

# The Consumers' Role in Risk Assessment

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Interest

European Food Safety Authority  
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David Byrne, Oct. 21, 2004:

I BELIEVE EU CONSUMER  
POLICY SHOULD FOCUS  
ON THE BROAD  
OBJECTIVE OF PUTTING  
CONSUMERS AT THE  
HEART OF EUROPE. . .

# Forums for Consumer Participation in the U.S. Food Policy Making

- ❖ **Citizen petitions** – set forth risk management options for government agencies
- ❖ **Public comment periods** – public review of regulatory activities of agencies
- ❖ **Public meetings** – opportunities to question public officials

# Social and Cultural Questions in Risk Assessment

- ❖ Ethical considerations and socio-cultural issues may have more of a role within risk management and risk communication
- ❖ However, risk assessments are shaped by risk management options, i.e. irradiation and *E.coli* O157:H7

# Transparency and Quality

- ❖ Transparency

Transparency and consumer involvement are critical, but undue delays should be avoided

- ❖ Quality of scientific advice

OMB “objectivity” standard requires peer-review which is good practice, but slows risk assessment process down

# Consumer Stakeholders Can Play an Important Role in Risk Assessments

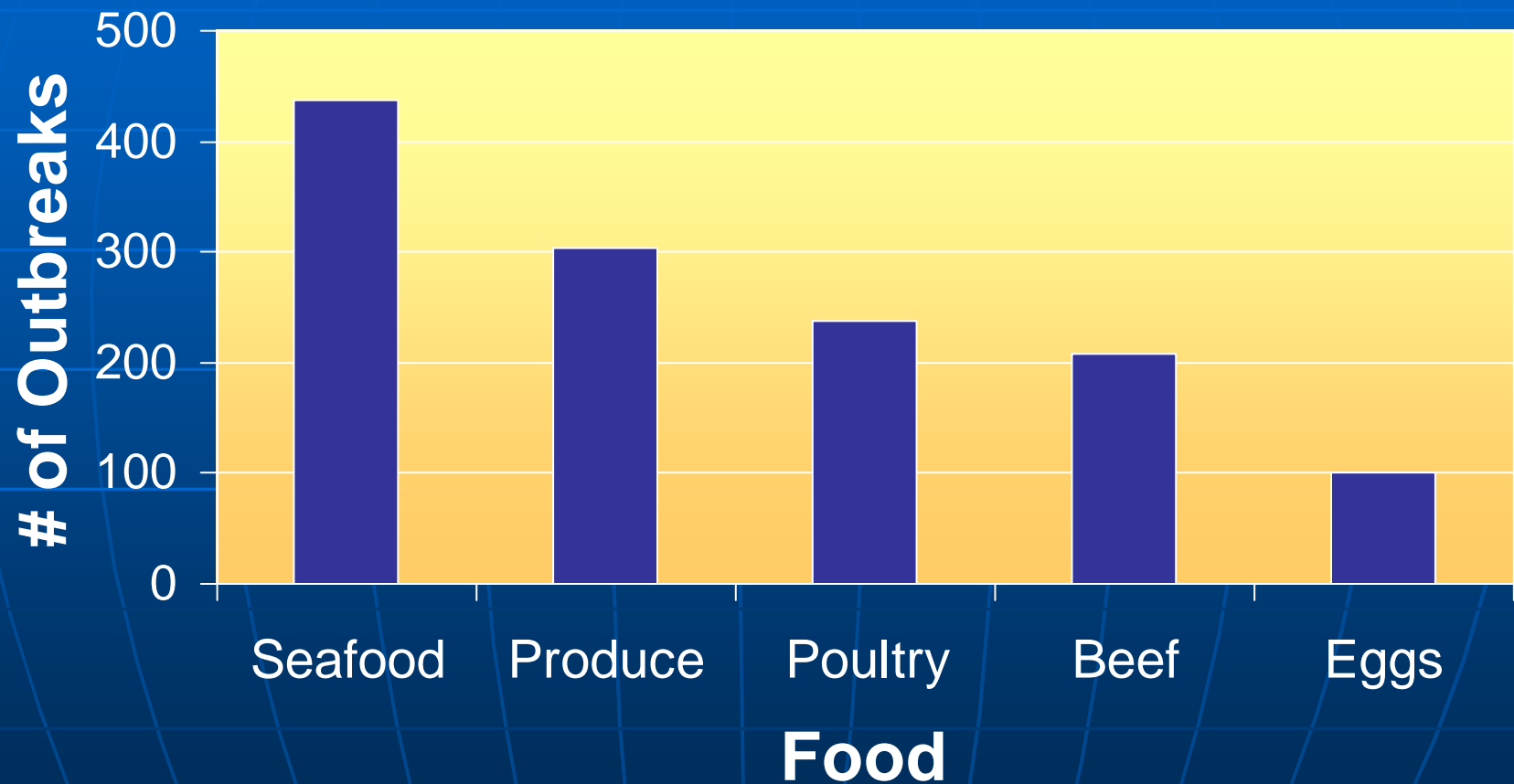
- Ensure the right questions are asked, incorporating the social and cultural issues as well as common sense risk management options
- Advocate for minimizing delays in risk management
- Provide unique data

# Unique Data

CSPI tracks food-borne illness outbreaks with the *Outbreak Alert!* database

- ❖ Contains over 4,000 outbreaks with both known food source and known etiology which occurred in the U.S. between 1990-2002
- ❖ Only source for outbreaks linked to specific foods, as well as specific pathogens
- ❖ Outbreaks are grouped according to US regulatory agency and placed in one of 13 food categories

