Biosafety of GMOs
Concepts, Principles & Practice

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Risk – the likelihood of danger happening

Risk Analysis: Identification of risks/possible sources of danger

Evaluation of the possibility of the risk occurring:
- When?
- Where?
- How extensive would the damage be?

Formulation of mitigating measures
- to avoid the risk from happening; to decrease the extent of damage

According to DA AO No. 8:

Risk analysis – parallel process done by:

Scientific Technical Review Panel (STRP) and

DA regulatory agencies

Bureau of Plant Industry (BPI) – for environmental safety
Bureau of Agriculture and Fisheries Product Standards (BAFPS)– for food safety
Bureau of Animal Industry (BAI)– for feed safety
Fertilizer and Pesticide Authority (FPA) – for safety of pest protected crops

Risk assessment concept & principles

Concept of substantial equivalence
- **international acceptance**
  OECD, FAO/WHO, Codex Alimentarius
- **comparative approach – risk identified by comparing GMO with a conventional counterpart that must have a history of safe use**

History of genetic improvement of food crops
~ 10,000 years of trial & error,
only last 100 yrs based on science
new varieties are not evaluated for safety

Hence, no established procedures for evaluating safety of food crops
Yet, many food crops are toxic when eaten raw – processing is important.

Concept of **substantial equivalence**

Establishment of substantial equivalence is not a safety assessment per se but that establishing the characteristics and composition of novel food as equivalent to those of a familiar, conventional food with a history of safe consumption means that the new product will be no less safe under similar consumption patterns and processing practices.

Concept of substantial equivalence

Advantages
provides flexibility in food safety assessment
can identify any differences whether intended or unintended
applicable in any step along the food chain
raw, unprocessed product
individual processed fractions
final food ingredient
final food product

Limitations
Need sufficient data to allow effective comparison
Dependent on a presence of a valid comparator with a well-documented history of safe use

Goal of safety assessment process for genetically engineered foods:

To examine the intentional and unintentional consequences of the specific modification on food components, including toxicants, allergens, in comparison with a counterpart food that has a history of safe use

Risk assessment is conducted on a case-by-case and on the basis of transformation event

Safety issues to be considered when evaluating a novel food (OECD, FAO/WHO)

1. Description of host organism that has been engineered nutrient composition, known antinutrients, toxicants allergenic potential, significant changes in these due to processing
2. Description of donor organism and introduced gene/s including any associated toxicities, allergenicities
3. Molecular characterization of the genetic modification, including description of the modification process and the stability of the introduced trait
4. Identification of the primary and secondary gene products, including a description of the characteristics of the inserted gene

Safety issues to be considered when evaluating a novel food

1. Evaluation of the safety of expected novel substances in the food, including an evaluation of any toxins produced directly by genetic engineering
2. Assessment of the novel food's potential allergenicity
3. Evaluation of unintended effects on food composition
   a) assessment of changes in the concentration of nutrients or naturally occurring toxicants
   b) identification of anti-nutrient compounds that are significantly altered in the novel food
   c) evaluation of the safety of compounds that show a significantly altered concentration

Environmental safety issues in evaluating crop for general release (commercial planting)

Gene Flow
- Gene transfer to related plants
- Gene transfer to unrelated species

Weediness potential

Secondary and non-target effects
- Effect on non-target organisms
- Potential to produce resistant pests

Does GM variety differ in the above from the non-GM variety?

Risk assessment by STRP and DA assessors involves assessment of scientific evidence submitted by technology developer

A peer review process for each scientific report
- Clear objectives
- Experimental approach suitable to attain objectives
- Methodology robust, use of accepted procedures
- Results clearly presented and interpreted in relation to objectives
- Conclusions are valid: logical interpretation of results

Evaluation of the total evidence
- Identify deficiencies – temper with "Need to know" vs. "Nice to know"
- Sufficient to provide a level of comfort – enable assessor to defend its position in any forum

Maintaining the objectivity of risk analysis process

- Identity of STRP/DA assessor not announced prior to evaluation of data
- STRP/DA assessors not allowed to conduct risk assessment experiments
- STRP/DA assessors are expected to
  - Ensure risk assessment is science-based & transparent
  - Help identify and evaluate possible risk posed by GM plant/plant product by evaluating the scientific evidence submitted by the applicant
  - Evaluate proposed mitigation measures for scientific bases, effectiveness and implementability
  - Submit the risk assessment report within 30 days after receipt of documents