

## **Session III: Environmental safety aspects of regulations for genetically engineered/modified animals (confined use/environmental release)**

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**India has opted to join the Cartagena Protocol on Biosafety. The Cartagena Protocol was adopted on January 29, 2000 and entered into force on September 11, 2003. This makes India responsible for not only ensuring biosafety for her own people, but also for the world community.**

**The Environment (Protection) Act, 1986**

**United Nations Conference on the Human Environment held at Stockholm in June, 1972: India participated, to take appropriate steps for the protection and improvement of human environment.**

**(vi) laying down procedures and safeguards for the prevention of accidents which may cause environmental pollution and remedial measures for such accidents; (vii) laying down procedures and safeguards for the handling of hazardous substances; (viii) examination of such manufacturing processes, materials and substances as are likely to cause environmental pollution**

Rules made under this act to be laid before parliament - Every rule made under this Act shall be laid, as soon as possible, before each House of Parliament.

Which means new rules can be made .....

MINISTRY OF ENVIRONMENT & FORESTS NOTIFICATION New Delhi, the 5th December, 1989 RULES FOR THE MANUFACTURE, USE/IMPORT/EXPORT AND STORAGE OF HAZARDOUS MICRO ORGANISMS/ GENETICALLY ENGINEERED **ORGANISMS** OR CELLS

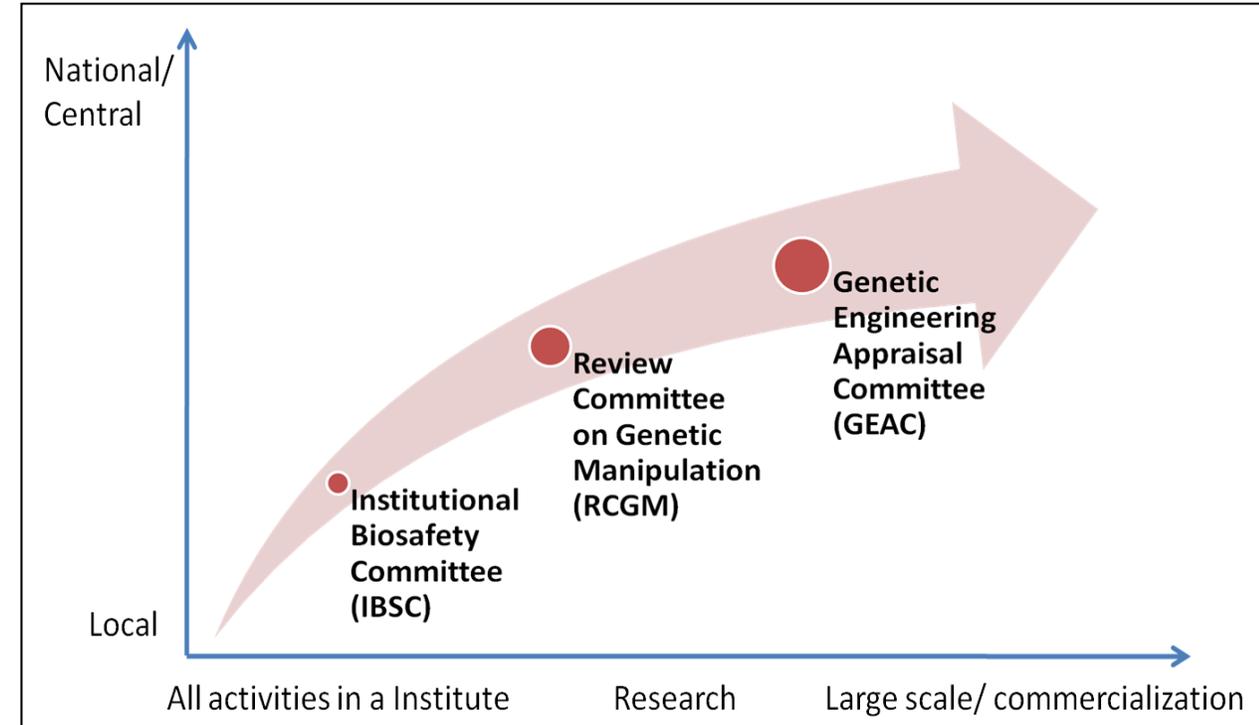
These rules may be called the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms/ **Genetically engineered organisms** or cells. **There is nothing special for animals**

These rules shall apply to genetically engineered organisms/micro-organisms and cells and correspondingly to any substances and products and food stuffs, etc., of which such cells, organisms or tissues here of form part.

