Integrating Risk Assessment into Cost Benefit Analysis:

Who pays? Who gains? And who cares?

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SCARCITY, CHOICE, AND COST

- Scarcity causes us to choose
- A choice means there is a cost
- Cost is what you had to give up

Risk = Cost

Risk of Injury
Risk to the environment
Risk of Illness
Borrow money

Benefits= reduction in costs

Prevention controls
Environmental controls
Preventive medicine
Save money


Risk Analysis
Risk Communication
Risk Assessment
Risk Manageme
Cost-Benefit Analysis


Risk Analysis
Risk Communication
Risk Assessment
Cost-Benefit Analysis
Risk Management

A risk assessment attempts to answer the following questions:

- What is the Hazard?
- Risk of what (health effects)?
- How many harmed?
- How often will it happen?
- What is causing it?
- How certain is the information you have?
- Who was involved in the estimation?
- How much risk reduced by options?

A Cost-Benefit analysis attempts to answer similar questions:

- How or where has the government or market failed?
- What will businesses and people do differently as a result of the policy choice?
- What will have to change on the cost and production side?
- What effects will the changes have on the targeted risk or risks?
- Are there risk tradeoffs that must be considered?

Who Pays? Who Gains?

Everyone at some point

- Private Costs
  - Incurred by producers and consumers
- External Costs
  - Costs to Society regardless of who pays to fix them.
- Social Costs = Private Costs + External Costs
  - Include both private and external costs to society arising from the production or consumption of a good or service.

Source: http://www.frbsf.org/education/activities/drecon/2002/0211.html

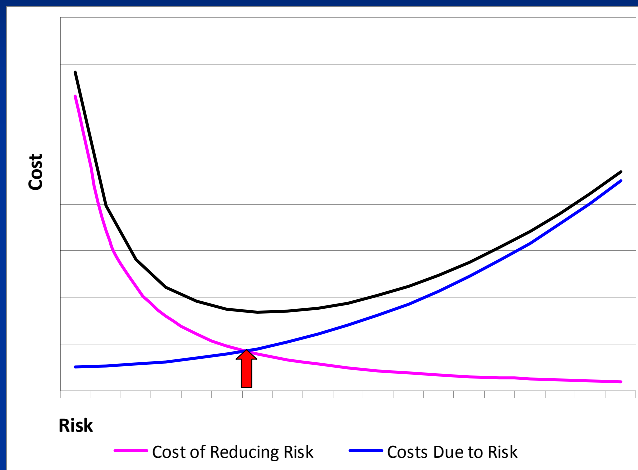
Regulatory Issues: Who cares?

Complications for risk managers arise because

- May require a multidisciplinary approach
- Uncertainty
- Some will gain - benefits
- Some will pay - costs
  - Gainers are generally more supportive than losers.
  - Payers, less supportive

Purpose of risk assessment and economic analysis is to inform risk management decisions.

Costs of risk and costs of risk reduction



Comparing Components of Risk Assessment and Cost-Benefit Analysis of Health and Safety Regulations

Risk Assessment (OMB Guidance)	Cost-Benefit Analysis (E.O. 12866)
Hazard identification	Impact identification (Government or market failure)
Dose response	Economic cause and effect (Industry practices and consumer behavior)
Exposure	Specific cause (Exogenous)
Risk characterization	Economic characterization (valuation by severity)

Source: Patty's Industrial Hygiene, Chapter 18, pp 695-826 (2011)

Economic Analyses Include:

Cost benefit analysis

- Estimate the benefits and costs of all possible regulatory alternatives
- Identify the regulatory option with the largest net benefits.

Cost effectiveness analysis

- Estimate the cost-effectiveness of each regulatory alternative.
- Identify the most cost-effective regulatory option.

