Enhancing The Safety of Lettuce & Leafy Greens

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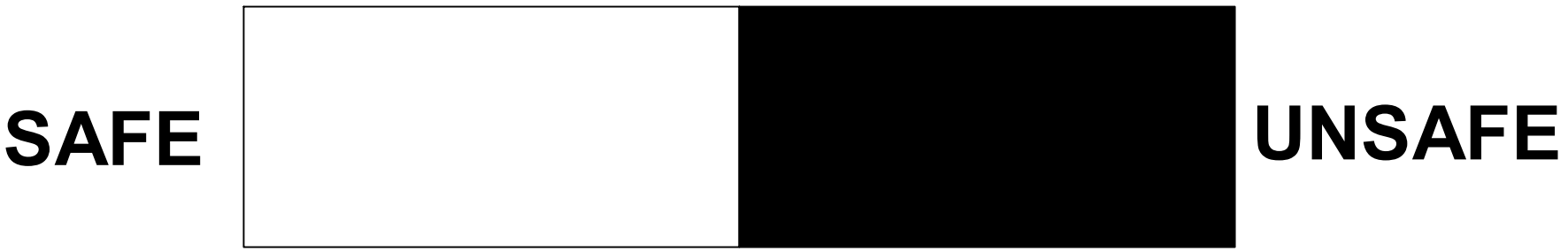
Defining Safety

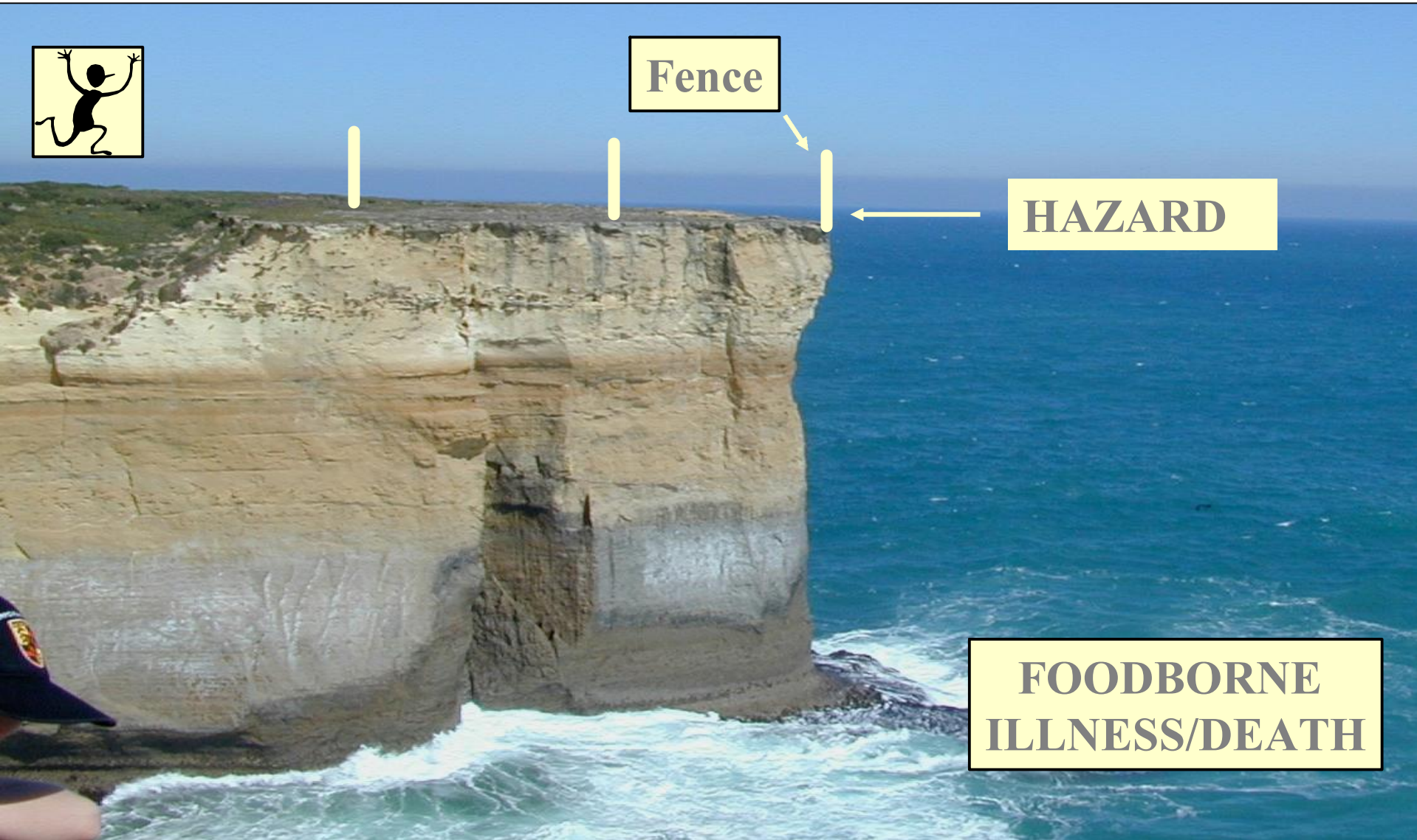
The goal of all food safety programs is: zero illnesses.

