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# **An Analysis of FSIS Statistical Practices Regarding Foodborne Pathogens**

**CSPI Integrity in Science Conference**

**July 12, 2004**

**Washington, DC**

**Michael Kowalcyk**

**Safe Tables Our Priority**



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## Our Family's Story



Kevin Michael Kowalcyk, age 2 1/2

12/10/98 - 8/11/01



## We Are Not Alone

According to the CDC, an estimated:

- **76 million** Americans are sickened
- **325,000** Americans are hospitalized
- **5,000** Americans die

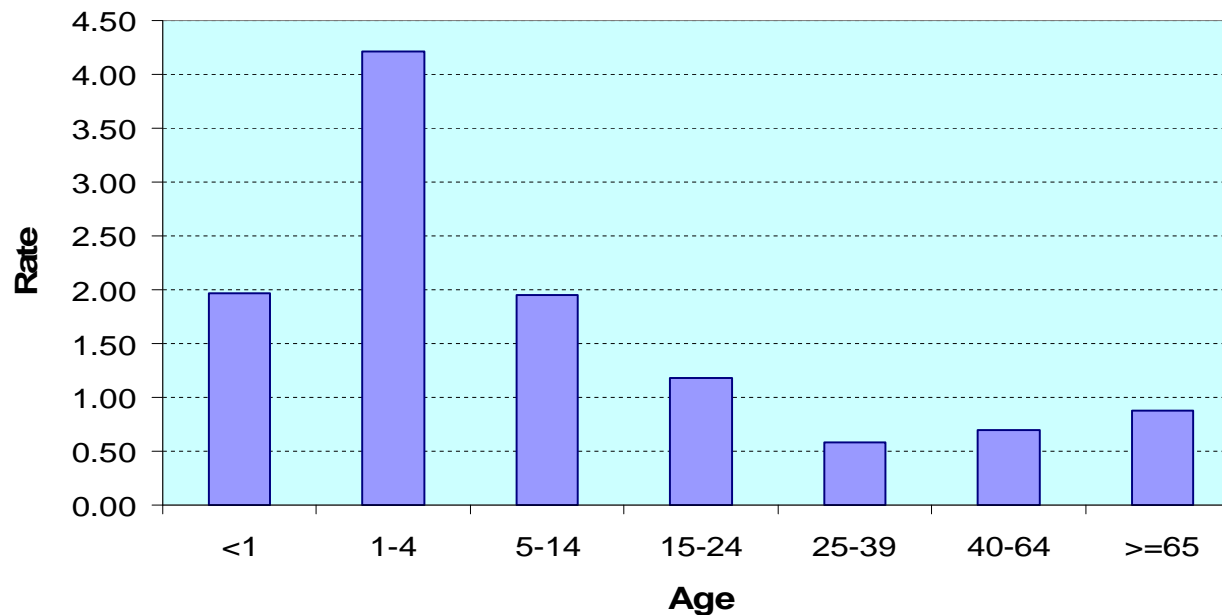
annually from preventable food-borne illnesses.



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## This is a Children's Health Issue

