UINT 2

- Biosafety guidelines of Government of India
- GMOs
- LMOs

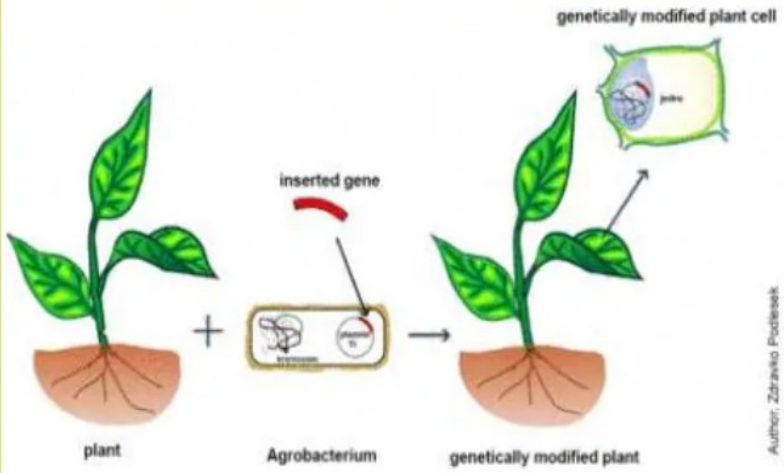
Genetically modified organism

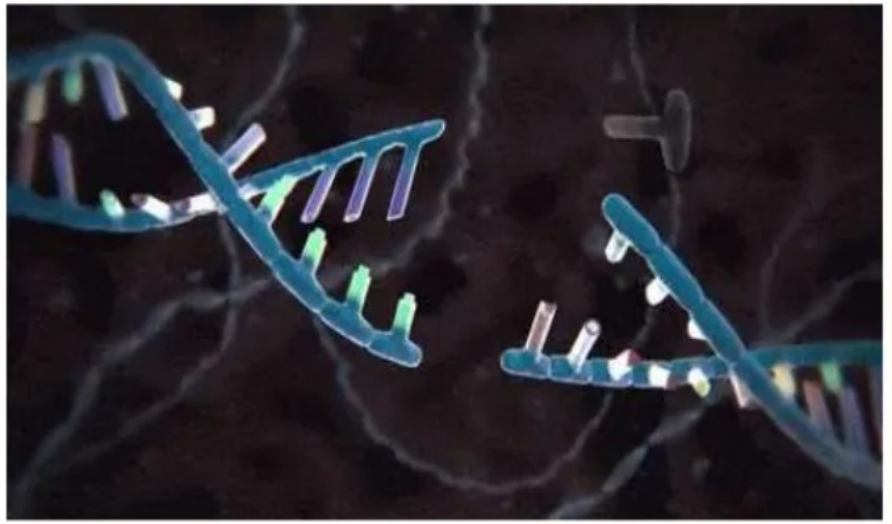
WHAT ARE GENETICALLY MODIFIED ORGANISMS?

- A genetically modified organism (GMO) is an organism whose genetic material has been altered using genetic engineering techniques.
- **Genetic engineering techniques OR Recombinant DNA technology** can be used for insertion of genes in plants not only from related plant species but also from unrelated species such as microorganisms.

How it modified?

