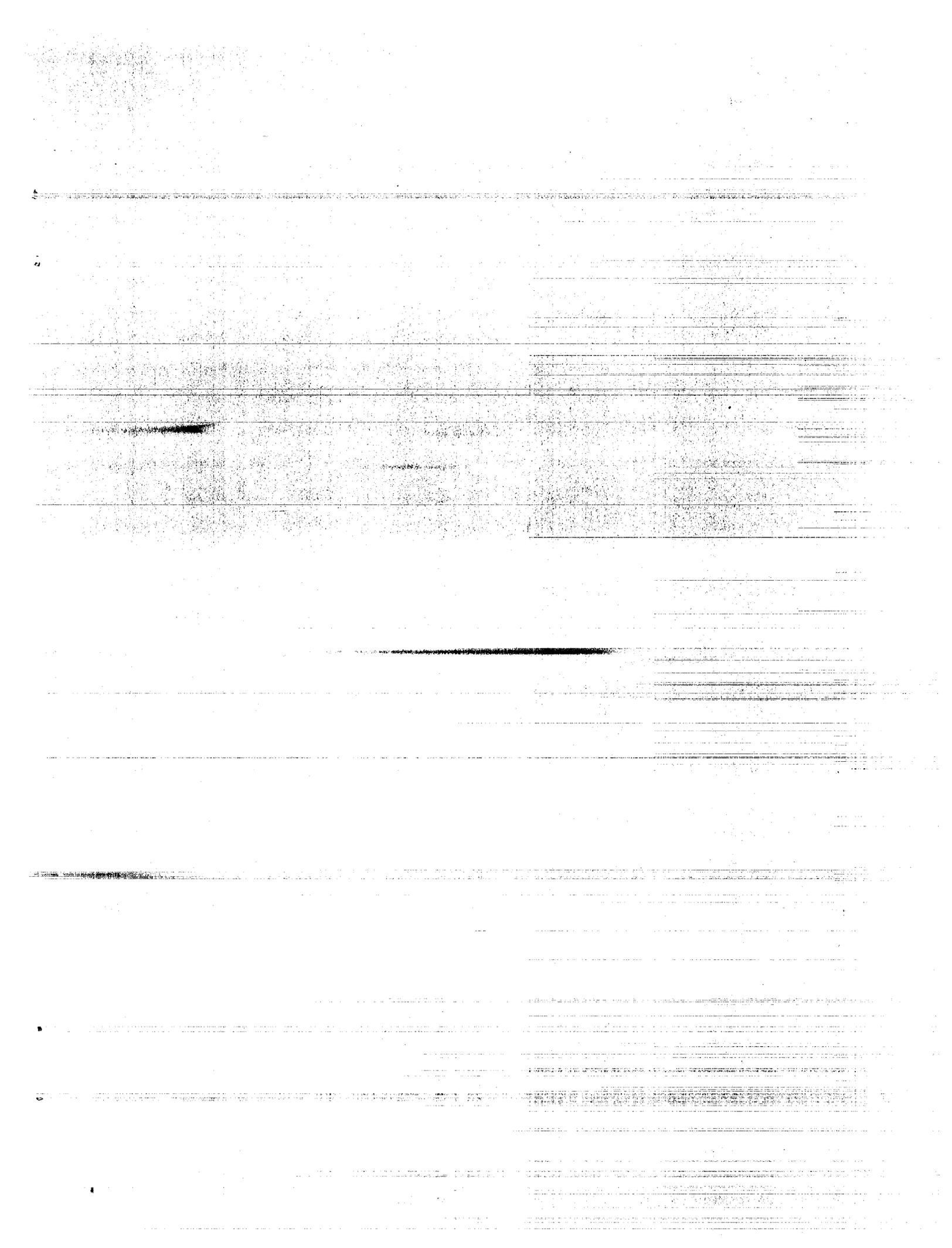
DR. BUCHANAN: I do want to correct one thing. While the one current outbreak being investigated is precipitating a large degree of activity, it was already well recognized here within FDA that there were concerns with unpasteurized juices. These concerns were actively being considered. It was not a single incident that led us to start this activity. There was a history of problems.

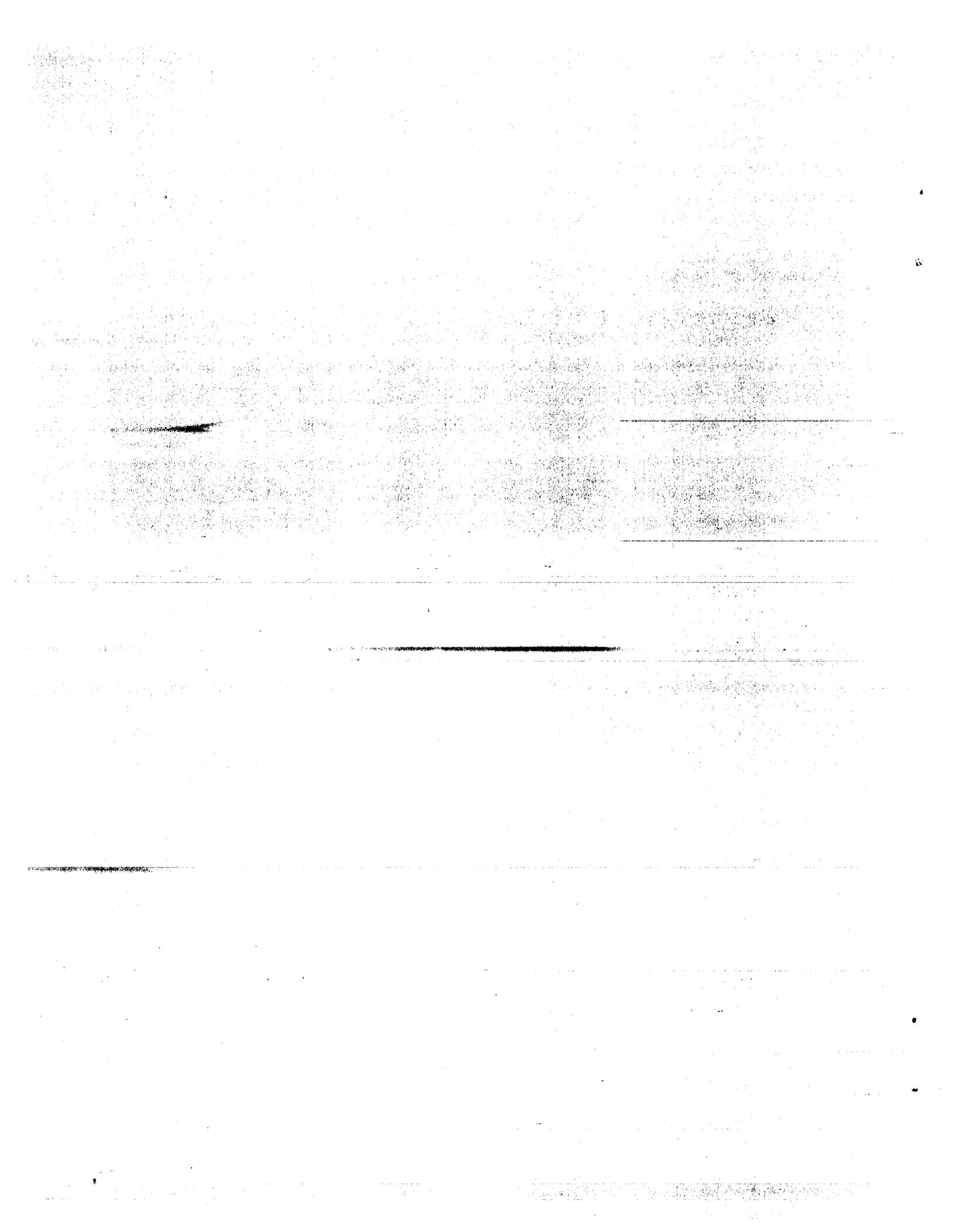
I also might note that we have done an extensive survey of the industry--I'm not sure if the results of that have been shared or talked about--that demonstrated a pattern of problems in a

substantial portion of that industry. A report of this survey is available on FDA/CFSAN's website.

MR. SCHWALM: I want to thank the panel and the participants for their questions. These have been important questions that have come up during the workshop. Having CFSAN managers who are very actively involved with developing our policies and our positions here to listen and understand is an important part of this workshop.







## **CONTINUING RESEARCH NEEDS – PANEL DISCUSSION**

### **INTRODUCITON**

(Includes excerpts from the transcript)

The purpose of this session is to talk about where we need to go and what are some of the regional issues that would impact on how to proceed. We have been conducting research on juice for some time now, but in many respects we're just starting. There continues to be a number of issues and several needs. Often when we hold a workshop of this nature, we get more questions than we get answers. We wanted to have an opportunity at the end of the session to talk about where we want to go.

In order to do this, we have brought together a panel with some regional representation. The panel includes Dr. Beelman representing the East Coast; Bob Tritten representing the Central States; and Dr. Mary Wang representing the West Coast. We also wanted to get some industry representation, and asked Jim Cranney to come over here from the U.S. Apple Association. Further, we wanted some of our research people, and we have Chuck Seizer from our research facility in Chicago.

We will ask each person to make about a 10-minute presentation regarding their observations and opinions on the subject of food safety for the apple cider industry and where FDA needs to proceed. We will then open it up at the end for discussion.



## CONTINING RESEARCH NEEDS – PANEL DISCUSSION

**Dr. Robert Beelman, Penn State University**

(Taken from the transcript)

Actually, I don't purport to represent the East Coast perspective. I'm from Penn State but I don't know exactly what everyone on the East Coast would want me to say. So I'm speaking for myself here, after observing what has been discussed at the workshop.

The one thing that has become clear to me during the past two days is that we need some kind of a post-processing intervention. I think we have to presume that it is true that *E. coli* can be present in the fruit.

I keep going back to the logic with canning low-acid foods and the 12 D concept with botulism. We require a 12 D process for low acid canned food because of a risk assessment kind of approach over the years. There really aren't very many botulism spores on most raw food commodities. We still give it a 12 D process because of the safety situation. I'm not saying that it's analogous, but there are some lessons from history here.

I'm also not saying it has to be pasteurization. Some of the work that has been done on the freezing and warming I think is very encouraging. The UV pasteurization process I think is also very encouraging.

I think the use of preservatives has been, for some reason, underplayed. I see very little information about the use of chemical preservatives. I know Randy Worobo has done some work on preservatives along with the UV pasteurization. I don't know why he didn't present the data. I guess he wasn't asked to.

Thus, it seems to me that we need some kind of a post-processing intervention, based on this paper that just came out from Maryland. Basically what it says, is that a lot of controls can be applied in the orchard and washing, and that all these controls are useful. However, the bottom line in that paper is that these types of controls can't be counted on to protect the public health.

So please don't assume that this is the East Coast perspective. This is my personal perspective. Of course I also have a personal interest because I'm working on preservatives. Nevertheless, knowing what goes on at all these cider operations, and I've been to a number of

them in Pennsylvania and other States. I just can't see the fact that all of the intervention steps along the way that we talked about earlier are going to be foolproof.

## **CONTINUING RESEARCH NEEDS – PANEL DISCUSSION**

**Mr. Jim Cranney, U.S. Apple Association**

(Taken from the transcript)

My name is Jim Cranney, from the U.S. Apple Association, and I wanted to thank FDA for the opportunity to come in today and say a few things from the industry standpoint. When FDA asked me to make a few comments, they asked me to address specifically research issues that are important for the industry and what the research orientation should be. Before I say specifically what those would be, I thought it might make some sense to just go back and look at this and sort of analyze really where we are.

When the first rule came out on the cider labeling, it really created a large change in the cider industry. We have been dealing with that for almost two years now, or going on three years. What has happened is that the larger and medium-size cider producers immediately converted to pasteurization.

What we've seen out in the trade -- in the industry, retailers and wholesalers of major supermarket chains -- is that they made it a requirement of their major suppliers to be able to supply what they considered to be a no-brainer, safe product. This means pasteurization, and they did it as soon as this became an issue three years ago. So essentially over the past three years what we've seen is that the major bulk of the supply of cider that's being processed in the industry has been subjected to pasteurization. Thus, at least you can say that there has been significant risk reduction from what we already had prior to the incident with Odwalla.

Where does that leave us? That leaves us essentially with a group of primarily smaller producers, in many cases very small producers, who do not pasteurize. I say this because it should have quite a bit of impact on the direction that USDA and FDA should take in terms of the research agenda that they follow.

It is not my intent to say specifically what the research ought to be. I'll let the researchers look at the whole spectrum of opportunity there. I do think, however that it does have to meet some really specific criteria. One criterion should be that it be practical. Controls should also be simple to implement by these types of small producers.

That means if you are a researcher and you get a very enlightened idea, to go down the research path. But then at the end you come to realize that it would cost the producer \$20,000 or

\$25,000 to implement it, then I would say that it does not meet the criteria. The reality is that most of these producers are probably looking at a cost of between \$5,000 and \$10,000 at the most. If they were in a position to be able to expend \$20,000 plus and dedicate those resources to the problem, there's a good chance that they would pasteurize.

It is important to understand that there's not necessarily a barrier out in the industry because the industry doesn't want to pasteurize. In a lot of cases, it's an economics problem. But in other cases, there really is a consumer demand for products that are not pasteurized, and that demand also has to be taken into consideration.

The other point that I wanted to make when we're working with these small producers, is whether we are really after zero risk? I think we get to a threshold policy issue here because we have to ask ourselves is the goal zero risk? And if it is really zero risk, then maybe there isn't any other answer.

Maybe there is no other solution besides pasteurization. But I would say that what industry is looking for here is a reasonable solution, and zero risk is not reasonable. There is precedent in regulations that say we don't have to have a completely zero risk.

Thus, I think that there still is room for these small producers to be able to produce their unpasteurized product. The amount of cider that these cider producers are producing in the grand scheme of things is small, but it's important to these individual cider producer because that is the source of income they need to sustain their own family. Cider producers over the last three years have been hurt in that area.

