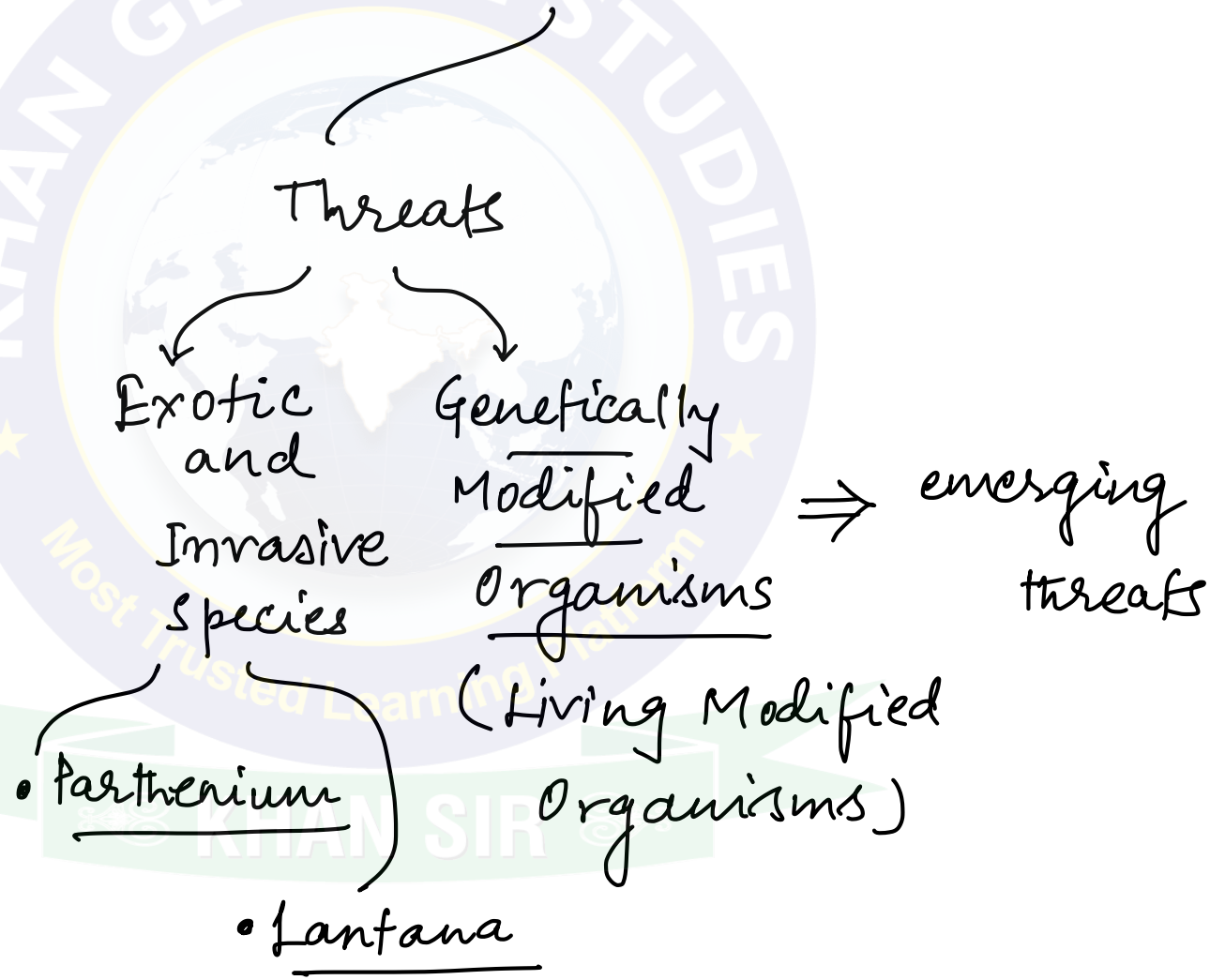
Biosafety for biodiversity



Mechanisms

Domestic

↓

Rules 1989 under Environment Protection Act, 1986

✓ (Govern research, trial, release, import, export, storage of LMO)

✓ Establishes diff. expert bodies

International

✓ Cartagena Protocol

↓

✓ controls transboundary movement of LMO

• Nagoya - KL Supp. Protocol

Loss & Compens^n

NBSAP

National Biodiversity Strategic Action Plan.

1. Biosafety in India

1.1. What is Biosafety?

- Biosafety is a broad term and its means 2 things:

a. **In general practice:** Biosafety is the **safe working practices** associated with handling of biological materials, particularly **infectious agents.**

b. In the context of biological diversity: Biosafety refers to **protecting the native biological diversity** from aggressive invasive species including **living-modified organisms.**

- Its main objective is to keep a **check on harmful biological agents,** toxins, chemicals, and radiation.