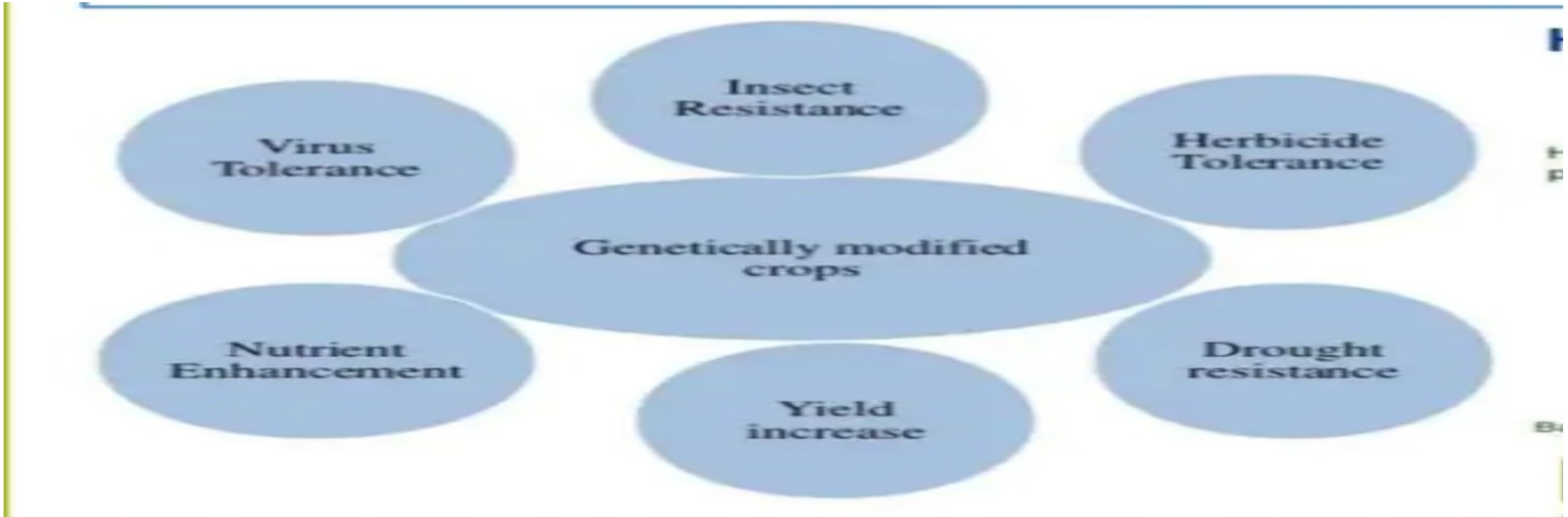
- Eliminating, modifying or adding copies of specific genes often from other organisms through modern molecular biology techniques.
- Other names: Recombinant DNA (rDNA)
  Genetic engineering
  Gene splicing

