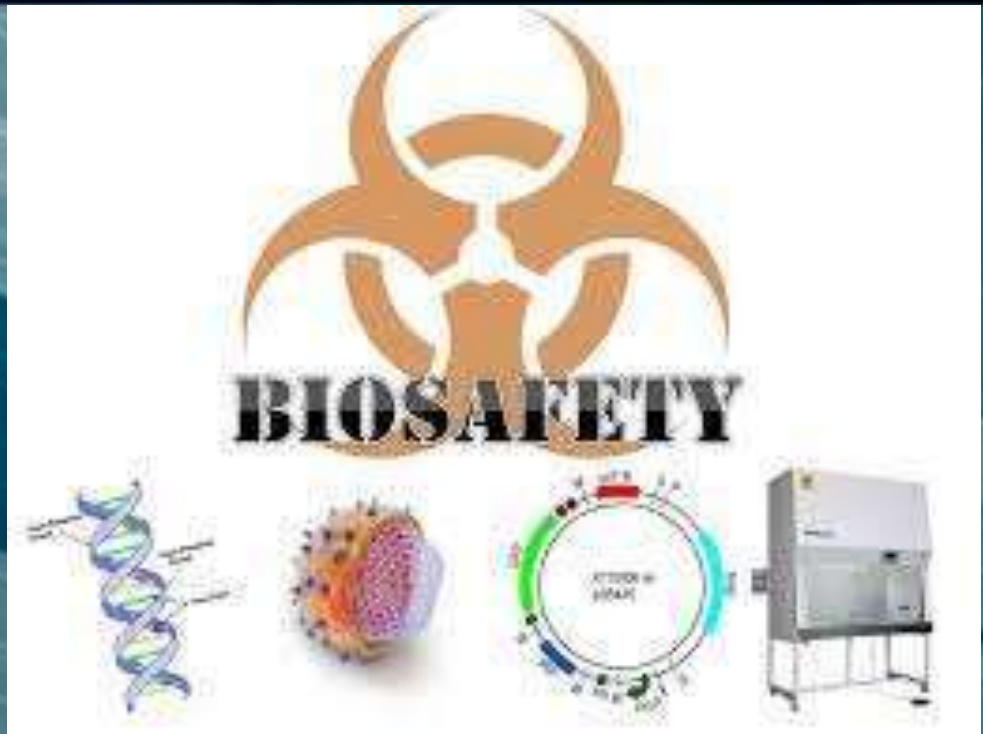
BIOSAFETY GUIDELINES

Subtitle



What is biosafety guidelines?

- Policy proposed or adopted by the Government to avoid the risks of GEOs on environment and public health.

Aim of biosafety guidelines

- Regulating rDNA research with organisms that have least or no adverse effect.
- Minimizing the possibilities of occasional release of GEOs from the laboratory
- Banning the release of GEOs if they are supposed to be causing potential risks in the environment

The rDNA Biosafety Guidelines Of India

- In India, DBT has proposed **"The recombinant DNA safety guidelines"** in 1983 and amended in 1990.
- These guidelines deals with a set of rules for production, use, import, export and storage of hazardous organisms.

In India, the rDNA guidelines has been implanted through three committees

- Institutional biosafety committee (IBSC)- controls research activities at institutional level.
- Review committee on genetic manipulation(RCGM)- reviews special situations where research with hazardous organisms in laboratory and grants permission to do that research.
- Genetic engineering approval committee(GEAC)- approves the GEOs for large scale production and use in India.

To perform certain gene manipulation experiments,theworkers need to acquire permission of review committee and approval committee before commencement

- Toxin gene cloning
- Cloning of genes for vaccine production
- Cloning of mosquito and tick DNA
- Cloning of antibiotics resistance genes
- Cloning of oncogenes
- Experiments with infectious animal and plant viruses
- Transgenesis experiment in animal cell cultures
- Transfer of toxicity genes into plants
- Gene therapy for hereditary diseases

CONTAINMENTS

- The term "Containment" is used in describing the safe methods for managing infectious agents in the laboratory environment where they are being handled or maintained.

Purpose of containments

- To reduce exposure of laboratory workers, other persons, and outside environment to potentially

Elements of containments

- Laboratory Practice and Technique
- Safety Equipment(primary barriers)
- Design Facility(Secondary Barrier)

types of containments

- Physical containment
- Biological containment

Physical containment

- The physical methods being adopted inside the laboratories to prevent escaping the GEOs to the environment
- It works on the principal of physical barriers
- It helps to keep the dirt in the laboratory itself