1.2. Importance of Biosafety

- **Preserve ecosystems:** Biosafety helps maintain ecosystem balance and

stability by preventing the introduction or spread of harmful organisms.

- **Protect native species:** Ensuring biosafety safeguards habitats and populations of native species, contributing to overall biodiversity.
- **Reduce extinction risk:** Biosafety measures reduce the risk of species extinctions caused by the introduction or spread of harmful organisms..
- **Genetic diversity:** Biosafety protects genetic diversity within species, increasing their resilience to threats like disease or climate change.
- **Food security:** Biodiversity is essential for maintaining genetic diversity in crops and livestock; biosafety helps protect these resources and ensure food system resilience.

Bt Cotton (2002) ↓ 93% Cotton

1.3. Some Related Concepts

1.3.1. Biological risk assessment

- Biological risk assessment is one of the key principles of biosafety.
- It is the process used **to identify the hazardous characteristics** of a harmful organism.

1.3.2. Biosafety Levels

- Biosafety levels (BSL) are used to **identify the protective measures** needed in a laboratory setting to protect workers, the environment, and the public.
- The four biosafety levels are BSL-1, BSL-2, BSL-3, and BSL-4, with BSL-4 being the highest level of containment.

1.3.3. Genetically Modified (GM) Crops

- The term 'genetically modified' (GM) refers to the **transfer of genes between organisms** using laboratory techniques

Recombinant DNA — a DNA with genetic info. from 2 or more sources

for cloning genes, splicing DNA segments together, and inserting genes into cells.

- Collectively, these techniques are known as recombinant DNA (rDNA) technology. → new combination of genes
- To produce a GM crop, **new DNA is transferred into crop cells.**
- Other terms used for GM plants or foods derived from them are genetically modified organisms (GMOs), genetically engineered (GE), bioengineered, and transgenic.

1.3.4. Biohazards

Mercury
Acridine Dye

- Biohazards are defined as any **biological or chemical substance that is dangerous** to humans, animals, or the environment.
- This can include body fluids, human tissue and blood, and recombinant DNA.

1.4. Biosafety Guidelines in India

1.4.1. Introduction

- In India, the manufacture, import, research and release of Genetically Engineered Organisms (GEOs), as well as products made by the use of such organisms are governed by **The Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells,** ("Rules 1989") notified by the Ministry of Environment, Forest and Climate Change (MoEFCC), on December 5, 1989, under the Environment (Protection) Act, 1986.
- A three-tier mechanism comprising the following has been established:

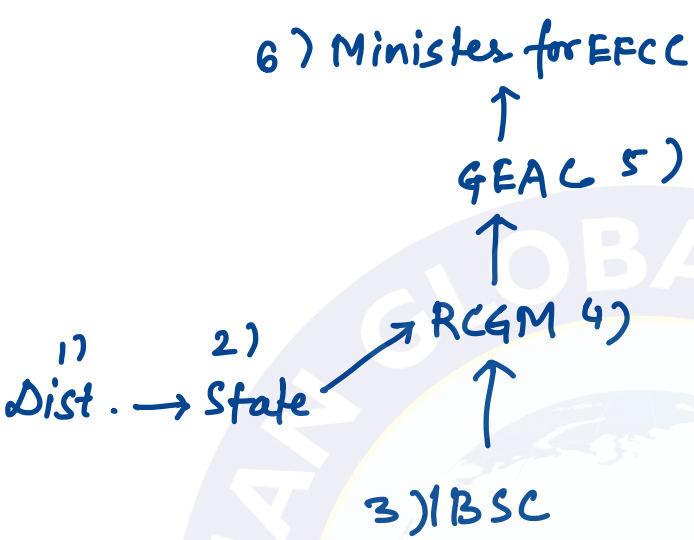
a. **Institutional Biosafety Committees** (IBSC) at the Institute/company;

b. the **Review Committee on Genetic Manipulation** (RCGM) in the Department of Biotechnology; and

c. the **Genetic Engineering Appraisal Committee** (GEAC) in the MoEFCC for granting approval for research and development activities on recombinant DNA products, the environmental release of Genetically Engineered (GE) crops and monitoring and evaluation of research activities involving recombinant DNA technology.

1.4.2. Scope of Rules, 1989

- These rules are very broad in scope essentially covering the **entire spectrum of activities involving GMOs** and products thereof.


6) Ministry for EFCC
GEAC 5)
RCGM 4)
1) Dist.
2) State
3) IBSC

- They also apply to any substances, cells, tissues, products, and foodstuffs, etc.
- New gene technologies apart from genetic engineering have also been included.