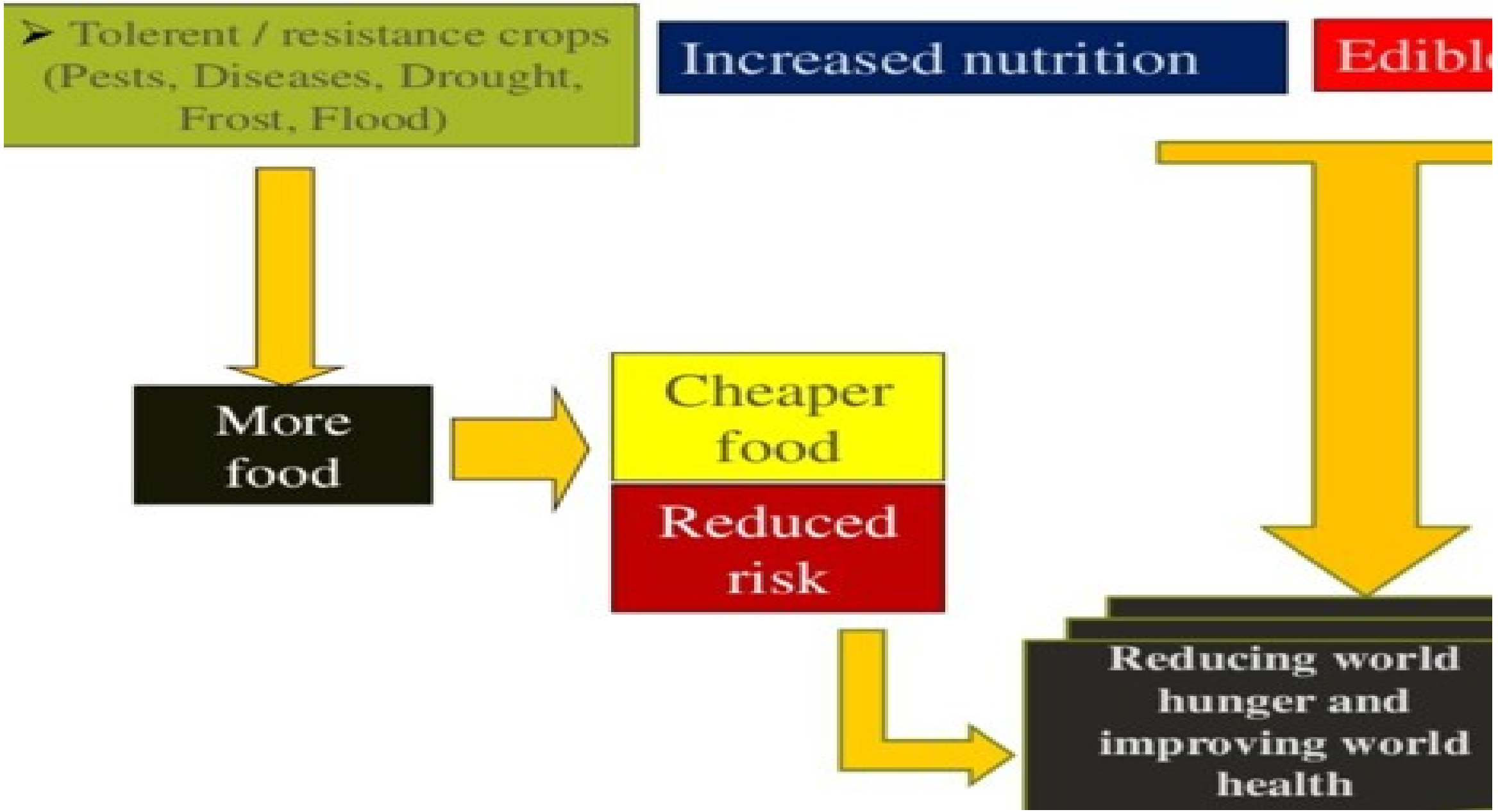




Where it use?

- Food - Canola, Soya bean, Golden rice and corn Etc.
- Medicine - Insulin, hormones and vaccine Etc.
- Genetically modified medicines can be produced cheaper and easier.




➢ Tolerent / resistance crops (Pests, Diseases, Drought, Frost, Flood)
Increased nutrition
Edible
More food
Cheaper food
Reduced risk
Reducing world hunger and improving world health

ros of genetically modified foods ?

nproved yield

lore resistant to disease

ess likely to be damaged by insect

olerance to herbicides

etter nutritional value

creased shelf life

nprovement in health and vironment

- Better climatic survival by increasing tolerance to draught, flood or frosty conditions to allow the use of previously inhospitable land
- Higher crop yields
- Reduced farm costs
- Increased farm profit

7,800 BCE

Oldest evidence of artificially selected crops

30,000 BCE

Artificial selection of wolves began

1973

Boyer & Cohen develop Genetic Engineering (GE)

1974

Jaenisch & Mintz create first GE animal

GE Experiment Moratorium

1975

Asilomar Conference sets guidelines for future GE experiments

U.S. Supreme Court allows patenting of GE organisms

1980

1982

FDA approves Humulin, the first pharmaceutical manufactured using GE technology

FLAVR SAVR Tomatoes become first GE food crop approved by U.S. Department of Agriculture

1992

1995

US EPA approves the first insecticide-producing crop

1996

Herbicide-resistant crops first introduced

2000

Golden Rice engineered to mitigate Vitamin A deficiency

The pharmaceutical ATryn becomes the first biological produced by a GE animal to be approved by the US FDA

2009

GM crops

1. Rice
2. Wheat
3. Corn
4. sunflower
5. Canola
6. Soy
7. Sugar beet
8. Papaya
9. Squash
10. Potato
11. Tomato
12. Brinjal
13. Alfa alfa

GMO Foods

For more information go to
olmag.co/gmo-foods

Tomato

Tomatoes have been genetically modified, but they are not being grown commerically at thia time

Rice

GMO rice has been approved but is not yet being used commercially

Sweet Corn

More than 70 percent of corn grown in the United States has been genetically engineered

Summer Squash

Farmers don't like GMO squash but some experts say GM squash have blended with wild squash

Canola Oil

87% of canola grown commercially, and 80% of wild canola is GMO

Yeast

GMO yeast for wine has been approved

Salmon

GMO salmon has not been approved by the FDA, but it will be very soon

Alfalfa

GMO alfalfa is contaminating non GMO alfalfa crops at a rapid rate

Wheat

Unapproved GMO has contaminated wheat fields, and we don't yet know the extent of it

Sugar Beets

90% of Sugar Beets (used to make 50% of our sugar) are GMO

Soy

More than 93% of soybeans the United States produces are genetically modified

Peas

Peas have been genetically modified but are not approved or availlable

Hawaiian Papaya

Most Hawaiian papaya is GMO, even many organic crops are contaminated

Cotton

At least half of cotton grown in the world is GMO

organic lifestyle MAGAZINE

What is Bt cotton ?