Although I was not here previously for the discussion regarding UV technology, I think that if the agency really is interested in significant risk reduction, this is a good area of focus. FDA should evaluate the petition that has been presented with significant vigor and expedite the petition review. Cider producers who want to utilize this technology should be able to do so without fear of some type of an enforcement action. I know specifically that there are many, many cider producers out there who would like to utilize this technology, but because of the regulatory hurdle, they are not able to incorporate it into their business.

My final point is not really research-oriented but it is communications oriented. I think that it is refreshing that we're finally talking about the science here and about data. Communication of science and data to the industry is important. I would like to encourage the agency to take the next step and go out to actually explain these types of issues to growers

personally, and cider producers, who tend to be growers, at their winter meetings. Unfortunately, many of the producers that we need to communicate with are in the middle of growing a crop, and they're not in a position to get on an airplane and come to Washington, D.C. They are in the midst of fighting off diseases and pests, trying to thin, and get their operations in order to be able to actually harvest a crop.

I know there is a significant amount of interest among producers to hear this information. They're very motivated and they want to do a better job. I think that FDA could do a significant service to the industry if they went out to the meetings during the winter and presented the data that's been presented at this meeting. I think it would be a big step forward along the lines of communicating and having growers actually implement the practical risk reduction measures that can make a difference.

Thank you very much for the opportunity to be here.



## CONTINUING RESEARCH NEEDS – PANEL DISCUSSION

**Dr. Charles Seizer,**  
National Center for Food Safety and Technology

(Taken for the transcript)

My name is Chuck Seizer, and I'm the Director of the National Center for Food Safety and Technology. The National Center for Food Safety and Technology is a group of 60 member companies, the U.S. Food and Drug Administration, Illinois Institute of Technology, and the University of Illinois at Urbana-Champaign. We work entirely on food safety problems and food safety solutions.

After listening to the discussion at this workshop, I think one conclusion is inescapable. There is going to have to be some sort of final intervention process in order to assure the safety of juice products. There are also a number of technologies that are out there that I think are pretty good candidates for being able to improve the safety of cider.

One that immediately comes to mind is some sort of light processing. UV light processing seems to be fairly inexpensive. As soon as the petition approval is through, it will be a very nice technology that even small cider producers can implement.

There are some other light technologies out there that should be considered. There is pulsed light. There are also people that are using Excimer lamps, which are essentially lasers, that do a very similar job. However, the cost of this technology is way up because it is more sophisticated. I think that's one thing that we need to avoid.

There's also a technique called high pressure processing that is being used. This technology would subject juice to pressures of 60,000 pounds per square inch or higher. An advantage of this technology is that it will handle particles. It works very nicely for juice, and you get a product that is very, very similar to your raw fresh product. Once again, there is going to be a cost issue because the equipment is very expensive, and it would probably be prohibitive for most small cider companies.

Another technology that we have not looked at recently is the use of membrane filters to clean up cider. You can effectively remove 100 percent of the microorganisms from cider using 0.2 micron membranes. The problem with this is that it also will make your apple juice as clear as can be, and it will not look like what your normal natural cider looks like. Further, if you try to

filter cider, you're going to clog your membranes in a matter of seconds, so you have to go through some pre-filtering. What you may be able to do, though, is to take part of the cider that won't go through the filter and give that a thermal treatment or something else, and then mix it back in with unpasteurized raw cider and come up with a raw product. That would be one alternative for producing a raw product, but there are some significant limitations. That technology is coming along, so maybe in a few years there will be something available there.

I think the area that is probably the most feasible is thermal, and I say that from two perspectives. One is removing heat, and the other is adding heat. The processes where you freeze cider look to be very efficacious, and likewise on the other side, where you add heat and bring it up to pasteurization temperature, looks like they're very good.

One thing that we have to be careful of is that we don't try to apply dairy technology, per se, to the thermal processing. Dairy equipment is designed for milk and not for apples, and there's a lot of differences. For one thing, the plates are not going to be in contact with the juice because you have pulp that's going through there, and the pulp will hang up on the dairy plates.

Another obvious example is that you don't have a homogenizer in line for doing apple cider, and you don't have some of the issues of control that go along with that. Likewise, especially for an aseptic operation, you're not going to want to have a flow diversion valve in the typical dairy sense because that introduces a significant microbiological risk. There are going to have to be some adaptations of the technology for high acid, and high acid pasteurized products have an incredible good track record. We need to take some of the experience that they have and incorporate that into any guidance that comes out in regulations.

What else is left? Pulsed electric field, for example, is fairly high technology, fairly expensive, and probably not going to do the job for you.

All these processes share a lot of common challenges that must be considered. Number one, you're going to have to find out how to start the equipment up, how to get it sterile, and put it in forward flow. We need to get it into forward flow so that we know the timing is correct, so that the product receives the processes it needs to receive.

We also need to deal with control factors. We need to know what to do in the event of a deviation. For example, if you're running one of the light pasteurizing units and one of the lamps burns out, what do you do with that product? You can discount the price and try to sell it today, or do you run it back through the system. Knowing what to do is a real concern.

How do you keep records? And record-keeping is one of the things that small producers have the most difficulty with. You need to keep good records. When did you put the juice into freezing, how long does it take to freeze, how long do I have to wait before I pull it out? These are going to be questions.

And then the last issue, of course, is training. So I think the big job that we have ahead is to get some sort of guidance out for some of these new technologies that are available, and just to start getting the training going.



# Continued Intervention Needs of the Cider Industry

## Central States Perspective

*Bob Tritten, Michigan State University Extension*

*Gerald Wojtala, Michigan Dept. of Agriculture*

The cider industry is still transitioning from practices associated with producing a raw agricultural commodity to those associated with producing a ready-to-eat processed food. This presents an ongoing educational need. The infrastructure that deals most effectively with the industry is Extension followed by state & local regulators. Cider makers are asking very practical questions; but unfortunately, we still can't provide straightforward answers. Gaps always exist between the new research and how to apply it in a real setting. These gaps will eventually narrow, but in the meantime, the industry is vulnerable to many influences.

Some cider makers have taken matters into their own hands and are positioning to take advantage of the changing marketplace. The virtual exclusion of a raw cider from the wholesale market immediately pushed large producers to adopt processing interventions. Approximately ten percent of Michigan cider makers now utilize thermal pasteurization or ultraviolet technology. This group has a large share of the cider market. They have been characterized as risk takers or "early adopters" in terms of using new technologies. Many of these are looked at as industry leaders and opinion shapers.

Other cider makers understand the transition that is underway but have looked for alternatives to pasteurization such as whole fruit sanitization. A large segment still exists that have not accepted the need for intervention. Of the 200 cider makers in Michigan operating prior to 1997, about fifteen percent opted to get out of the business altogether. Another fifteen percent did not produce cider in 1998. It is anticipated additional cider makers will make similar business decisions if additional processing interventions like pasteurization are mandated. However, there is a demonstration of willingness to accept new technologies when cider makers are adequately informed and given options.

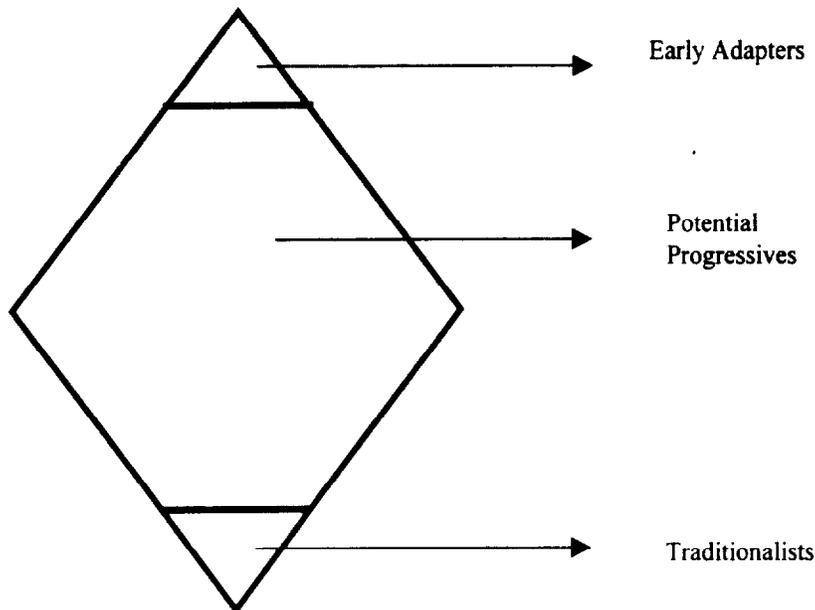
### Continuing research needs

1. **Practical applications of the research.** Taking pure research and applying it in a real setting. This could involve setting design criteria or setting standards. Also, there's a need to take into account the level of operator knowledge - should each operator using pasteurization equipment be an expert in the PMO or should the equipment be designed to meet the standards?
2. **A benchmark to measure a cider mill against.** What elements serve as the baseline requirements? Is there a way to determine if a mill falls below the benchmark?
3. **GMPs still needing research:**
  - A. Apple transportation and storage practices & duration of storage

- B. Equipment design (washer/brusher performance, contact surfaces, transfer lines, etc.)
  - C. Equipment cleaning & sanitizing methods (chemicals, frequency, application)
  - D. Preharvest practices (irrigation, fertilization, pesticide application, orchard management)
  - E. What is the most effective design for washing & brushing equipment?
  - F. How should water be used in the fruit cleaning/ sanitization process?
4. **An expanded selection of interventions from which to choose.** Right now, the choice is pretty much a thermal pasteurizer or a U.V unit. But both of these have limitations for the diversity experienced in the industry. (U.V. is technically not approved since a food additive petition hasn't been filed. Many problems have been encountered with the first generation of thermal pasteurization units adapted for cider).
  5. **A reliable source of information.** Who can provide guidance to the industry - extension? regulators? industry associations? salesmen? Right now, the education infrastructure lacks information to help the industry make good decisions. The regulators also lack information to make good regulatory & public health policy.
  6. **An understanding of the levels of risk reduction.** How much risk do GMPs cover, how much do additional interventions cover - and how much is acceptable?
  7. **Education.** There will be a continued need to deliver information. The areas most frequently requested by the cidemakers
    - A. Cleaning & sanitizing methods specific to cider equipment
    - B. A comparison of interventions & their cost & effectiveness & ease of use
    - C. Other GMPs
  8. **Verification.** The need to clearly define how interventions can be verified. Who decides if someone is achieving 5-logs in the actual mill where the intervention is used. How do operators or regulators make the decision?
  9. **Performance standards.** There will be an increasing need for verifying if a given intervention met its target. Examples: What should the microbial load be on sanitized fruit? What indicator organisms should be used to verify pathogen destruction? What tests can verify if cider reached 160°F?

**CIDER INDUSTRY DIVERSITY**  
Dr. John Tilden  
Michigan Department of Agriculture

The Cider industry is a multi-faceted industry. Practices are not the same throughout the industry. Individualism and diversity are part of the cider heritage in the U.S. The following schematic attempts to represent the dynamic that must be considered in order to seek change in the industry.



### **Early Adapters**

Early adapters are those that quickly use new technology. They tend to be the larger volume operators (but not always). After the virtual elimination of the wholesale market for raw cider, many were forced to become early adapters in order to retain or gain market access. This group makes up about 10% of the industry.

Acceptance of processing interventions for this group can be stated: "build it and they will come" and they may even help you build it.

### **Potential Progressives**

This group is seeking information with which to make business decisions. It is the identified target of educational efforts. Members of this group are willing to

attend workshops and training. And readily adapt technical information to fit their specific operation. The majority in the industry falls into this category.

Acceptance of interventions will require reliance on educational infrastructure. These folks need to be convinced and will approach new ideas with a little healthy skepticism. Unfortunately, the network for microbial issues is not in place like the network for pesticide issues; but it's getting there.

### **Traditionalists**

This group consists of those who have not made significant progress toward viewing their operation as a food processing plant and still view cider as an agricultural commodity. Many traditionalists have gone out of business and more will as safe cider requirements become established. About 10-15 % of the industry may fall into this group.

Acceptance of interventions by traditionalists will require education, persuasion, regulation, and even enforcement.

6/99

APPLE CIDER FOOD SAFETY CONTROL WORKSHOP  
JULY 15-16, 1999  
**Continuing Research Needs on Interventions – Panel Discussion  
West Coast Perspective**

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Large quantities of fresh unfermented apple juice have been consumed in the United States since the colonial days. Consumers brought their own jugs or bottles to the cider mill to draw fresh juice from the bulk dispenser fully aware of the fresh quality and its short shelf-life. Within the past 50 years, the juice industry has made great strides with notable advances in the technology of juice processing, extraction and preservation methods. Consumer's continual quest for fresh foods has recently created a flourishing market niche for fresh unpasteurized juice products. However, the transmission of emerging pathogens (i.e., *E. coli O157:H7*) associated with unpasteurized apple cider/juice has been recognized as a public health hazard. We are now at the turn of the century and there is a need for extensive research to identify the problem, whether it is from agricultural practices, harvesting and storage, production methods, or processing methods. Therefore, new preventive and control measures must be quickly identified and scientifically defined to protect against new dangerous situations where emerging pathogens could contaminate raw fruits and survive in an acidic environment. The juice industry and regulatory agencies must cooperate to establish standardized performance criteria to ensure the safe production of all minimally processed fresh apple cider/juice products with extended shelf-life.