The physical containment include

- Air filtration
- Sterilization lights
- Waste disposal
- Protective handling

Biological containment

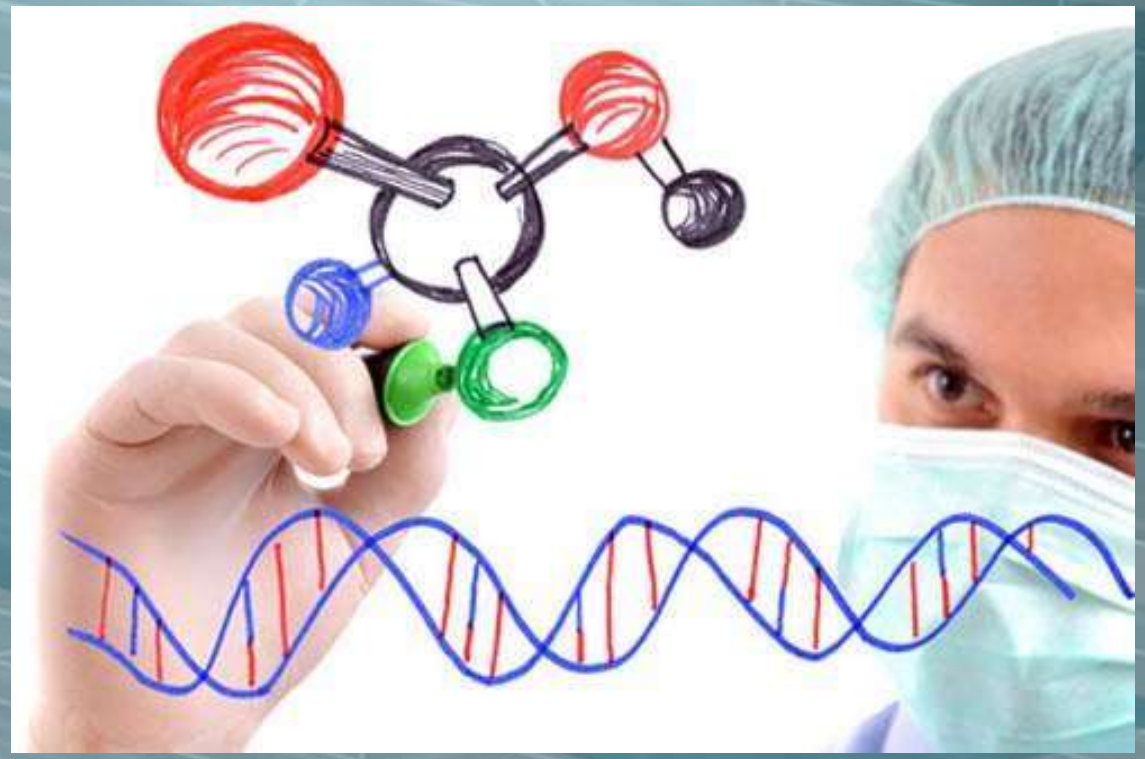
- The biological principles used in the laboratories to prevent the escape of GEOs or microbes
- Biological containment makes the organisms unable to survive in the outside environment

Implementation of biosafety guidelines

- The rDNA biosafety guidelines are implemented for the government of India by four committee
  - Recombinant DNA advisory committee (RDAC)
  - Institutional biosafety committee (IBSC)
  - Review committee on genetic manipulation (RCGM)
  - Genetic engineering approval committee (GEAC)

Recombinant DNA advisory committee (RDAC)

- Organized by the Department of Biotechnology (DBT) under the Ministry of science and technology
- It provides regulatory control to the implementation committees



The RDAC has been arranging meeting once in six months or sooner to discuss about the standards of safety regulations

- These meeting helps to
  - Evolve long term policy for R/D in rDNAresearch
  - Formulate suitable safety guidelines
  - Train the research and technicians about the hazards and risks of rDNA research techniques

Institutional biosafety committee (IBSC)

- This is a small committee established by every institution engaged in rDNA research and the related production activities
- It monitors rDNA research activities at the institutional level
- This committee is formed of head of institution, 3or more scientists, a medical officer and one DBT nominated person

Role of IBSC

- Sends report to RCGM regarding observance of safety guidelines on accidents risks and on deviations if any
- Reviews the requirements of guidelines for safety new projects
- Allows some person to take training on biosafety in research activities
- Takes emergency plans in urgent situations
- Attempts to provide medical care to persons working in the laboratory

Review committee on genetic manipulation (RCGM)

- The RCGM is functioning under DBT
- It is formed of
  - Department of biotechnology (DBT)
  - Indian council of medical research (ICMR)
  - Indian council of agricultural research (ICAR)
  - Council of scientific and industrial research (CSIR)
  - Department of science and technology (DST)

RCGM functions

- Establishes the procedural guidance manual for regulatory process with GEOs
- It reviews the risk potentials of GEOs in the laboratory and field experiments
- It decides which containment have to be followed for experiments with risky hazardous microbes
- It advices custom authorities on import of GEOs and other biological materials from other nations
- It provides advice on IPR and patents