1.4.3. Mandate of Rules, 1989

- In accordance with Rules, RCGM shall function from the Department of Biotechnology to **monitor the safety-related aspect** in respect of ongoing research projects or activities involving hazardous microorganisms, GE organisms and cells and products thereof.
- RCGM shall **bring out manuals of guidelines** specifying procedure for regulatory process with respect to activities involving GE organisms in research use as well as industrial & environmental applications with a view to

ensure human health and environmental safety.

- All ongoing research projects involving hazardous microorganisms, GE organisms or cells and products thereof shall be reviewed to **ensure that adequate precautions and containment conditions are being met.**
- RCGM shall lay down procedures restricting or prohibiting the production, sale, importation and use of such hazardous microorganisms, GE organisms or cells.

1.4.4. Implementation of Rules, 1989

Rules, 1989 are implemented by MoEFCC jointly with the Department of Biotechnology (DBT), Ministry of Science & Technology and state governments. **Six Competent Authorities** and their composition have been notified under these Rules that includes:

Recombinant DNA Advisory Committee (RDAC)

No decision

- This committee constituted by the DBT takes note of developments in biotechnology at national and international levels.
- The RDAC is **advisory in nature** and expected to give recommendations from time to time on safety regulations in research and applications of GMOs and products thereof.

Institutional Biosafety Committee (IBSC)

- It is necessary that each institution intending to **carry out research activities** involving genetic manipulation of microorganisms, plants or animals should constitute the IBSC.

Review Committee on Genetic Manipulation (RCGM)

- The RCGM functions as a body under the Department of Biotechnology

to monitor the **safety related aspects** in respect of on-going research projects and activities involving GE organisms/hazardous microorganisms.

Genetic Engineering Appraisal Committee (GEAC)

- GEAC is the apex committee functioning in MoEFCC and has representatives from concerned ministries/agencies and experts.

State Biotechnology Coordination Committee (SBCC)

- SBCC is **constituted in each State** where research and applications of GMOs are underway.

District Level Committee (DLC)

- DLCs are constituted in districts, wherever required to monitor the safety regulations in installation engaged in the use of GMOs/hazardous microorganisms and its applications in the environment.

- Each DLC is **headed by the District Collector** (officer responsible for administration of a district) with officers concerned with public health, environment, pollution control etc. at the district level.

Ref:

1.4.5. Approvals and prohibitions

Rules, 1989 provide for compliance with the biosafety safeguards and any violation and non-compliance in this area attracts punitive actions provided under the EPA, 1986. The approvals and prohibitions under Rules 1989 are summarised below:

- **No person shall import, export, transport, manufacture, process, use or sell** any GMOs, substances or cells except with the approval of the GEAC.
- Use of pathogenic organisms or GMOs or cells for research purposes shall only be allowed in laboratories or

inside laboratory areas notified for this purpose under the EPA, 1986.

- Experiments for the purpose of education involving GMOs can be undertaken with the oversight of IBSCs.
- Deliberate or unintentional release of GMOs not allowed.
- Production in which GMOs are generated or used shall not be commenced except with the approval of GEAC.

1.4.6. Indian Knowledge Biosafety Portal (IKBP)

- It was launched in May, 2019.
- It is a web-based portal, with a major thrust to reach out to researchers, industry and other stakeholders to **provide the latest scientific information and regulatory guidance** related to the authorization of GMOs/LMOs and products thereof.
- The IBKP provides information on:

- Relevant Acts and Rules related to Biosafety of GMOs/LMOs in India.
- Biosafety, Biocontainment guidelines, Checklists, etc.
- Database on various ongoing research activities on GMOs/LMOs and products thereof in the country including scientific Risk Assessment and Risk Management Plans (RARMPs).
- Linkages to international developments and scientific information.
- IBSC registrations/renewals and annual compliance records.

1.4.7. GM Crop in India

- *Bt* (*Bacillus thuringiensis*) cotton is the **only GM crop that has been approved for commercial cultivation in 2002** by the Government of India.
- *Bt* Brinjal resistant to brinjal shoot fly developed by M/S Mahyco in collaboration with University of Agricultural Sciences, Dharwad; Tamil

Nadu Agricultural University, Coimbatore and ICAR-Indian Institute of Vegetable Research, Varanasi was approved by GEAC in 2009. However, due to the 10-year moratorium imposed on GM crops by the Technical Expert Committee (TEC) appointed by the Supreme Court of India, no further action on commercialization has been taken.

- The Parliamentary Standing Committee on Science and Technology, Environment and Forests, in its **report on 'Genetically modified crops and its impact on the environment',** submitted to parliament on August 25, 2017, recommended that **GM crops should be introduced in the country only after critical scientific evaluation** of its benefit and safety, and also recommended restructuring of the regulatory framework for unbiased assessment of GM crops.

