Some Comments on the Trans Fat Experience

Catherine E. Woteki, Ph.D., R.D.
Global Director of Scientific Affairs
Mars, Inc.

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?

• 1988, Surgeon General's Report on Nutrition	• No adverse effect
• 1989, IOM/NAS Diet and Health	• No adverse effect
• 1993, NCEP	• Increases LDL-C
• 1995, Dietary Guidelines	• May raise C

What and when did the scientific community know about the health risks of trans fats?

• 2000, Dietary Guidelines	• Increases C, decreases HDL-C
• 2002, IOM	• Increases LDL-C
• 2005, Dietary Guidelines	• Increases LDL-C
• 2005, NCEP	• Increases LDL-C
• 2005, IOM	• Increases LDL-C

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?