Source: OMB Circular A-4

Valuation of a “Statistical” Life (VSL)

- Willingness to pay (WTP) for additional safety – what consumers (voters/taxpayers) show they will spend in their own risk decisions
- WTP for your own risk reduction depends on such factors as: aversion to risk, income, voluntary nature of the risk…

Methods of Calculating Value of Statistical Life

- Estimates of wage premiums
- Estimates of consumer choice premiums
- Contingent valuation studies
- Foregone Earnings

Wage premiums

WANTED

EVIL GENIUS seeks minions to sacrifice their lives in world domination attempt. Must be prepared to work 24-7 for fascist psychopath for no pay. Messy death inevitable but costumes and laser death rays provided. No weirdos.

Call: 1-900-MWAH-HAHA

Health Valuation challenges at FDA

- Most food related gastrointestinal illnesses are not fatal and have multiple endpoints
- Affecting mostly children and the elderly
- Needed to look beyond traditional approaches and uses for quality adjusted life years (QALYs)
- Monetizing the measures
  - Value of a statistical life divided by discounted years of life lost = $ per QALY
  - $ Acute illness = monetized QALYs + medical costs

Estimating the Burden of Foodborne Illness

- **Valuing Health Loss**
  - **Quality Adjusted Life Days (QALDs)**
    - **Using QWB and EQ-5D scale**
    - **Value of a statistical life (VSL)**
- **Doctor and hospital costs**
  - **Visits**
  - **Medication**
- **Lost productivity**
  - **Work costs**
  - **Social costs**

Valuation of Non-Fatal cases

- Needed to look beyond traditional approaches and uses for quality adjusted life years (QALYs)
- Other measures considered included
  - Quality of Well-Being Scale
  - Rosser and Kind Index
- Monetizing the measures
  - Value of a statistical life divided by discounted years of life lost = $ per QALY
  - $ Acute illness = monetized QALYs + medical costs

EQ5D Health Status Classification System

- Mobility
- Self-Care
- Usual Activities
- Pain/Discomfort
- Anxiety/Depression

- I have no problems walking about
- I have some problems walking about
- I am confined to bed

Values for QALDS and VSL

QALD value	
QALY value (Q=V/Y)	QALD value (Q/365)
$100,000	$274
$300,000	$822
$500,000	$1,370

- VSL = $5M and $7M (Viscusi and Aldy 2003)
- Average Baseline QALD Value for Population = 0.84 (IOM report 2006)

Slide credit Angela Lasher, FDA

Valuation of non fatal chronic complications

- Added chronic complications such as reactive arthritis by lengthening duration of symptoms.
- Value of chronic complications ≈

≈(QALD loss/symptom) x (days) x ($ of QALD)+ Medical Costs

- Introduced uncertainty into the QALY and $ per QALY calculations.

Example:

Illness Burden of an Outbreak: *Salmonella* Outbreak

In July of 2004, the Pennsylvania DOH investigated a *Salmonella* Javiana outbreak. Illnesses had been reported in 11 counties throughout Pennsylvania. The investigators linked the reported outbreak to Roma tomatoes sold in sandwiches, wraps, and salads. About 330 Pennsylvanians who ate the sandwiches experienced salmonellosis, and the outbreak was believed to have sickened another 80 people in nearby states.

- 410 people x 7.8 QALDs lost = 3,198 QALDs lost
- 410 people x $9193 = $3.8 million (med. $5M)

Need an Integrative Approach: Risk Assessment and Cost-Benefit Analysis

- Science
- Risk Assessment
  - Baseline Risk
  - Risk mitigation
- Change in Risk
  - Lives saved (mortality)
  - Illnesses prevented (morbidity)
- Benefit Analysis

  Benefits= Reduced Risk X Value of reduced risk

Decision making is complicated because:

- You are the problem owner and lack the expertise to solve the problem.
- Uncertainty - don't know the cause and don't know how to solve the problem
- Ambiguity – Analysts nightmare
  - belief vs. knowledge
  - Perfect world vs. reality
  - Academics vs. practitioners
  - Paradigms and prior beliefs

Problem

Uncertainty

- Decision-makers either ignore or hate uncertainty because they fear:
  - Undermining public confidence

or

  - opening regulations to legal challenges

- Fear can make decision makers put pressure on analysts to just give them number

Just give me a number!