Production, manufacturing, processing, storage, import, drawing off, packaging and repackaging of the Genetically Engineered Products: drugs and pharmaceuticals and food stuffs

# Biosafety Regulation in Biotechnology

- In India, biosafety regulations are governed by the Rules 1989, framed under Environment (Protection) Act, 1986
- Mandates protection of human health and environment from harm, if any, caused by activities involving use of genetically modified organisms (GMOs/LMOs) and Hazardous microorganisms.



**All research and large scale/ commercialization of GMOs is regulated by IBSC/RCGM/GEAC**

**Also, there is a Recombinant DNA Advisory Committee (RDAC) and State Biotechnology Coordination Committee (SBCC) / District Level Committees monitor the activities and field trials.**

**GEAC** shall also be responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment **including experimental field trials**. The Committee has representatives from of Environment, Forests and Wild life , Department of Biotechnology, Indian Council of Agricultural Research, Indian Council of Medical Research, Council of Scientific and Industrial Research, Director General-Health Services, Plant Protection Adviser, Central Pollution Control Board and three outside experts in individual capacity. The committee or any person/s authorized by it shall have powers to take punitive action under the Environment (Protection) Act. **This is where acceptance of a genetically engineered product for field/market gets blocked as of today.**

Certain experiments for the purpose of education within the field of gene technology or microorganism may be carried out outside the laboratories and laboratory areas mentioned in sub rule (2) and will be looked after by the Institutional Biosafety Committee. *This is the only rescue to continue research*

**DELIBERATE OR UNINTENTIONAL RELEASE** (1) Deliberate or unintentional release of genetically engineered organisms/hazardous microorganisms or cells, including deliberate release for the purpose of experiment shall not be allowed. (2) The GEAC may in special cases give approval of deliberate release or Limited field studies

Guidelines and Standard Operating Procedures for conduct of confined field trials of regulated GE Plants were issued by DBT and MoEFCC in 2008 . **Nothing like this for animals, yet.**

# INDIAN BIOSAFETY REGULATORY FRAMEWORK

- In India, all activities related to Genetically engineered organisms (GE organisms) or cells and non-GE hazardous microorganisms and products thereof are regulated as per Rules, 1989”

Competent Authorities	Role
Recombinant DNA Advisory Committee (RDAC)	Advisory
Institutional Biosafety Committee (IBSC)	Regulatory/ Approval
Review Committee on Genetic Manipulation (RCGM)	
Genetic Engineering Appraisal Committee (GEAC)	
State Biotechnology Coordination Committee (SBCC)	Monitoring
District Level Committee (DLC)	

**RCGM** shall bring out Manuals of guidelines specifying procedure for regulatory process with respect to activities involving genetically engineered organisms in research, use and applications including industry with a view to ensure environmental safety. All **ongoing projects** involving high risk category and controlled field experiments shall be reviewed to ensure that adequate precautions and containment conditions are followed as per the guidelines.

Appears, **research projects** may be approved, with **tabs**

It appears that regulatory considerations for use of products based on new and emerging technologies will be on a case by case basis

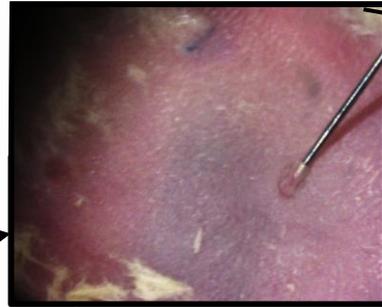
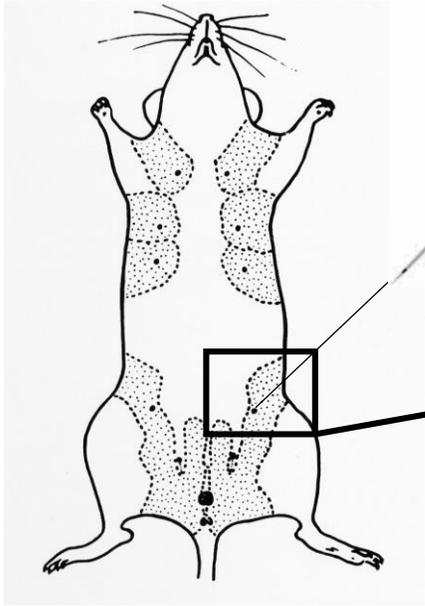
The most important job lies with the promoters of GM technology is to generate appropriate rules on one side and on other side, convince consumers, environmental activists and farmers that among various alternatives available for sustainable food production, GM technology is the best option to address India's food security.

