The Evaluation of Food Derived from Modern Biotechnology

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Introduction

• Talk on human health aspects only, it will not cover environment or trade
• Limited to scientific assessments
• No reference to management issues
Introduction

- Misconception, GM food not assessed ‘en bloc’
- Each variety tested in its own right
- Testing of conventional foods not performed therefore baseline does not exist
Human Health Assessment

- Toxicology Assessment
- Dose Response Tests
- Dietary Exposure and Risk Characterization
- Occupational Exposure
Who does the assessments?

- Conducted at National level
- Decision reports maintained by National Competent Authority
- At international level OECD, ICGEB RASM
- http://www.icgeb.org/~bsafesrv/rasm
Safety Aspects of Genetically Modified Foods of Plant Origin

29 May - 2 June 2000, Geneva, Switzerland
Long-Term Effects

- Very little known about long-term effects of any foods
- Pre-market safety assessment provides already assurance that the GM food is as safe as conventional
- Epidemiological studies are unlikely to identify adverse effects
- Randomised Controlled Trials could be used to investigate long-term effects
- Traditional animal testing problematic
Occurrence of Unintended Effects

• “Predictable” effects based on metabolic connections or information of the insertion site

• “Unexpected” effects
  – Statistically significant differences should be assessed for their biological significance
  – Potential occurrence of unintended effects is not specific to the use of recDNA techniques
Detection of Unintended Effects

- **Targeted Approach**
  - single specific compound analysis

- **Non-targeted Approach**
  - profiling/fingerprint analysis
  - Future GM plants are likely to be more complex with increased chances of unintended effects
Concept of Substantial Equivalence

• Compares GM with conventional foods
• S.E. is not a means to an end but a starting point of the safety assessment
• Application of S.E. contributes to a robust safety assessment framework
Concept of Substantial Equivalence

- There are no adequate alternative strategies that would provide a better safety assurance for GM foods
- Compositional analysis is not the sole basis for determining safety
- Standard safety testing of whole foods as for food additives not possible
- Refinements could be pursued in the step of compositional analysis by development of new profiling techniques
Nutritional Aspects

• Intended and unexpected changes in nutrient levels may affect the nutritional status of the individual.

• Need for integrated toxicological and nutritional assessment
  – Bio-availability, stability, processing should be taken into account
  – Impact of individual changes on overall nutrient profile must be determined
Consequences of Horizontal Gene Transfer

- Drug resistant cell populations could compromise therapy, depending upon selection pressure.
- Prevailing resistance levels, clinical importance of the drug, and alternative therapies should be evaluated.
- No evidence that current antibiotic resistance marker genes pose health problems.
Alternative Transformation Technologies

• Non-antibiotic resistance marker-genes
• Removal after transfer (CreLox system)
• Alternatives should be evaluated for their safety
Evaluation of Allergenicity of Genetically Modified Foods

22 - 25 January 2001, Rome, Italy
Most Common Food Allergens

• More than 170 foods cause food allergies

• Most common foods “The Big Eight”:
  - cow’s milk  - peanuts
  - eggs  - soybeans
  - fish  - tree nuts
  - crustaceans  - wheat
Post Market Surveillance

• Pre-market allergenicity assessment provides satisfactory safety assurance

• Post market evaluation should be considered:
  - wide genetic variability
  - different geographical dietary intake
Feasibility Post Market Surveillance

- Traceability and labelling of GM foods
- Lack of background data on incidences of food allergies
- Confounding factors
- Diet changes over time
- Lack of trained experts
Safety assessment of Foods derived from Genetically Modified Micro-organisms

24-28 September 2001, Geneva, Switzerland
Strain identification and characterisation

- Host must be characterised from scientific, manufacturing and safety perspective
- GMM must be as safe as host strain
Gene transfer

• A natural phenomenon of prokaryotes
• Chromosomal integration minimises the spread of a recombinant construct
• Avoid sequences that would stimulate integration into other genomes or provide a selective advantage
Genetic stability

- Genetic plasticity of microbes may influence the fate of the recDNA.
- Stability also influenced by position of the recDNA (chromosome or plasmid).
Pathogenic potential

- History of safe use suggests microbes used in fermentation are free from pathogenicity islands
- Genetic modification could produce a metabolic imbalance
- Look out for toxin genes being switched on
- ‘Cross-talk’ between microbe and intestinal immune system can be affected
Safety and nutritional assessment

- Application of the concept of substantial equivalence important in identifying similarities and differences
- Safety of GMMs must be evaluated in terms of the food matrix in which they are consumed
Interactions between the GMM, the intestinal flora and the mammalian host

- Exact composition of GI flora not known
- GI flora may be influenced by phenotypic expression of GMM and horizontal gene transfer (direct or indirect effects)
- Possibility of DNA transfer (conjugative, transformation)
Exposure

• The degree of intake of food GMMs needs to be considered in the pre-market evaluation

• Identifying effects against background of conventional foods is difficult

• Methods to monitor exposure to GMMs must be considered
• In future the safety of food will be evaluated also at the international level

• Risk assessment information should move as freely over the borders as food itself

• When using the same risk assessment language over the borders, credibility of messages will increase
• No appreciable risk to human health of crops currently on the market
• Decision-making takes other factors into consideration
• WHO study: Modern Biotechnology, Human Health and Development
• Future: International evaluation