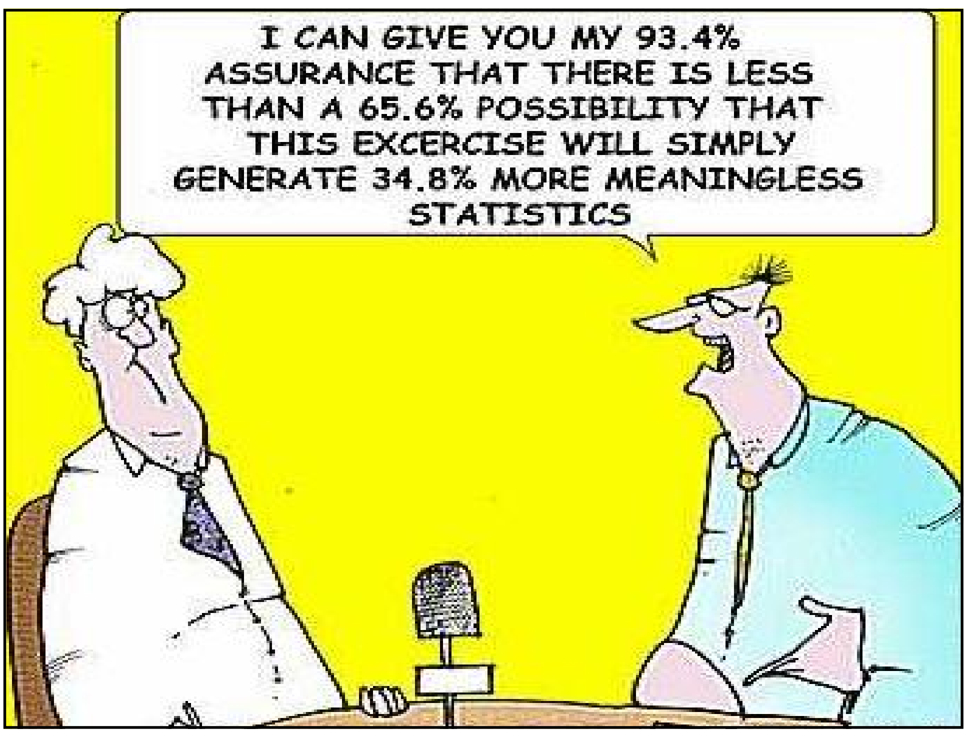
Complications in decision making arise because of different types of uncertainty

- May require a multidisciplinary approach
- Limitations of available data

Or

- Limitations of available data are not known

- Expert elicitation can reduce uncertainty in a risk assessment and economic analysis which in turn inform risk management decisions.



Problem

- How do we get from little or no data to a risk assessment to a policy decision?
- Many analytical tools can help

Analytical Tools

Given our reality some traditional tools are limited

- Sensitivity Analysis
- Decision trees
- Influence diagrams
- Engineering-economic analysis
- Multi-attribute decision making
- Probabilistic techniques
- Multi-Criteria Decision Analysis (MCDA)
- Expert Elicitation

Decision making can be made a little less complicated

- Uncertainty can be made explicit by systematically integrating expert knowledge.
- Analysts such as risk assessors and economists can combine information, analyze potential outcomes and point to optimal solutions.
- With the help of experts, analysts may have better or more data to analyze
- With the help of experts, analysts can inform decision makers
- More informed decisions lead to better decisions

OMB circular A-4

- p. 41: "In formal probabilistic assessments, expert solicitation is a useful way to fill key gaps in your ability to assess uncertainty. In general, experts can be used to quantify the probability distributions of key parameters and relationships. These solicitations, combined with other sources of data, can be combined in Monte Carlo simulations to derive a probability distribution of benefits and costs."

What is Expert Elicitation?

- It's a process used when asking experts for their opinion that helps them consider and specify their beliefs or state of knowledge about quantities that are needed in a quantitative decision analysis.