Food safety programs identify and manage risks (i.e. potential hazards).

Produce Food Safety = Prevention



Food Safety Programs Control, Reduce or Eliminate Hazards



Industry Response

Is This a Compliance Issue or Unidentified Risk Factors?

Long-Term Action Plan

- Best Practices
- Compliance
- Research

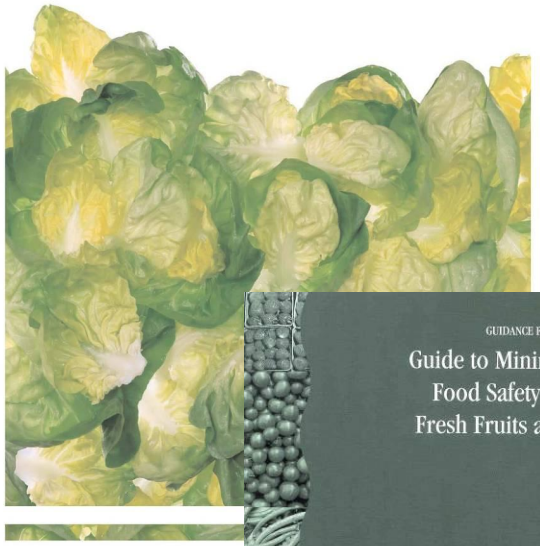
Best Practices

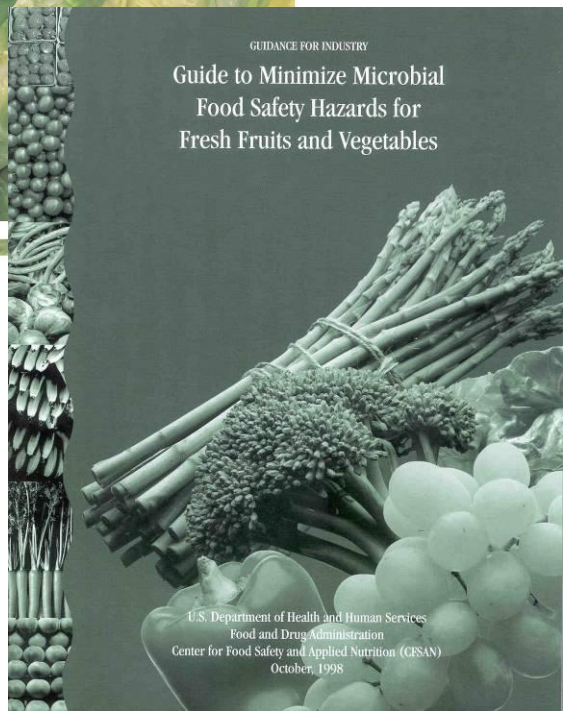
"Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables"

