Some Comments on the Trans Fat Experience

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Some questions

• What did the scientific community know and when did they know it?
• What methods of assessing risk were available to FDA during the rulemaking?
• Are there better ways to assess the risk and the alternatives that will not unduly burden?
• How do we make better science and risk-based nutrition policies?
What and when did the scientific community know about the health risks of trans fats?

- 1989, IOM/NAS Diet and Health
- 1993, NCEP
- 1995, Dietary Guidelines

- No adverse effect
- No adverse effect
- Increases LDL-C
- May raise C
What and when did the scientific community know about the health risks of trans fats?

- 2000, Dietary Guidelines
- 2002, IOM
- 2005, Dietary Guidelines
- 2005, NCEP
- 2005, IOM

• Increases C, decreases HDL-C
• Increases LDL-C
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FDA’s conclusion:

• “Strong agreement among the expert panels that the available evidence is sufficiently compelling to conclude that trans fat intakes increase coronary heart disease risk.”
Regulatory Alternatives

- Take no action
- Permit voluntary labeling of trans fat and nutrient content claims
- Consider alternatives to proposal:
  - trans fat on line below saturated fat
  - report trans fat differently
  - allow “low” and “reduced” trans fat claims
- Propose labeling at food service establishments
Regulatory Impact Analysis

• Alternative fats to replace trans fats
  – FDA assumed a range of ingredient substitutions including saturated and cis-unsaturated fat
  – Not enough information to project the substitutions for trans fat due to consumer choice
  – Most plausible replacement in baked products 50% cis-mono and 50% sat fat
Health Benefits and Costs

• 3 years from effective date 1/06 estimate:
  – prevent 600-1200 heart attacks
  – save 250-500 lives
  – cost savings of $900 m - $1.8 b/y in medical costs, lost productivity and pain and suffering
  – industry will incur one-time cost of $140-250m
Are there better ways to assess risk and alternatives?

- Risk assessment
- Evidence-based reviews
But there are lots of questions

- Fundamental DRI/risk management question: What are the endpoints? Role for evidence-based reviews?
  - Prevention of deficiency disease
  - Maintenance of body pool or stores
  - Maintenance of function (variety of measures)
  - Chronic disease risk factor reduction (total/LDL cholesterol, blood pressure, etc.)
  - Chronic disease prevention
  - Prevention of toxicity
Possible next steps

• Give risk assessment a try
  – pick a nutrient and risk assessment model(s)
  – hold a workshop, think it through
  – try to work through defining questions/endpoints, what data exist, what data would be needed, what assumptions would be made

• Evaluate
  – what would it take in terms of data, resources
  – appropriateness to nutrition in terms of biology, public health
Would a more formal risk assessment have resulted in:

• More informed policy with realization of supply issues?
• Inclusion of food service establishments?
• Less confusion about trans fats in partially hydrogenated oils and good alternatives?
• Extended an already lengthy rule-making process?