# Top Five Single-Food Vehicles of Outbreaks, 1997-2001





# The Outbreak Alert! Database

- ❖ Alerts consumers to food safety hazards
- ❖ Gives policy makers and public-health officials information needed to identify disease trends
- ❖ Helps legislators set goals and priorities for food safety

# The Outbreak Alert! Database

- ❖ Contains the outbreak data from CDC, confirmed news reports, scientific journals, government reports and other sources
- ❖ Represents only about 25% to 30% of reported foodborne outbreaks (others include unknown food or pathogens)
- ❖ Represents only a small percentage of actual food-borne illnesses

# Example: *E. Coli* O157:H7

## USDA 2001 Draft Risk Assessment

	USDA <sup>1</sup>		CSPI	
	Outbreaks	Cases	Outbreaks	Cases
Due to GROUND BEEF	44	418	51	521
Due to a FOOD vehicle	88	1,957	116	2,423
Due to any identified vehicle	146	3,773	--	--

<sup>1</sup>From: *Escherichia coli* O157:H7 Risk Assessment Team, *Draft Risk Assessment of the Public Health Impact of Escherichia coli* O157:H7 in Ground Beef (Sept 2001)

## *E. coli* O157:H7 due to GROUND BEEF

Data Source	Outbreaks	Cases
USDA (All vehicles)	44/146=30%	418/3773=11%
USDA (Food vehicles)	44/88=50%	418/1957=21%
CSPI <sup>2</sup> (Food vehicles)	51/116=44%	521/2423=21%

<sup>2</sup> 6% of CSPI *E. coli* O157:H7 outbreak data from non-CDC sources

# Are Risk Assessments Asking the Right Questions?

ARE RISK ASSESSMENTS FOCUSED  
ON:

- ❖ PUBLIC HEALTH OUTCOMES?
- ❖ COMMON SENSE and CULTURALLY  
ACCEPTED SOLUTIONS?

# Example: EGG SAFETY

- ❖ In 1997, CSPI petitioned FDA to require on-farm SE control programs AND diversion of eggs from infected flocks: COMMON SENSE SOLUTION SUPPORTED BY EMPIRICAL DATA
- ❖ In 1998, a joint FDA/USDA SE Risk Assessment concluded that diversion of eggs from SE-infected flocks was one of the most effective SE control programs: Diversion of 25% of all eggs from SE-positive flocks resulted in a predicted 25% reduction of SE cases
- ❖ This risk assessment was out-of-date before any risk management action was taken!

# Advocating a Speedy Process

- ❖ Risk assessment SHOULD NOT DELAY risk management activities
- ❖ Better to make an imperfect RM decision which can be amended, than to delay all action until a comprehensive RA is completed
- ❖ Delays could result in UNNECESSARY DEATHS

# Example: EGG SAFETY

- ❖ The 1998 risk assessment supported on-farm sanitation and egg diversion programs
- ❖ 2004 FDA proposed a regulation to require SE control programs and diversion of eggs, BUT the rule cited dramatically different estimates of human illness
- ❖ The same month, USDA released a new draft risk assessment for egg products



# What did we get?

- ❖ SIX more years of illnesses and deaths from SE in eggs
- ❖ Competing illness estimates for SE:
  - 1998 FDA/USDA Risk Assessment
    - 660,000 SE illnesses
  - 2004 FDA Proposed Rule
    - 118,000 SE illnesses
  - 2004 USDA Risk Assessment
    - 350,000 SE illnesses
- ❖ Duplicative risk assessments

CONSUMERS JUST WANT SAFER EGGS!

# *Listeria* in Ready-to-Eat Meats

- ❖ A 1998 outbreak from ready-to-eat meats caused over 100 consumers to become ill, 15 died and 6 women had miscarriages
- ❖ BUT despite the urgency, USDA delayed taking mandatory risk management action until a risk assessment was complete, as required by law

## *Listeria* (continued)

- ❖ A risk ranking for LM in all foods was initiated by FDA in 2001 and completed in 2003
- ❖ USDA conducted a separate risk assessment on ready-to-eat (RTE) meats, completed in 2003  
(WHY DO WE NEED A RISK ASSESSMENT WHEN WE KNOW THESE PRODUCTS ARE KILLING PEOPLE?)
- ❖ While we waited, small LM outbreaks continued. In 2002, a large multi-state LM outbreak from ready-to-eat meats caused over 120 illnesses, including 13 deaths and 3 miscarriages
- ❖ USDA's final *Listeria* regulation was completed in 2003

# What did we get?

## CSPI's Press Release

"After five years of waiting, the Bush administration today issued a near-final regulation requiring hot dog and ready-to-eat meat processors to test their plants for the presence of *Listeria*. But without a minimum requirement for testing, the rule has no minimum guarantee of consumer protection."

"Despite two major risk assessments, USDA claims it doesn't have enough science to mandate minimum testing requirements for both meat plants and their products. Consumer protection against *Listeria* has been delayed for years and consumers have suffered serious harm."

# The Role of Stakeholders in Risk Communication

- ❖ Media wants an independent source

- ❖ Crisis situations:

CSPI's advice on which meat products to avoid following finding of BSE in the U.S. was carried widely in the New York Times, USA Today, Washington Post, and many local newspapers around the country

# Conclusions

- ❖ Consumer organizations can help shape risk assessments by ensuring that risk assessment focuses on common-sense risk management options
- ❖ Risk management decisions should not wait for completion of the risk assessment
- ❖ Given limited resources, many consumer organizations may choose to focus on developing risk management strategies and participating in risk communication activities rather than risk assessments

# Outbreak Alert!



Closing the Gaps in  
Our Federal Food-Safety Net

Center for Science in the Public Interest  
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Available on the web at [www.cspinet.org](http://www.cspinet.org)