What…. ?

- Is an intensive process, driven and constrained by the mental models of the knowledge of experts
- Knowledge even from experts is more tacit than explicit, so it's more difficult to describe, examine and use.
- Expert elicitation techniques make tacit knowledge more explicit
- Expert elicitation also makes uncertainty more explicit

Unless you are Mr Spock….

- Kirk: Mr. Spock, have you accounted for the variable mass of whales and water in your time re-entry program?
  Spock: Mr. Scott cannot give me exact figures, Admiral, so... I will make a guess.
  Kirk: A guess? You, Spock? That's extraordinary.
  Spock: [*to Dr. McCoy*] I don't think he understands.
  McCoy: No, Spock. He means that he feels safer about your guesses than most other people's facts.
  Spock: Then you're saying,
  [*pause*]
  Spock: It is a compliment?
  McCoy: It is.
  Spock: Ah. Then, I will try to make the best guess I can.

Many methods used

- There are many methods used for EE
- Most popular
  - Delphi method
  - Nominal group technique
- New methods to elicit expert and collective judgment

Why should we use expert elicitation?

- Framing considerations- better than committee decisions
- We (experts and non experts alike) all have opinions, but most of us usually are not thinking about characterizing everything that interests us in the form of a probability distribution.

Another reason why

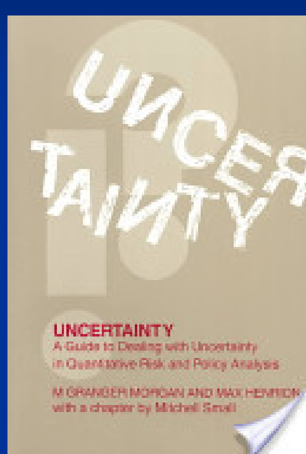
….*committees traditionally give all experts equal weight (one person, one vote). This assumes that experts are equally informed, equally proficient and free of bias. These assumptions are generally not justified.*"

-Willy Aspinal, NATURE | Vol 463 | 21 January 2010

More reasons why

- Advantages of Expert Elicitation
  - Speed in which an elicitation
  - can be conducted
  - Confidentiality
  - Anonymity
  - New technologies are helping to lower the cost of such activities while expanding the types of people who can be queried.

When should we use EE?



- P. 102"**When** the value of an uncertain quantity is needed in policy analysis, and limits in data or understanding preclude the use of conventional statistical techniques to produce probabilistic estimates about the only remaining option is to ask experts for their best professional judgment."

Expert elicitation should be implemented when

- You have a problem or risk event

AND

- additional vetted sources of information cannot adequately inform a hardware failure or human error rate.

or

- Acquiring additional vetted sources of information is not feasible (because of statutory or legal reasons, or it is too costly to obtain given the magnitude of a risk event)

When?

- An appropriate use of expert elicitation is to provide estimates on new, rare, complex, or otherwise poorly understood phenomena.
- Not a Panacea
- Not useful for addressing politically motivated problems

Need an Integrative Approach: Risk Assessment and Cost-Benefit Analysis

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- Risk Assessment
  - Baseline Risk
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Foodborne Outbreaks in the U.S. and Worldwide, 1997-2007

Contaminant Year Location	Year	Location	Number of Persons Infected	Disease Vector	Industry
International Incidents					
Salmonella	2004	MultiState USA and Canada	550+	Tomatoes	Agriculture
HAV	2004	Egypt*	351	Orange juice	Manufacturing
HAV	2005	India (Kerala)	1180	Water/sewage	Water
HAV	2006	Bulgaria	205	Water	Water
Domestic Incidents					
HAV	1997	MultiState** USA	353	Strawberries	Agriculture
HAV	2000	Minnesota	38	Undetermined restaurant food	Restaurant
HAV	2003	Pennsylvania	500+	Green onions	Agriculture
HAV	2005	California	60+	Lettuce	Agriculture
£ coli	2006	Nationwide	Not available	Spinach	Agriculture
E. coli	2006	MultiState*** USA	71 +	Lettuce	Agriculture
£ coli	2007	Nationwide recall	Not available	Lettuce	Agriculture

