



Measuring the benefits and costs of FDA food safety regulations: 15 years of experience

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Federal Institutional Requirements for Economic Analysis

- Identify Need for Regulation
- Identify Regulatory Options
- Estimate Costs and Benefits of Options

Elements of Good Regulatory Analysis

- Public health problem
 - baseline impact of hazard
 - baseline practices that potentially contribute to or mitigate the problem
- Why regulation is the best way to address the problem
- Regulatory options for addressing the problem
- Specific changes in behavior of all affected
- Costs of changes in behavior
- Effectiveness of changes in behavior
- Value of the reduction in the public health problem
- Variability and uncertainty in estimates

Use Numbers

- Work hard to quantify everything
- Monetize benefits
- Quantitatively characterize variability and uncertainty
- “If it is not quantified, it doesn’t count.”



Seafood HACCP (1995)

- Quality control system applied to all seafood sold in the US
- Baseline annual illnesses: 114,000
- First year costs: \$69 million - \$162 million
- Fourth year costs: \$38 million - \$80 million
- First year benefits: \$73 million - \$108 million
- Fourth year benefits: \$87 million - \$158 million
- Annual illnesses prevented: 20,000 – 59,000



Iron Supplements (1997)

- Warning statements for supplements containing iron and unit-dose packaging for supplements 30+mg iron per dosage
- Baseline annual illnesses: 300
- First year costs: \$54 million
- Recurring costs: \$5 million
- Annual benefits: \$25 million – \$54 million
- Annual illnesses prevented: 300



Juice HACCP (2001)

- Quality control system applied to all juice sold in the US
- Baseline annual illnesses: 9,000
- First year costs: \$34 million - \$58 million
- Recurring costs: \$22 million
- Annual benefits: \$126 million
- Annual illnesses prevented: 6,000



Egg Processing (2009)

- Processing controls for shell eggs sold in the US produced by farms with over 3,000 layers
- Baseline annual illnesses: 142,000 (69,000 – 273,000)
- First year costs: \$88 million
- Fourth year costs: \$81 million (\$58 – \$117 million)
- First year benefits: \$1,231 million
- Fourth year benefits: \$1,417 million (\$228 – \$9,472 million)
- Annual illnesses prevented: 79,000 (30,000 – 191,000)



Value of Regulatory Analyses in WTO Issues

- Public health need is clearly identified
- Value of protecting citizens is compared with the cost of protection
- Options are explored for finding least cost means of protection
- All geographic locations are considered equally in identifying options and estimating costs



Important Capabilities

- Regulatory analysts trained in Economics
- Data to estimate foodborne illness
- Data to estimate affected entities
- Analyst access to
 - epidemiologists
 - food technologists
 - laboratory scientists



Resources

- Adler, M.D., “**QALYs and Policy Evaluation: A New Perspective**”, 2005
<http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/phpNx.pdf>
- Ellig, J., Guiora, A. and McKenzie, K., **A Framework for Evaluating Counterterrorism Regulations**, 2006
http://www.mercatus.org/uploadedFiles/Mercatus/Publications/20060908_PS_terrorism_Complete.pdf
- Food and Drug Administration, HHS, “**Final Rule: Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation**”, **Federal Register**, Vol. 74, No. 130, Thursday, July 9, 2009, pp. 33030-33101, especially pp. 33050-33086.
<http://edocket.access.gpo.gov/2009/pdf/E9-16119.pdf>
- Kirkpatrick, C. and Parker, D., **Regulatory Impact Assessment: Towards Better Regulation?**, 2007
- Leach, P., **Why Can't You Just Give Me the Number: An Executive's Guide to Using Probabilistic Thinking to Manage Risk and to Make Better Decisions**, 2006
- National Center for Environmental Economics, **Guidelines for Preparing Economic Analyses: External Review Draft**, 2008
<http://yosemite.epa.gov/ee/epa/eeerm.nsf/vwRepNumLookup/EE-0516?OpenDocument>
- Office of Management and Budget, **Circular A-4, “Regulatory Analysis”**
<http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf>
- Zerbe, Jr., R.O. and Bellas, A.S., **A Primer for Benefit-Cost Analysis**, 2006