The West Coast states are major producers of apples and apple cider/juice products and there is a vested interest in all food safety issues to promote local economy and to protect public health. What is unique in California in addressing the fresh apple cider/juice problem is the proactive food safety approach through effective communication. First of all, the regulatory agencies (state Health Department and Department of Agriculture, the county Ag Commissioner Office, the local health department and the U.S. FDA representatives) sat down with the industry and listened to their concerns and shared food safety information. All parties involved were committed to jointly develop some reasonable solutions; and the result was an establishment and implementation of a voluntary Apple Hill (Placerville, CA) Quality Assurance Program (AHQAP). The key factor is the pride of ownership in producing a quality juice product with minimal risk for the consumers. In addition, the "bloom to bottle" concept included participating apple growers convinced to meet the juicers specifications for tree-picked quality apples. AHQAP contains a comprehensive HACCP-based training program, step-by-step method to comply with the good manufacturing practices (GMP) requirements, apple grower's certification of only tree-picked quality apples, environmental monitoring of cleaning and sanitation procedures, and a third party verification of the records.

The cooperative team effort between the industry and regulatory agencies continued to expand to include academic researchers to find science-based solutions for a 5-log pathogen reduction in apple juice production. After the promulgation of the regulation for labeling of fresh juice warning statement in 1998, a multi-partnership for research was formed under the President's Food Safety Initiative and cutting-edge research projects were conducted in a small commercial facility in Apple Hill. The federally funded research projects are to find effective pre-and post- processing treatments to provide a scientific baseline information for determining the reduction of pathogens on apples before they are used to make fresh juice. Meanwhile, with all the ongoing concurrent events, the AHQAP apparently has made an impact on many fresh juice processors statewide, and many have adopted comparable QAP on a voluntary basis to reduce the risk of contamination in fresh apple juice. Before substantive scientific data are available, the "bloom to bottle" food safety QAP model can easily be extended to other parts of the country. Other regional apple growers and juice processors should implement a similar HACCP-based QAP when marketing a quality fresh juice with reduced risk direct to consumers.

APPLE CIDER FOOD SAFETY WORKSHOP  
CLOSING SUMMARY

Darrell Schwalm and Dr. Art Miller

MR. SCHWALM: We had hoped that Dr. John Kvenberg would be available to provide a closing summary of the workshop, but, in his absence, let Art and I say a few things in terms of what we've gotten out of this.

The first thing is that when we put this conference together, we knew that this was not going to be one of those workshops where FDA had all the answers and we were going to present the answers to you. Sometimes government has the tendency to wait until it has the answers before it begins communicating with its constituency. This is obviously not the approach FDA is applying here, and the purpose of this conference was not to communicate answers.

Instead, I think that we all, including myself, will go away from the workshop with an increased awareness of the problems surrounding the safety of apple cider. We understand where we're at right now, what are some of the issues and the questions, and where we need to be going. I also hope that you share with me the understanding this will not be an easy process.

There is a concern about the apple cider industry, and an effort is being made to preserve the fresh portion of the industry. There is also a concern about small processors in the apple cider industry, and an effort is being made to address their unique needs. On the other hand, apple cider is a food product, and there are important public health issues involved. We also have, as NFPA has pointed out to us, a larger segment of the industry that thermally processes apple juice. If there is a problem with one firm anywhere in the industry, that problem affects everybody else. So, it's not an easy situation, and there are several different issues involved.

I think that another important understanding that I will take away from this workshop is a confirmation that prerequisite programs and sanitation are a vital component. Poor sanitation has been the source of the problems when there have been outbreaks. If nothing else, the industry and regulators must try to improve sanitation. Perhaps this is the best thing that we can do right now in terms of reducing the risk. Hopefully, we all have a renewed commitment to do work, at a minimum, towards these types of improvements.

In conclusion, I'm really happy and very pleased, that we had such good representation at the workshop. We will remember the challenge that Jim Cranney gave us in terms of going out

to the industry. Hopefully we will be able to bring a summary of this meeting together from the materials that have been presented, and maybe update these materials; and to make sure that this information gets out. However, if FDA can not do this, we have given you each a procedures manual. We invite you to go back and make copies of it, talk to your local people, and distribute it to your industry. Don't just rely upon FDA being able to get out to these local meetings. I don't know if that is going to be possible. So please be our advocates in terms of giving the information out the best that you can.

DR. MILLER: One of the lectures I give has to do with the subject of emerging pathogens. That whole lecture can be boiled down to the fact that we have an idea but do not necessarily know where these pathogens are coming from. We have all been eating ever since we all emerged from the primordial soup. What has changed to suddenly make people sick?

The apple cider industry presents a classic example of the problem with emerging pathogens. We have an industry who, as John Kvenberg said yesterday, has been providing a food beverage since before this nation was a nation, and here it is in the '90s and we're suddenly concerned about its safety. What has changed?

We know that the pathogens have changed. In fact, we could probably say that the first *E. coli* O157:H7 outbreak that we're aware of occurred back around 1980 in apple cider. Have the sanitation practices of the industry, changed? Well, we know that there has been some consolidation of firms, but we still have an awful lot of small cider processors. Surveys have shown that sanitation conditions probably have changed little.

To boil this all down, what we are saying is that we are not certain exactly how things have changed or what has changed or how much, but the fact is that we do have people who are getting ill as a result of this product. And the bottom line from the FDA perspective is public health.

We called this meeting for the purpose of exploring new and promising technologies, and I think we have heard about a number of these technologies. We still have an enormous number of questions on where the technologies need to be applied, are they efficacious, and how and where they should be applied.

We tried to add some perspective to these issues this morning by talking about hazards in the context of risk assessment and risk analysis. This seems to be the direction in which the agency is moving since we know that the research can't provide all the answers as fast as

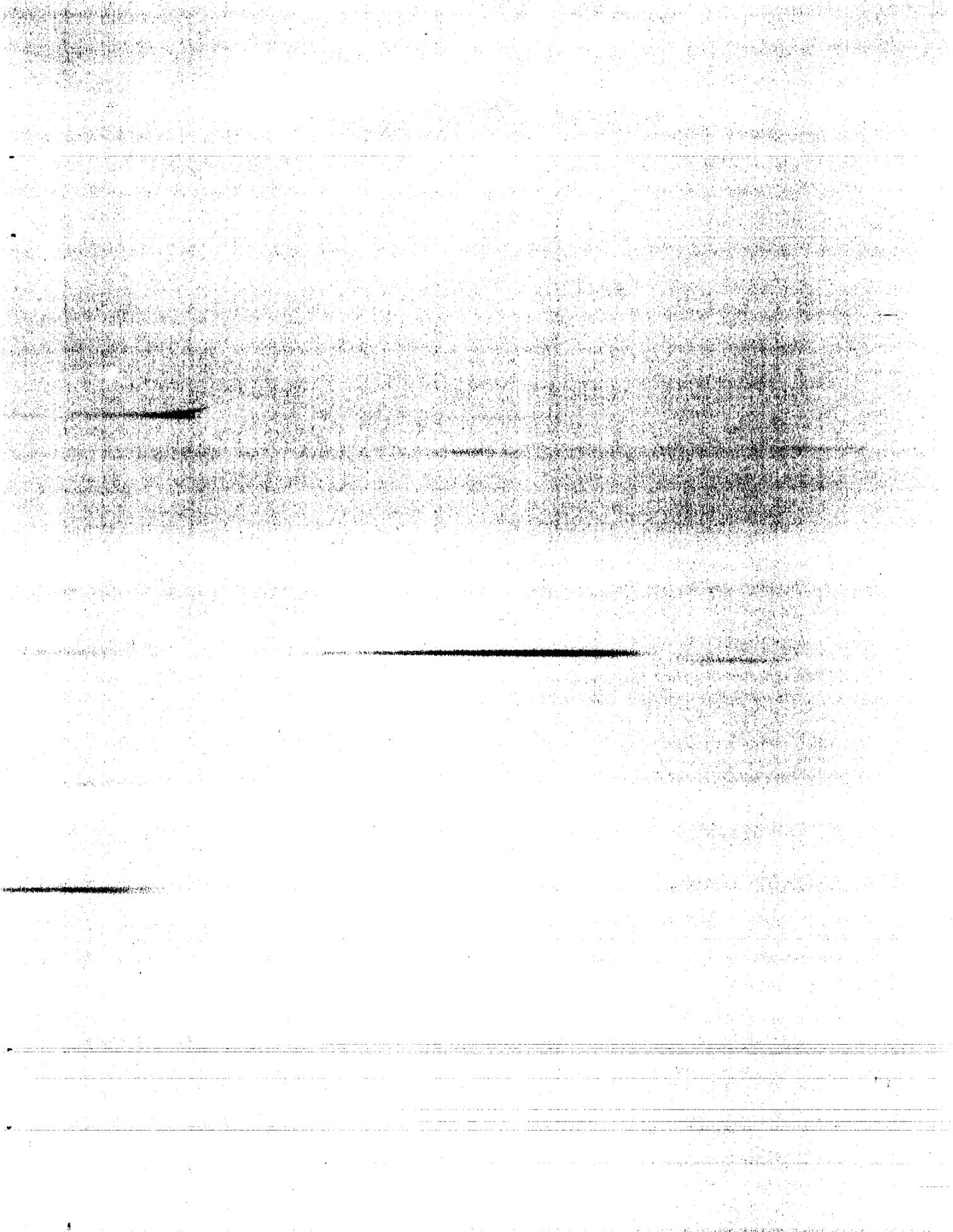
possible. In my estimation risk assessment allows us to stay ahead of the research, as we heard this morning, because it allows us to come up with the "what if" scenarios. By coming up with the "what if" scenarios, we can then develop hypotheses that can be tested. Thus, I think it's a very valuable tool.

Finally, as a result of these risk assessments, there is always the need for more research. I think better than many other meetings that I have been through, we have identified where the research needs are. And I think we have, at least in my mind, come up with a road map of how we need to proceed.

Thank you very much for coming, and everybody have a safe trip home.

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**Apple Cider - Food Safety Solutions**  
**Presented by**  
**Allen W. Matthys, Ph.D.**  
**Vice President, Regulatory Affairs**  
**National Food Processors Association**  
**At the**  
**Apple Cider Food Safety Control Workshop**  
**July 15-16, 1999**

Good Afternoon, I am Allen Matthys, Vice President of Regulatory Affairs for the National Food Processors Association. NFPA is the principal scientific trade association representing the \$430 billion food processing industry. With three laboratory centers, NFPA is the leading authority on food science and safety for the food processing industry.

In October 1996, an outbreak of E. coli O157:H7 was traced to raw apple juice packed and sold through West Coast states. The original cases were reported in Washington and Oregon (66 cases and one death).

NFPA convened its juice processor members to evaluate the situation. They determined that all juices should be pasteurized or receive an equivalent treatment and authorized NFPA to communicate the following position to FDA. For this reason all these companies were pasteurizing their juices.

**“NFPA’s overriding position is that juice or juice ingredients should receive pasteurization or an equivalent process sufficient to render the juice or juice ingredients free of vegetative cells of microorganisms of public health significance. In this regard we recommend that FDA initiate an appropriate regulatory proceeding to address this and other related issues.”**

Alternative processing methods that may provide an equivalent kill step include high pressure sterilization, pulsed electric, UV light, electron beam treatment, irradiation, ultra filtration, or use of one or more of the preceding treatments in combination with an anti-microbial compound (benzoate or sorbate).

This position was communicated to FDA at Public Hearings in December 1996, in a February 1997 letter, and in comments filed with the Agency in response to an August 28, 1997 draft Notice of Intent to Develop a HACCP Program, Interim Warning Statement, and Education Program for Juice.

In developing this position NFPA considered several options including current GMP regulations, the possibility of labeling of unpasteurized juice (including possible warning statement), and juice HACCP. We concluded that the only means of assuring that juice did not contain potentially pathogenic microorganisms was to include a microbial control step (or steps) that has been scientifically proven to be effective in providing a level of protection equivalent to pasteurization in the process. A warning statement was not

deemed sufficient to communicate the potential for illness (and FDA has proposed to exempt certain manufacturers from that requirement).

In addressing how the Agency could move expeditiously to incorporate mandatory pasteurization or an equivalent process, we reviewed the current GMP regulations under 21 CFR Part 110 Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food. This regulation applies to all processed foods.

At 21 CFR Part 110.80(a)(2) the regulation states that: **“Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the Act .”**

This regulation gets right to the heart of the matter. NFPA urges the agency to enforce its regulations. This is, after all, a **“Shall”** which makes compliance with the regulation mandatory. The majority of the juice industry favors mandatory pasteurization or an equivalent process to eliminate potential human pathogens from the product.

By FDA’s own estimate 98 percent of all juice consumed in the US, or over 2 billion gallons, is pasteurized – just like milk – or equivalently treated. No reported illnesses have been attributed to pasteurized juice. Two percent of juice, or about 38 million gallons per year are not pasteurized or otherwise treated.

Within the past six months there have been outbreaks of illness attributable to raw juice or juice ingredients. These include imported frozen raw Mamey puree (13 cases, typhoid fever – *Salmonella*), raw apple juice in Canada (*E. coli* O157:H7), raw orange juice in Australia (435 cases - *Salmonella*), and raw orange juice from Arizona (104 cases – *Salmonella muenchen*).

FDA estimates that these raw juices cause about 6,000 to 6,200 annual cases of illness. These outbreaks could be eliminated in an instant by FDA enforcement of existing regulations. So for 1997 and 1998 by FDA’s estimate some 12,000 or more cases of illness occurred which were readily preventable. A sad commentary for an Agency that has as its mission the protection of public health.”

However, rather than begin enforcing existing regulations in 1997, the agency instead chose to propose new regulations. The proposed HACCP regulations would include all juice processors – including those that pasteurize their juice – rather than focus on the source of the problem - that two percent of that juice supply which has not been treated to destroy potential pathogens. Since pasteurized juices are not responsible for any illnesses mandating HACCP for processors of pasteurized juices will not affect public safety in any way. However, the paperwork burden of HACCP will fall on these establishments.

Under the direction of NFPA’s Juice Products Committee and Microbiology and Food Safety Committee, NFPA scientists conducted research into the heat resistance of *E. coli*

O157:H7, *Salmonella sp.*, and *Listeria monocytogenes* in various juice products. The research has been completed and is undergoing peer review prior to publication. Data will be shared with FDA officials to assist them in confirming minimum “flash pasteurization” operations aimed at providing appropriate consumer protection.