Source: Waterman F.A., Ibrahim J.K., March, 2009 JEH

Recent History of Salmonella Outbreaks Associated with Tomatoes

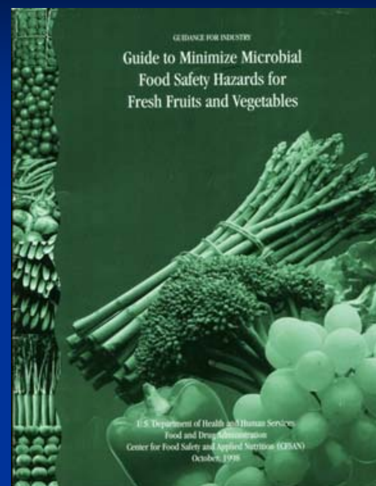
Year	*Salmonella serotype*	*Number of cases*
1998	*S. Baildon*	*86 cases*
2000	*S. Thompson*	*29 cases*
	S. Newport	*512 cases*
2002	*S. Newport*	*12 cases*
	S. Javiana	*90 cases*
	S. Javiana	*471 cases*
2004	*S. Braenderup*	*123 cases*
	S. Newport	*71 cases*
2005	*S. Enteriditis*	*77 cases*
	S. Braenderup	*76 cases*
2006	*S. Newport*	*107 cases*
2007	*S. Typhimurium*	*186 cases*

Source: Keys, 2007

Problem

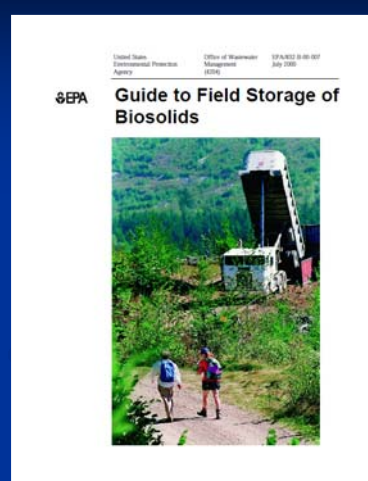
- No "kill step" exists for *Salmonella* in fresh produce
- Prevention of contamination is only solution
- Contamination can occur via
  - Animals
  - Water
  - Workers
  - Processing

Guidance for Industry: Guide To Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables



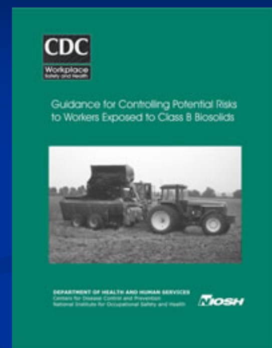
FDA
October, 1998

Guide To Field Storage of Biosolids and Other Organic By-Products Used in Agriculture and for Soil Resource Management



