Workshop on Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved through Biotechnology: Case Studies

Organized by:
ILSI International Food Biotechnology Committee (IFBiC)

12 September 2006

Ministry of Press Public Relations
Fragoudi 11 & Al. Pantou
Athens, Greece

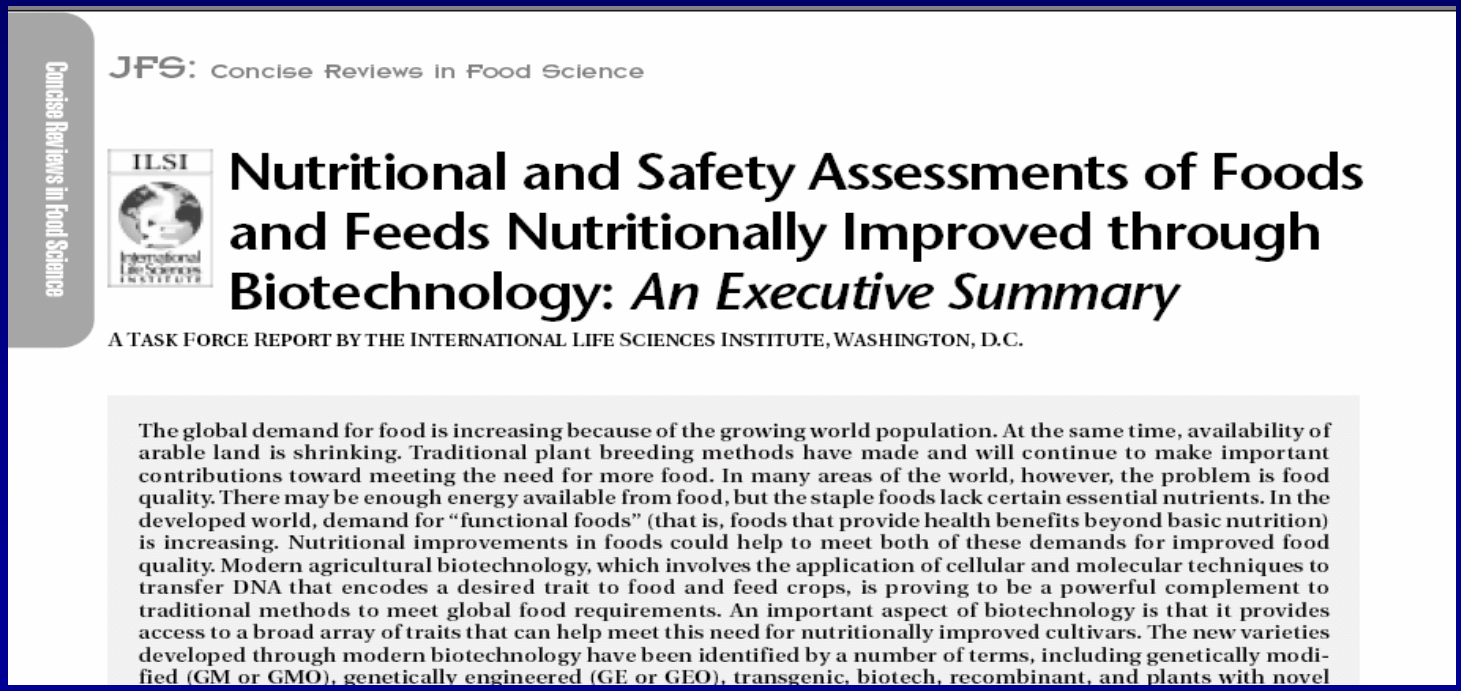
Kevin C. Glenn
Sr. Science Fellow, Monsanto
Task Force Chair