- BT cotton is a genetically modified pest-resistant plant cotton variety, modified by the insertion of one or more genes from **Bacillus thuringiensis** (common soil bacteria).
- he 'Bt' (Bacillus thuringiensis) genes present in the GM crops kill the insects like bees, ladybird beetles, butterflies, etc. •

Milled rice is provitamin-A-free.

Symptoms of vitamin A deficiency (VAD) include;

- Night blindness,
- Increased susceptibility to infection and cancer, anemia (lack of red blood cells or hemoglobin),
- Deterioration of the eye tissue, and cardiovascular disease
- Nearly **9 million children** die from malnutrition each year.
- **Golden rice is GM crops is yellow because it contains to the β-carotene (provitamin A)**

Trait	Advantage	Sample Product
Pest-Resistance	Less damage by insect, virus, bacteria, etc.	Corn
Herbicide-Resistance	Hebicides will kill only weeds, not crops	Cotton
Delayed Ripening	Can be shipped with less damage	Tomato
Miniature Size	Improved eating quality	Watermelon
Improved Sweetness	Better tasting	Sweet peas
Cold-Resistance	Withstands freezing and thawing	Strawberries
High Starch	Absorbs less oil when fried	Potato
Polyester Gene Added	Better fiber properties	Cotton
Growth Hormone Added	Faster growth	Salmon
Hepatitis B Virus Protein Added	May provide immunity to Hepatitis	Banana

Types of GM Foods

1. **First-generation crops**

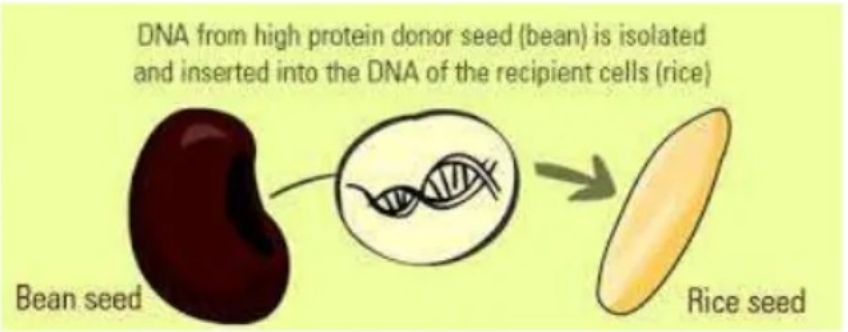
- Traits such as herbicide tolerance, better insect resistance and better tolerance to environmental stress.
- The ensuing crops are not significantly different from the traditionally grown crops in terms of appearance, taste and nutrition.
- Examples of such crops are herbicide resistant soybean, insect-resistant maize, and herbicide and insect-resistant potato.

2. **Second-generation crops**

- Increased levels of protein, modified or healthier fats, modified carbohydrates, increased flavor or increased micronutrients.
- Examples rice with a higher level of beta-carotene,
- tomatoes with higher levels of carotenoids,
- maize with increased vitamin C,
- soybean with improved amino acid composition, and potatoes with higher calcium content.

3. Third Generation

- Increased ability to resist abiotic stress
- Create "pharma plants" to help produce active pharmaceutical products.
- In Feb 2009, the U.S. Food and Drug Administration (FDA) approved recombinant anti-thrombin prevention of blood clots, hereditary anti-thrombin deficiency.
- This is 1st human biologic drug derived from the milk of goats that have been genetically engineered to produce human anti-thrombin in their milk.



- **DISADVANTAGES**
- **Risk to Human Health:**
- GM crops **allergen reaction,** because GMO foods contain foreign genes,
- For example a proposal to incorporate a gene from Brazil nut to soybean was abandoned because of the fear of causing unexpected allergic reaction.
- Risks of GMOs to human health are related mainly to **toxicity, allergenicity and antibiotic resistance** of the new organisms/products.