## **HHS NEWS**

*U.S. Department of Health and Human Services*

P99-14  
FOR IMMEDIATE RELEASE  
July 10, 1999

FOOD AND DRUG ADMINISTRATION  
Print Media: 202-205-4144  
Broadcast Media: 301 827-3434  
Consumer Inquiries: 888-INFO-FDA

### **FDA ISSUES NATIONWIDE HEALTH WARNING ABOUT SUN ORCHARD UNPASTEURIZED ORANGE JUICE BRAND PRODUCTS**

The Food and Drug Administration is issuing a nationwide warning to consumers against drinking unpasteurized orange juice products, both frozen and liquid, distributed under a variety of brand names by Sun Orchard Inc. of Tempe, Arizona, because they have the potential to be contaminated with *Salmonella Muenchen*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy individuals may suffer short-term symptoms such as high fever, severe headache, vomiting, nausea, abdominal pain and diarrhea. Long-term complications can include severe arthritis.

Although the company has already issued a warning and undertaken a recall of the affected product, FDA is taking this action because of continuing reports of illness related to this product.

The product comes in a variety of forms distributed to retail stores, restaurants and other dining institutions. The product sold in retail stores comes in clear plastic gallon, half-gallon, quart, pint, 12 ounce and half-pint containers. The fresh, unpasteurized orange juice has an enjoy by date of July 7, 1999 or earlier stamped on the side. The products are identified on the labels as freshly squeezed or fresh orange juice. The following labels are involved: Sun Orchard, Earls and Joey Tomatoes, Viola, Trader Joe's, Aloha, Zupan, Markon, and Sysco.

In addition, to these liquid retail products, a frozen form of the unpasteurized juice was sold under the brand name Vareva especially to restaurants, food services and other institution. Therefore the agency recommends that consumers check their freezers for the recalled product and inquire about the source of any unpasteurized orange juice they may be served at a restaurant or other dining facility.

To date dozens of illnesses have been reported throughout the United States and Canada.

The potential for contamination was noted after several individuals in Pacific Northwest became ill after drinking the juice. Subsequent investigation confirmed the presence of *Salmonella Muenchen*.

Sun Orchard has stopped production of unpasteurized orange juice and is currently pasteurizing all of its juice products.

Consumers who have purchased unpasteurized orange juice labeled with any of the above listed trade names are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 206-780- 8042 or 212-213-7012.

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*This is a mirror of the page at [HTTP://www.fda.gov/bbs/topics/NEWS/NEW00685.html](http://www.fda.gov/bbs/topics/NEWS/NEW00685.html)*

## FACTS ABOUT JUICES AND SAFETY

July 7, 1998

- 98% of all juices are pasteurized or subjected to equivalent “kill steps,” making them safe for consumption – just like pasteurized milk.
- 2% of all juices are not pasteurized and are not safe from contamination by disease-causing organisms like *E. coli* O150:H7, *Salmonella* spp. and *Cryptosporidium parvum*.
- 98% of juices – over 2 billion gallons – pose no health risk to consumers because they are heat treated.
- 2% of juices – about 38 million gallons, or more than 600 million servings – are responsible for an estimated 6,000 – 6,200 illnesses per year because they are not pasteurized.
- Even if FDA’s proposed labeling requirement for unpasteurized juices is finalized and enforced, 84% - 95% of these 6,000 + attacks will continue to occur annually (FDA estimates a 5 – 16% reduction if labels are mandated).
- Since pasteurized juices are not responsible for any illnesses in a given year, mandating the Hazard Analysis and Critical Control Point (HACCP) program for processors of pasteurized juices will not affect public safety in any way.
- Of the 900 juice processors in FDA’s Official Establishment Inventory, all but a very few utilize pasteurization, so a substantial number of companies and their employees may face tough times as they struggle to meet HACCP’s burdens.
- The FDA estimates the annual economic savings of requiring unpasteurized juices to be pasteurized at \$174 - \$251 million – and no illnesses.
- The FDA estimates the savings of labeling unpasteurized juices at \$1 million to \$6 million – with little change in the number of illnesses.
- Under FDA’s proposal, all restaurants, juice bars, and other retail processors selling juice on-site for immediate consumption will be exempt from the labeling and HACCP requirements. This accounts for over 15% of unpasteurized juices and over 4,000 establishments.

## **Patulin – Establishment of an Action Level**

Presented to

**FDA Food Advisory Committee**

by

**Allen W. Matthys, Ph.D.**

**Vice President**

**Regulatory Affairs**

**National Food Processors Association**

**June 24, 1999**

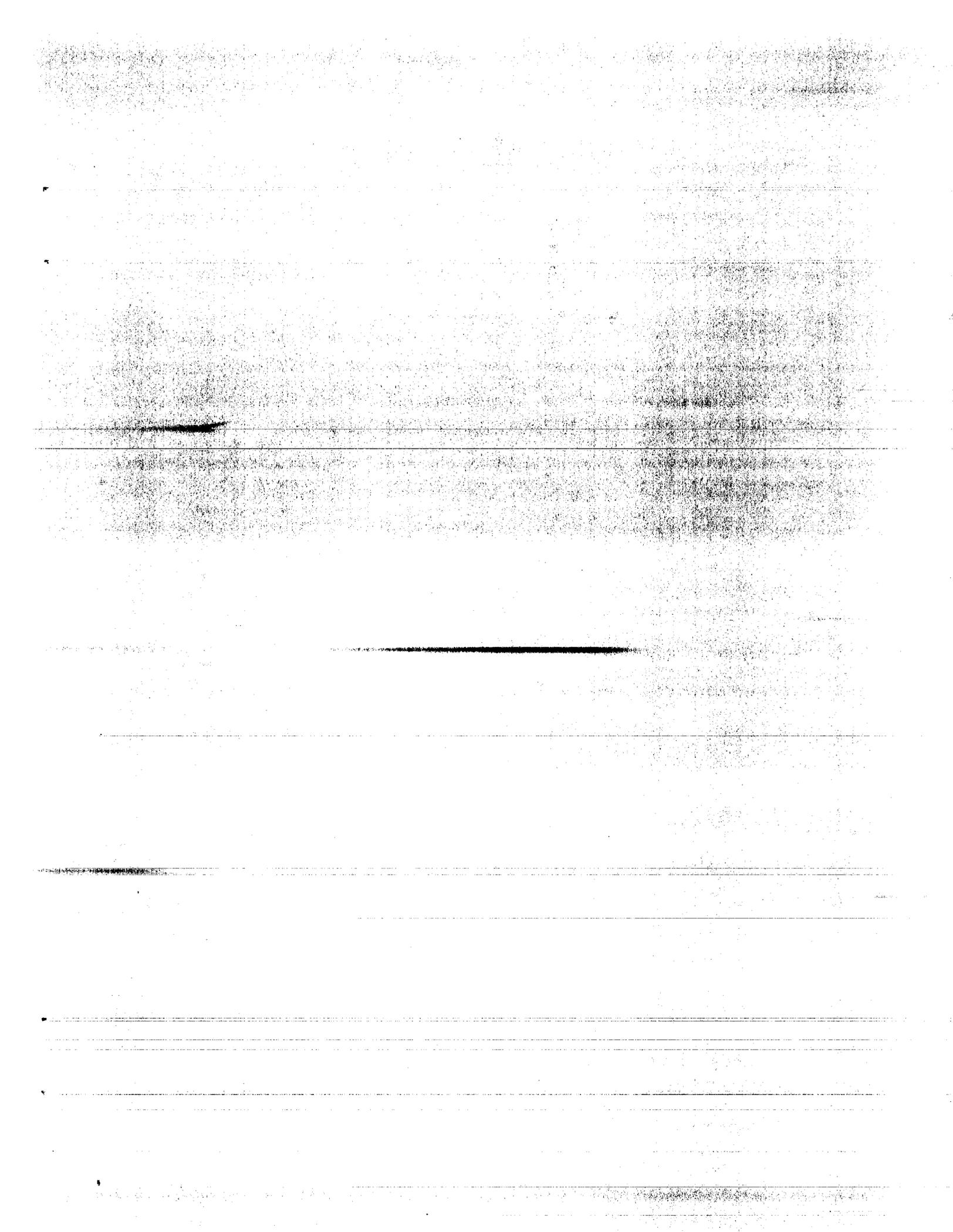
Good Afternoon, I am Allen Matthys, Vice President of Regulatory Affairs for the National Food Processors Association. NFPA is the principal scientific trade association representing the \$430 billion food processing industry. With three laboratory centers, NFPA is the leading authority on food science and safety for the food industry. For more than 90 years, the food industry has relied on NFPA for government and regulatory affairs representation, scientific research, technical services, education, communications, and crisis management. The issue of patulin in apple juice has been reviewed extensively by NFPA's Juice Products Committee.

Patulin is produced by various molds that infect apples. If moldy apples are used to produce apple juice, patulin is likely to be present in the juice. The presence of patulin serves as a good indicator of the quality of the fruit used to reduce the juice. Patulin levels in excess of 50µg/kg in apple juice and single strength apple juice from concentrate are more likely to be associated with excessively moldy fruit. Proper fruit selection, handling, sorting, storage, culling, and washing can assure that only good quality fruit is used to make apple juice. Use of these good manufacturing practices can reasonably assure that the juice will not exceed 50 µg/kg.

On November 1, 1996, NFPA requested the Food and Drug Administration establish a guideline or action level of 50µg/kg as a maximum limit for patulin in apple juice and single strength apple juice from concentrate used as an ingredient in food intended for human consumption. This action was taken on behalf of members of NFPA's Juice Products Committee. Many U.S. companies that process and/or purchase apple juice and apple juice concentrates have product specifications establishing a maximum limit for patulin of 50 µg/kg based on single strength apple juice. The US Food and Drug Administration has not established a maximum level for patulin in apple juice but has supported establishment of a 50µg/kg limit for apple juice and concentrate in international trade at the Codex Committee on Food Additives and Contaminants (CCFAC).

Because the U.S. FDA has no defect action level or guidance limit for patulin in apple juice, NFPA members report rejecting shipments of imported apple concentrate which exceed the 50 µg/kg limit established in their company specifications. They speculate this product is being diverted to other companies that have not established limits for patulin. NFPA members report that the product rejection rate has decreased from about 10-15% to 2-5% from 1996 to 1998, as suppliers became aware of the need to meet these specifications.

The 50 $\mu$ g/kg of patulin level falls within current analytical capabilities ( $\pm 10$   $\mu$ g). The current "AOAC Official Method 995.10, Patulin in Apple Juice" was collaboratively studied using levels of 20, 50, 100 and 200  $\mu$ g of patulin/L of apple juice (J. AOAC Int. 79, 451(1996). One laboratory notes that if the initial sample tests as 30  $\mu$ g or less the shipment is accepted, if  $>30$  but 50  $\mu$ g or less additional samples are tested to confirm the product is within the 50  $\mu$ g/kg limit established by the company. The test is not sufficiently accurate to quantify below 30  $\mu$ g/kg.



**ADDENDUM TO REQUIREMENTS AND RECOMMENDATIONS FOR APPLE  
CIDER PROCESSING**

<p><b>ASSOCIATION OF FOOD AND DRUG OFFICIALS</b></p> <p><b>APPLE CIDER</b></p> <p><b>THERMAL PASTEURIZATION EQUIPMENT RECOMMENDATIONS</b></p>
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May 26, 1999

Currently available scientific information suggests that adequate pasteurization for apple cider produced from most varieties of apples is achieved at a temperature of 160°F for 6 seconds. An exception to this is cider produced from "*Red Delicious*" apples which requires a temperature of 160°F for 11 seconds or 170°F for 2 seconds.

Consumers and apple cider processors alike should have confidence that cider which is labeled pasteurized has, in fact, undergone an adequate pasteurization process. We believe that compliance with the following apple cider pasteurization equipment recommendations can help provide reasonable assurance that your cider has been properly pasteurized.

**I. RECORDER CONTROLLER**

A. Purpose:

To automatically record pasteurization temperatures and times and automatically control the position of the flow diversion device.

B. Location:

The sensor should be located within 18 inches of, and upstream from the flow diversion device.

C. Design and Operation:

The recorder controller or Safety Thermal Limit Recorder (*STLR*) is an electronic instrument actuated by either a Bourdon coil attached to an ether derivative (water and glycerin) filled capillary which responds to temperature changes or may be one of the newer type electronic programmable recorder controllers which utilize electronic remote temperature sensing devices and computer logic.

**II. INDICATING THERMOMETER**

A. Purpose:

To indicate the accurate temperature of the product.

B. Location:

At the end of the holding tube and as close as practicable to the recording thermometer sensor.

C. Specifications:

1. Type:

a. Mercury In Glass (MIG) - Mercury actuated, direct reading, corrosion resistant case.

(1) Scale: Span not less than 25°F including pasteurization temperature plus or minus 5°F, graduated in 1.0°F divisions.

(2) Accuracy: Tested against known standard upon installation and then at least once a year thereafter.

(3) Thermometric response: 4 seconds to travel 63% (12° which includes the pasteurization range) of a 19° span.

b. Digital Reference Thermometer (DRT) - On November 27, 1991 the FDA, through M-b-314, allowed the use of the digital reference thermometer (DRT) as a replacement for the mercury actuated (MIG) indicating thermometer for use in pasteurization systems.

(1) Scale: Temperature indicated to at least 0.1°F.

(2) Accuracy: Tested against known standard upon installation and then at least once a year thereafter.

(3) Thermometric response: 4 seconds to travel 63% (12° which includes the pasteurization range) of a 19° span.

III. HOLDING TUBE

A. Purpose:

Section of piping of sufficient length to provide a minimum holding time at a predetermined temperature for heated product in a continuous flow pasteurizer.

B. Design and Operation:

1. Permanent supports to assure alignment and proper slope to preclude air entrapment and assure uniform product flow. The minimum upward slope is 0.25 inch per running foot, or 2.1 centimeters per meter.