March 12, 2006

www.cfsan.fda.gov/guidance.html

Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain





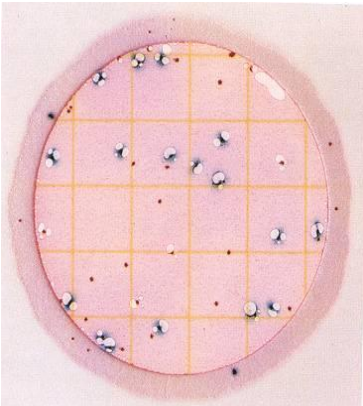
California Department of Health Services
Food and Drug Branch
Fresh-cut Produce Re-Wash Panel
April 4, 2006

Compliance

- Various Requirements
- Various Auditing Schemes
- Supplier & Buyer Business Practices

Will Microbiological Testing Assure Food Safety ?

- Safety Cannot Be Tested Into A Product
- Negative Tests Don't Prove Absence
- What will you test for ?
- Micro Testing Can Be Used To Identify Abnormal Performance (places data in context)
- Focus On Process Not Product



Random Sampling

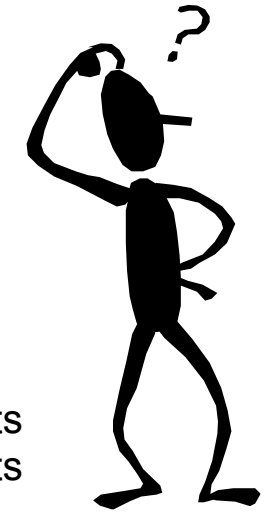
Table 1. Probability of accepting a defective lot with indicated proportion of defective sample units

	Number of Sample Units			
% Defective	**15**	**30**	**60**	**100**
0.1	0.99	0.97	0.94	0.90
0.5	0.93	0.86	0.74	0.61
1	0.86	0.74	0.55	0.37
2	0.74	0.55	0.30	0.13
5	0.46	0.21	0.05	0.01

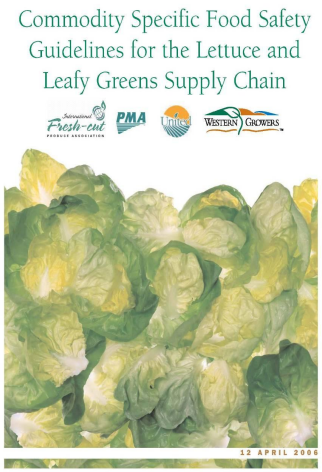
Adapted From: Microorganisms in Foods 7 - Microbiological Testing in Food Safety Management, 2002 International Commission on Microbiological Specifications for Foods (ICMSF) Kluwer Academic / Plenum Publishers NY, NY

Example 1
Defect Level: 0.5%
Samples Units Tested: 30
Analysis: 86% probability that all 30 samples will be found negative and the lot will be accepted.

Example 2
Defect Level: 0.7%
Number of samples required to detect the defect with 95% probability: 428 sample units
Number of samples required to detect the defect with 90% probability: 329 sample units



GAPs "Best Practices" Metrics



- Identify Significant Risk Factors
- Identify/Incorporate Appropriate Metrics
  - Research/Technical Reports
  - Statutes
  - Process Capabilities
- Supplements and Amends Commodity Specific Guidance (not a stand alone document)
- Provides Harmonized Guidance
- Compliance
  - Marketing Orders
  - Regulations
  - Customer Requirements

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GAPs "Best Practices" Metrics

- Water Use
- Soil Amendments
- Non Synthetic Crop Treatments
- Flooding
- Animal Intrusion
- Adjacent Land Use

Are these the most significant risk factors?