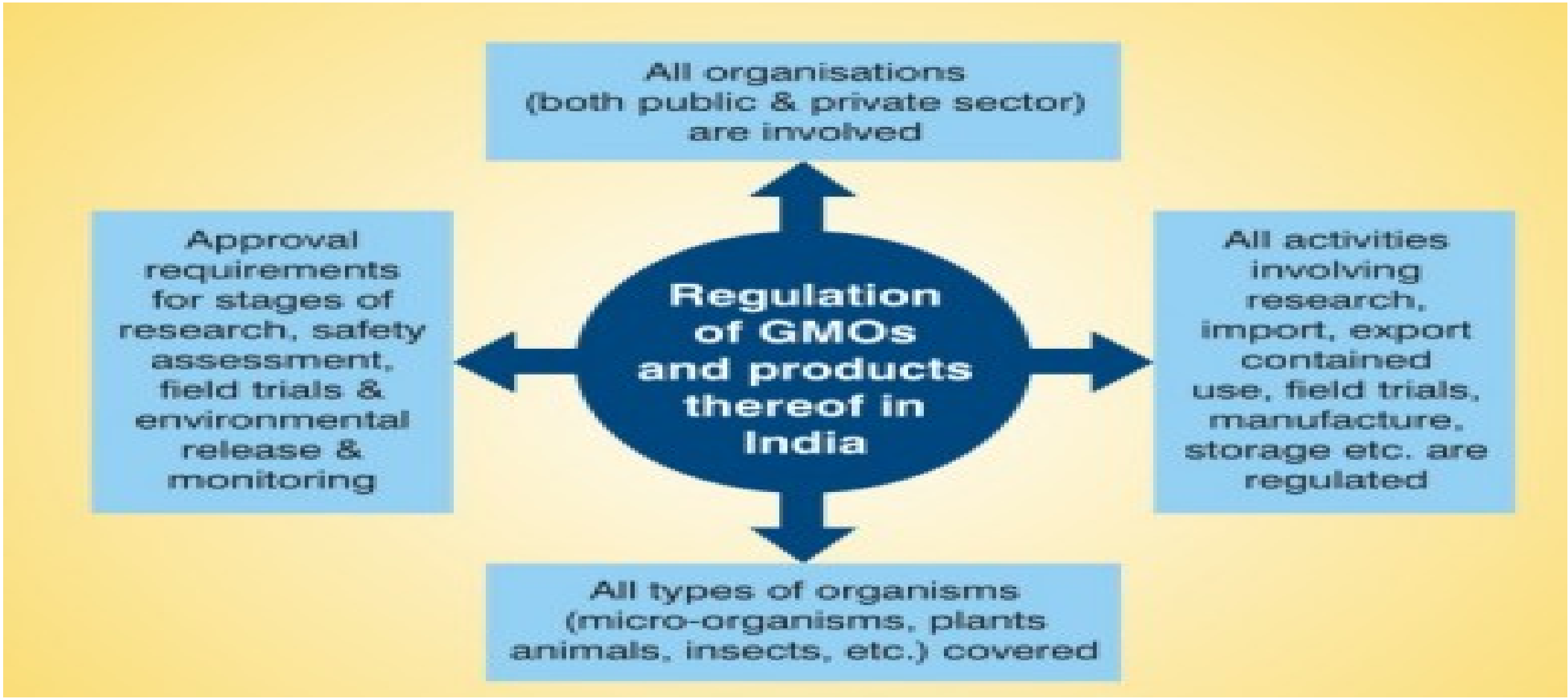
- **For example a proposal to incorporate a gene from Brazil nut to soybean was abandoned because of the fear of causing unexpected allergic reaction**
- **GENE FLOW** - Accidental cross breeding between GMO plants and traditional varieties through pollen transfer can contaminate the traditional local varieties with GMO genes resulting in the loss of traditional varieties of the farmers. Gene may flow through seed or pollen. The risk of gene flow to the wild relative or related species is raised as threat to the biodiversity in might causing **unpredictable change on the ecology** in total.
- **Loss of Biodiversity**
- destructive situations increases when single varieties are used in cropping system in place of multiple varieties.
- **Changes in the soil ecology:**
- transgenic plants may leak different compounds than conventional plants,
- **Risks associated with use of bacterial resistance genes in the generation of GM plants**

- **Loss of Biodiversity :**
- The use of some GM crops can have negative impacts on non-target organisms and on soil and water ecosystems.
- For example, GM herbicide-tolerant corn and soy, will destroy all types insects
- **Changes in the soil ecology:**
- transgenic plants may leak different compounds than conventional plants,

- **Regulatory Mechanism**
- India has a well-defined regulatory mechanism for development and evaluation of GMOs
- The Department of Biotechnology (DBT) and the Ministry of Environment & Forests (MoEF) are the two apex regulatory bodies

- Rules have been notified by MoEF in 1989 under Environmental Protection Act, 1986 (EPA),
- These rules cover procedures for the manufacture, import, use, research and release of GMOs as well as products
- The objective of the rule is to ensure that the use of GMO is safe to the environment and beneficial to the human beings.