India's first Biosafety level-3 containment mobile laboratory

- India's first Biosafety level-3 containment mobile laboratory was launched in Nashik, Maharashtra, on 18 February 2022.
- It has been designed by the Indian Council of Medical Research.
- It has been set up **to investigate newly emerging and re-emerging viral infections** that are highly infectious and of lethal potential to human beings.

Recombinant DNA Safety Guidelines, 1990

- The guidelines cover **areas of research involving genetically engineered organisms.**
- It also deals with the genetic transformation of green plants, rDNA

technology in vaccine development and large scale production and deliberate/ accidental release of organisms, plants, animals and products derived by rDNA technology into the environment.

- The issues relating to Genetic Engineering of human embryos, use of embryos and foetuses in research and human germ line gene therapy are excluded from the scope of the guidelines.

2. Genetic Engineering Appraisal Committee (GEAC)

2.1. What is GEAC?

- The Genetic Engineering Appraisal Committee (GEAC) functions in the Ministry of Environment, Forest and Climate Change.

- As per Rules, 1989, it is **responsible for appraisal of activities i**nvolving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle.
- The committee is also responsible for appraisal of proposals relating to release of genetically engineered (GE) organisms and products into the environment including experimental field trials.

2.2. Chair and Member

- GEAC is chaired by the Special Secretary/Additional Secretary of MoEFCC and co-chaired by a representative from the Department of Biotechnology.
- Presently, it has **24 members and meets every month** to review the

applications in the areas indicated above.

2.3. Functions

- To appraise activities involving large-scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle.
- To appraise proposals relating to the release of genetically engineered organisms and products into the environment including experimental field trials.
- The committee or any persons authorised by it has the power to take punitive action under the Environment (Protection) Act, 1986.

3. Cartagena Protocol on Biosafety

3.1. What is Cartagena Protocol on Biosafety?

- It is a **legally binding,** international agreement, **supplemental to the Convention on Biological Diversity.**
- The Protocol seeks to protect biological diversity by managing the movements of Live Modified Organisms (LMOs) between countries.
- It establishes a **procedure for prior informed agreement** to ensure countries have the necessary information to make decisions about the importing of LMOs into their territory.

3.2. Objective of Cartagena Protocol on Biosafety

- The objective of the Cartagena Protocol is to contribute to **ensuring an adequate level of protection** in the field of the **safe transfer, handling and use of LMOs resulting from modern biotechnology** that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

3.3. Adoption

- It was **adopted on 29 January 2000** as a supplementary agreement to the CBD and **entered into force on 11 September 2003.**
- **India is a signatory** to the Cartagena Protocol on Biosafety and **ratified it on January 23, 2003.**

3.4. Living Modified Organisms (LMOs)

- The protocol defines a 'living modified organism' as any living organism that **possesses a novel combination of genetic material** obtained through the use of modern biotechnology.
- 'Living organism' means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids.

3.5. Governing body

- The governing body of the Protocol is called the **Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol** (also the COP-MOP).
- The main function of this body is to review the implementation of the

Protocol and make decisions necessary to promote its effective operation.

- Decisions under the Protocol can only be taken by Parties to the Protocol.
- Parties to the Convention that are not Parties to the Protocol may only participate as observers in the proceedings of meetings of the COP-MOP.

3.6. What does the Biosafety Protocol do?

- It establishes an **Advance Informed Agreement** (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory.
- It contains the precautionary approach of the Rio Declaration on Environment and Development.

- The Protocol provides for practical requirements that are deemed to contribute to the safe movement of LMOs. Parties are required to take measures for the safe handling, packaging and transportation of LMOs that are subject to transboundary movement.
- The Protocol also establishes a **Biosafety Clearing-House** (BCH) to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol.

4. Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress

4.1. What is the Supplementary Protocol?

- It was adopted as a **supplementary agreement to the Cartagena Protocol on Biosafety.**
- It is a **binding agreement,** providing that States must require operators to take response measures in the event of damage resulting from LMOs which find their origin in a transboundary movement.

4.2. Adoption

- It was **adopted on 15 October 2010** at the fifth meeting of the Conference of the Parties serving as the meeting of the Cartagena Protocol on

Biosafety (COP-MOP 05), held in Nagoya, Japan.

- It entered into force on **5 March 2018.**

4.3. Core obligations

- **Supports efforts:** Assists parties in addressing damage to biodiversity caused by LMOs by providing essential elements for legal frameworks.
- **Domestic law:** Parties must include rules and procedures in their domestic laws to address potential damage from LMOs.
- **Existing laws:** The requirement can be fulfilled using existing domestic laws if they already address the necessary elements.
- **Supplementary Protocol:** Parties must adhere to this protocol to provide appropriate response measures.

- **Response measures:** Obligates parties to act in the event of damage from LMOs or potential damage if timely measures are not taken.