# INTRADUCTAL PERFUSION DELIVERY gene IN MICE MAMMARY GLAND

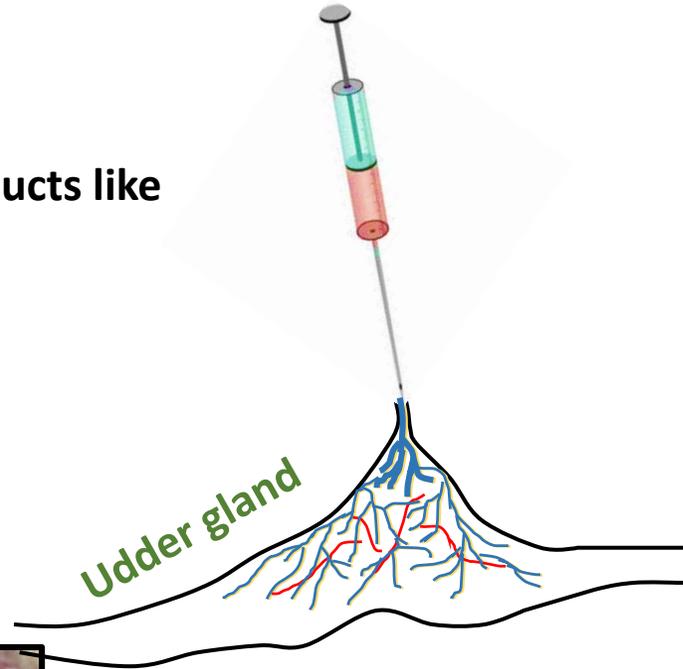
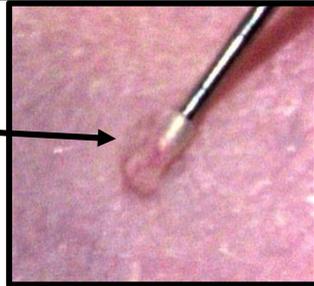
**Alternates to transgenic animals.**

**Will it ease getting license to generate certain products like therapeutic proteins ?**

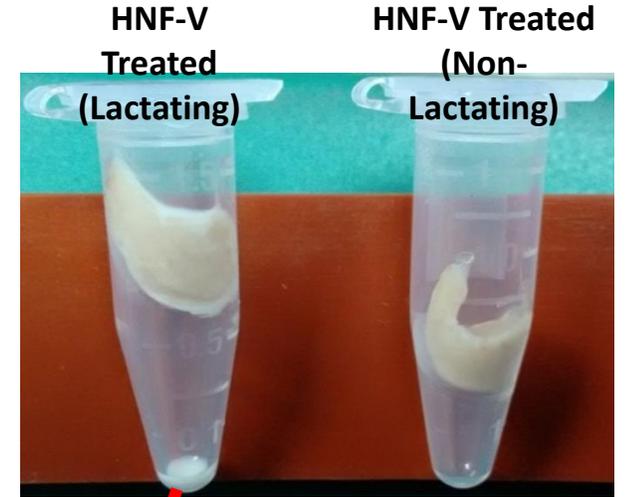
10ul Hamilton Gastight Syringe



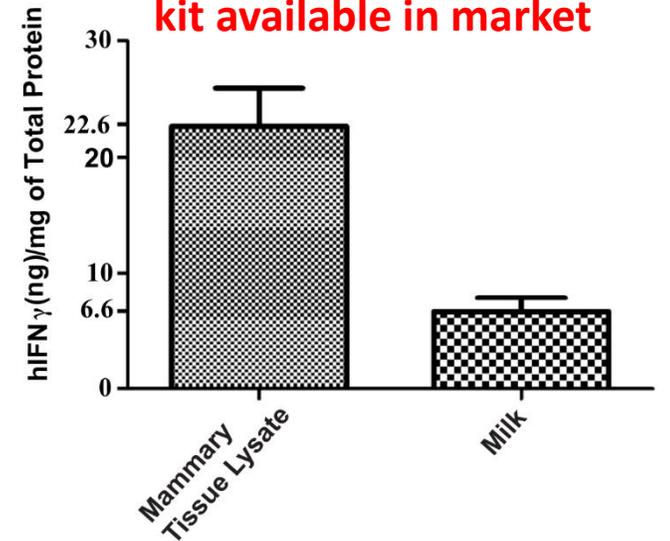
TEAT



No germ line integration.



ELISA for hIFN $\gamma$  – from human kit available in market



Not a Transgenic animal