KEY FEATURES OF RULES 1989



IMPLEMENTING AGENCIES

These rules and regulations are implemented by:

- Ministry of Environment and Forests
- Department of Biotechnology
- State Governments

Six Competent Authorities and their composition have been notified under these Rules, which are as follows:

i. Recombinant DNA Advisory Committee (RDAC)

ii. Institutional Biosafety Committees (IBSC)

iii. Review Committee on Genetic Manipulation (RCGM)

iv. Genetic Engineering Approval Committee (GEAC)

v. State Biosafety Coordination Committees (SBCC)

vi. District Level Committees (DLC).

While the RDAC is of advisory in function, the IBSC, RCGM, and GEAC are of regulatory function. SBCC and DLC are for monitoring purposes. The composition of each committee is defined in the Rules, 1989. In addition to the above, a Monitoring cum Evaluating committee (MEC) has been set up by the RCGM to monitor the field performance of GM crops.

rDNA Advisory committee

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Institutional Biosafety Committees (IBSC) Department of Biotechnology, Ministry of Science and Technology.

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Review Committee on Genetic Manipulation (RCGM) Department of Biotechnology

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Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment and Forests

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State Biotechnology Coordination Committee (SBCC)

↓

District Level Committee (DLC) in the districts

- Advisory work
- Approval work
- Monitoring work

- **Recombinant DNA Advisory Committee**
- The Advisory Committee functions under the **Department of Biotechnology.**
- The Committee scrutinizes national and international biotechnology developments.
- It shall make periodic recommendations, suitable and appropriate safety regulations', for GMO research and application.
- The Committee is to develop the long-term policy for research and development and educate researchers and technicians on the hazards and the methods to avoid those hazards.

Review Committee on Genetic Manipulation (RCGM)
The RCGM is constituted by the **Department of Biotechnology** to monitor safety related aspects in the ongoing research projects and activities involving genetically engineered organisms or micro-organisms.

The Committee also brings out manuals on guidelines with respect to activities involving GMOs in research, use and applications.
Every ongoing project involving 'high-risk category and control1ed field experiments' requires review by the RCGM for ensuring strict adherence to adequate precaution and containment.

- **Genetic Engineering Approval Committee (GEAC) Apex Body**
- The GEAC functions under the **Ministry of Environment and Forests and is responsible for approval of activities involving large-scale use of GMOs in research, industrial production and application.**
- The GEAC issues clearance only from the environmental angle.
- The Committee authorises release of GMOs and products into the environment, including field trials.
- That means large-scale experiments beyond RCGM's jurisdiction have to be authorized by the GEAC only

- **State Biotechnology Co-ordination Committee (SBCC)**
- The SBCCs can 'inspect, investigate and take disciplinary actions' against statutory violations through the nodal department and the State Pollution Control Board or the Directorate of Health or Medical Services.
- The Committee shall undertake periodic; reviews of the safety and control measures in industries and institutes.
- **District Level Committee (DLC)**
- The DLCs at the district levels are to monitor the safety regulations in insta1Iations.
- The DLC or its representatives shall make on-site visits and find out hazards and risks associated, with a view to meeting any emergency.
- They shall prepare off-site emergency plans and shall regularly submit reports to the State Biotechnology Co-ordination Committee or the Genetic Engineering Approval Committee

- **Institutional Bio-safety Committee (IBSC)**
- The Committee shall consist of the head of the institution, a medical expert, a scientist well versed in DNA work and a candidate of the DBT.
- The research institution shall prepare an updated on-site emergency plan (with the help of the IBSC) according to the manual or guidelines of the Review Committee of Genetic Manipulation.
- The copies of the plans shall be served to the State, District Level Committees and the Genetic Engineering Approval Committee. A designated
- Principal Investigator (P.I.) in every research organization should explain the Institutional Bio-safety Committee about the nature of experiments being carried out.
- The Investigator should obtain permission from the Institutional Bio-safety Committee or from the Review Committee of Genetic Manipulation through the Institutional Bio-safety Committee , if the risk falls in a higher category.