EPA/832-B-00-007
July, 2000

Guidance For Controlling Potential Risks To Workers Exposed to Class B Biosolids

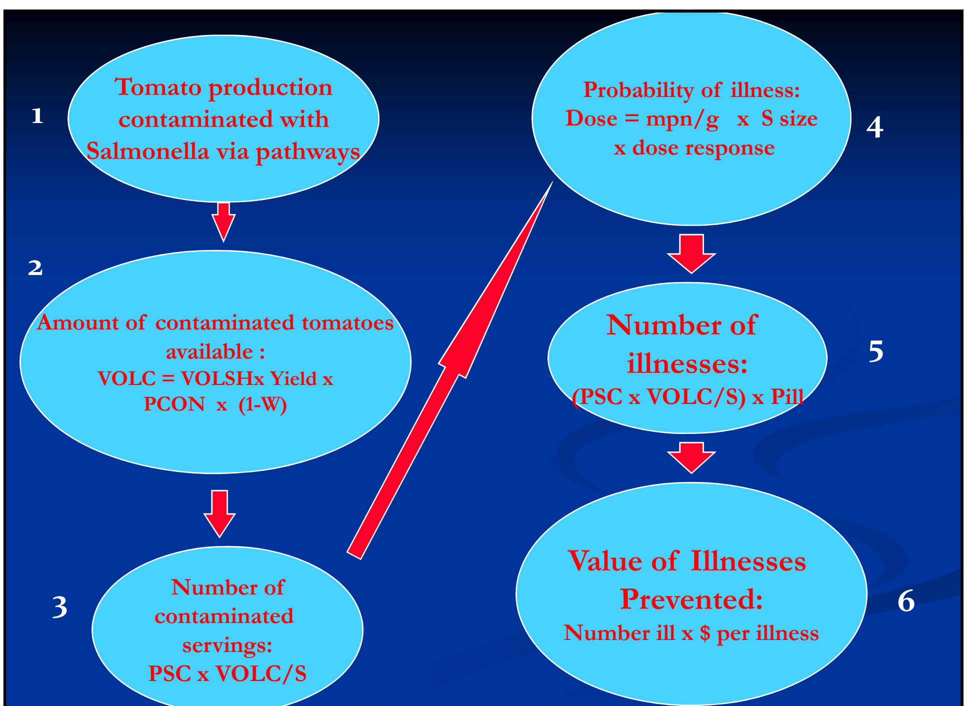


DHHS (NIOSH) Publications
Number 2002-149
July 2002

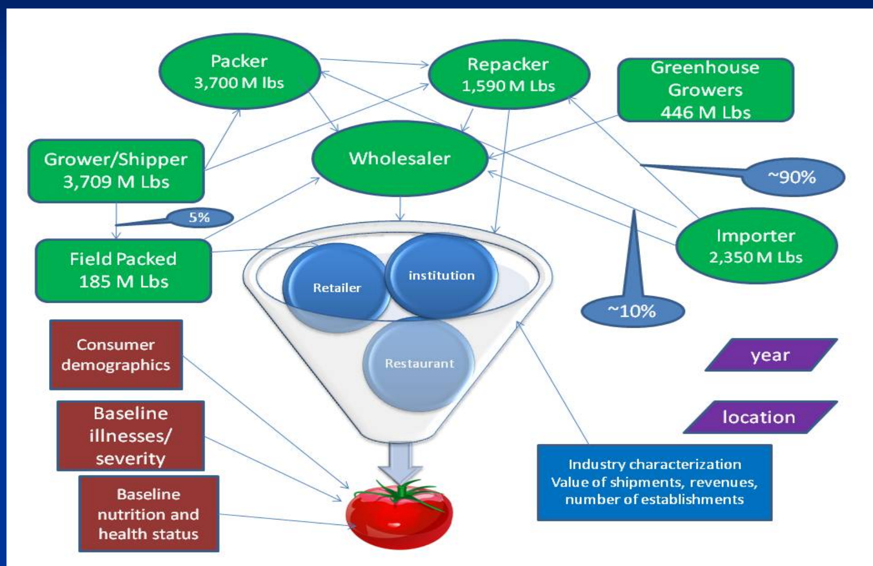
Comparing Components of Risk Assessment and Cost-Benefit Analysis of Health and Safety Regulations

Risk Assessment	**Cost-Benefit Analysis** **(E.O. 12866)**
Hazard identification	Impact identification (Government or market failure)
Dose response	Economic cause and effect (Industry practices and consumer behavior)
Exposure	**Specific cause (Pathways in the supply chain)**
Risk characterization	Economic characterization (valuation by severity)