IFBiC Convened a Task Force and Expert Panel in 2001

- Goal was to develop a scientific framework and basis for the safety and nutritional assessment of nutritionally enhanced products
- Document was peer reviewed by 23 scientists
- Refined by 26 attendees from the 8th Meeting of the OECD Task Force on the Safety of Novel Foods and Feed, Paris, December 2003
- Published:
  - Executive Summary: *Journal of Food Science,* March 2004
  - Complete document: *Comprehensive Reviews in Food Science and Food Safety,* (April 2004)

Peer-Reviewed Journal Publication

- **Executive Summary:** ***Journal of Food Science*****, March 2004**



Concise Reviews in Food Science

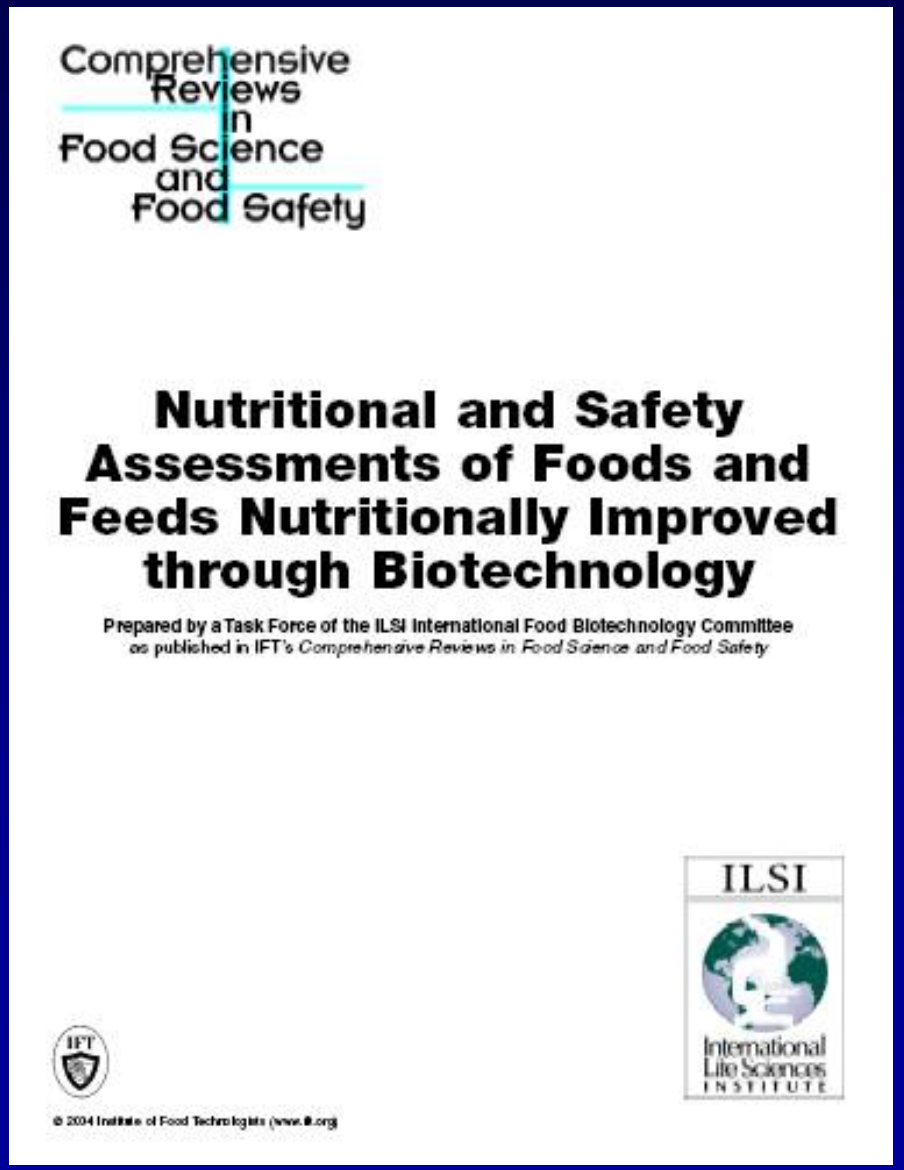
JFS: Concise Reviews in Food Science

Nutritional and Safety Assessments of Foods and Feeds Nutritionally Improved through Biotechnology: *An Executive Summary*

A TASK FORCE REPORT BY THE INTERNATIONAL LIFE SCIENCES INSTITUTE, WASHINGTON, D.C.