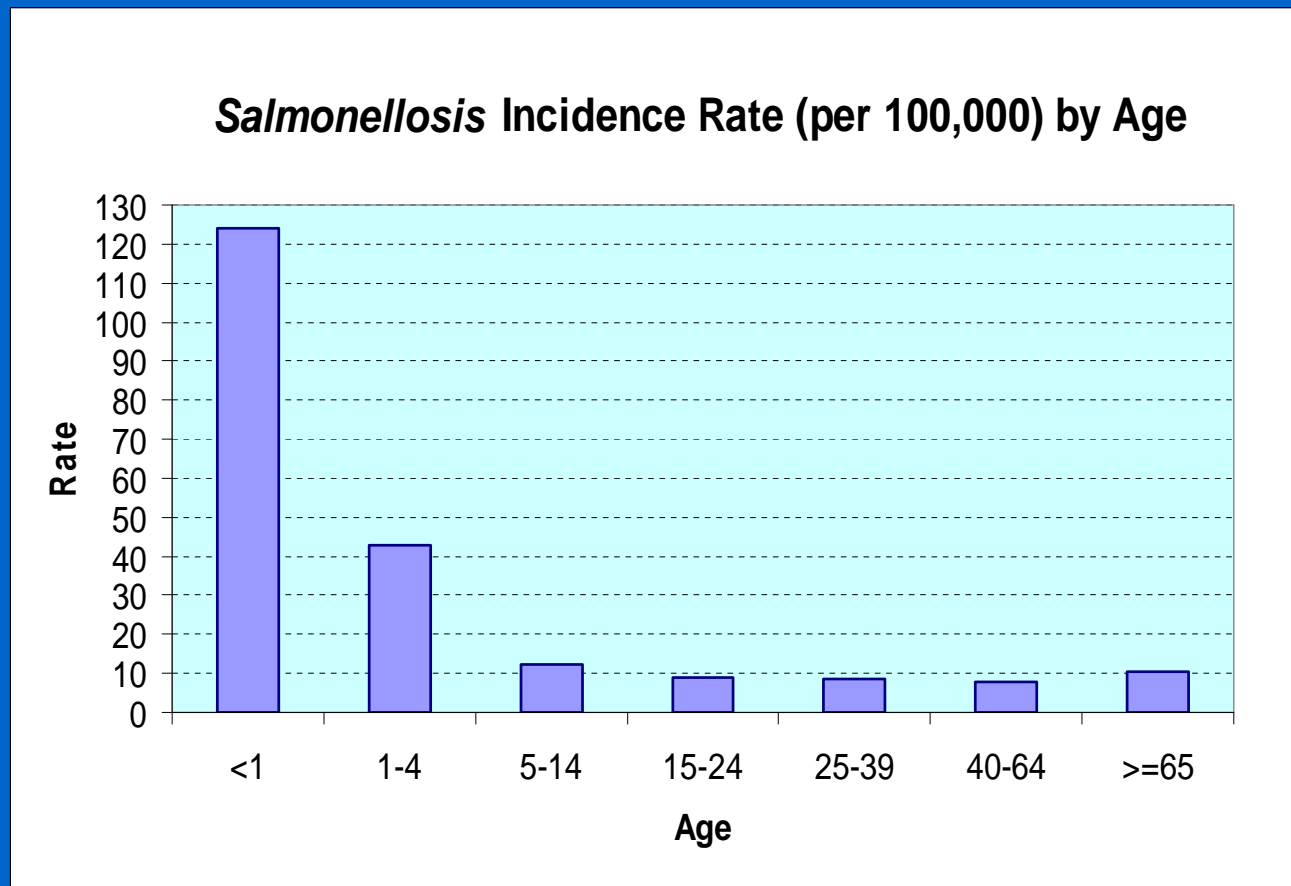
***E. coli* O157:H7 Incidence Rate (per 100,000)  
by Age**



Source: Centers for Disease Control and Prevention.

Summary of notifiable diseases, United States, 2001. MMWR 2001;50(No. 53):14-15.

