



Using Economic Analysis in FDA Nutrition Regulations

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Requirements for Federal Agencies to Analyze Regulations

- Paperwork Reduction Act (1980)
- Executive Order 12866 (1993)
- Unfunded Mandates Reform Act (1995)
- Regulatory Flexibility Act (as amended 1996)
- Congressional Review Act (1996)



Basic Requirements for Economic Analyses of Federal Regulations

- 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

Narrow Purpose of Regulatory Analysis

- Informing
 - not deciding, not advertising
- Regulatory
 - not clinical practice
- Policy
 - sufficient for law and decision making



Economic Analyses of Major Nutrition Regulations

- Nutrition Labeling (1993)
- Folic Acid Fortification (1996)
- *Trans* Fat Labeling (2003)



Nutrition Labeling (1993)

- Standardized labeling of nutrition information, established standards for and authorized nutrient content claims and health claims
- Baseline (over 20 years):
 - nutrition-related CHD & cancer:
 - 725,000 cases; 308,000 deaths
 - life-years lost: 2,281,000
- Costs (over 20 years discounted at 5%): \$1.4 - \$2.3 billion
- Health effects of rule (over 20 years):
 - CHD & cancer prevented:
 - 39,000 cases; 13,000 deaths
 - life-years saved: 81,000
- Benefits (over 20 years, discounted at 5%): \$3.6 billion

Folic Acid Fortification (1996)

- Required fortification of enriched grain products with folic acid to prevent neural tube defects
- Annual costs:
 - \$27 million in product changes and
 - possible unquantified health costs from masked anemia associated with vitamin B12 deficiency (breakeven number of cases between 390-1,230)
- Health effects of rule:
 - prevent 25-125 neural tube defects; 5 - 30 deaths
- Annual monetized benefits: \$220 million - \$700 million

Trans Fat Labeling (2003)

- Required reporting of *trans* fat in Nutrition Facts and authorized a “*trans* fat free” claim
- Annual costs: \$140 million - \$275 million
- Health effects of rule:
 - prevent 600 - 1,200 heart attacks; 250 - 500 deaths
 - life-years saved: 2,000 - 4,000
- Annual monetized benefits: \$1 billion - \$2 billion

FDA Methodology for Cost Estimation

- Engineering cost model for product changes
 - number of products
 - cost per product
- Cost of any negative health consequences
- Cost of behavioral changes

FDA Methodology for Benefit Estimation

- Product of
 - number of illnesses prevented
 - number of QALYs saved per illness prevented
 - monetary value of a statistical life year
- Same data used for cost-effectiveness measures (cost/illness, cost/QALY)

Contributions of Economic Analysis

- Social Science
 - human behavior, not just molecular behavior
- Quantification
 - exposure
 - health effect
 - behavioral change
- Best estimate of consequences
 - apply data beyond clinical trial data



Resources

- Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations, Federal Register, 56:229, November 27, 1991, pp 60856 – 60877. available at <http://www.foodrisk.org/exclusives/NLEA/documents/proposed/FederalRegProposed60856-60877.pdf>
- Regulatory Impact Analysis of the Final Rules to Amend the Food Labeling Regulations Federal Register, 58:3, January 6, 1993, pp 2927 – 2941. available at <http://www.foodrisk.org/exclusives/NLEA/documents/FedRegisterVol58PartI-V-2927-2941.pdf>
- Final Rule Amending Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid, Federal Register, 61:44, March 5, 1996, pp 8781 – 8797.
- Final Rule on *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, Federal Register, 68:133, July 11, 2003, pp 41433-41506.