The global demand for food is increasing because of the growing world population. At the same time, availability of arable land is shrinking. Traditional plant breeding methods have made and will continue to make important contributions toward meeting the need for more food. In many areas of the world, however, the problem is food quality. There may be enough energy available from food, but the staple foods lack certain essential nutrients. In the developed world, demand for "functional foods" (that is, foods that provide health benefits beyond basic nutrition) is increasing. Nutritional improvements in foods could help to meet both of these demands for improved food quality. Modern agricultural biotechnology, which involves the application of cellular and molecular techniques to transfer DNA that encodes a desired trait to food and feed crops, is proving to be a powerful complement to traditional methods to meet global food requirements. An important aspect of biotechnology is that it provides access to a broad array of traits that can help meet this need for nutritionally improved cultivars. The new varieties developed through modern biotechnology have been identified by a number of terms, including genetically modified (GM or GMO), genetically engineered (GE or GEO), transgenic, biotech, recombinant, and plants with novel

Complete document: April, 2004



ILSI Task Force

Expert Working Group	
Ian Munro & Jason Hlywka	Cantox, Inc./ U. of Toronto
Martina McGloughlin	U. of California, Davis
Bruce Chassy	U. of Illinois
Richard Phipps	U. of Reading
Harry Kuiper & Gijs Kleter	Wageningen University

ILSI Task Force Members	
Bayer CropScience	Ray Shillito
Dow AgroSciences	Joseph Dybowski
DuPont/Pioneer	Matthias Liebergesell
Monsanto	Kevin Glenn
Renessen	David Russell
Syngenta Seed	Catherine Kramer

Impact of Task Force on Improved Nutrition Crops

- Referenced by the EFSA Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed (the EFSA Journal [2004] 99, 1–93)
- Cited by Japan and Australia in their country comments to Codex
- Presented at scientific conferences in 2004 & 2005 (e.g., In Vitro Biology, IFT, ISSX, Eurotox)
- ILSI IFBiC-sponsored workshops held in Argentina, Japan and Korea

Developments Since Publication of the 2004 ILSI Document

- The comparative safety assessment process
  - Identifies differences that warrant additional assessment
  - Follow-up safety assessments should not be triggered by fixed numeric limits for analytes
- It is essential to balance the need to assess safety risks of the product with the intended benefits
  - Significant decreases in disease, suffering and/or death related to meeting fundamental nutritional needs
- Comparing genetic changes due to domestication and breeding with biotechnology:
  - Larger in scale
  - Less well defined

Developments Since Publication of the 2004 ILSI Document

- Safety assessment of proteins
  - A tiered, weight of evidence approach developed by an IFBiC Task Force
- Comprehensive, untargeted "omic" analytical methods
  - Useful screens for unintended changes
  - Requires standardized, validated methods
  - Public repositories needed on baseline transcriptomes, metabolomes and proteomes are available
- Milk, meat and eggs from animals consuming GM crops
  - No scientific evidence for any difference from animals fed conventional crops

Case Studies of Improved Nutrition Crops

- **Lysine maize** (*biotech feed*)
  - Maize is nutritionally deficient in lysine
  - Lysine was increased to reduce the need for synthetic lysine in some animal diets
- **Double Embryo Maize** (*biotech food*)
  - Cereal grains represent the staple diet for nearly 70% of the world population
  - Maize with two embryos increases both oil and protein, enhancing nutritional value
- **Golden Rice 2** (*biotech food*)
  - Micronutrient deficiency, like vitamin A deficiency (VAD) is a global public health challenge
  - Each year, VAD affects ~2 million children, >250,000 become blind each year, 125,000 die
  - β carotene, the most important provitamin A carotenoid, is increase in Golden Rice 2
- **β-carotene-enriched sweetpotato** (*conventional food*)
  - Sweetpotato is a secondary staple food crop in Eastern and Southern Africa
  - Orange-fleshed sweetpotato was selected as a crop biofortified with β carotene to control VAD
- **ASP-1 modified sweetpotato** (*biotech food*)
  - The protein content and quality of sweetpotatoes is relatively low, resulting in protein-energy malnutrition
  - Both the protein content and quality are improved by introducing the asp-1 protein