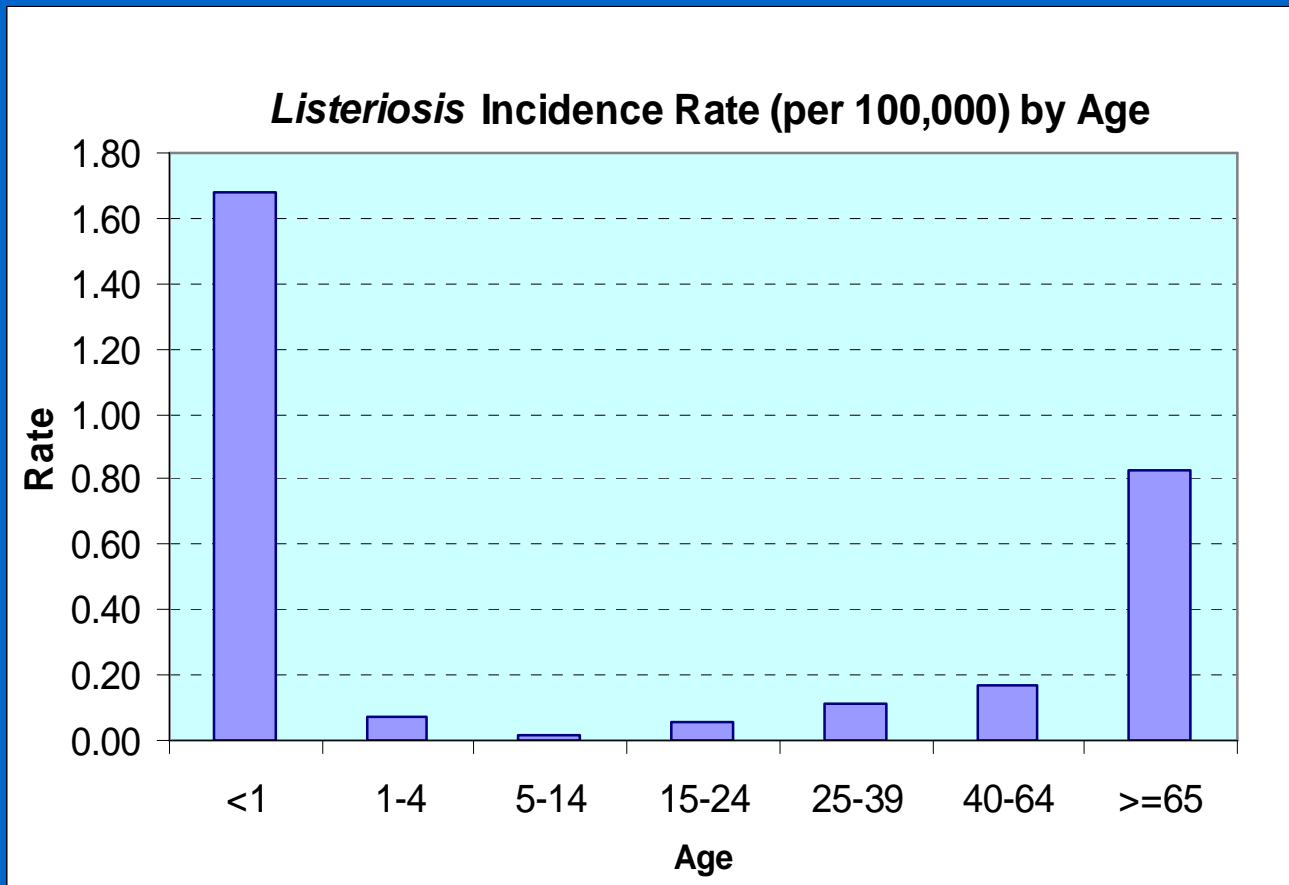
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## Economic Costs Are Significant

USDA's Economic Research Service (ERS) estimates that *Campylobacter*, *Salmonella*, *E.coli* O157:H7, *Listeria monocytogenes* and *Toxoplasma gondii* cause **\$6.9 billion** in medical costs, lost productivity, and premature deaths in the United States each year.

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# Hazard Analysis and Critical Control Points (HACCP)

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## HACCP Final Rule

### General Overview of the Comments and the Final Rule

9CFR Part 304, et al; 7/25/96; Part II, p. 38812

*“Pathogen-specific performance standards for raw products are an essential component of the FSIS food safety strategy because they provide a direct measure of progress in controlling and reducing the most significant hazards associated with raw meat and poultry products. The Salmonella standards being established in this final rule, which are based on the current national baseline prevalence of Salmonella (expressed as a percentage of contaminated carcasses), are a first step in what FSIS expects to be a broader reliance in the future on pathogen-specific performance standards. FSIS plans to repeat its baseline surveys and collect substantial additional data through other means and, on that basis, adjust the Salmonella performance standards and possibly set standards for additional pathogens, as appropriate.... Future FSIS efforts on such performance standards will reflect the fact that achieving the food safety goal of reducing foodborne illness to the maximum extent possible will require continuous efforts and improvement over a substantial period.”*

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# USDA Testing Programs for Foodborne Pathogens

- Microbiological Baseline Surveys (pre-HACCP)
- HACCP Verification Testing Program

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# Microbiological Baseline Surveys



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## Microbiological Baseline Surveys

Designed to provide national prevalences and levels of selected microorganisms in following products:

Broiler Chickens

Market Hogs

Turkeys

Cows/Bulls

Steers/Heifers

Ground Beef

Ground Chicken

Ground Turkey

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## Microbiological Baseline Surveys