2. Fabricated to eliminate short circuiting (no alterable sections).

3. Starts at the salt injection port and ends at the flow diversion device.

4. Designed to assure temperature variation not to exceed 1°F.

5. Heat should not be applied to the holding tube at any point.

#### IV. TIMING (METERING) PUMP

##### A. Location:

In basic High Temperature Short Time (HTST) systems, the conventional timing pump will be the only flow promoting device in the system. Timing pumps, when used in systems with product-to-product regenerators, should always be placed downstream from the raw regenerator. This is to assure that during operation, raw product pressures in the product-to-product regenerator are relatively less than pressures on the pasteurized side of the plates. Timing pumps may be speed adjustable but are always set at the fastest minimum legal pasteurization time(s) and sealed to prevent unauthorized changes. Some timing pumps are electronically controlled and this controller should also be sealed to prevent unauthorized changes. Timing pumps may operate at any time except when the dual stem flow diversion device mode switch is in the "Inspect" position or unless during the diverted flow, the flow diversion device is properly assembled and the microswitch is in the proper position.

##### B. Types:

1. Positive displacement type: Positive pumps may be of several types, two of which are in common usage in the continuous flow pasteurizer.
  - a. Gear driven type pump (where two rotors or impellers revolve within an oval case). Close tolerances between the gears and the outer case make the space or pockets between the teeth or lobes carry the fluid around the periphery of the pump body. The size of these pockets and the speed at which they revolve determine the volume that will be pumped. It is important to remember that the efficiency of these impeller type pumps may be greatly influenced by the temperature and type of liquid they are pumping. This becomes important when performing the holding time test for systems with these types of pumps.
  - b. Belt/pulley driven piston type pump such as the homogenizer. Homogenizers are very efficient positive displacement pumps and are frequently used as the timing pump in continuous pasteurizers.
2. Magnetic flow meter based system which uses a centrifugal pump in conjunction with product flow controlling methods.
3. Centrifugal Pumps

##### C. Controls:

1. The timing pump should be considered operating at maximum speed and capacity to assure that the minimum holding time requirements are satisfied.
2. The pump should also be interwired with the flow diversion device and recorder controller. This is to prevent the flow of raw product into the pasteurized side of the system.
3. Generally, there is only one primary timing device in the system. When two positive displacement pumps are used as timing pumps, both should be timed separately and together to assure minimum holding times are achieved.

## V. FLOW DIVERSION DEVICE (FDD)

High Temperature Short Time (HTST) continuous flow pasteurization equipment should be equipped with either a single or dual stem FDD.

### A. Single Stem:

#### 1. Purpose:

To safely and accurately control and separate raw and pasteurized product flow.

The single stem flow diversion device is a specially designed three way valve that, in conjunction with a recorder controller, is capable of automatically controlling the direction of product flow in a pasteurizing system. It should be manually cleaned.

#### 2. Operation:

- a. The single stem flow diversion device is air activated for the open position (forward flow) and spring activated for the closed (divert or fail-safe) position. To activate (open) the valve, compressed air is admitted above the diaphragm. This compresses the spring and moves the valve to seal off the divert line and opens the forward flow port. Compressed air to the top of the diaphragm is controlled through an air activated solenoid valve. This solenoid is activated by a signal from the recorder controller microswitch when the preset cut-in temperature is reached. Loss of air pressure or electrical signal from the recorder controller causes the spring to automatically return the valve to the closed or fail-safe divert position.
- b. When the flow diversion device is properly assembled and in the fully diverted position, the microswitch roller will be positioned in the valve diaphragm push plate groove. In this position, the microswitch provides power to the timing pump and the red light on the recorder controller.
- c. When the flow diversion device is in the forward flow position, the roller rides above the groove and the microswitch energizes the green light and the frequency pen arm on the recorder controller. During legal forward flow, the timing pump is energized by the recorder controller switch.
- d. If, during diverted flow, the diversion device is not properly assembled or seated, the microswitch roller will be mispositioned out of the groove and the timing pump will not run. This prohibits any raw product from entering the forward flow port of the valve during divert.

#### 3. Basic Requirements:

- a. Systems should be provided to insure proper operation of the FDD to operate only when properly assembled and then only when in the fully forward or full diverted position.

3. Basic Requirements (*cont'd.*):

- b. It should be impossible to tighten the stem packing nut so as to prevent the valve from assuming the fully diverted position within the prescribed time (1 sec.).
- c. Leak escape ports should be unobstructed and on the forward flow side of the flow diversion device seat. The forward flow seat should close tight enough so that any leakage past the seat will not exceed the capacity of the leak escape device. The poppet valves, as they are known, are held in place by springs and "O rings." When the valve is in diverted flow, the leak detectors allow product which leaks past the sealing rings (gaskets) of the valve plunger to escape to the atmosphere. In forward flow the springs hold these poppets against their seat preventing leakage. Product pressures in excess of 20 psi may prevent their proper seating and result in leakage.
- d. The length of the connecting rod should not be adjustable. Power failure or loss of air pressure should automatically move the valve to the failsafe (*diverted*) position. The flow diversion device should be located downstream from the holding tube. The divert line should be self-draining and should be free of restrictions or valves unless readily identifiable and are so designed that stoppage of the divert line cannot occur.

B. **Dual Stem:**

1. Purpose:

- a. To safely and accurately control and separate raw and pasteurized product flow.
- b. A dual stem flow diversion device is basically two, three-way valves in tandem which automatically control the direction of product flow. This type of valve or device was designed to be cleaned in-place.

2. Operation:

- a. Each manufactured brand of valve is slightly different in design, however, all have two bodies with an interconnecting yoke, pneumatic actuators and spring-loaded valve plungers.
- b. All are designed to move to, or remain at, the fail safe divert position in the event of loss of power or air pressure.
- c. Each valve is actuated by a quick exhaust type solenoid valve that controls the air to each valve.
- d. Microswitches (or proximity switches on some models) are located near the top of each actuator stem in the valve bonnet, and operate and function identical to those in the single stem flow diversion device. (Control power signal to the timing pump, frequency pen and panel indicator lights).

3. Basic Requirements:

- a. Systems should be designed to insure proper operation of the flow diversion device only when properly assembled and only when in the fully forward or fully diverted position.
- b. It must be impossible to tighten the stem packing so as to prevent the valve from assuming the fully diverted position within the prescribed time (< 1 sec.).
- c. Leak escape ports must be unobstructed and on the forward flow side of the flow diversion device seat. The forward flow seat should close tight enough so that any leakage past the seat will not exceed the capacity of the leak escape device. This requirement design should eliminate any back pressure from being applied to the divert and leak detect ports of the flow diversion device.
- d. The length of the connecting rod should not be adjustable.
- e. Power failure or loss of air pressure should automatically move the valve to the fail-safe (diverted) position.
- f. The flow diversion device should be located downstream from the holding tube.
- g. The divert line should be self-draining and should be free of restrictions or valves unless readily identifiable and are so designed that stoppage of the divert line cannot occur.
- h. The leak detect line should be designed to discharge all leakage to the outside, or to the constant level tank. This leak detect line must be separate from the divert line and should not have any restrictions.

A sight glass must be installed in the leak detect line if connected to the constant level tank. This sight glass must be of the full see through (clear material providing vision on both sides of the cross fitting) design and be installed in the vertical line.

The only exception to this requirement is the provision for a transparent tube assembly which may be installed horizontally.

- i. All dual stem valves which have both bodies mounted vertically must have the sealed time delays. There is a newer model of the G&H FDD that because of the connecting "yoke" configuration is exempt from this requirement. These time delays are as follows:
  - (1) At least one second between actuation of the divert valve and the leak detect valve, when moving from the diverted flow to the forward flow position. The purpose of this is to flush the connecting line of any possible raw product remaining in this connecting "yoke." On systems having identifiable restrictors in the divert line, the maximum time delay (divert valve to leak detect valve "flush time") should never exceed 5 seconds which prevents the possibility of underprocessed product (< 15 seconds) from entering into the pasteurized side of the system.

3. Basic Requirements:

i. *(contd.)*

- (2) When the switch is moved from “**PRODUCT**” or “**PROCESS**” to the “**INSPECT**” position, the valve should immediately assume the “**DIVERT**” position and all flow promoting devices should be immediately de-energized. After all flow promoting devices have completely stopped (or have been effectively valved out of the system) the flow diversion device may move to the “**FORWARD FLOW**” position for inspection or servicing.
- (3) A maximum of one second time delay is allowed during transition movement times of the flow diversion device provided that a one second maximum "off" time delay is allowable to maintain the flow promoting device in the "on" position through the travel time of the valve(s) (NCIMS-93). This removes the requirement for de-energizing the flow promoters (i.e., timing pumps) during times required for the flow diversion device to move to the forward or divert flow position.

## VI. REGENERATOR PRESSURE RELATIONSHIPS

A. Purpose:

Pasteurized and raw products are separated by only thin stainless steel plates and a series of gaskets in the regenerator section. That is the reason that the pasteurized product **SHOULD ALWAYS** be under greater pressure than the raw product in the system. In the event of leakage due to either gasket or metal failure, the pasteurized product will be forced into the raw side of the regenerator and not vice versa.

B. Operation:

This pressure relationship should always be maintained during all phases of operations. This includes initial start-up, during processing (including diverted flow), and during any periods of sudden loss of power or shutdown.

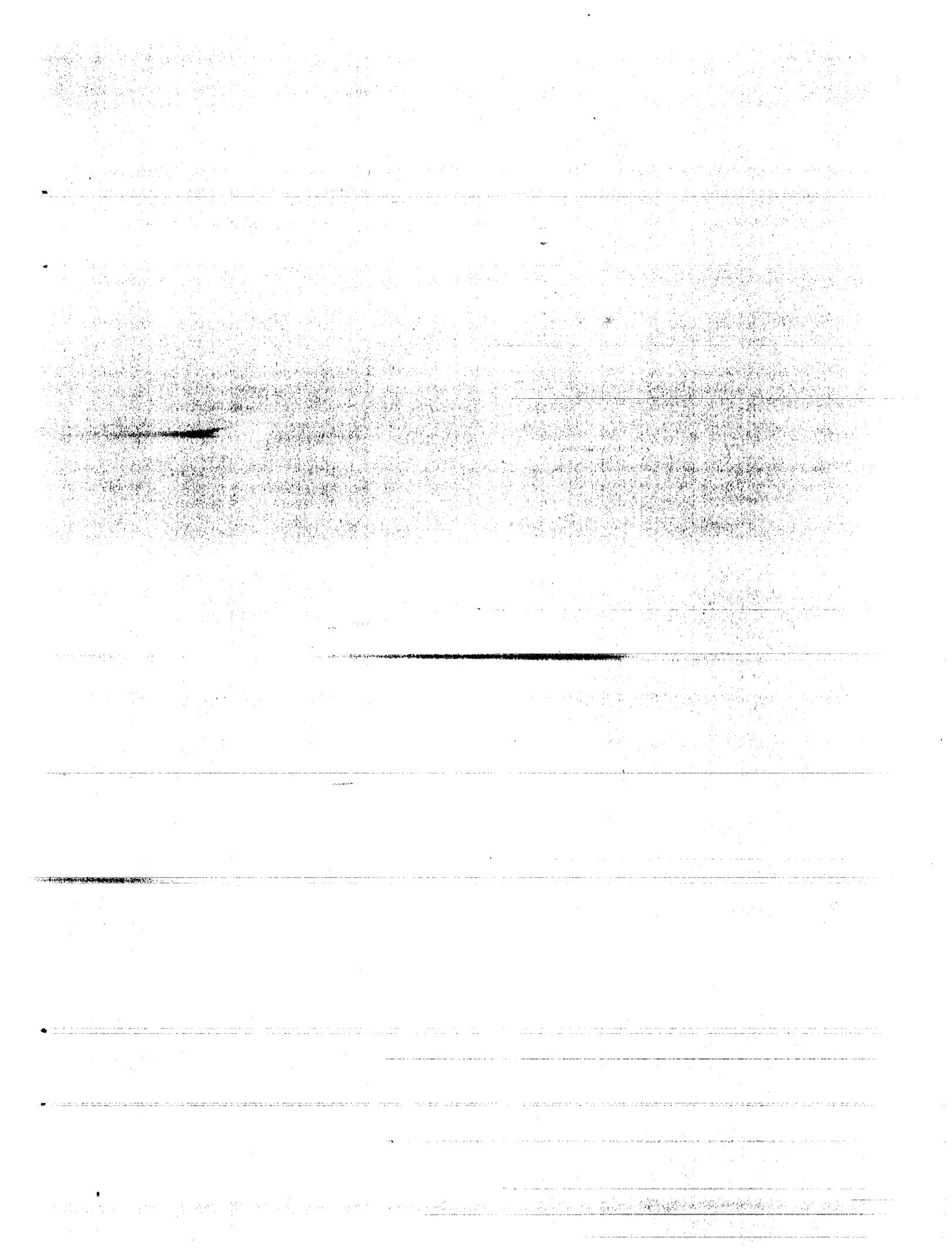
C. Basic Requirements:

