Biosafety Regulatory Framework for GMOs in India

- ‘**BIOSAFETY’:** Protecting human and animal health and biodiversity from the possible adverse effects of the products of modern biotechnology

- Biosafety Regulatory System **essential** for biotechnology programme

- **Broad outlines:**
  - Introductory
  - EPA
  - Statutory Rules
  - State Government’s Role
  - Identification of Gaps
  - Streamlining Initiatives

Indian Biosafety Regulatory System

- Combination of existing and new legislations
- Mix with non-statutory guidelines
- Shared responsibility
- Scope to evolve

Why Regulations are Necessary for Using GMOs and Products Thereof?

- GMOs and and their products are to play important role including human and animal health care system, agriculture, industrial products, environment management

- Concurrently, there could be unintended hazards and risks from the use of GMOs and products thereof, if the new technology was not properly assessed before use

- A GMO can be safe but this can be unsafe too depending upon the trans-genes, the host organism and the environment where the GMO is being tested

- GMOs can be microorganisms, plants, and animals

REGULATORY FRAMEWORK IN INDIA

1. GOVERNMENT RULES FOR GMOs
2. RECOMBINANT DNA GUIDELINES, 1990
3. GUIDELINES FOR RESEARCH IN TRANSGENIC PLANTS, 1998
4. SEED POLICY, 2002
5. PREVENTION OF FOOD ADULTERATION ACT
6. THE FOOD SAFETY AND STANDARDS BILL, 2005
7. PLANT QUARANTINE ORDER 2003
8. TASK FORCE ON APPLICATION OF AGRICULTURAL
9. BIOTECHNOLOGY
10. DRAFT NATIONAL ENVIRONMENT POLICY, 2004
11. DRAFT NATIONAL BIOTECHNOLOGY STRATEGY 2005

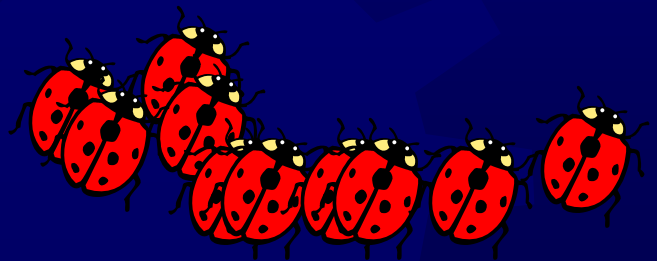
The Indian Environment (Protection) Act 1986

- Umbrella legislation
- ‘Hazardous substances’
- Central Government’s powers
- Legal provisions
  - Search and seizures: CrPC
  - Penalties
    - 5-7 years imprisonment
    - Rs.1 lakh fine
    - Rs.5,000/day additional fine

‘Environment’ includes water, air and land and the relationship which exists among and between water, air and land and human beings, other living creatures, plants, micro-organisms and property.

Indian EPA implementation structure for GMOs (1989 RULES)

In order to contain possible hazards to environment from the release of GMOs, the Ministry of Environment and Forests has notified in December 1989, the "**Rules for the manufacture, use, import, export and storage of hazardous Micro-organisms/ Genetically Engineered Organisms or Cells**" under the Environment (Protection) Act (EPA)1986.



1989 Rules: MoEF

- Objective: protect environment, nature and health
- Deals with applications of gene technology and hazardous micro-organisms
- Includes:
  - Classification of micro-organisms or genetically engineered products
  - Scheme of approvals
  - Administrative mechanism
  - Punitive provisions

…1989 Rules: MoEF

GENETIC ENGINEERING

A technique by which heritable material generated outside and inserted into a cell or organism. Includes combinations/ deletions of parts of genetic material.

GEAC APPROVAL

- Import
- Export
- Transport
- Manufacture
- Process
- Use
- Sell

Hazardous MO/GEO

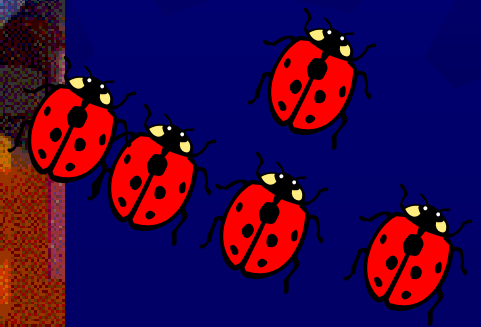
Substances/ Cells

APPLICATIONS OF 1989 RULES

- Manufacture, import and storage of microorganisms and gene technological products

- Genetically engineered organisms/ microorganisms and cells and correspondingly to any substance and products and food stuffs, etc., of which such cells, organisms or tissues form part

- New gene technologies in addition to cell hybridization and genetic engineering



Regulatory Mechanism

- Ministry of Environment and Forests
- Department of Biotechnology

- Recombinant DNA Advisory Committee (RDAC)
- Review Committee on Genetic Manipulations (RCGM)
- Genetic Engineering Approval Committee (GEAC)
- State Biosafety Coordination Committee (SBCC)
- District Level Coordination Committee (DLCC)

Administrative Mechanism

ADVISORY

- RDAC

- Serviced by DBT
- Reviews biotech developments
- Recommends safety regulations

APPROVALS

- GEAC
- RCGM
- IBSC

GEAC

- Serviced by MoEF
- Environmental clearance
  - Large scale use
  - Release into environment
- Supervises implementation
- Punitive powers

ENFORCEMENT

- SBCC
- DLCC

SBCC

- Powers to inspect, investigate and punish statutory violations
- Post release monitoring
- State nodal agency