Following pathogens were targeted:

- *Clostridium perfringens*
- *Staphylococcus aureus*
- *Listeria monocytogenes*
- *Campylobacter jejuni*
- *E. coli* O157:H7
- *Salmonella*

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## Microbiological Baseline Surveys

- Used to establish performance standards
- Performance standards are selected so that there is 80% probability that plants operating at an acceptable level will have test results showing that.
- Methods are outlined in *Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper (FSIS, 1998)*

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## Microbiological Baseline Surveys

*“Because of the importance of the baseline data, the committee recommends that a new baseline survey be conducted on a periodic basis to evaluate the microbiological status of carcass, trim, ground product, and ready-to-eat products, both at the site of production and at retail. It is important that data for this new baseline be collected in such a way as to address two concerns.*

*First, it should be possible to compare the results of the new baseline to the old baseline to determine if the situation is improving, worsening or remain unchanged.*

*Second, the new baseline should be as representative and statistically valid as possible and should correct sampling deficiencies that were present in the first baseline study.”*

Scientific Criteria to Ensure Safe Food, National Academies Press, 2003

Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food  
Food and Nutrition Board, Board on Agriculture and Natural Resources,  
Institute of Medicine, National Research Council of the National Academies



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# HACCP Verification

## Testing Programs

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# HACCP Verification Testing Program

*Salmonella*

*E. coli* O157:H7

*Listeria monocytogenes*

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# HACCP Verification Testing Program

## Background

- Regulatory in nature
- Designed to track establishment performance
- Not statistically designed
- Different establishments may be sampled from year to year
- Prevalences represent unweighted test results from sampled establishments



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## *Salmonella* Verification Testing Program

The prevalence data reported here for *Salmonella* in raw meat and poultry products have certain limitations that restrict the range of valid statistical inferences. The PR/HACCP verification testing program is strictly regulatory in nature and was designed to track establishment performance rather than to estimate nationwide prevalence of *Salmonella* in products. Because the program is not statistically designed, different establishments may be sampled from year to year, confounding rigorous trend analyses. Furthermore, it is important to note that the prevalence estimates computed from the FSIS's pre-HACCP baseline studies and surveys were nationally representative because they were weighted on the basis of the production volume of the sampled establishments. In contrast, the PR/HACCP *Salmonella* prevalences from the regulatory testing program reported here represent unweighted test results from sampled establishments.

Progress Report on *Salmonella* Testing of Raw Meat and Poultry Products, 1998-2002  
US Department of Agriculture

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## *Listeria* Verification Testing Program

The data presented here are from regulatory testing programs that change from year to year and even within years and thus any comparisons should be made with caution. The findings are referred to as prevalence data in that they are presented in terms of the percentage of regulatory samples that are found to be positive. These programs have not been designed to test for statistically significant change from one year to the next. The aggregate data do, however, provide an overall indication of trends.....

None of the RTE sampling programs, either before or after December 2000, were designed to provide statistical estimates of national product prevalence. These programs do, however, provide an indicator of whether pathogen prevalence is increasing or decreasing across different product categories.

Microbiological Testing Programs for Ready-to-Eat (RTE) Meat and Poultry Products  
US Department of Agriculture



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## HACCP Verification Testing Program

*“FSIS’ current random nationwide sampling of plants for the presence of E. coli O157:H7 does not verify the effectiveness of HACCP systems and does not measure the extent of a hazard.”*

Semiannual Report to Congress, FY 2003 – Second Half  
USDA Office of Inspector General

## ***E. Coli O157:H7 Verification Testing Program***

*“FSIS’ E. coli O157:H7 testing program cannot be used to measure the effectiveness of HACCP on either a company or a nationwide basis. The sampling program, as designed, does not provide scientific, risk-based data to measure the extent of an existing hazard. The data that is produced does not reflect industry performance because*

- a) plants like ConAgra, that performed their own E. coli O157:H7 testing on carcasses were exempt from sampling of ground beef,*
- b) sampling plans do not take into account all relevant plant operational or processing factors, and*
- c) samples taken at the plants that are selected are not always representative of the lot of production or final product.”*

Food Safety and Inspection Service Oversight of Production Process and Recall at ConAgra Plant (Establishment 969)

Report No. 24601-2-KC, September 2003

USDA Office of Inspector General Great Plains Region Audit Report

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**Is USDA using**  
**good scientific practices**  
**in collecting and presenting data**  
**in regard to their testing programs**  
**for foodborne pathogens?**

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## FSIS Sampling for Ground Beef Shows *E. coli* O157:H7 Downward Trend

WASHINGTON, Sept. 17, 2003 – The U.S. Department of Agriculture’s Food Safety and Inspection Service today released data showing a drop in the number of *E. coli* O157:H7 positive samples in ground beef collected to date in 2003 compared with past years.