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Water Safety Approach

- Microbial Action Levels Based on Safe and Sanitary Intended Use
- Testing Frequency Based on Source Variability
- Microbial Indicators Used To Measure System Performance (generic *E. coli*)
- Decision Tree Based Actions





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Water Uses

- **PREHARVEST Foliar Applications**
  Edible Portions of the Crop ARE Contacted by Water (e.g. overhead sprinkler irrigation, pesticides/fungicide application, etc.)
  geo mean<126 CFU/100ml single sample <235 CFU/100ml
- **PREHARVEST Non-foliar Applications**
  Edible Portions of the Crop are NOT contacted by Water (e.g., furrow or drip irrigation, dust abatement water)
  geo mean<126 CFU/100ml single sample<576 CFU/100ml
- **POSTHARVEST Direct Product Contact or Food Contact Surfaces** (e.g. re-hydration, core in field, harvest equipment cleaning, bin cleaning, product cooling, product washing) <2 MPN/100ml

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Water Uses

- **Stop Using the Water Source**
- **Perform a Sanitary Survey**
- **Take Corrective Actions**
- **If Water Has Been Used for Crop Production**
  test produce for pathogens (e.g. *E.coli* O157:H7, *Salmonella*)

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Soil Amendments

- Raw Manure
- Composted Soil Amendments
- Physically Heat Treated Soil Amendments

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Soil Amendments Approach

- Physical, Chemical or Biological Treatment
- Output Micro Testing to Verify Process
- Risk Based Application Interval

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Non-Synthetic Crop Treatments

Any crop input (foliar or soil) used for pest control, greening, disease control, fertilizing, etc. that contains animal manure, an animal product and/or animal by-product that is reasonably likely to contain human pathogens.
(e.g. compost teas, bio-fertilizers, etc.)

- Physical, Chemical or Biological Treatment
- Output Micro Testing to Verify Process
- Risk Based Application Interval

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Flooding

In the November 4, 2005 FDA "Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce/leafy greens" the agency stated that it *"considers ready to eat crops (such as lettuce/leafy greens) that have been in contact with flood waters to be adulterated due to potential exposure to sewage, animal waste, heavy metals, pathogenic microorganisms, or other contaminants. FDA is not aware of any method of reconditioning these crops that will provide a reasonable assurance of safety for human food use or otherwise bring them into compliance with the law. Therefore, FDA recommends that such crops be excluded from the human food supply and disposed of in a manner that ensures they do not contaminate unaffected crops during harvesting, storage or distribution."*

CSG Definition

"The flowing or overflowing of a field with water outside a grower's control, that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of the edible portions of fresh produce in that field.

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Flooding Approach

- **Harvest Distance From Flooding**
- **Verification**
- **Formerly Flooded Ground**
  - Production Practices To Reduce Risks
  - Risk Based Time Interval
  - Micro Testing to Validate Process

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Animal Intrusion Approach

- Evidence of Intrusion
- Animals of Significant Risk
- Decision Tree Based Actions
  - Pre-Harvest Assessment
  - Harvest
- Harvest Distance From Intrusion
- Verification

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Adjacent Land Use

- Composting Operations
- CAFO's
- Compost On Adjacent Farms
- Grazing Lands
- Leach Fields
- Fallow Areas (Woods, etc.)

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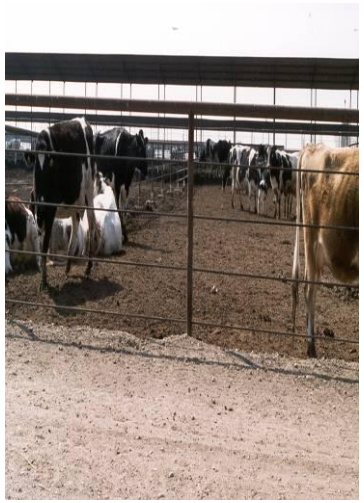
Adjacent Land Use Approach

Proximate Safe Distance

Potential Contamination Source



Mitigation Measures / Risk Factors

Risk Factors

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Next Steps

Best Practices

- Gather Stakeholder Input
- Revise/Update “Best Practices”
- Stakeholder Review
- Publication of “Best Practices” Recommendations

Compliance

- Marketplace
- Government Regulation (Marketing Orders)

Research

- Private Research
- Public/Private Research
- Public Research

Summary

Food safety development and implementation is a reiterative, evolving, long-term process of continuous improvement.

Market Force Compliance

Understand Risk Factors

Formulate Effective Strategies

Communicate!!!

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