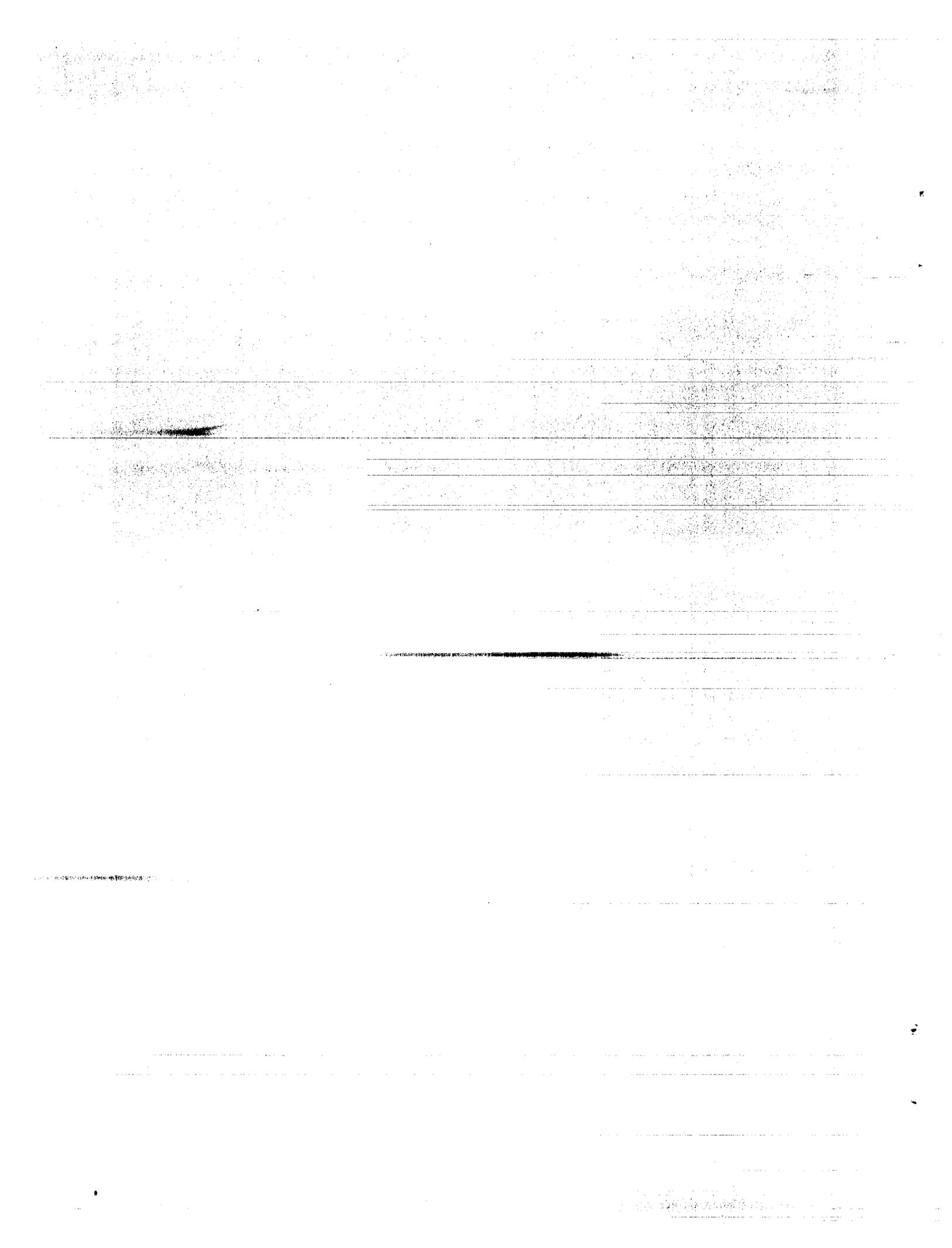
1. The overflow level of the balance tank should be lower than the product level within the regenerator.
2. The timing pump should be located between the outlet of the raw regenerator and the beginning of the holding tube.
3. No pump, other than a properly designed, installed and operated booster pump, should be installed between the balance tank and the raw product inlet to the regenerator.

C. Basic Requirements (cont'd.):

4. Generally, the product should enter the raw side of the regenerator at the bottom, unless the system has a start-up regenerator by-pass line, properly valved to allow unobstructed drainage of raw product back to the balance tank during loss of power or shutdown.
5. Pasteurized product at the outlet from the pasteurized regenerator should rise to a vertical elevation of at least 12 inches above the highest raw product in the pasteurizer system and at that point or higher should be open to the atmosphere through a sanitary vacuum breaker.
6. No flow promoting device which can affect the pressure relationships within the regenerator may be located between the pasteurized product outlet of the regenerator and the vacuum breaker.
7. During shutdown or loss of power, the vacuum breaker closes off the product line resulting from atmospheric pressure being applied on the breaker disc. This produces a capillary type action holding the pasteurized product with the 12 inch rise of piping which produces a back pressure on the pasteurized side of the product-to-product regenerator to approximately 1 psi. The pasteurized product is simultaneously held in a static position by the forward flow valve seat of the flow diversion device, which prohibits any back drainage into the holding tube. During this time, the raw product is undergoing a pressure reduction which is facilitated through the small drilled holes in the raw product deflector plates located at or near the bottom of the plate. To facilitate this, the outlet to the raw product regenerator may be disconnected.

VII. All frequency controllers, if used, should be set at 60 Hz during pasteurization cycle. Clean-in-Place (CIP) function is exempt from this requirement.





## Efficacy of Sanitizing Agents for Pathogen Reduction in Cider Production

Michael J. Beck\*

*Retail Cider Production Facility, Uncle John's Cider Mill, St. Johns, Michigan*

### ABSTRACT

The objective of this study was to determine the effectiveness of sanitizers on apple surfaces and its affect on cider. During the autumn of 1997 and 1998, apple and cider samples were assessed for bacterial level. Samples were tested for Total Aerobic Plate Count (TAPC), Coliforms & Escherichia coli (E.coli). Various tests took place involving the facilities in house lab and unpublished tests from Michigan Department of Agriculture (MDA). Samples in 1997 used a chlorine (NaOCl) flume wash followed by a washer/scrubber Chlorine Dioxide (ClO<sub>2</sub>) wash. Samples in 1998 used a Peroxyacetic acid flume wash followed by the same ClO<sub>2</sub> wash. 1997 samples used a variety of drop apples; table sorts and tree run fruit. 1998 samples did not include drop apples. Production methods were followed by the plants Quality Assurance program(1).

Key Words: Apples, cider, and sanitizers

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A concern over the safety of unpasteurized apple cider has developed after some outbreaks of *E. coli* in 1996(2). Regulations from FDA (3) and local government (4) have come about from the result of these outbreaks. Pasteurization of apple cider is an accepted method of pathogen reduction. However, lower cost alternatives to pasteurization need to be developed because most small producers can not justify the high cost of pasteurization equipment. Furthermore, pasteurization alters the flavor, texture and appearance of cider. Sanitizing agents have shown promise in pathogen reduction. Municipalities have used ClO<sub>2</sub> in potable and wastewater treatment plants for decades, (5) and has been used successfully in the treatment of pathogens on retail package fruit (6).

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Data has shown that hydrogen peroxide solutions have achieved a pathogen reduction in excess of 4-log (7). Washes using NaOCl solutions can provide a 1log reduction in pathogens (8). All of these are economically feasible and practical methods for use in smaller production plants.

### MATERIALS AND METHODS

Materials and equipment used were chosen because they were designed for practical use in working environment. In addition, all methods are readily available and economically feasible.

Preparation of aqueous chlorine dioxide. Solutions of ClO<sub>2</sub> were generated on site with a ClO<sub>2</sub> generator from CH<sub>2</sub>O™ International, Olympia Washington. 2 –3 ppm ClO<sub>2</sub> was pumped directly into a washer scrubber and applied directly to whole apple surfaces.

Determination of chlorine dioxide concentrations. Titration tests were used to determine ClO<sub>2</sub> ppm in water. Test kits were supplied by the manufacturer and results were recorded daily.

Preparation of aqueous NaOCl solutions. 5.25% sodium hypochlorite was added to flume water to achieve dilutions between 50 – 200ppm. Mean concentrations were 150 ppm.

Determination of NaOCl concentrations. Total Chlorine test strips was used to determine chlorine strength.

Preparation of Peroxyacetic acid solutions. A premixed solution manufactured by ECOLAB Inc., St. Paul MN (Tsunami®) was added to flume water to achieve concentrations up to 80ppm.

Determination of Tsunami® concentrations. Titration tests supplied by the manufacturer were used to determine Tsunami® concentrations.

Testing of whole apples and apple cider. Various methods were used to determine microbial counts. Testing took place in house and occasionally tests were conducted by MDA. No attempt was made to recover damaged cells from low cider pH. Samples of apples were taken before and after sanitizing washes. Cider samples

were taken directly from the bulk tank. Cider samples were tested with Neogens' Hygicult® Series. Plate Count Agar was used for aerobic organisms. Violet Red Bile Agar (VRBA) was used to detect coliform levels.  $\beta$ -Glucuronidase agar ( $\beta$ -GUR) was used to detect generic *E. coli* levels. 100ml samples were taken for tests and allowed to incubate for 24 hours. Sample results would then be recorded in plants haccp plan. Hygicult® tests have a sensitivity of  $10^3$  CFU/cm<sup>2</sup>.

Late in the processing season in 1998, a MethylUmbilliferone glucuronide (MUG) was added to cider sample testing. This test was effective in testing for both coliform and general e-coli. This testing method has a sensitivity of  $>1$  CFU/cm<sup>2</sup>. All in house samples were recorded in the plants haccp plan. Variables vital to test results are also recorded in the plants haccp plan. MDA made several plant inspections during the 1997 and 1998 processing seasons. Their tests included swabs throughout plant and on the food contact surfaces. Samples were also taken on whole apple surfaces and finished product.

## RESULTS AND DISCUSSION

Generic *e. coli* was never found in any samples taken in processing seasons 1997 or 1998. All methods of whole fruit washing shows some form of log reduction in organisms (Figure 1 & 2). Furthermore, bacteria levels dropped in 1998 due to the change in manufacturing practice of not using windfall apples (Figure 2). Silk et al (9) displayed similar characteristics in another cider study. Hygicult® tests are not a most probable number test and if comparison charts are not used, they can become subjective in their interpretation. Late in processing season 1998, MUG testing was added to cider sampling. MUG tests are a most probable number test. This method of sampling is also more sensitive and can achieve results that are more accurate. Both methods of sampling required 24 hrs. of incubation at 37°C.

MDA testing revealed much about plant sanitation and the quality of apples coming into the plant. Results of these tests would show us where the plant could use improved sanitation. Consequently, bacterial levels were reduced throughout the plant and in the finished product. This could skew the results of sampling slightly. The largest variable in bacterial reduction was the increased contact time of the sanitizers on fruit. When the plant had the ability to slow its process down to close to minimum speeds tests

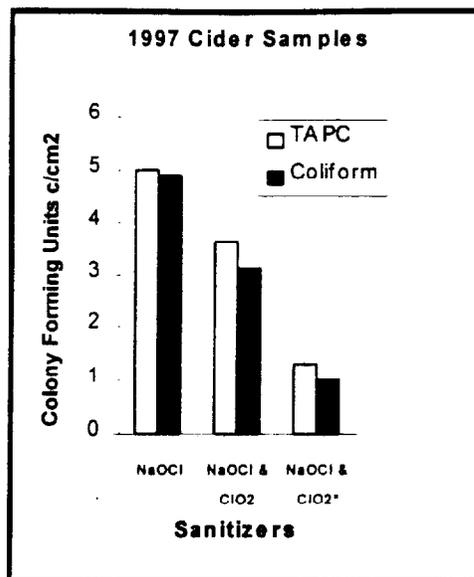


Figure 1. 1997 cider sampling results. Cider apples used were a combination of tree run fruit, table sorts, and windfall apples.

\* Test samples when sanitize contact time was increased.

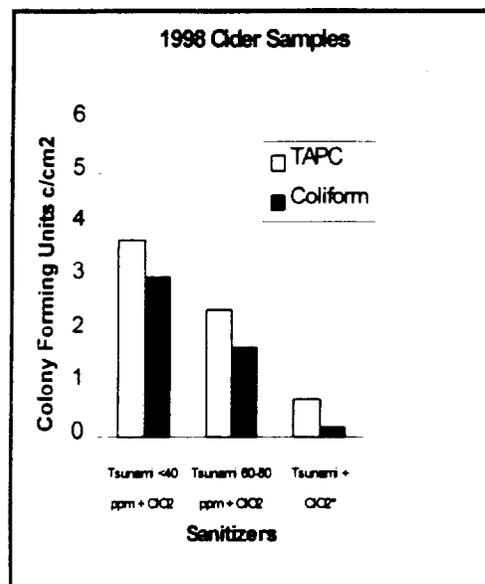


Figure 2. 1998 cider sampling results. Cider apples used contained no drop apples.

\* Test samples when sanitizer contact time was increased.

indicated no form of organisms living in cider. sanitizer levels would affect bacterial kill. (Figure 1 & 2). Sanitizer strength would deviate from day to day. However, Chlorine Dioxides standard deviation is significantly lower. Metering devices make ClO<sub>2</sub> simple to use.

Because of high flume water solids NaClO strength would drop steadily throughout the day. However, Tsunami® would stay close to same strength consistently under the same conditions. Sanitizers did not off gas odors or cause irritation in use. Although, mixing sanitizers in flume tank did give off unpleasant odors. When mixing proper safety precautions should be followed. Care should taken when priming the Chlorine Dioxide unit for seasonal startup.

The combination of sanitizers and good manufacturing practices can achieve adequate bacterial kill. Furthermore, sanitizers had no effect on cider taste and quality. In addition, a substantial shelf life extension was achieved as a byproduct of sanitizer use. Results of this study substantiates previous findings. Further research needs to focus on validation of these processes so that cider producers may take advantage of them.