Six competent authorities

Statutory committee	Function	Administrating agency
rDNA Advisory Committee (RDAC)	Advise on biosafety of emerging technologies	Department of Biotechnology, Ministry of Science and Technology
Institutional Biosafety Committee (IBSC)	R&D and Contained Experiments	Set up in registered Institutions, Universities and Private Companies; report to RCGM
Review Committee on Genetic Manipulation (RCGM)	Scientific risk assessment of plants, animals, biopharma, microbes and Guidelines	Department of Biotechnology, Ministry of Science and Technology
Genetic Engineering Appraisal Committee (GEAC)	Final Approval for environmental release including confined field trials	Ministry of Environment and Forests and climate change
State Biotechnology Coordination committee (SBCC)	For monitoring and supervision at state level	Concerned State Governments
District Level Committee (DLC)	Depending upon the need for local supervision and compliance	

Composition of SBCC and DLC

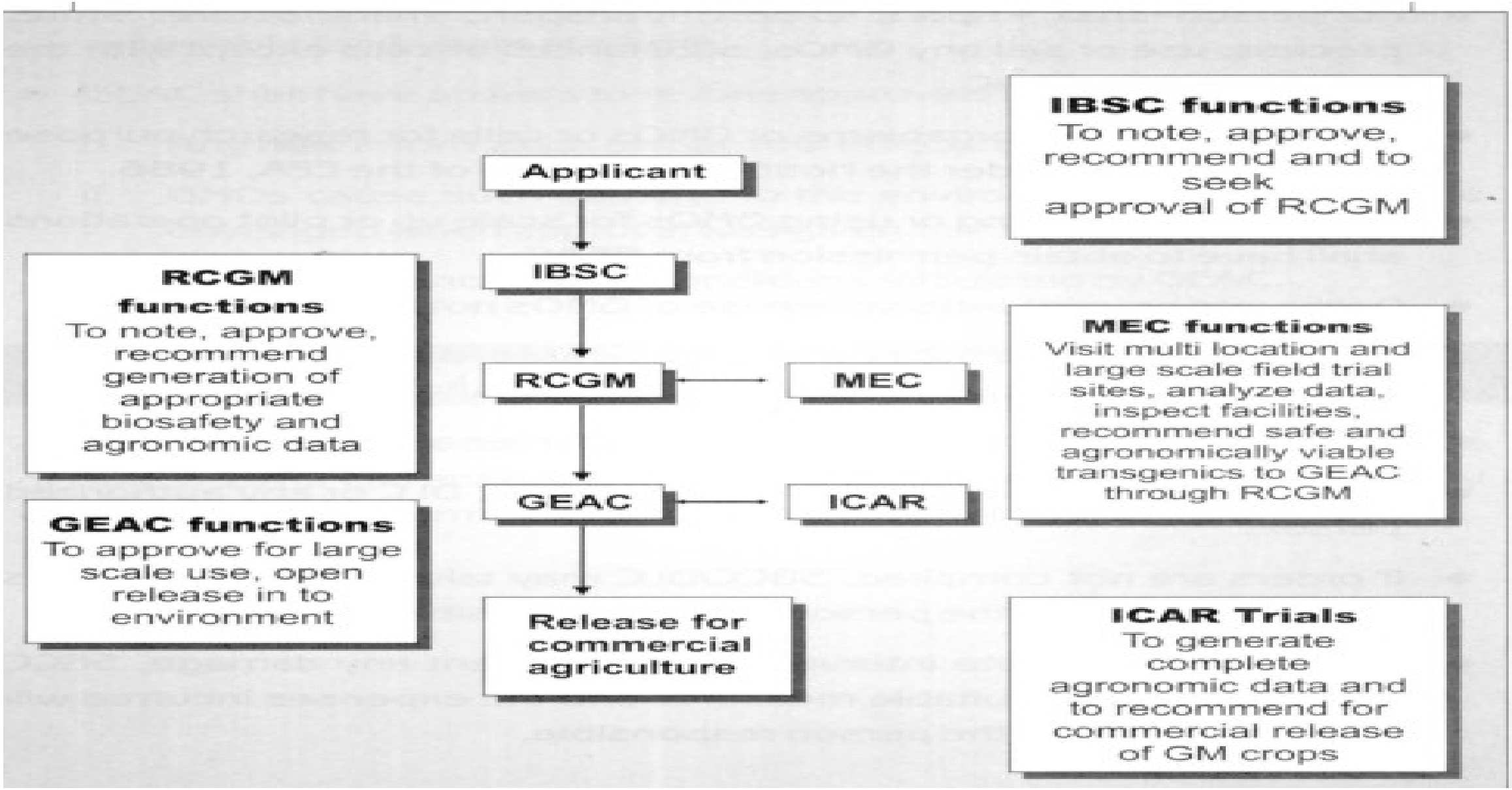
SBCC

(i) Chief Secretary - Chairman
(ii) Secretary, Department of Environment Member Secretary
(iii) Secretary, Department of Health - Member
(iv) Secretary, Department of Agriculture - Member
(v) Secretary, Department of Industries and Commerce - Member
(vi) Secretary, Department of Forests - Member
(vii) Secretary, Department of Public works/Chief Engineer, Department of Public Health Engineering - Member
(viii) State microbiologists and Pathologists - Member
(ix) Chairman of State Pollution Control Board

DLC

i) District Collector - Chairman
ii) Factory Inspector Member
iii) A representative of the Pollution Control Board - Member
iv) Chief Medical Officer (District Health Officer) Member (Convenor)
v) District Agricultural Officer Member
vi) A representative of the Public Health Engineering Department Member
vii) District Microbiologists Pathologist (Technical expert) - Member
viii) Commissioner Municipal Corporation - Member

PROCEDURE FOR APPROVAL OF GM CROPS



Cartagena Protocol

Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (Biodiversity Convention, CBD) was adopted at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in 1992. The Convention now has a total of 193Parties. It was ratified by Switzerland in 1994.

The signatory states of the CBD undertake to conserve biodiversity in their own territories, support appropriate measures for the conservation and sustainable use of biodiversity in developing countries, and regulate equitably the access to genetic resources and their utilization.

The Cartagena protocol on biosafety

Introduction