- It assists the **Bureau of India standards (BIS)** to evolve standards of products coming from rDNA technology
- The monitoring group of RCGM visit frequently to laboratories where rDNA works are going on and inspects safety conditions in those lab

GENETIC ENGINEERING APPROVAL COMMITTEE (GEAC)

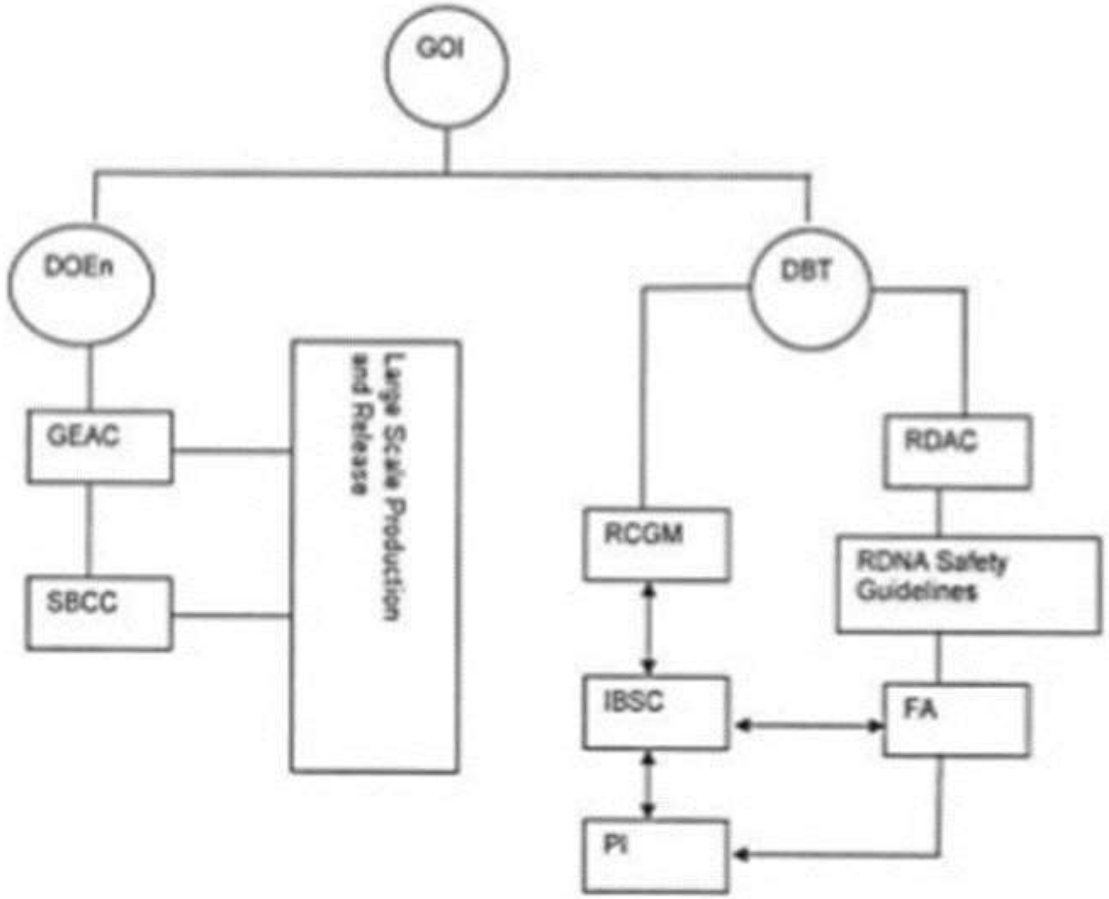
- This is a higher level committee working under the Department of Environment and Forests.
- It has full power to permit
  - Large scale use of genetically engineered organisms
  - rDNA products
  - R/D of rDNA technology
  - Industrial production of rDNA products
  - Release of GEOS in environment and field use

The GEAC gives approval for

- Import, export, transport,production and sale of GEOs and other organisms
- Release of GEOs from the laboratories to environment
- Large scale culture and use of GEOs and microbes in industries
- Use of GEOs in field application and experimental trials
- Monitoring the risks and accidents due to GEOs

Mechanism of implementation

Institutional mechanism for implementation of guidelines frame work for implementation



GOI	-	Government of India
DBT	-	Department of Biotechnology
RDAC	-	Recombinant DNAAdvisory Committee
IBSC	-	Institutional Biosafety Committee
RCGM	-	Review Committee on Genetic Manipulation
DOEn	-	Department of Environment
GEAC	-	Genetic Engineering Approval Committee
SBCC	-	State Biotechnology Coordination Committee
PI	-	Principal Investigator (R&D/Industry/Others)
FA	-	Funding Agency (Govt./Private & Public Institutions)

THANK YOU