

Probability and Provability in the Regulation of Food Additives and Contaminants

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Probo

□ Latin

From probus ("good, virtuous")

□ Verb

- approve, commend
 - test, inspect
 - demonstrate, prove
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Statistics and Probability

□ Statistics

- Frequency (e.g. in a Population)
- Mathematical Probability as a Scientific Theory – Frequentist Interpretation Needed

□ Probability

- (Un)Certainty, Proof
 - Forms of Argument
 - Statistical Probability – What usually happens as what may be expected to happen
 - Alternative Propositions (e.g. Model Uncertainty)
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Propositional Probability

- Probability Trees, Not Distributions
 - Not Statistics
 - Quantifiable, but Mathematical
 - Statistical Probability may be used as a relative scale
 - Ian Hacking, re Pascal's Wager: "Pascal does not speak of a quantitative measure of degree of belief. He is saying we are in the same epistemological position as someone who is gambling with a coin whose aleatory properties are unknown"
 - Weight of the Evidence
 - Can be Semi-formal, but..
 - Subjective in the End
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Burdens of Proof

- Regulatory decision making often involves burdens of proof which may vary in different decision contexts
 - Transparency vs Authority
 - Standards of Evidence
 - Responsible Parties
 - Additives vs Contaminants
 - Food Additives are added intentionally and must undergo premarket approval
 - Contaminants are present in food without being added intentionally, and removal requires intervention of some sort.
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Food Additives and Safety Factors

- *The “100-fold margin of safety” is a good target but not an absolute yardstick as a measure of safety. There are no scientific or mathematical means by which we can arrive at an absolute value. However, this factor of 100 appears to be high enough to reduce the hazard of food additives to a minimum and at the same time allow the use of some chemicals which are necessary in food production or processing. – Lehman and Fitzhugh, 1954*
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Transparency, or Lack Thereof

- In the case of food additives, the FFDCA (section 409(c)(5)(C)) specifies that FDA approval of a food additive shall depend upon “safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate”
 - Since the decision involving the appropriate magnitude of a safety factor is made by experts, there is no formal process for either describing the magnitude of the uncertainties or for prescribing the impact of uncertainty on the decision.
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Contaminants in Food

- The Federal Food Drug and Cosmetics Act (FFDCA) in section 401(a)(1)) specifically prescribes different standards for contaminants that added as a result of human activity from those that are natural in origin.
 - A substance with an anthropogenic source will be considered illegal if it “contains any poisonous or deleterious substance which may render it injurious to health”
 - A naturally occurring compound will be excepted as long as “the quantity of such substance in such food does not ordinarily render it injurious to health.”
 - While the distinction between “may render” and “ordinarily render” is in need of interpretation, it is clear that the law dictates that a different and more stringent standard is to be applied when human activity is responsible for the contamination.
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Translating Words and Numbers

- Significance Tests Aren't Very Useful
 - Significance is not a Statistical Concept
 - No Model Comparison
 - Confidence Intervals
 - The (un)certainty about what you actually want to know
 - Translations: Yes, Probably, As-Likely-As-Not, Probably Not, No
 - My (Subjective) Equations:
 - "May Render" \approx >No
 - "Ordinarily" \approx >As-Likely-As-Not
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Responsible Parties

Food Additives

- Premarket Approval
- Burden is on manufacturer to show that the additive is safe under conditions of intended use

Contaminants

- No Approval, just Disapproval
 - Burden is on the agency to meet burden of proof
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Why Different Standards of Evidence Are Necessary

Food Additives

- Easy to Control – Just Don't Add It
- Premarket Approval: Information Precedes Use
- Precautionary Principle is Practical

Contaminants

- Difficult to Control
 - So many chemicals, so little information
 - It's already there - there is no precaution
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If Contaminants Were Treated Like Food Additives