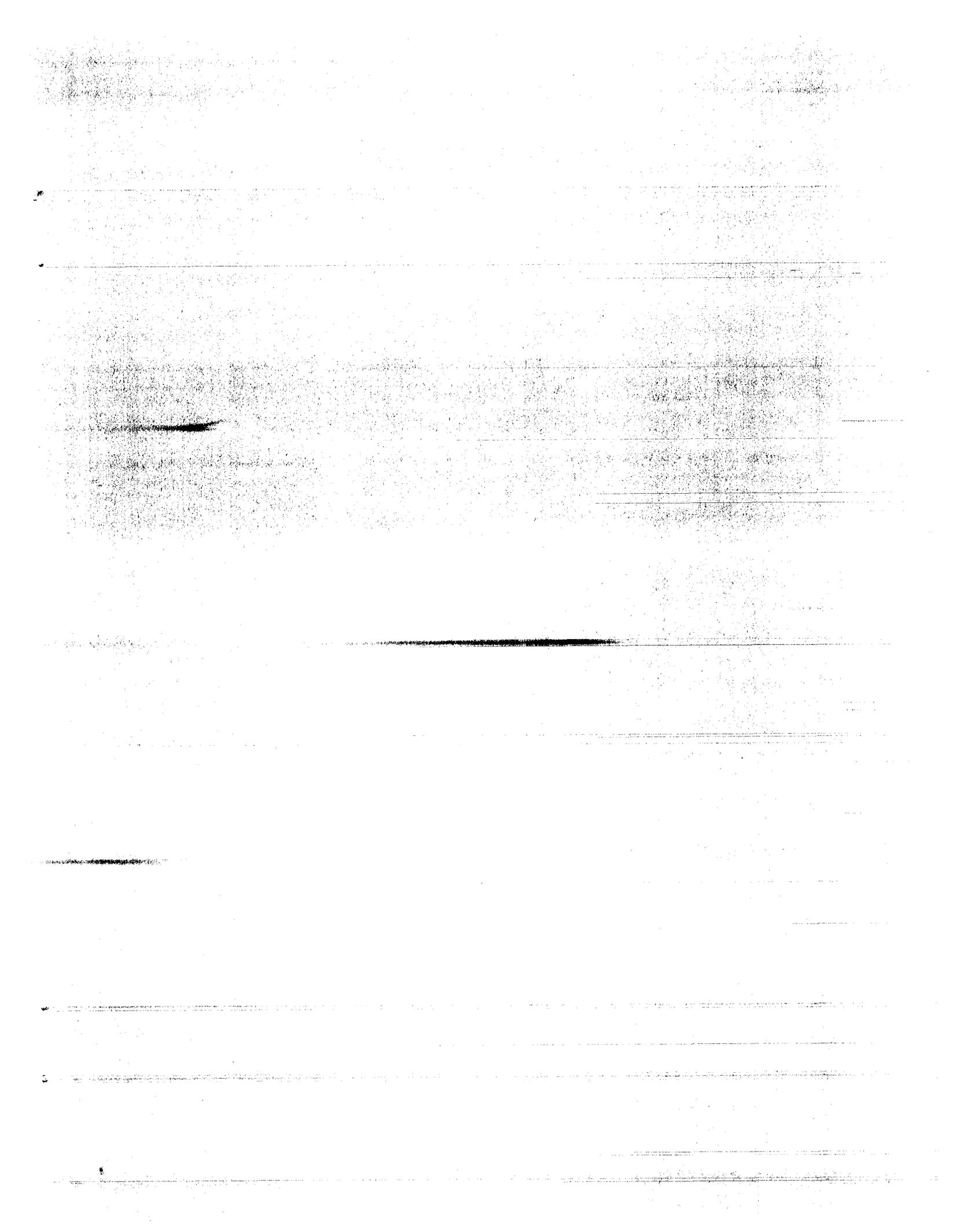
## ACKNOWLEDGEMENTS

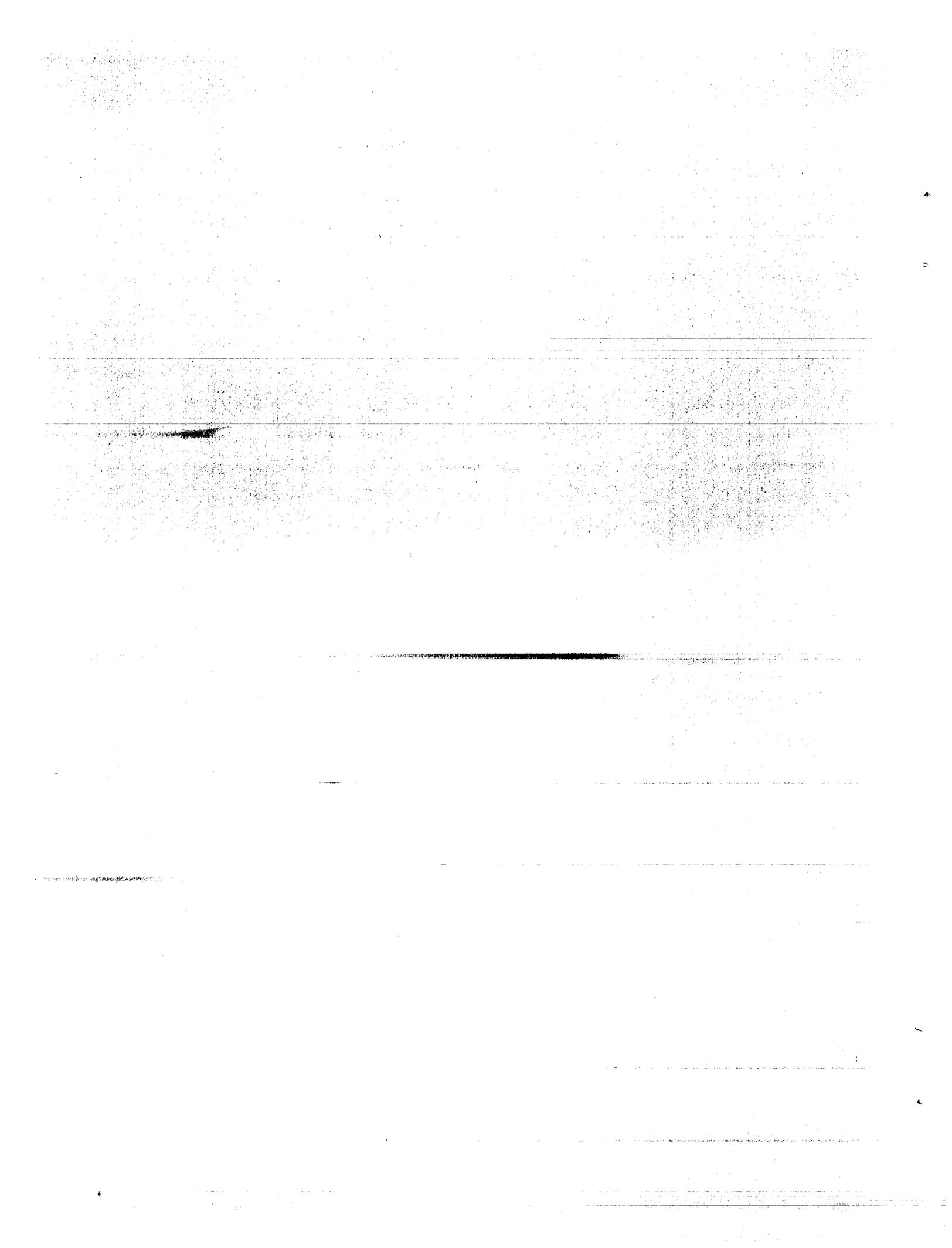
Many thanks to the companies that helped make this research possible. Michigan Orchard Supply, Allegan, MI; CH<sub>2</sub>O International, Olympia, WA; Ecolab®, St. Paul, MN. Special thanks to John Tilden, Jerry Wojtala, Doug Park and the Michigan Department of Agriculture for their help and expertise in this project. Plus, many thanks to Bob Tritten and MSU extension for their help.

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# **Recommended Good Manufacturing Practices Fresh Apple Juice**

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**Working Draft Version 3.8 - 6/3/98**

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## **I. Introduction**

On April 21, 1998, the Food and Drug Administration proposed two regulations to improve the safety of both fresh and processed fruit and vegetable juices. The first regulation would require processors of packaged fruit and vegetable juices to implement a hazard analysis and critical control point plan for their operations:

Hazard Analysis and Critical Control point (HACCP); Procedures for the safe and sanitary Processing and Importing of Juice.

The second regulation would require warning labels on all packaged juice products that have not been pasteurized or otherwise treated to eliminate harmful microbes:

Food Labeling: Warning and Notice Statements: Labeling of Juice and Products

Cider is a popular and unique product. It is directly marketed to consumers from multiple stages in our farm to fork system of product delivery. Recent concerns about enhancing the safety of fresh apple juice/cider have heightened industry, consumer and regulatory awareness. This document is an effort to aggregate the best recommendations possible for the production of fresh apple juice/cider.

As with any GMP recommendation, these guidelines should always be reconciled with current state and federal rules and regulations as appropriate.

This document is a minimum Good Manufacturing Practice (GMP) for fresh juice production. It focuses on production of fresh juice alone; from receiving raw fruit to delivery of finished product. It does not address the use of preservatives such as potassium sorbate or sodium benzoate. Limited information regarding the use of these preservatives can be found under Section VII: General Preservative Information. Use of Good Manufacturing Practices can improve the quality and safety of fresh juice.

Many sources were used to produce this document. As with a multitude of issues surrounding food safety, opinions can be varied. We have tried to incorporate in this document a very broad sweep of currently accepted recommendations. As a working document, we continue to solicit comments concerning these suggested GMPs. Please feel free to send email to Dr. Mark R. McLellan at [mrm1@cornell.edu](mailto:mrm1@cornell.edu)

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**Flow Chart** of cider production. This flow chart outlines the basic steps of cider production.

Fresh unpasteurized apple cider is newly pressed apple cider (juice), which has not been treated. With all of the discussion about fresh ciders and juice we might want to consider a set of suggested definitions of apple ciders and juices. In these definitions, the word "fresh" designates a non-shelf stable juice which is either unpasteurized or pasteurized. Without the adjective "fresh", we define a product which must be hermetically sealed and processed to a shelf stable state.

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## II. Administrative Guidelines:

### A. General Issues

1. Processors must develop and implement a Quality Assurance Plan (QAP).
2. Designate a manager(s), or employee(s) as the official Quality Control Supervisor(s).

### B. Records

Records should be available and be supplied on demand as evidence to establish food safety. These records should be legible, permanent, accurate and signed and dated by the individual(s) responsible.

Documentation should include but not be restricted to the following:

- Water quality
- Harvest of tree picked fruit (declaration of...)
- Grower/supplier agreements
- Fruit identification from field (receipt) to bottle - Lot Traceability
- Sanitation practices in the field
- Sanitation practices in the processing plant
- Training programs
- Pest control programs
- Environmental monitoring of processing facility

See List of Suggested Documentation in Section VI.

### **C. Personnel 21CFR110.10**

Supervisors - Also see: Quality Control Supervisor's Responsibilities in Section V.

- Ensure proper operations and training occur.
- Remove employees with boils, sores, infected wounds and other abnormal sources of microbial contamination from contact with food.
- Perform other day to day responsibilities

General Personnel - Also see: General Plant Personnel Responsibilities in Section V.

- Participate in a general sanitation training program.
- Participate in a personal hygiene training program.

### **D. Plant and Grounds 21CFR110.20**

1. The grounds about the food plant under the control of the operator should be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

- Proper storage of equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pest.
- Maintain roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
- Adequate draining areas that may prevent contamination of food by seepage, foot-borne filth, or providing a breeding place for pest.
- Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

2. Cider/Juice processing and other food processing operations should be located in a separate enclosed room.

3. Plant buildings and structures should be suitable in size, construction and design to facilitate maintenance and sanitary operations for food manufacturing purposes. The plant and facilities should:

- Provide sufficient space for equipment, and storage of materials as is necessary for the maintenance of sanitary operation and the production of safe food.
- Permit the taking of proper precautions to reduce the potential for contamination of food, food contact surfaces, or food packaging materials with microorganisms, chemicals, filth, other extraneous material.
- Be constructed in such a manner that floors, walls, and ceiling may be adequately cleaned and kept clean and kept in good repair. Floors should be made of a non-porous material.
- Provide adequate lighting in hand washing areas, dressing and locker rooms and toilet rooms and in all areas where food is examined.
- Provide, where necessary, adequate screening or other protection against pest.
- Cold storage entry doors should be covered with plastic curtains to exclude dust and insects.

4.) An environmental facility monitoring program should be maintained in the processing facility to verify sanitation.

- A description of the environmental monitoring program in your facility should be

documented. Methods, equipment and frequency of environmental monitoring should be detailed.

5.) A Pest Control Program should be maintained

- The processor should take measures to control rodent populations, and to exclude pests from the facility. Buildings and grounds surrounding the facility should be kept clean and free of debris which can harbor rodent populations.
- Use rodenticides in accordance with state and federal laws and regulations.

**E. Sanitary Facilities and Controls 21CFR110.37**

1.) The water supply should be sufficient for the operations intended and shall be derived from an adequate stable source. Flume, wash and rinse water should not be recycled.

2.) Plumbing should be of adequate size and design and adequately installed and maintained to:

- Carry sufficient quantities of water to required locations throughout the plant.
- Properly convey sewage and liquid disposable waste from the plant.
- Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
- Provide adequate floor drainage in all areas where floors are subject to flooding type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
- The facility should be reviewed for proper back flow devices where applicable and the well should meet all construction criteria. Facility's water supply should be reviewed for proper backflow devices, where applicable, checked regularly and documented.

3.) The plant and equipment should be in good repair.

4.) All surfaces coming into contact with foods should be of food grade materials

- Acceptable food grade materials: plastic, stainless steel, or hardwood with proper food grade coating.
- Equipment should present no possible introduction of heavy metals, glass and/or lubricants into the product.
- Equipment that comes in contact with the product should be lubricated with food grade lubricants.
- Proper boiler compounds must be used.
- Galvanized buckets, pipes or sheeting should not be used.
- Equipment made of brass or having brass fittings, that come in contact with apple juice / cider can not be used. The acidic cider / juice will leach copper out of brass.

5.) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms should be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

6.) Each plant should provide its employees with adequate, readily accessible toilet facilities. Employees must not be penalized for use of sanitary facilities during work

hours.

7.) Hand washing facilities should be adequate and convenient and be furnished with soap or sanitizer and running water at a suitable temperature.