Recommendations Common to Improved Nutrition Crop Case Studies

1. The safety assessment begins with a comparison of the new food or feed with an appropriate conventional line with a history of safe use

2. The necessary data should be determined on a case-by-case basis and in the context of the proposed use of the product in the diet and consequent dietary exposure

3. The safety of any newly introduced protein(s) into a crop needs to be determined

4. Compositional analysis needs particular attention given to evaluation of the targeted metabolic pathway

5. The phenotypic properties of the crop should be assessed when grown in representative production sites

Recommendations Common to Improved Nutrition Crop Case Studies

6. Studies in laboratory animals provide added safety assurance by confirming observations from other components of the safety assessment
7. When appropriate, premarket human studies may assess the biological or biochemical impact of the improved nutrition crop
8. Premarket assessment should demonstrate that the introduction of the improved nutrition crop will not adversely change in a significant manner the nutrient intake for a large cross-section of consumers
9. The opportunity for benefits needs to be considered along with the possible risks for a balanced assessment
   - ✓ Benefits - to alleviate undernutrition for a potentially large number of people consequences of the adoption of improved nutrition crops
   - ✓ Risks – currently part of the comparative safety and nutritional assessment of new products

Workshop Agenda

Plenary Session

8:30	**I.**	**Welcome, Background, Workshop Objectives, and Agenda**	**Dr. Marci Levine** *ILSI*
		(***Note:*** ***The timing includes 5 minutes for taking and recording questions from the audience.***)	
8:45	**II.**	**Introduction of Case Studies**	**Dr. Kevin Glenn** *ILSI IFBiC Task Force Chair*
9:00	**III.**	**Case Study 1: Lysine Maize**	**Dr. Richard Phipps** *Univ. of Reading*
9:15	**IV.**	**Case Study 2: Double Embryo Maize**	**Dr. Martina McGloughlin** *Univ. of California, Davis*
9:35	**V.**	**Case Study 3: Golden Rice 2**	**Dr. Bruce Chassy** *Univ. of Illinois*
9:55	**VI.**	**Case Study 4: Transgenic Sweetpotato (with ASP-1 protein)**	**Dr. Ray Shillito** *Bayer CropScience*
10:05	**VII.**	**Case Study 5: Conventional Sweetpotato (with provitamin A)**	**Dr. Gijs Kleter** *Univ. of Wageningen*
10:25–10:35		**Process, Logistics, Questions and Expectations for Breakout Sessions**	**Dr. Kevin Glenn**
10:35–10:50		**Break**	

Workshop Agenda

Breakout Group Discussions		
10:50 – 12:30 - VIII	(A) Risk–benefit analysis of nutritionally improved foods and feeds	Dr. Bruce Chassy
	(B) Dietary exposure to nutritionally improved foods and feeds	Dr. Martina McGloughlin
	(C) Pathway analysis, including "-omic" technologies, and proper safety assessment of identified changes	Dr. Gijs Kleter
	(D) Safety and nutritional requirements for conventional and GM products	Dr. Richard Phipps
12:30 – 13:30	LUNCH, Off-Site	
13:30 – 14:15	Breakout Group Discussions—Wrap-up	
Plenary Session		
14:15 - 16:45	Reports from Breakout Groups (15 min with 15 min discussion)	Dr. Kevin Glenn
16:45 - 17:00	Wrap-up, Next Steps	Dr. Kevin Glenn
17:00	Adjourn	