Administrative Mechanism

APPROVALS

- RCGM
- Manuals of guideline
- Approvals: RG III & above research
- Approvals: contained filed trials
- Approvals: import for research
- Monitors research projects safety aspects
- Advisory role
- Link: IBSC: GEAC

- IBSC
- Institute level
- Approval role
- - R G I: Intimation
- - R G II: Approval
- - R G III & above: recommendation
- Site emergency plan
- Adherence of guidelines
- Nodal point for interaction

ENFORCEMENT

- DLCC
- Monitors safety regulations in installations
- Post release monitoring
- Reports: SBCC, GEAC

General approval procedures for recombinant products

Proposal

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Institutional Biosafety Committee with DBT Nominee

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RCGM's approvals

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Based on the pre-clinical trial data, RCGM conveys its recommendations to the applicant and copy to the DCG(I) and to GEAC

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RDAC approves the protocol and recommends for conducting human clinical trials

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IBSC examines the human clinical trial data and sends it for RCGM and DCG (I) for Recommendation to GEAC for environmental release

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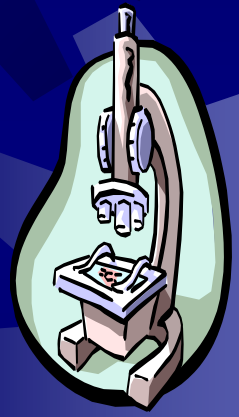
GEAC approval for Environmental Release

IN ORDER TO EVALUATE PROPOSALS, DBT HAS ISSUED FOLLOWING GUIDELINES:

- Recombinant DNA Safety Guidelines, 1990
- Recombinant DNA Safety Guidelines and Regulations, 1994
- Revised Guidelines for Safety in Biotechnology, 1994
- Revised Guidelines for Research in Transgenic Plants, 1998
- Guidelines for generating pre-clinical and clinical data for rDNA vaccines, diagnostics and other Biologicals, 1999.



Revision of Guidelines is a continuous process

Seed Policies and Legislation

- Enactment of the Seeds Act, 1966
- Seed Review Team-SRT (1968)
- National Commission on Agriculture's Seed Group (1972)
- Seed Control Order (1983)
- New Policy on Seed Development (1988)
- National Seeds Policy (2002)
- The Seeds Bill (2004)
- Formulation of National Seed Plan (2005)
- The Seeds Bill, now

The main features of the National Seed Policy, 2002

1. Development of new and improved varieties of plants
2. Timely availability of quality seeds
3. Compulsory registration of seeds
4. Creation of infrastructure facilities
5. Quality assurance, promotion of seed industry,
6. Abolition of licensing for seed dealers,
7. Facility for import of best quality seeds,
8. Encouragement to export of seeds
9. Creation of Seed Banks and National Seed Grid.

The Prevention of Food Adulteration Act, 1954 - Introduction

- The Prevention of Food Adulteration Bill was passed by both the house of Parliament and received the assent of the President on 29th September, 1954.
- It came into force on 1st June, 1955 as THE PREVENTION OF FOOD ADULTERATION ACT, 1954 (37 of 1954).

- In this Act unless the context otherwise requires,—

i. "**adulterant**" means any material which is or could be employed for the purposes of adulteration;

ii. "**adulterated**"—an article of food shall be deemed to be adulterated.

OBJECTIVE

- To make provision for the prevention of adulteration of food.
- preventing import, manufacture, sale or distribution of adulterated and misbranded food
- To prevent all types of food adulterations

History of Food laws in India

- Finally Indian **food safety standard bill 2005** is signed into law.
- In 2006 **Food Safety and Standards Act, 2006** came into enforcement with two objective :
  - To introduce a single statute relating to food and
  - To provide for scientific development of the food processing industry
- On 5th Aug 2008 FSSAI is constituted.
- On 5th May 2011 FSS Rules are notified in to the Gazette.
- On 5th Aug 2011 FSS Rules and Regulation came into enforcement.

FOOD SAFETY - Why needed ?

- Food safety means an assurance that the food is acceptable for human consumption according to its intended use
- "Standard", in relation to any article of food, means the standards notified by the Food Authority.
- It is of vital importance to all consumers & food business operators- engaged in production, processing, distribution & sale.
- It provides confidence to consumers that the food they buy and eat will do no harm to them and that they are protected from adulteration/fraud.

Objectives of the Act

An Act to consolidate the laws relating to food and

to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption and for matters connected therewith or incidental thereto.

August 24, 2006 came into effect.

Plant quarantine structure and policy in India

Operations are carried out by the Directorate of Plant Protection, Quarantine and Storage, which functions under Ministry of Agriculture

Plant Quarantine (Regulation of Import into India) Order, 2003 :

- to prevent the introduction and spread of exotic pests that are destructive by regulating the import of plants and plant products through adequate policy and statutory measures
- to support India's agricultural exports through credible export certification
- to facilitate safe global trade in agriculture by assisting and by providing phytosanitary certification

(Shah, 2003)

National Environment Policy, 2006

- It the first initiative in strategy-formulation for environmental protection in a comprehensive manner.
- It undertakes a diagnosis of the causative factors of land degradation with a view to flagging the remedial measures required in this direction.
- It recognizes that the relevant fiscal, tariffs and sectoral policies need to take explicit account of their unintentional impacts on land degradation.

NATIONAL ENVIRONMENT POLICY, 2006 (CONTD.)

- The solutions offered to tackle the problem comprise:
- Adoption of both, science-based and traditional land-use practices,
- Pilot-scale demonstrations,
- Large scale dissemination,
- Adoption of Multi-stakeholder partnerships,
- Promotion of agro-forestry,
- Organic farming,
- Environmentally sustainable cropping patterns
- Adoption of efficient irrigation techniques.