- Provide hand washing and where appropriate, hand sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
- Provide sanitary towel service or suitable drying devices.
- Provide hand or glove dip stations where appropriate.

## F.) Recalls

Every packer and processor should maintain an effective system of control so that they are able to notify all their affected consumers and quickly recall any product posing a health risk.

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# III. Processor's Guidelines

## A. General Issues

### Equipment and Utensils 21CFR110.40

- 1.) The plant and equipment should be in good repair.
- 2.) Whenever possible throughout the cider/juice processing operation, equipment should be made of food grade materials.
  - All surfaces coming into contact with foods should be of food grade materials.
- 3.) Holding, conveying and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, should be of a design and construction that enables them to be maintained in an appropriate sanitary condition.
- 4.) All plant equipment and utensils should be so designed and of such material and workmanship as to be adequately cleanable, and should be properly maintained.
- 5.) Utensils and equipment should be properly cleaned with potable water, sanitized, dried, and stored on racks well off the floors. See SOP #2 Cleaning Equipment and SOP #6 Cleaning Press Cloths Section IV.
- 6.) Brushes for hand and mechanical cleaning should be assessed for effectiveness and replacements kept one hand at the processing location.
- 7.) Brushes for hand cleaning should be of proper design, have sanitizing solution available during processing and stored where they may be properly protected.
- 8.) Knives used for removing undesirable portions of apples should be clean, stored properly and have sanitizing solution available during processing.

9.) Shovels used to fill mill with apples should be made of food grade material, cleanable, kept clean, cleaned before each use. Shovels should not be placed on the floor. Shovels used to fill the mill should be labeled and used only for this purpose.

10.) Product pumps should be of a sanitary design which can be clean and sanitized.

11.) Equipment should present no possible introduction of heavy metals, glass and/or lubricants into the product.

12.) Equipment that comes in contact with the product should be lubricated with food grade lubricants only.

13.) Proper boiler compounds should be used.

14.) Galvanized buckets, pipes or sheeting should not be used.

15.) Equipment made of brass or having brass fittings, that come in contact with apple juice / cider should not be used. The acidic cider / juice will leach copper out of brass.

#### **Cleaning & Sanitizers 21CFR110.35**

1.) Substances used in cleaning and sanitizing should be free from undesirable microorganisms and should be safe and adequate under the conditions of use 21CFR178.1010 Refer to Information on Food Plant Sanitizers Section V.

2.) Cleaning compounds, sanitizing agents, and pesticide chemicals should be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food packaging materials.

3.) After each day's operation, equipment should be dismantled or disassembled as far as possible, and thoroughly cleaned and sanitized. See SOP #7 for Cleaning pipes / tubing Section IV.

- Equipment should not be rinsed after sanitizing. Equipment should be air dried off the floor.

4.) Cleaning and Sanitizing process should be assessed for effectiveness and such records should be kept on file at the processing plant. A microbial swab test done weekly (on equipment) should be done to assess effectiveness of cleaning procedures. This can be done by an in house laboratory. A result of <10 colony forming units (CFU) is considered clean.

- A standardized swab procedure should be developed, involving description of how swab should be taken, i.e. 2" swab taken at specific sites on processing equipment.
- Microbial swabbing should be done after total sanitation is completed.
- Separate swab tests should be done at critical control points.
- It is recommended that only those identified as QA personal take swabs, the fewer the people involved in this procedure will result in higher consistency of swab samples.
- Description of procedure and documentation of results should be kept on file.

5.) Commercial 5.25% liquid chlorine can be used as an effective sanitizer.

- 6.) Scented or fragrance bleaches should not be used.
- 7.) Recommendations for solutions: See SOP #1 Mixing Sanitizing Solutions Section IV.
  - Fruit wash solution:  
50 - 100 ppm Chlorine solution.
  - Equipment sanitizing solution:  
100 - 200 ppm chlorine solution or 25 ppm Iodine solution
- 8.) Concentration / strength of sanitizer used in apple wash process or for sanitizing equipment and utensils should be checked periodically.
- 9.) All relevant regulations promulgated by the Federal, State and local government agencies for the application, use, or holding of these products should be followed.

### **Containers**

- 1.) Containers and lids should be made of material certified for use in food.
- 2.) Store supplies of apple juice/cider containers and ingredients off the floor in a clean, dry area, free of insects and vermin.
- 3.) Store apple juice containers in their original closed plastic bags, until use, to avoid environmental contamination.
- 4.) Store open plastic bags of apple juice containers in resealed plastic bags or in a screened or enclosed area.
- 5.) Containers should be stored inverted with open tops down to avoid environmental contamination.
- 6.) Inspect containers carefully before filling and / or sanitize them thoroughly. Refilling used, consumer containers risks contamination of filling equipment and cider.

## **B. Fruit Procurement**

### **Processes and Controls 21 CRF 110.80 - Inspection of raw materials**

See SOP #3 SOP for Receiving Raw Fruit in Section IV.

- 1.) Use only tree picked fruit. Receive certification, i.e. written assurance of quality, from fruit providers of only tree picked fruit being provided.
  - Provide the growing practices if fruit is grown by the processor. Provide grower agreements when processing fruit purchased outside.
- 2.) Purchase apples only from growers who provide a "Grower Agreement" in Section V. stating the fruit was produced and harvested using cultural and production practices that minimize the potential for microbial contamination.
  - Maintain a list of grower agreements on file.

**Apple Standards USDA Standards**

1.) Apples used in processing should meet or exceed the minimum standards for "U.S. Cider" grade.

- Provide documentation of how fruit is graded to meet the minimum "U.S. Cider" grade

2.) Purchased apples from commercial packing houses should meet commercial "peeler grade" standards ("U.S. 1" Processing Grade).

- Provide Documentation to verify the grade of apples purchased from the packing house. Documentation may include a shipper, invoice, or other information which indicates the grade of fruit received. Maintain record from packer that meets the requirements listed in #1 & #2

**Lot Traceability**

1.) Processors should maintain identification of fruit from field (receipt) to bottle.

- Describe the method of maintaining identification of fruit containers from the field through processing. Example: bin tags, grower/ranch name on bins etc. # of bins accepted, LOT TRACEABILITY

2.) Processors should document source of fruit used for each separate production lot.

- Documentation should include:
  - Date of pressing
  - Date of bottling
  - Use-by-date

**C. Raw Fruit Storage 21 CRF 110.80**

1.) Handle and store apples in clean containers.

- Harvesting bins should be inspected and cleaned before filling.

2.) Fruit should be kept in cold storage, in an enclosed area, free of flies, insects and rodent activity. Animals (cats, birds, dogs, wild animals etc.) are prohibited from processing and storage areas.

- Provide descriptions of storage areas
- Optimum cold storage temperature is 32°F. Cold storage temperatures should not exceed 40°F.
- In general follow a "First in first out rule." Fruit should be use in order as received and order of fruit maturity.
- Documentation should be kept on file for storage facilities
  - 1.) Free of contamination statement
  - 2.) Documentation of monitoring/inspection for pest control & temperature monitoring and sanitation log.

**D. Sorting, Washing and Inspection of Fruit**

1.) Prior to washing, grade, sort and inspect all apples. Remove all extraneous matter and decayed, moldy and otherwise undesirable fruit. Sort out all rotted or partially rotted produce. As a general rule: "If you wouldn't eat it.. don't press it"

Produce of this quality adds an undue burden to an effective washing process and taxes chlorine levels in any sanitizing steps. Some sorting may be done during the early stages of washing. Again, this measure will lessen microbial load problems, but is not a guarantee that pathogens will be eliminated on incoming produce. See SOP #4 for Sorting Fruit Section IV.

- A detailed method of fruit sorting, washing and inspection should be outlined and kept on file.

2.) Use water in the processing facility that meets drinking water standards.

- Describe the source of water in the processing facility and provide documentation that it meets drinking water standards. Municipal water - certification from city,
- Other water sources: water should be tested 1-2 months prior to use, treated if necessary, and tested immediately prior to season's processing.
- Testing of water should be done if any situation occurs that may contaminate or make water's safety questionable.
- Testing for potability of water supplies must be done by a certified lab

3.) A source of pressurized potable running water should be available in the processing rooms for cleaning of equipment, fruit and the interior of the facility.

4.) Wash fruit in water containing an approved anti microbial agent in which levels are monitored at appropriate intervals. See Sop #5 for Fruit Washing Section IV.

- Documentation of how the anti-microbial agent is applied, monitored and how concentrations will be adjusted to appropriate levels should be kept on file.

5.) Wash water should be at least 10°F warmer than fruit being processed.

6.) Rinse apples with potable water before grinding and pressing. (Refer to water testing in Section II, D, #2 above.)

- Documentation of rinse water monitoring should be kept on record.
- Assessment of rinse procedure should be monitored at appropriate intervals.

## **E.) Grind**

1.) Grinding / crushing equipment should be cleaned prior to start up and during processing as needed.

2.) Sanitize as recommended in SOP #2 Cleaning Equipment Section IV.

3.) All equipment should be made of food grade materials.

## **F.) Extraction**

1.) Filter and press cloths should be specifically designated for this purpose.

2.) During processing, the cloths should be handled in a sanitary manner, which includes

hanging the cloths on a line, placing them off the floor, or in a clean container between runs.

3.) At the end of each day's operation, press cloths should be cleaned, rinsed, and sanitized.

See SOP #6 Cleaning Press Cloths Section IV.

4.) The filter / press cloths may be dried by spreading them on a clean line in a well ventilated, enclosed area away from flies and vermin.

5.) Press racks should be made of food grade plastic or hardwood which should to be maintained free of excessive cracks or crevices. Hardwoods should have no splinters or separated wood fragments.

6.) Press racks should be kept off the floor.

7.) At the end of each day, used racks should be cleaned, sanitized, and allowed to dry in a well ventilated enclosed area.

8.) All tubing carrying cider/juice should be approved for food use and all plastic tubing should be transparent.

9.) Tubing should be protected from abrasion or breakage and capable of being easily replaced.

10.) If tubing passes through spaces that are not readily accessible, the tubing should be one piece and easily cleaned.

11.) Tubing should be as continuous as possible with coupling kept to a minimum.

12.) Periodic disassembling, cleaning, and sanitizing of tubing, clamps, couplings, and connections should be performed. See SOP #7 Cleaning Pipes / Tubing Section IV.

13.) Tubing should be positioned so that no pockets of liquid remain when the tubing is rinsed.

14.) Tubing should be cleaned and sanitized after each day's run.

15.) Tri-clamp fitting tubing is recommended to transport product; threaded tubing is more difficult to clean and provides an area where contamination can occur.

## **G.) Holding Tanks / Bulk Tankers**

Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, should be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

See SOP #2 for Cleaning Equipment and SOP #8 Cleaning Bulk Tankers in Section IV.

- Tank integrity should be maintained and monitored regularly. Cracks, dents and dead spots are impediments to good cleaning.
- Badly dented, cracked or leaking containers should be immediately disposed of.
- All tanks should be cleanable and be able to be inspected.

- Stationary tanks should be mounted on a cleanable structure.

## H.) Cider/Juice Transport

Cider/Juice should be transported and stored in clean non-porous, non-corrosive, easily cleanable, closed containers of food grade materials.

- All containers should be properly labeled re: lot traceability and press / use by dates.
- Bulk juice / cider should be transported at refrigeration temperatures.

## I.) Bottling & Packaging

- Cider / Juice should only be sold in new containers with new caps.
- Containers should be properly labeled.  
The following information should be provided on the container:

- a.) Brand name
- b.) Commodity (apple cider or apple juice)
- c.) Ingredients -- if additives are used
- d.) Use-by-date
- e.) Manufacturer (packer or distributor) name, including city, state, zip code
- f.) Keep refrigerated
- g.) Net quantity
- h.) Bottle label contains "Fresh Unpasteurized"
- i.) Cap contains label "Fresh Unpasteurized"

See SOP #9 for Bottling and Packaging in Section IV.

## J.) Bottled Juice Storage

### Temperature Management:

Product temperature should be controlled until it reaches the consumer market (to include transportation to market.)

- Indicate the location of refrigeration units and document how the refrigeration unit will be monitored to meet current state law. Maximum temperature for fresh juice storage is 45°F.

### Warehousing and Distribution 21CFR 110.93

1.) Storage and transportation of finished food should be under conditions that will protect food against physical, chemical and microbial contamination as well as against deterioration of the food and the container.

2.) Routine product testing by the manufacturer should be conducted on warehoused product on a regular basis.

### Natural or Unavoidable Defects in food for Human use 21CFR 110.110

Some foods, even when produced under current good manufacturing practice.

contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

### **K. Waste Disposal**

- 1.) Press Pomace should be properly disposed of away from the facility.
  - Pomace residue should not be left overnight. Pomace residue removal helps control insects and rodents on the property.
- 2.) Effective measures should be taken to protect finished food from contamination by refuse.
- 3.) When refuse is unprotected it should not be handled simultaneously in a receiving, loading or shipping area if that handling could result in contaminated food.

### **L. Off-Season Facilities Issues**

- 1.) During the off-season, press racks and cloths should be stored so that birds, animals, insects, etc. are unable to come in contact with them.
- 2.) Any equipment, utensils, or chemicals (supplies) not used in food processing should not be stored in the processing or storage areas at any time.

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## **IV. Standard Operating Procedures**

Standard Operating Procedures for:

- SOP #1 Mixing Sanitizing Solutions
- SOP #2 Cleaning Equipment
- SOP #3 Receiving Raw Fruit
- SOP #4 Sorting Fruit
- SOP #5 Fruit Washing
- SOP #6 Cleaning Press Cloths
- SOP #7 Cleaning Pipes / Tubing
- SOP #8 Cleaning Tanks & Bulk Tankers
- SOP #9 Bottling and Packaging

## **V. Miscellaneous Documentation**

Information on Food Plant Sanitizers

Quality Control Supervisor's Responsibilities

General Plant Personnel's Responsibilities

Grower Agreement

Washington State Department of Agriculture Recommendations, February 13, 1997