

Assessing the Risks of Biotech Foods

Jeff Wolt

Biosafety Institute for Genetically Modified Agricultural
Products

Iowa State University

jdwolt@iastate.edu

Plan of Presentation

- risk assessment as applied to food safety
- key considerations in food safety risk assessment
- application of these considerations to biotech foods
- frameworks for biotech food safety risk assessment
- harmonization of risk assessment frameworks

Risk

- the likelihood of harm to occur under relevant conditions of exposure
- ideally risk describes the joint probability of exposure and effect

$$\text{Risk} = f(\text{exposure, effect})$$

Risk Assessment

- objective stepwise process of characterizing exposure, effect, and consequent risk – leading to a risk conclusion stating what is known as well as what is unknown, variable, and uncertain
- a transparent, science-based process

The Risk Assessment Process

- links to the risk management process
- follows well established frameworks
- sets overall assessment goals
- iterative
- proceeds in tiers
- quantitative to the fullest extent possible

The Risk Management Process

- weighing policy alternatives
- selecting the most appropriate regulatory action
- integration of risk assessment with social, economic, and political concerns
- leading to a decision

Risk Assessment Links Research to Risk Management

Data Acquisition, Verification, & Monitoring



Risk Assessment

Problem
Formulation

Exposure & effects
characterization

Risk
Characterization



Risk Management

Safety

- societal judgment as to the acceptability of risk
- reflected in risk management decisions (i.e., policies)

Food Safety

- the degree of confidence that food will not cause harm to the consumer

Food Safety Risk Assessment

- predicts the likelihood of harm resulting from exposure to chemicals, microbes, or physical agents in the diet

Joint Institute for Food Safety and Applied Nutrition (JIFSAN)

Biotech Food Safety Risk Assessment

- all foods can contain allergens, toxins, and antinutrients
- biotech foods pose the same types of inherent risks to human health as conventional foods
- these risks are evaluated before marketing a biotech food, they are not routinely evaluated in conventional foods

GAO-02-566 Genetically Modified Foods (2002)

Substantial Equivalence

- baseline for understanding biotech food safety
- biotech foods pose heightened risks if they contain allergens, toxins, and antinutrients, at levels that are not comparable to conventional food counterparts

Testing Profile for Biotech Food

- source of the transferred genetic material
- nature of the transformation
- protein expression profile
- protein toxicity
- animal performance
- amino acid sequence similarity
- process stability and digestibility
- nutritional and compositional profile
- dietary exposure

Frameworks for Biotech Food Safety Assessment

- emerging national, regional, and international frameworks
- high level similarities
 - recognition of risk assessment
 - substantial equivalence as a baseline
 - broadly common data elements
- but ...

Frameworks for Biotech Food Safety Assessment

- ... the devil is in the details
 - distinguishing risk assessment vs. risk management
 - science findings vs. policy decisions
 - lack of specific risk assessment guidance
 - timing of the data need
 - import permits vs. environmental releases
 - depth of data required
 - acute vs. subacute toxicity testing
 - differing data interpretations
 - 6 vs. 8 monomer match in amino acid sequence

The Case for Harmonization

- asynchronous approvals between importing and exporting nations
- overlapping data requests
- need-to-know vs. nice-to-know
- conflicting testing paradigms
- conflicting data interpretations
- conflicting messages concerning safety
- high developer uncertainty

Progress within CODEX

- Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, 2003
- Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants, 2003
- Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms, 2003
- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, 2003

Progress within CODEX

- Proposed Draft Principles for the Application of Traceability/Product Tracing in the Context of Food Import and Export Inspection and Certification Systems (N04-2005)

Summary: Assessing the Risks of Biotech Foods

- risk assessment – a science-driven process
- risk management – a policy-driven process
- principles of food safety risk assessment are no different for conventional vs. biotech foods
- biotech foods, however, are held to a higher standard of safety

Summary: Assessing the Risks of Biotech Foods

- data elements for biotech food safety risk assessment
 - have been well elaborated
 - are reflected in international guidance
- specific data needs and interpretation
 - vary in ways that hinder timely and harmonized decisions
 - the risk assessment and risk management process needs further international elaboration

A Final Thought: Risk vs. Benefit