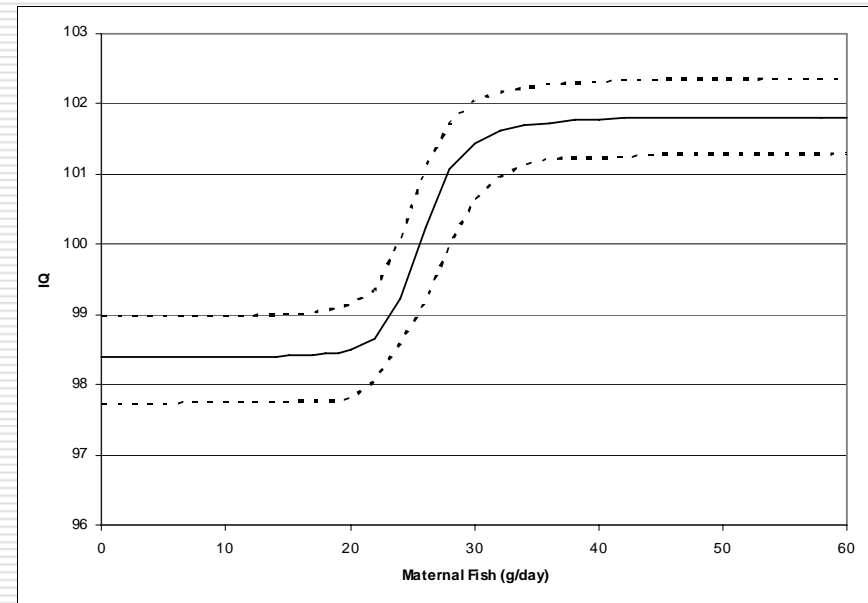
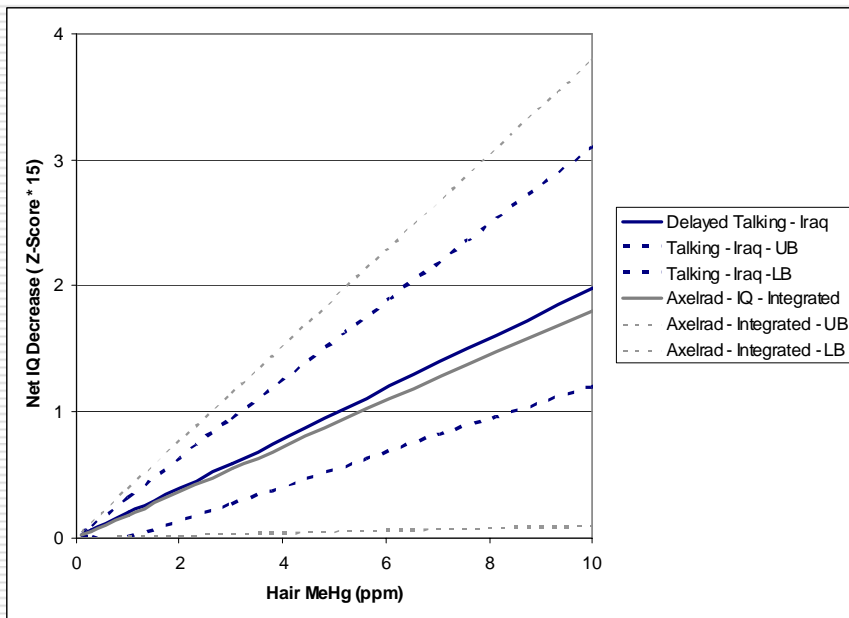
Water

- Lowest Lethal Dose ~10 liters
- Safety Factor of 10: 1 liter
- Safety Factor of 100: 100 mL

Toxic Nutrients

- Manganese
 - Selenium
 - Vitamin A
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Managing Risk and Benefit



Optima by Fish Species

Species	Optimum (g/day)	Max Benefit (IQ)
Sardines	63 (11, 336)	2.3 (1.5, 3.2)
Shark	16 (1, 42)	1.2 (0.0, 2.4)

Management Options

Regulation

- What IQ deficit corresponds to an “injury”?

Advice

- Eat / Don't Eat certain types of fish

Consumer Information

- What may be expected to happen if certain types of fish are consumed?
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Uncertainty and Fish Advisories

- No legal basis = no established burden of proof
 - No side of safety to err upon = central estimate
 - Average or expected value, presumes statistical basis, long-run return
 - Median, as-likely-as-not, reasonable certainty
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In Summary

- Formal Risk Assessment Engenders Formal Risk Management
 - The Impact of Uncertainty on the Decision Must be Dealt With Transparently
 - Uncertainty cannot be expected to impact all decisions in the same way
 - Degree of Control
 - Other Consequences
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