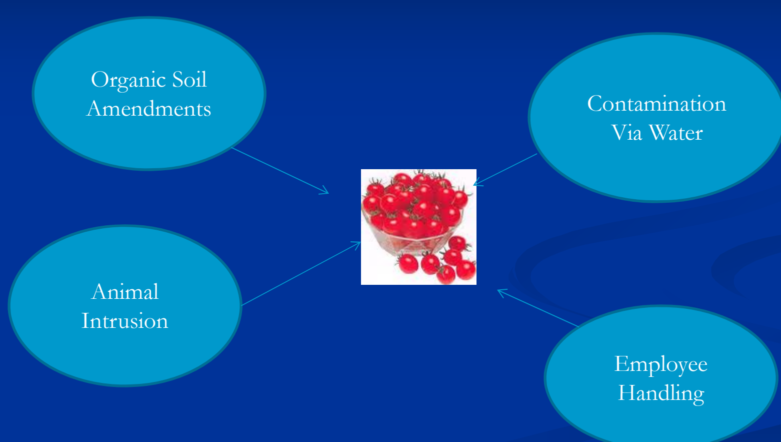
Fresh Tomato Pathways From Grower to Consumer



Fresh Tomato Pathways From Grower to Consumer



Pathways for Salmonella Contamination in Tomatoes



Problem

- No "kill step" exists for *Salmonella* in fresh produce
- Prevention of contamination is only solution
- Contamination can occur via

1 Animals	1 Water	1 Workers	1 …
2 Water	2 Processing	2 Equipment	2 …
3 Workers	3 Equipment	3 Animals	3 …
4 Processing	4 Workers	4 Equipment	4 …
5 Equipment	5 Animals	5 Water	5 …
6 Other?	6 …	6 …	6
…			

Study by Eastern Research Group (ERG):

Effectiveness of Pre- & Post Harvest Practices in Reducing *Salmonella* Contamination Risk in Fresh and Fresh-Cut Tomatoes

Study Goals

- Identify greatest contributors to contamination risk in fresh and fresh-cut tomatoes
- Identify and assess effectiveness of control interventions most likely to substantially reduce the incidence of *Salmonella*

Slide credit: Aylin Sertkaya, ERG

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Elicitation Methodology

- Modified Delphi technique
  - Panel of experts
  - Expert interaction through moderator
  - Iterative approach to eliciting opinion

Step 1: Questionnaire Design

Step 2: Pilot Elicitation

Step 3: Full-scale Elicitation

Step 4: QA/QC of Data

Step 5: Follow-up Elicitation

Slide credit: Aylin Sertkaya, ERG

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Expert Selection

- 6-member panel
- Selection criteria
  - Conflict of interest
  - Qualifications
  - Availability/willingness
- Expert identification
  - FDA recommendations
  - Recommendation by other experts
  - Literature review - *Salmonella*, tomato production, etc.
  - Citation analysis

Composition of the Expert Panel

Panel Member Type	Count
Academic Researcher	2
Agricultural Ext. Specialist	2
Grower	1
FDA Researcher	1
Total	**6**

Slide credit: Aylin Sertkaya, ERG

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Sample Elicitation Form

53 such worksheets
191 scenarios total

Using the sliders provided, please compare the relative riskiness of each of the **PRE-PLANTING IRRIGATION** scenarios below in relation to the baseline scenario noted in dark gray. If you feel the scenario you are evaluating increases the risk of *Salmonella* contamination, survival, or growth compared to the baseline risk, please adjust the location of the slider to the right. If you feel the scenario decreases the risk, please adjust the location of the slider to the left. The larger the increase or decrease, the farther away you should move the slide from the baseline. Please consider only the risk associated with each scenario, and not the likelihood that a scenario will occur. If we have not included a factor that you think affects a scenario's relative risk, please take into account the possibility that it may or may not be present. Please also take into account the way a scenario may both increase and decrease risk.