- The Convention on Biological Diversity was finalized in Nairobi in May 1992 and opened for signature at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro on 5 June1992. It entered into force on 29 December 1993. Today, the Convention is the main international instrument for addressing biodiversity issues. It provides a comprehensive and holistic approach to the conservation of biological diversity, the sustainable use of natural resources and the fair and equitable sharing of benefits deriving from the use of genetic resources. Biosafety is one of the issues addressed by the Convention.

- This concept refers to the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology. At the same time, modern biotechnology is recognized as having a great potential for the promotion of human well-being, particularly in meeting critical needs for food, agriculture and health care. The Convention clearly recognizes these twin aspects of modern biotechnology. On the one hand, it provides for the access to and transfer of technologies, including biotechnology, that are relevant to the conservation and sustainable use of biological diversity. On the other hand, it ensure the development of appropriate procedures to enhance the safety of biotechnology in the context of the Convention's overall goal of reducing all potential threats to biological diversity, taking also into account the risks to human health.

- At its second meeting, held in November 1995, the Conference of the Parties to the Convention established an Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety, focusing specifically on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. After several years of negotiations, the Protocol, known as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, was finalized and adopted in Montreal on 29 January 2000 at an extraordinary meeting of the Conference of the Parties.

- The conclusion of the Biosafety Protocol has been hailed as a significant step forward in that it provides an international regulatory framework to reconcile the respective needs of trade an environmental protection with respect to a rapidly growing global industry, the biotechnology industry. The Protocol thus creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimizing the possible risks to the environment and to human health.

The Protocol was adopted on 29th January 2000 and entered into force from September 11, 2003. As on date, 135 countries have approved the Protocol

India approved the Protocol on January 23, 2003 and the Ministry of Environment & Forests (MoEF) is the **nodal ministry for implementation** of Cartagena Protocol.

The main function of Conference of Parties is to **review the implementation of the Protocol** and **make decisions necessary to promote its effective operation.**