Of the samples collected and analyzed through Aug. 31, 0.32 percent tested positive for *E. coli* O157:H7, down from 0.78 in 2002 and 0.84 in 2001.....

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## *Listeria* in FSIS Ready-To-Eat Products Shows Significant Decline

WASHINGTON, Oct. 17, 2003 – The U.S. Department of Agriculture’s Food Safety and Inspection Service today released data showing a one year, 25 percent drop in the percentage of positive *Listeria Monocytogenes* samples and a 70 percent decline compared with years prior to the implementation of the Hazard Analysis and Critical Control Points (HACCP) system.

Of the random samples collected and analyzed between Jan. 1 and Sept. 30, 2003, 0.75 percent tested positive for *Listeria monocytogenes*, compared with 1.03 percent in 2002; 1.32 percent in 2001; 1.45 in 2000; 1.91 percent in 1999; 2.54 percent in 1998; 2.25 percent in 1997; 2.91 percent in 1996 and 3.02 in 1995.....

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## Tests Show Salmonella in Meat and Poultry Products Declines 66 Percent

WASHINGTON, Nov. 24, 2003 – Agriculture Secretary Ann M. Veneman today announced that the rate of *Salmonella* in raw meat and poultry dropped by 66 percent over the past six years and by 16 percent compared with 2002.....

Of the random samples collected and analyzed between Jan. 1 and Oct. 31, 2003 by FSIS, 3.6 percent tested positive for *Salmonella*, as compared with 4.29 percent in 2002; 5.03 percent in 2001; 5.31 percent in 2000; 7.26 percent in 1999 and 10.65 percent in 1998....

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## Answer: NO

- Using incomplete data in comparisons
- Presenting unweighted “prevalences”
- Making inappropriate comparisons
- Do not provide appropriate caveats in presenting data

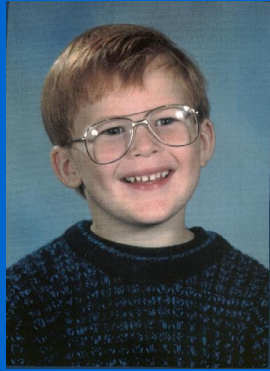
## CONCLUSION

USDA is not presenting data in a transparent manner and is not using good scientific practices.

# The Faces of Foodborne Illness



Lauren Rudolph  
Died, Age 6  
*E.coli* O157:H7



Alex Donley  
Died, Age 6  
*E.coli* O157:H7



Brianne Kriefall  
Died, Age 3  
*E.coli* O157:H7



Kevin Kowalcyk  
Died, Age 2  
*E.coli* O157:H7



Nicole Westman  
Died, Age 3  
*E.coli* O157:H7



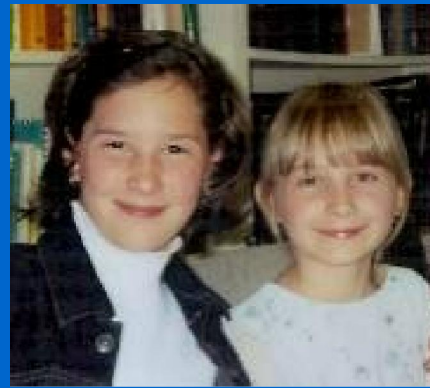
Brooke Fisher  
Died, Age 2  
*E.coli* O157:H7



Pam & Louise Berger  
*Listeria* Victim



Julia Capriotti  
*Listeria* Victim



Elizabeth Tikitri & Jordan Keane  
*E.coli* O157:H7 Victims



Ryan McIntosh  
*E.coli* O157:H7 Victim



Aimee Ermil  
*E.coli* O157:H7 Victim