International aspects of the quality and safety of Foods derived from modern Biotechnology

Outline

- Introduction
- Rules 1989 for GMOs
- Act for Genetically modified Foods safety
- Framework for safety assessment
- General considerations while making GM food
- Safety assessment of GM food

INTRODUCTION

- Genetically modified (GM) or transgenic plants, are being developed with the aim of enhancing productivity

- Improving the nutritional value of foods and livestock feeds has been also made using the RDT and GE.

- As more GE plants are released and the resultant food products are commercially available *concerns have been expressed about their safety.*

Cont…

- In Genetic manipulation of plants, there is a possibility of introducing unintended changes along with the intended changes.

- This unintended change may have an impact on the nutritional status or health of the consumer.

Rules 1989 for GMOs

- In India, the manufacture, import, use, research and release of GMOs as well as products made by GMOs are governed by the rules notified by Ministry of Environment and Forests (MoEF), Government of India on December 5, 1989 under the Environmental (Protection) Act 1986 (EPA).

- **These rules and regulations, commonly referred to as Rules 1989**

- The regulatory agencies responsible for implementation of the Rules 1989 are MoEF, DBT, Government of India, through six competent authorities

1) Recombinant DNA Advisory Committee (RDAC)
2) Review Committee on Genetic Manipulation (RCGM)
3) Genetic Engineering Approval Committee (GEAC)
4) Institutional Biosafety Committees (IBSC)
5) State Biotechnology Coordination Committees (SBCC)
6) District Level Committees (DLC)

Recombinant DNA Advisory Committee (RDAC)

Main functions

•Review developments in Biotechnology at National and International levels.

•Recommend suitable and appropriate safety regulations for India in r-DNA research, use and applications.

Review Committee on Genetic Manipulation (RCGM)

Main functions

- To note and to approve r-DNA work.
- To ensure adherence of r-DNA safety guidelines of government.
- To ensure experimentation at designated location, taken into account.
- To Prepare plan about risk of experiments

Genetic Engineering Approval Committee (GEAC)

- To permit the use of GMOs and products there of for commercial applications.

- To adopt producers for restriction or prohibition, production, sale, import & use of GMOs both for research and applications under EPA.

- To authorize large-scale production and release of GMOs and products there of into the environment.

State Biotechnology Coordination Committees (SBCC)

- Powers to inspect, investigate and to take punitive action in case of violations

- To review periodically the safety and control measures in various institutions handling GMOs.

- To act as agency at State level to assess the damage, if any, due to release of GMOs and to take on site control measures.

- The Committee coordinates the activities related to GMOs in the State with the Central Ministries.

District Level Committees (DLC)

- To monitor the safety regulations in installations
- Has powers to inspect, investigate and report to the SBCC or the GEAC about violations under EPA.
- To act as nodal agency at District level to assess the damage, if any, due to release of GMOs and to take on site control measures.

Institutional Biosafety Committees (IBSC)

- To bring out guidelines specifying producers for regulatory process on GMOs in research, use and applications to ensure environmental safety.
- To lay down producers for restriction or prohibition, production, sale, import & use of GMOs both for research and applications.
- To authorize imports of GMOs/ transgenes for research purposes.
- To authorize field experiments in 20 acres in multi-locations in one crop season with up to one acre at one site.
- To undertake visits to GM experimental plots

Act for Genetically modified Foods safety

- The Ministry of Health and Family Welfare (MoHFW) is primarily responsible with ensuring the availability of food that is safe.

- In 2006, the **Food Standards and Safety Act, 2006** was implemented by the Food Safety and Standards Authority and includes genetically modified foods under the food category.

- The ICMR as the scientific advisory body of MoHFW, has formulated the guidelines to establish the safety assessment of foods derived from GE plants

Framework for safety assessment

- The safety assessment of foods derived from GE plants follows a stepwise process aided by a series of questions.

- Factors taken into account in the safety assessment include

- Identity
- Source
- Composition
- Effects of processing/cooking
- Transformation process
- The recombinant DNA (*e.g.*, stability of insertion, potential for gene transfer)
- Expression product of the novel DNA

General considerations while making GM food

1. Description of the non-transgenic host plant and its use as food.
2. Description of the donor organisms
3. Description of the genetic modification
4. Characterization of the genetic modification

Cont…

1. **Description of the non-transgenic host plant and its use as food.**

- Common or usual name; botanical name; and, taxonomic classification
- Centre of origin and history of cultivation
- Plant’s genotype and phenotype relevant to its safety, including any known toxicity or allergenicity
- History of safe use for consumption as food

Cont…

2. Description of the donor organisms

- Common name
- Scientific name
- Taxonomic classification
- Information about the natural history of the organism as concerns human health
- Information on naturally occurring toxins, anti-nutrients and allergens
- Pathogenicity to human

Cont…

3. **Description of the genetic modification.**

- Information on the specific method used for the modification (*e.g.* *Agrobacterium* mediated transformation or direct transformation methods)
- Details of modifications to be introduced, (*e.g.*, changes in amino acid sequence that may affect expression of the expressed protein)
- Details of toxic nature, allergic nature and pathogenicity of that gene and protein

Cont…

4. Characterization of the genetic modification

- Molecular and biochemical characterization of the genetic modification needs to be carried out
- The characterization and description of the inserted genetic materials
- The number of insertion sites
- Copy number of inserted gene
- Nature of promoter region
- The gene product(s) function
- The phenotypic description of the new trait

Safety assessment of GM food

1. Assessment of possible toxicity
2. Assessment of possible allergenicity
3. Biochemical analysis of protein produced after GM
4. Intended nutritional modifications
5. Unintended effects

Cont…

1. Assessment of possible toxicity

- Possible toxicity is checked by checking the carcinogenic and mutagenic nature of protein produced by GM
- Possible toxicity is also checked using experimental animals like mouse

Cont…

2. Assessment of possible allergenicity

- Human IgE response to oral exposure of that compound
- Any significant similarity between the amino acid sequence of the protein and that of known allergens
- Evidence of contact allergy by checking skin inflammation or dermatitis

Cont…

2. **Biochemical analysis of protein produced after GM**

- Weather acts as anti-nutrients
- Biochemical analysis of protein can be studied using HPLC or GC

Cont…

3. Intended nutritional modifications

- Weather the right compound has been formed or not or intended modification has been made or not.

Cont…

4. Unintended effects

- Unintended effects can result from the random insertion of DNA sequences into the plant genome
- which may cause disruption or silencing of existing genes, activation of silent genes,
- or modifications in the expression of existing genes
- Unintended effects may also result in the formation of new or changed patterns of metabolites.

Thank you