Pre-Planting Irrigation Water Source	Treated to Control Microbial Levels	Lower Risk ← Baseline Risk ↓ Higher Risk →
Flowing surface water	Treated	
Flowing surface water	Untreated	
Still surface water	Treated	
Still surface water	Untreated	
Shallow well water	N/A	
Deep well water	N/A	
Secondary-treated reclaimed wastewater	N/A	
Tertiary-treated reclaimed wastewater	N/A	
Untreated irrigation runoff water	N/A	
Potable water, filtered or unfiltered	N/A	

Please share any comments you may have about this page:

Arbitrarily chosen baseline scenario

Corresponding scale numbers deliberately hidden

N/A = Not applicable
Properly treated includes water that has been tested and treated when necessary.
Not properly treated includes water that has not been tested, or has been tested but not treated when necessary.
Still surface water includes ponds and reservoirs.
Flowing surface water includes rivers, canals, irrigation ditches, etc.
A deep well is a well that is 100 ft. deep or deeper. A shallow well is less than 100 ft. deep.

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Combining Expert Judgments

- Mathematical aggregation
  - No way to objectively assign "weights" to experts' responses
  - All experts viewed as being equally qualified to respond to questions
  - Simple average of relative risk scores across the 6 experts

Slide credit: Aylin Sertkaya, ERG

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Determining "Effective" Practices

- Assumed tomato production is equally distributed across all scenarios for activity/condition, j, in a production stage, i, i.e.:

$$s_{11} = s_{12} = \ldots = s_{1m_{ij}}$$

- Computed baseline relative risk score for production stage, i, as:

$$r_i^0 = \sum_{k=1}^{m_{i1}} \left(s_{1k} \times r_{1k}^0\right) \sum_{k=1}^{m_{i2}} \left(s_{2k} \times r_{2k}^0\right) \ldots \sum_{k=1}^{m_{in}} \left(s_{jk} \times r_{jk}^0\right)$$

- Computed effect of implementing a scenario associated with an activity/condition *j* in production stage *i* on relative risk as:

$$r_i' = \sum_{k=1}^{m_{i1}} \left(s_{1k} \times r_{1k}'\right) \sum_{k=1}^{m_{i2}} \left(s_{2k} \times r_{2k}'\right) \ldots \sum_{k=1}^{m_{in}} \left(s_{jk} \times r_{jk}'\right)$$

- Computed % reduction in relative risk at the production stage *i* from implementing the scenario as: $\Delta = 1 - \frac{r_i'}{r_i^0}$

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Practices Most Likely to Reduce Risk

- Stage 1 – Growing
  - Use of potable water for spray treatments
  - Use of potable water for irrigation
- Stage 2 – Harvest
  - Providing personal hygiene training to all employees
  - Having bathroom monitors at latrines
- Stage 3 – Packing
  - Daily sanitation of packing equipment in a closed-sided facility
  - Use of potable water for wet dump tanks
- Stage 4 – Fresh-cut processing
  - Monitoring processing equipment for microbial counts
  - Providing personal hygiene training to all employees
- Stage 5 – Transportation and storage
  - Use of dedicated trucks for transport
  - Storing produce below 41°F (5°C) for less than 5 days

Slide credit: Aylin Sertkaya, ERG

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Lessons Learned

- Provided data unavailable elsewhere
- Comparing scenarios' impact on risk better drew on experts' knowledge than prompting for direct probabilities would have
- Experts' knowledge limited to their own experience and understanding of existing studies
- Degree to which scenario scores moved away from baseline varied among the experts
- Trade-off existed between providing scenarios simple enough to rank and fully capturing the complexity of tomato production activities

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Effectiveness of Harvest Stage Practices in Reducing Contamination Risk in Tomatoes Contamination Risk in Tomatoes Salmonella

Activity/Condition	Scenario	Relative Reduction in Production Stage Baseline Risk
Personal hygiene training for employees involved in harvesting	Provided to all employees involved in harvest	38.25%
Presence of bathroom monitors present at lattrines used by employees invovled in harvesting	Monitors are Present	29.59%
Frequency of harvest bins and totes sanitation	Daily	25.62%
Distance to latrines used by employees involved in harvesting	5-minute walk or less	19.03%
Use of protective barriers between crates used in harvest	Barriers between stackable crates are separated by liners or other protective barriers	16.73%

Source: ERG, 2009

Questions?